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Health Law Journal

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SPECIAL EDITION The New York State Attorney General's Role in Health Care

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A Final Message from the Section Chair 2002-2003 (A Year of Significant Accomplishments for the Section and Its Chair)

As health lawyers, we are all familiar with the Surgeon General's admonishments regarding smoking. The Surgeon General's report which originally highlighted the dangers of smoking also warned about the health risks associated with obesity, but received little public response until recently. At this time there is an increasing public awareness of both the heightened



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health risks which obesity poses, as well as the breadth of the problem among the American populace.

A year ago I started my term as Chair of the Health Law Section in my bed recovering from gastric bypass surgery. This was my personal major battle against the maladies incident to morbid obesity. At that time I was very optimistic about the prospects for improving my health and quality of life, while being excited and somewhat anxious about the daunting responsibility of leading an organization for which I have a strong personal and professional commitment. Thanks to my talented and caring surgeon, Mark A. Bessler, M.D., and the wonderful team of caregivers at New York-Presbyterian Health System, I was physically prepared for the challenge of being the Chair, while balancing my work responsibilities with my activities as a spouse, a parent of three young men, and an involved community member. Over the course of the year, I have lost one-hundred and thirty-five (135) pounds. I literally became a new man. I exercise regularly and enjoy engaging in physical activities, such as dancing with my wife and bicycle riding with my sons. I wanted to briefly write about this wonderful metamorphosis so that my experience can serve as an inspiration for those of you within the Section and the New York State Bar Association who may share this condition with me. I wish to thank all of those within the Section and the Association for their personal support and encouragement during my post-surgical recovery and my tenure as Section Chair.

I am pleased to introduce another outstanding issue of the *Health Law Journal*. However, it is truly with mixed emotions that I present my final report as Section Chair. I am happy to join the company of the distinguished past Chairs of the Section, but I will miss the excitement and energy of serving as Section Chair. This edition of the *Journal* focuses on the Office of the New



York State Attorney General, and as such is another collector's issue. It features an introduction by the Honorable Eliot A. Spitzer, New York State's premier Attorney General. This issue of the *Journal* also contains articles written by department chiefs on Mr. Spitzer's staff, as well as articles about the Attorney General's Office from private sector health law practitioners. Once

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again, I wish to acknowledge the superb leadership of Robert Swidler and Professor Dale Moore, the *Journal's* Co-Editors. They continue to ensure that the *Journal* is timely, topical and practical for health law practitioners. Additionally, I would also like to recognize David Nocenti, Counsel to the New York State Attorney General, without whose assistance this issue of the *Journal* would not have been possible.

Once again, I am delighted to report that the state of the Section is good. The Section continues to remain in the black financially, membership is growing, and the Section is buzzing with activities. As you may recall, in the previous editions of the *Journal* I reported on the status of the very ambitious agenda which I set for the Section for this Association year. I am exhilarated to announce that the Section—through the tireless efforts of its officers, committee Chairs, and the other members of the Executive Committee—has substantially achieved all of its nine agenda items. The following is a listing of the nine tangible goals which I charted for the Section and which served as a consistent mantra for me and the Executive Committee during my tenure as Chair:

- 1. Enhancing committee activity
- 2. Expanding membership involvement
- 3. Increasing visibility with the New York State legislature
- 4. Focusing on one or more consumer/patient projects
- 5. Increasing the membership (Target: 1,200 members)
- 6. Building upon the relationship with the state's Medical Society

- 7. Maintaining the high quality of the Section's *Journal*
- 8. Maintaining the high quality of the Section's programs and MCLE programs
- 9. Improving the Section's Web site

In my final communication to the membership, I would like to review some of the actions taken by the Section to achieve these goals, as well as some planned activities for the rest of the Association year.

Report on Recent and Ongoing Section Activities

Through the hard work and superb efforts of the Section's Membership Committee and the Membership Department of the Association, the Section now has achieved its goal of 1,200 members—as of the date of the writing of this report, the Section has 2,008 members, representing a growth of approximately 100 members since my previous report.

The Section's Annual Meeting Program and the Annual Luncheon Meeting were a huge success. There were 165 attendees at the program, one registrant less than the all-time record number of 166 attendees. There was a new record set for the number of persons attending the luncheon (124 attendees).

The day began with early-morning meetings of many committees of the Section. These committee meetings were generally well attended. After the hour-long committee meetings, the educational program began. The morning segment of the program, "Not-For-Profit Health Care Systems: Their History, Structure and Future," was sponsored by the Section's Health Care Providers Committee under the leadership of Edward S. Kornreich. The program included a stellar array of presenters: Professor Kathleen Boozang of Seton Hall University School of Law; William Josephson of the New York State Attorney General's Office; Eric Stonehill of Harris Beach LLP; Michael Whiteman of Whiteman Osterman & Hanna LLP; and Edward S. Kornreich of Proskauer Rose LLP, who served as a presenter and Chair of the morning program. The afternoon program was entitled, "Private Practice and Public Responsibility: Emerging Issues in Mental Disability Law." The afternoon program was sponsored by the Section's Special Committee on Mental Health Issues under the direction of its Co-Chairs, J. David Seay and Henry A. Dlugacz, and co-sponsored by the Association's Committee on Issues Affecting People with Disabilities, chaired by Kathleen E. Surgalla. This component of the program highlighted issues concerning assisted outpatient treatment (Kendra's Law), adult homes and mental illness, and the enforcement of claims under the Americans with Disabilities Act. This part of the program also featured an outstanding panel of presenters,

which included: John Carroll of the New York State Office of Mental Health; John A. Gresham of New York Lawyers for the Public Interest; Carolyn Reinach-Wolf from the Law Offices of Carolyn Reinach-Wolf; Donald P. Berens of the New York State Department of Health; Lisa Newcomb of the Empire State Association of Adult Homes and Assisted Living Facilities; Jeanette Zelhof of MFY Legal Services, Inc.; Judy Preston of the U.S. Department of Justice; and Deborah Bachrach of Manatt, Phelps & Phillips, LLP. Both David Seay and Henry Dlugacz served as moderators. I also wish to acknowledge Lynn Stansel, the Section's Secretary, for her work in spearheading the organization of the Annual Meeting program.

The luncheon meeting was entertaining and productive. However, the luncheon began on a somber note with the observance of a moment of silence to mark the passing of Barry A. Gold, the first Health Law Section Chair. Francis J. Serbaroli then presented the report of the Nominating Committee. The Section elected its officers for Association year 2003-2004. The officers for the upcoming Association year are: James W. Lytle, Chair; Phillip Rosenberg, Chair-Elect; Lynn Stansel, Vice-Chair, Mark Barnes, Secretary; and Peter J. Millock, Treasurer. It is a first-rate slate of officers. I congratulate them and thank them for their commitment to this organization. During the luncheon, the Section paid tribute to the Immediate Past Chair, Robert Abrams, for his innovative and creative leadership of the Section. A draft copy of Legal Manual for New York Physicians was displayed to the membership as one of the centerpiece projects initiated during Bob Abrams' tenure as Section Chair. The Section was honored to have his wife, Linda, at the luncheon to share in this acknowledgment. The Section also recognized the law firm of Manatt, Phelps & Phillips, LLP for its commitment to underwrite the monetary prizes for the newly established Barry Gold Memorial Health Law Student Writing Competition. Ms. Barbara Katz Arky accepted a certificate of appreciation from the Section on behalf of Manatt, Phelps & Phillips, LLP. Ms. Hortense F. Mound, the first female Chair of the Association's Committee on Public Health (a predecessor to the Health Law Section) who served from 1965-1968, was honored by the Section for her work on public health legislation and her pioneering role as a female leader within the Association. As is customary, the Section was treated to remarks by the General Counsel of the New York State Department of Health, Donald P. Berens, Jr. Don presented a brief overview of the Health Department's achievements during the past year and a forecast of some of its future agenda items.

In conjunction with the Association's Membership Department, the Section also co-sponsored (with the Entertainment, Arts and Sports Law Section) a cocktail party for law students during the Annual Meeting. I was delighted to share a few brief remarks about the Health Law Section and the benefits of Section membership with the attendees.

On March 11, the Section's In-House Counsel Committee under the outstanding leadership of Karen Gallinari sponsored a half-day meeting program entitled, "MD Joint Ventures: Legal Issues and Panel Discussion." The program was FREE and was approved for a total of 3.0 MCLE credit hours for those who attended the program in person. As is now the practice of the Section, telephone participation in meetings is an option regularly offered to the membership, however no MCLE credits were approved for those attendees. The program was hosted at the elegant offices of Proskauer Rose LLP. The program assembled a premier cadre of talented and experienced health law practitioners. The panel of speakers included Fred Miller of Garfunkel, Wild & Travis, P.C.; Edward S. Kornreich of Proskauer Rose, LLP; Robert Belfort of Manatt, Phelps & Phillips, LLP; and Peter J. Millock of Nixon Peabody, LLP. The attendees were treated to a well-organized and well-run program, with superb written materials and a first-rate exploration of the subject. The Section extends its gratitude to the In-House Counsel Committee and its Chair for arranging this meeting program. The Section also thanks Edward S. Kornreich and the law firm of Proskauer Rose LLP, as well as Lynn Stansel, Lisa Bataille, the Section's Association Liaison, and the Association's Meetings Department for their assistance with this meeting program.

Report on Planned Section Activities

In March, the Section will be submitting additional information to the New York Bar Foundation concerning its grant request. At its January meeting, the Foundation deferred action on the grant proposal pending receipt of additional information. As previously reported in the Journal, the Section is requesting that the Foundation partially fund the development and distribution of a 12- to 15-minute videotape for health care consumers on the importance of creating a health care proxy. This project is being spearheaded by Douglas Sansted, Co-Chair of the Biotechnology and the Law Committee; Kathleen Burke, Co-Chair of the Ethical Issues in the Provision of Health Care Committee; and myself. The Radio Drama Network Foundation, and its Board Chair Himan Brown have informally committed to provide some technical and financial support for this Section project. The project is still seeking a well-recognized and respected individual to introduce the video, as well as additional organizations to provide financial and technical support for this undertaking. Interest in the video has been expressed by the Chairs of the Trust and Estates Law and Elder Law Sections of the Association.

By the end of April, the Section's first major publication, Legal Manual for New York Physician, will be available. Although originally expected to be released in January, the sheer volume of the publication has caused some delay. As you may recall, this publication is the brainchild of the Section's Immediate Past Chair, Robert Abrams. This book contains a comprehensive but brief review of the laws affecting physicians in New York State. It is a must-purchase publication for all physicians who practice in New York and their lawyers. This book is the product of a collaborative effort between the Health Law Section and the Medical Society of the State of New York. Donald Moy, a member of the Health Law Section and the General Counsel for the Medical Society, was instrumental in orchestrating this joint project. The distinguished authors of this book are members of the Section who willingly gave countless hours of time to authoring and editing this book as a service to the Section. This book is very reasonably priced and offered at a discount for members of the Section.

The beginning of May is the deadline for finalization of the Section's white paper on New York State's physician disciplinary process. Presently, the Section's Professional Discipline Committee is reviewing the draft and offering suggestions. In recognition of the diverse perspectives within the Section on this issue, the paper will not represent the unanimous position of all members of the Section. This paper is anxiously awaited by many groups within the Association, as well as outside of the Association. It is unfortunate that a draft of the white paper was published by an upstate medical society without the Section's permission. The Section regrets any problems that this unauthorized publication of the draft may have caused.

On May 6th, the Section's Health Care Internet Committee under the fine leadership of Anne Maltz and Charles A. Mele sponsored a program entitled, "The Appropriate Use of the Internet In Medical Practice." It was once again FREE to members of the Health Law Section, with a charge for non-Section members. The program was approved for 2.0 hours of MCLE credits. The program was hosted by the law firm of Shearman & Sterling in New York City. Among the featured speakers on the program were Laura Gribbin of Frier & Levitt and Steven Lawrence Katz, M.D. of WebMD. The Section is grateful to Shearman & Sterling for providing the use of its facilities for the program.

Additionally, in May the Section (in conjunction with the Association's Continuing Legal Education Committee) will sponsor a four-city program entitled, "Fundamentals of New York Health Law." The program will be a brief but comprehensive review of health law in New York State. It is a full-day program and will be offered in Albany and Long Island on May 16, and in Rochester and New York City on May 30.

The Section is considering holding another Lobbying Day in Albany. The purpose of the meeting would be to present the Section's soon-to-be-finalized white paper on the state's process for physician discipline, and to advocate for the enactment of the Family Health Care Decision Act into law. Representatives of the Section would once again meet with key members of the legislative and executive branches of the state government.

Information regarding the Barry A. Gold Memorial Health Law Student Writing Competition has been distributed to area law schools and is on the Section's Web site. The deadline for the submission of an article has been extended until June 1, 2003.

For information regarding the activities of the Section Committees please refer to this *Journal* and the Section's Web site. I once again urge you to join the listserv and to be involved with the Section's committees, programs, and the *Journal*.

In closing, I am pleased to know that I pass the leadership to Jim Lytle, a great Chair-Elect and soon to be an outstanding Chair. At this juncture, I wish to thank the many people who made my year as Chair both an enjoyable and a productive experience. At the outset, I must acknowledge Lisa Bataille for her good work, advice, and support for the Section's agenda. I would also like to thank the Association's Membership Department (Pat Wood and Karin) for their hard work in assisting in the Section's efforts to increase membership. I would also wish to thank my employer, the New York City Health and Hospitals Corporation, and specifically Alan D. Aviles, General Counsel, and Dr. Benjamin Chu, President, both of whom have been supportive of my work as Health Law Section Chair and my post-surgical recovery. I must also thank my wife, Sandy, and my three children (Stephen, Matthew and Christopher) for allowing me to share some of my precious personal time with Section business. Finally, I must thank the outstanding individuals who serve as Section officers, Chairs, Co-Chairs, members-at-large and liaisons. Their dedication and hard work is taking this section to higher levels, and have made my tenure as Chair particularly rewarding.

Salvatore J. Russo

<section-header>Did You Know? Back issues of the Health Law Journal (2000-2003) are available on the New York State Bar Association Web site. (your ony State Bar Association Web site. Click on "Sections/Committees/ Health Law Section/ Member Materials/ Health Law Journal" For your convenience there is also a searchable index in pdf format. To search, click "Find" (binoculars icon) on the Adobe tool bar, and type in search word or phrase. Click "Find Again" (binoculars with arrow icon) to continue search. Note: Back issues are available at no charge to Section members only. You must be logged in as a member to access back issues. For questions, log-in help or to obtain your user name and password, e-mail webmaster@nysba.org or call (518) 463-3200.

A Note from the Editors

In a remarkably short time, New York State's Attorney General Eliot Spitzer achieved national prominence as an exceptionally energetic, steadfast and principled attorney general. He and his staff seem to be everywhere, forcefully asserting the interests of New York's consumers, employees, investors, and patients.

Health lawyers have been watching the increased activism of the Attorney General's office with great interest, and with a need to know more about this development and its significance for their field. First and most basically—health lawyers need to understand the AG's statutory role and operational practices in health care: e.g., what his different bureaus are doing in the healthcare field; what actions require his office's approval; what assistance they can offer; and what actions will attract his office's unfavorable attention.

But beyond that, we need to understand and debate the policy implications of AG activism in health care. Health lawyers share and support the AG's aim of protecting patients, combating fraud and abuse, and safeguarding access to care. But we also know well that the healthcare field is not suffering from a dearth of governmental oversight. Nearly every aspect of healthcare is subject to voluminous regulations and intensive review by multiple regulatory agencies—sometimes working at cross-purposes. This *Journal* explored the negative impact of over-regulation and overly-aggressive enforcement in a recent special edition.¹ It is in this context that new and enhanced initiatives by the AG are occurring.

Accordingly, this special edition of the *Journal* both explains and examines the role of the Attorney General in healthcare.

We at the *Journal* are delighted and honored that Attorney General Eliot Spitzer and his staff contributed articles-excellent articles-to this edition. We express our appreciation to the Attorney General and to the other authors from his staff: Joseph Baker, Bureau Chief of the Health Care Bureau; David Sharpe, Assistant Attorney General in the Health Care Bureau; Jay L. Himes, Bureau Chief of the Antitrust Bureau; Robert L. Hubbard, Director of Litigation, Antitrust Bureau; William Josephson, Bureau Chief of the Charities Bureau; Thomas Conway, Bureau Chief of the Consumer Frauds and Protection Bureau: Rose Firestein. Assistant Attorney General, Consumer Frauds and Protection Bureau; William J. Comiskey, Deputy Attorney General in charge of the Medicaid Fraud Control Unit (MFCU); and Kevin Ryan, MFCU Public Information Officer. You concluded that telling the health law bar about your objectives and activities will advance the public interest. We agree.

Also, we owe a special thanks to David Nocenti, Counsel to the Attorney General, for his support for this edition, and for his help in making it happen.

Next we must thank the health law attorneys and others who contributed to the multi-author article, "Other Views on the Role of the AG in Health Care": Edward Kornreich, Pat Formato, Harold Iselin, Ben Golden, Robert Wild, and Mark Thomas.

And finally, we once again need to thank our regular columnists for their commitment to the *Journal*: Claudia Torrey, Leonard Rosenberg, Frank Serbaroli and James Lytle.

Endnote

1. Special Edition—Penalizing Providers: Enforcement or Exploitation?, NYSBA *Health Law Journal* (Winter 2002).

Robert N. Swidler and Dale L. Moore



In the New York State Legislature

By James W. Lytle

As of this writing, the 2003 legislative session has been dominated by the fiscal crisis enveloping New York (and most other states) and overshadowed by world events. The legislature is expected to spend much of the earlier part of the legislative session grappling with closing a budget gap estimated as high as \$12 billion, while also addressing a series of proposals advanced by Governor Pataki to strengthen the state's response to terrorism. Drastic cuts to health care and education programs were included within the Governor's Executive Budget proposal. At this writing, the Legislature-passed budget seems headed toward a gubernatorial veto, which may be overriden. Although the state has faced a series of difficult budgets over the past 25 years, the prospect of the state actually running out of cash to meet its obligations has added a greater urgency to the current debate.

While these issues will likely dominate the 2003 legislative debate, certain other health care proposals may actually receive closer and perhaps more favorable attention, if only because the legislature may be looking for an opportunity to advance positive proposals that may not involve the expenditure of state funds. A number of health care initiatives or health-related bills meet that description.

For example, agreement was reached on a bill to extend and strengthen existing no-smoking laws. The long-stalled "Family Health Care Decisions Act," which would authorize family members and loved ones to make health care decisions for the incapacitated under certain circumstances, has been re-introduced and is being supported by a growing number of organizations. A package of proposals relating to reform of the adult home industry is likely to be given serious consideration in light of the public and press attention to those issues. Proposals to address various aspects of the medical malpractice issue, to improve patient safety and reduce medical errors, and to impose staffing ratios in various health care settings are again being debated.

One new proposal, strongly supported by disease-related health organizations and spearheaded by Christopher Reeve, would establish a "Reproductive Cloning Prohibition and Research Protection Act" in response to federal restrictions on the emerging area of stem cell research. The bill (A.6249-A) is intended to ban "cloning," while, at the same time, permitting the conduct of other stem cell research that is regarded by scientists as offering promise for treating debilitating diseases and conditions, including cancer, heart disease, Parkinson's disease and spinal cord injury.

The legislation would prohibit reproductive cloning, defined as "creating a human embryo through somatic cell nuclear transfer for the purpose of the gestation and subsequent birth of a human being, or the gestating of a human embryo, created through somatic cell nuclear transfer, or resulting fetus for that purpose." "Therapeutic cloning"—defined as "creating a human embryo through somatic cell nuclear transfer for the purpose of medical or scientific research or medical treatment"would be specifically exempted from that prohibition, as would stem cell research, in-vitro fertilization and "research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, tissues, organs, plants or animals other than humans or cells other than human embryos." The bill would also establish a legislative commission on human cloning to advise the legislature on matters relating to genetic engineering, stem cell research and cloning.

The bill responds to federal legislation, known as the Human Cloning Prohibition Act, passed by the House of Representatives on February 26. That legislation has concerned advocates for continued medical research because it may be deemed to ban any form of stem cell research, including those specifically authorized by the proposed state legislation.

The bill, which was introduced by Speaker Sheldon Silver, has already passed the Assembly. Its status in the Senate is uncertain: a largely comparable bill (S.3013) had been introduced by Senator Hannon but was amended, shortly after Assembly passage, to direct the Task Force on Life and Law to study the issue and report to the legislature on any regulatory or legislative recommendations it might have.

As a new service to members of the Health Law Section, we will begin including on the Section's Web site a selective listing of health care legislation under consideration in Albany. One of our hopes is not only to inform our members of the existence and status of legislation but to prompt our active committees to take positions on legislation of interest to health care practitioners. We hope you'll check out the legislative summary on the Web site and share your comments on bills of interest with your colleagues in the Section.

Compiled by James W. Lytle, managing partner of the Albany offices of Manatt, Phelps & Phillips, 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 Courts

By Leonard Rosenberg

Court of Appeals Declines to Extend Exception to New York's "At-Will" Employment Doctrine to an Industry-Employed Physician

Horn v. The New York Times, 2003 WL 443259 (Feb. 25, 2003). Horn involved a physician who had been employed as the Associate Medical Director of the New York Times (the "Times"). There was no written employment agreement between the physician and the Times. The physician alleged that her "primary responsibilities" at the Times were to provide medical care, treatment and advice to the Times' employees, including determining whether injuries suffered by employees were work-related, thus making the employees eligible for Workers' Compensation benefits. During the course of her employment, the physician alleged that, on several occasions, administrators in various departments at the Times directed her to provide them with confidential patient medical records without the knowledge and consent of the employees and instructed her to provide false information to employees regarding the causes of their injuries in order to reduce the number of Workers' Compensation claims filed by the Times' employees. The physician alleged that her position was "phased out" as pretext by the Times for her failure to comply with the administrators' improper requests and directives.

The physician commenced an action against the Times alleging that her employment carried with it an "implied and fundamental understanding which requires no written expression, that the physician will conduct her practice on the employer's behalf with the ethical standards of the medical profession...." It was further alleged that the Times breached a covenant of good faith and fair dealing implied in the



employment agreement by terminating the physician for failing to comply with the Times' improper requests. The physician also

claimed that compliance with the requests and directives would have required her to violate patient confidentiality and other provisions of the Education Law governing physician conduct as well as subject her to professional sanctions. The motion court denied the Times' motion to dismiss the complaint, and held that the physician stated a cause of action under the narrow exception to New York's strict "at-will" employment doctrine recognized by the Court of Appeals in Wieder v. Skala, 80 N.Y.2d 628, 593 N.Y.S.2d 752 (1992). The Appellate Division, in a split decision, affirmed the denial of the Times' motion.

The Court of Appeals reversed and dismissed the physician's claim for breach of the covenant of good faith and fair dealing. The Court began its analysis by retracing the history of case law governing New York's "at-will" employment doctrine. The doctrine permits an employer to discharge an employee for any reason or no reason at all, if the employment is not for a definite term or otherwise subject to any contractual restriction of the right to discharge. The Court then explained its prior ruling in Wieder, which involved an attorney who was purportedly fired from his position as an associate in a private law firm for demanding that the firm's partners comply with their ethical obligations to report professional misconduct by one of the firm's attorneys to the proper disciplinary authorities.

According to the Horn Court, three primary considerations led to the conclusion that the plaintiff in Wieder stated a valid claim against the law firm for breach of the implied covenant of good faith and fair dealing. First, the Court noted that the "only purpose" for the *Wieder* plaintiff's association with the defendant law firm was to provide legal services to the firm's clients as a member of the Bar. Second, the ethical obligation at issue in *Wieder* was "indispensable to the unique function of attorney self-regulation." The third issue was that the Wieder plaintiff and the defendant law firm were engaged in a "common professional enterprise" and were "mutually bound to follow" the ethical obligation at issue.

In applying these considerations to the facts presented in Horn, the Court concluded that the physician's claim did not fall within the narrow confines of Wieder. First, the Court held that the physician rendered professional medical services for the benefit of both the employees and employer, and not just as a physician, but in "furtherance of her responsibilities as part of corporate management." Thus, the Court concluded, the provision of professional services was not the "only purpose" of her employment with the Times, unlike the plaintiff in Wieder. Second, while recognizing the importance of patient confidentiality and other rules governing the physicianpatient relationship, the Court held that such rules were not "critical to professional self-regulation" like the rule at issue in Wieder. Finally, the Court held that "because of the absence of a common professional enterprise between [the physician] and the Times, the Education Law provisions cited by [the physician] do not impose a mutual obligation on the employer and the employee

in this case." Because the physician's claim failed to satisfy any of the central considerations or criteria which supported the holding in *Wieder*, the Court dismissed the claim for failure to state a cause of action. [Justice Smith filed a lengthy dissenting opinion in which he concludes that the physician's claim in this case falls squarely within *Wieder*.]

Federal Court of Appeals Holds that Medical Care Component of HMO's Treatment Determination Is Not Necessarily Preempted by ERISA

Cicio v. Does, 321 F.3d 83 (2d Cir. 2003). In a matter of first impression, the Court of Appeals for the Second Circuit held that the Employee Retirement Income Security Act of 1974 (ERISA) did not necessarily bar a state law claim for medical malpractice. Upon review of the district court's determination that all of the plaintiff's state law claims were based upon an adverse benefits determination, and thus, were preempted by ERISA, the Second Circuit reversed that portion of the district court's order that dismissed the plaintiff's medical malpractice claims. In reaching its decision, the Court found that a determination as to whether, in choosing one course of treatment over another, Vytra had made a pure eligibility determination or a "mixed eligibility and treatment decision" could not be resolved on a motion to dismiss. The Court cautioned, however, that it would not "rule out the possibility that the defendants can demonstrate, as a matter of fact, that dismissal" is warranted.

In 1998, after Carmine Cicio's cancer was first diagnosed, his treating physician wrote a detailed letter to Vytra to request insurance authorization for a tandem double stem cell transplant. Approximately one month later, Vytra Healthcare's medical director, defendant Dr. Spears, denied the request, stating that the requested procedure was "not a covered benefit." Mr. Cicio's physician

again wrote to Vytra, arguing that, together with high-dose chemotherapy, the double stem cell transplant offered the patient a better chance for survival than any other treatment and enclosed supporting medical literature. Three weeks later, Dr. Spears again denied the request for approval of the tandem cell transplant but approved a single stem cell transplant that had not been requested. By the time Dr. Spears issued this second response, however, Mr. Cicio was no longer a viable candidate for a stem cell transplant. He died less than two months later.

Mr. Cicio's widow filed a complaint in New York Supreme Court, Suffolk County, alleging eighteen state law claims against Vytra, Dr. Spears and eight unidentified Vytra physicians, including claims for medical malpractice, negligence, negligent infliction of emotional distress and breach of contract, all based upon Vytra's denial of treatment. The defendants removed the case to the United States District Court in the Eastern District of New York and sought to dismiss the action on the ground that all of the claims were preempted under Sections 502(a) and 514(a) of ERISA, 29 U.S.C. §§ 1132(a)(1)(B) & 1144(a). The matter was referred to a Magistrate Judge who rejected the plaintiff's arguments, including her argument that preemption did not apply to her medical malpractice claims because Vytra's conduct involved mixed eligibility and treatment decisions. The district court adopted the Magistrate report and recommendation in full, noting that "[d]efendants' roles, including that of Dr. Spears, were administrative" and, thus, were benefits determinations preempted by ERISA.

On appeal, the Second Circuit began its analysis by determining that all of the plaintiff's claims arose from a "common nucleus of operative facts . . . to wit, the denial by Dr. Spears of authorization for a double stem cell transplant." The Court concluded that to the extent the plaintiff alleged that Vytra had failed to timely conduct an appeal of the denial of care and had misrepresented its benefits coverage, such claims were preempted by ERISA. Thus affirming the district court's dismissal of these claims, the Second Circuit turned to consider the plaintiff's remaining medical malpractice claims.

The Court acknowledged that a decision "lack[ing] a significant application of medical judgment" would properly be treated as a pure benefits determination. However, correspondence between Mr. Cicio's treating physician and Vytra's Dr. Spears, "strongly suggest[ed] . . . [an] additional[] . . . or . . . alternative [contention] . . . that Dr. Spears, in making negligent medical decisions about Mr. Cicio's condition, was engaged in medical malpractice." The Court further noted that "[b]y denying one treatment and authorizing another that [Mr. Cicio's treating physician] had not specifically requested, Dr. Spears at least seems to have engaged in a patient-specific prescription of an appropriate medical treatment." Consequently, the Court of Appeals found that the complaint, read together with the relevant correspondence, "could implicate a state law duty concerning the quality of medical decisionmaking, in addition to and independent of [plaintiff's] claims concerning the administration of benefits."

Notwithstanding the "considerable force" of defendants' argument that Dr. Spears' decision constituted a benefits determination preempted by ERISA, the Court found that recent Supreme Court decisions had, in effect "thrown 'cold water'" on earlier ERISA preemption jurisprudence. Acknowledging the difficulty in distinguishing between pure coverage determinations and 'eligibility decision[s] [that] cannot be untangled from physicians' judgments about reasonable medical treatment'-particularly when such determinations are made regularly by third-party payors—the Court,

applying the relevant standards on a motion to dismiss, concluded that Vytra's decision "must be treated as a mixed decision because it allegedly involved both an exercise of medical judgment and an element of contract interpretation."

Court Holds that Federal Nursing Home Reform Act Protects Certain Quality Assurance Documents from Disclosure in Response to Grand Jury Subpoenas

In re Subpoena Duces Tecum to Jane Doe, Esq., 2003 WL 441990 (Feb. 25, 2003). The Court of Appeals analyzed the Federal Nursing Home Reform Act in holding that records generated by, or at the behest of, a nursing home's quality assurance committee are protected under federal law from disclosure in response to a grand jury subpoena. Other records, however, that are not expressly related to quality assurance, are not similarly protected from such disclosure even if a quality assurance committee reviewed such records.

This appeal arose from subpoenas issued by a grand jury investigating facility management and resident care in three Erie County nursing homes. The subpoenas sought numerous documents and reports related to the investigation. Appellant argued that because the requested documents had been generated by the homes' quality assurance committees, those documents were protected by the work product privilege applicable to quality assurance committees. The New York Attorney General, as Respondent, argued that the records were subject to disclosure because the nursing homes, under state regulation, were required to maintain such records, and that the documents were not generated by members of the quality assurance committees.

The Court of Appeals reviewed the history and intent of the Federal Nursing Home Reform Act (FNHRA), noting that the purpose of

the 1990 Congressional amendment (which created the nondisclosure provision protecting records of quality assurance committees) was to allow those committees to candidly assess the quality of health care services without fear of reprisal from those reviewed. The Court analogized a nursing home's quality assurance committee to a hospital's quality assurance committee in applying the privilege to the nursing homes at issue. The FNHRA specifically provides that the State may not require disclosure of "records of [a quality assurance] committee," except in narrow circumstances unrelated to this appeal. Thus, the critical issue in the Court's analysis was exactly which records qualified as "records of the committee."

The Court separated the requested records into two categories: records that had been maintained by nursing homes in compliance with federal and state requirements, which may have been used by the quality assurance committees, and records that had been created or generated for quality assurance purposes. The Court held that only the latter class of records are protected under FNHRA. The Court reasoned that when a document is not "expressly related" to quality assurance, the fact that a committee might review such information, even for a collateral quality assurance purpose, does not confer the document with protection from disclosure. All documents expressly related to quality assurance, generated by or at the direction of the quality control committee, are protected under FNHRA. Accordingly, after classifying the various classes of requested documents, the Court ordered the various subpoenas quashed as to documents in the protected class, and ordered the other class of documents to be disclosed.

Appellate Court Upholds the Constitutionality of Kendra's Law

Matter of K.L., 2002 WL 31973910 (2d Dep't 2003). The Appellate Divi-

sion for the Second Department recently determined that Mental Hygiene Law section 9.60 does not violate the Equal Protection Clauses of the United States and New York State Constitutions. Mental Hygiene Law section 9.60, better known as Kendra's Law, was enacted largely in response to the death of Kendra Webdale, a woman allegedly killed at the hands of a diagnosed schizophrenic who pushed her in front of an oncoming subway train in Manhattan in 1999. The law was intended to provide the severely mentally ill with essential services and monitoring to promote continuity of care and the ability to live safely in the community.

These essential services and monitoring are referred to as assisted outpatient treatment (AOT). Kendra's law allows certain designated persons to petition the court to compel a mentally ill person who meets specified criteria to comply with an AOT plan.

The case arose when the Oueens County Supreme Court denied a psychiatric patient's application to dismiss an AOT application and, after a hearing, issued an order and judgment compelling the patient to comply with an AOT plan for 180 days. The patient, relying on Rivers v. Katz, N.Y.2d 485 (1986). contended that Kendra's Law was unconstitutional because it did not require a judicial finding that the subject of the AOT order lacks capacity to make a reasoned treatment decision. In Rivers, the Court of Appeals held that the state, in exercising its parens patriae power, cannot force an involuntarily committed patient to take antipsychotic medication unless there is a judicial determination that the patient lacks the capacity to make a rational treatment decision.

The appellate court distinguished Kendra's Law, however, based on a legislative finding that there are mentally ill persons who are capable of living in the community with supportive services, but without routine care and treatment, are prone to relapse and become violent or suicidal. The appellate court emphasized that Kendra's Law requires that persons be invited to participate in developing an AOT plan and that a finding of incapacity is not warranted when the trial court must find that a person requires AOT to prevent a relapse or deterioration likely to cause serious harm to the patient or others.

The patient also specifically challenged Mental Hygiene Law section 9.60(n), which sets forth a procedure for removing from the community to a hospital an assisted outpatient who fails to comply with an AOT order. More specifically, the patient contended that the subsection does not meet the constitutional mandates of procedural due process because it does not require a pre-removal judicial hearing.

In denying the patient's constitutional challenge, the appellate court found that the 72-hour observation period permitted by the subsection does not constitute a substantial deprivation of liberty, and the additional safeguard of a judicial hearing would not significantly reduce the possibility of an erroneous removal decision. The appellate court also found that the state's scarce clinical resources could be better utilized for the purpose of diagnosis and treatment, and that any detention beyond the initial 72 hours was governed by statutory provisions which included sufficient notice and hearing provisions to meet procedural due process.

Appellate Court Affirms Award of Attorneys' Fees to Hospital and Physician Defendants in Peer Review Lawsuit

Sithian v. Spence, 750 N.Y.S.2d 783 (2d Dep't 2002). This column previously reported a decision issued by Justice Joseph J. Maltese, New York Supreme Court, Richmond County, that awarded over \$235,000 in costs and attorneys' fees to the defendants in a peer review lawsuit. The award was based on a provision in the Health Care Quality Improvement Act (HCQIA) which states that an award of fees and costs shall be made to prevailing defendants if the court finds that the suit was brought for frivolous reasons, without foundation, or in bad faith.

In this case, a physician, whose hospital clinical privileges to perform certain surgical procedures were suspended, thereafter filed lawsuits against the hospital, the hospital's administrators, members of its medical staff, and members of its board of trustees, as well as the outside expert retained to review the physician's medical charts. The physician alleged, among other things, that statements made in the medical peer review proceedings were defamatory. The suits sought over \$30 million in damages against the hospital and the individual defendants. One of the suits was commenced while the suspension was under review by the hospital's board of trustees.

After the New York Public Health Council ruled that the hospital's actions complied with Public Health Law section 2801-b (which requires that hospital credentialing determinations be related to patient care, competency, or institutional objectives), and that the physician had been provided with due process, the defendants moved for summary judgment dismissal of all claims. The motion asserted immunity from liability under HCQIA and under New York Public Health Law section 2805-j. HCQIA provides participants in the medical peer review process with immunity from liability if certain due process and other criteria are met. Congress enacted HCQIA to discourage retaliatory litigation and encourage meaningful medical peer review. Defendant's motion was granted and the dismissal was

affirmed on appeal by the Appellate Division for the Second Department. Thereafter, the defendants moved for an award of costs and attorneys' fees.

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

The physician appealed from the award of attorneys' fees. The Appellate Division for the Second Department affirmed the award in all respects, finding that the record supported the motion court's conclusion that the suit was frivolous and in bad faith. The appellate court therefore ruled that the motion court "providently exercised its discretion" in awarding attorneys' fees under HCQIA.

Notably, the Appellate Division went even further than affirming the underlying fee award. The court ruled that under HCQIA, the defendants were also entitled to an award of attorneys' fees incurred in defending against the appeal, and remitted the matter to the motion court for a determination of that amount.

This case appears to be the first instance in which a New York State appellate court has affirmed an award of attorneys' fees under HCQIA.

Complaint Against Health Care Providers Who Reported Suspected Child Abuse Dismissed on Basis of Statutory Immunity

Diaz v. Montefiore Medical Center, 750 N.Y.S.2d 283 (1st Dep't 2002). A complaint filed against health care providers for their participation in reporting suspected child abuse was dismissed by the motion court by reason of the qualified statutory immunity conferred by section 419 of the New York Social Services Law (SSL). Section 413 of the SSL requires health care providers to report suspected child abuse to the state and section 419 provides immunity from liability for those who make such reports. In this case, the court granted defendants' motion to dismiss, and the Appellate Division affirmed.

The court held that defendants were entitled to immunity because "the allegations of the complaint, even when given the benefit of every reasonable inference in plaintiffs' favor, fail to allege conduct on the part of defendants-respondents so grossly negligent as to render the statutory shield ineffectual."

Internal Grievance Policy Held Insufficient to Limit Hospital Employer's Right to Terminate At-Will Employee

Oross v. Good Samaritan Hospital, 751 N.Y.S.2d 580 (2d Dep't 2002). Plaintiff, a former employee, brought an action alleging breach of an employment agreement and discrimination. The defendant hospital moved for summary judgment asserting that plaintiff was an at-will employee whose employment was terminated solely on the basis of her misconduct. The trial court denied the summary judgment motion, but the Appellate Division, Second Department reversed, and dismissed the action in its entirety. The Appellate Division held that, as the hospital had made a *prima facie* showing that plaintiff was an atwill employee, the burden was on plaintiff to come forward with admissible evidence that her employment could be terminated only for cause. Plaintiff alleged that she relied upon a grievance procedure outlined in the hospital's employee handbook to prevent her termination.

However, the court ruled that "a limitation on an employer's right to terminate at-will employment will not be inferred solely from the existence of an internal grievance procedure in a policy manual."

Non-Party Hospital's Bylaws Not Discoverable in Action Against Surgeon for Lack of Informed Consent

Catalano v. Moreland, 750 N.Y.S.2d 209 (4th Dep't 2002). Plaintiffs commenced an action alleging that the defendant surgeon committed medical malpractice in failing to obtain the informed consent of plaintiff, Candace Catalano, prior to surgery at Kenmore Mercy Hospital. The hospital was not named as a defendant in the action. Plaintiffs moved before the trial court, seeking to compel the production of the hospital's bylaws. The trial court denied plaintiffs' motion, and the Appellate Division, 4th Department affirmed the trial court's ruling.

The Appellate Division concluded that the non-party hospital's bylaws were not "material and necessary" to the prosecution of the action. It held that plaintiff would be required to prove her claim by production of expert testimony to the effect that, in providing professional medical treatment, defendant "failed to disclose alternatives thereto and failed to inform plaintiff of reasonably foreseeable risks associated with the treatment, and the alternatives, that a reasonable medical practitioner would have disclosed in the same circumstances."

The court noted that the reasonableness of defendant's conduct would be measured not against the hospital's bylaws, but against what would have been disclosed by a reasonable medical practitioner. The court also held that, insofar as the bylaws set forth the standards of care and procedures concerning peer review and quality management, they were not discoverable.

Physician's Complaint Dismissed for Failure to Pursue Administrative Remedy with Public Health Council

Shatkin v. Kaleida Health, 751 N.Y.S.2d 817 (4th Dep't 2002). Physician filed defamation and related tort claims against health system that denied his renewal application for medical staff privileges and reported the denial to the National Practitioner Data Bank. The court granted the health system's motion for summary judgment and dismissed the complaint, because the physician had not sought administrative review of his complaint with the New York State Public Health Council (PHC) as provided for in Public Health Law section 2801-b. New York case law generally requires PHC review of a physician's grievances concerning hospital privilege determinations before judicial review may be sought. In this case the court held that the physician's failure to seek PHC review barred his claims for wrongful termination, and likewise barred his attempted use of substitute claims.

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

In the New York State Agencies

By Frank Serbaroli



Chemical Dependence Outpatient Services

Notice of adoption. The Department of Health repealed section 505.27

and added a new section 505.26 to title 18 N.Y.C.R.R., which authorizes the Department to provide Medicaid reimbursement for the new outpatient chemical dependence programs licensed under Article 32 of the New York Mental Hygiene Law. Filing date: November 5, 2002. Effective date: December 2, 2002. See N.Y. Register, November 20, 2002.

Physician Profiling

Notice of emergency rulemaking. The Department of Health added part 1000 to title 10 N.Y.C.R.R. to implement the Patient Health Information and Quality Improvement Act of 2000. The Act requires the Department to collect information and create individual profiles on physicians that will be available for dissemination to the public. Information to be disseminated about the physicians includes criminal convictions and medical malpractice information. Filing date: December 6, 2002. Effective date: December 6, 2002. See N.Y. Register, December 24, 2002.

Environmental Laboratory Standards

Notice of emergency rulemaking. The Department of Health amended section 55-2.13 of title 10 N.Y.C.R.R. to establish minimum standards for laboratory testing of biological and chemical agents of terrorism. Filing date: December 17, 2002. Effective date: December 17, 2002. See N.Y. Register, December 31, 2002.

Adult Day Health Care Regulations

Notice of emergency rulemaking. The Department of Health repealed parts 425-427 of title 10 N.Y.C.R.R. and added a new part 425 to title 10 N.Y.C.R.R to ensure that individuals receive adult day health care when appropriate and that providers are accountable for providing necessary and appropriate care. Filing date: December 23, 2002. Effective date: December 23, 2002. *See* N.Y. Register, January 8, 2003.

Smoking Cessation Products

Notice of emergency rulemaking. The Department of Health gave notice of its intent to amend section 85.21 of title 10 N.Y.C.R.R. and section 505.3 of title 18 N.Y.C.R.R. to add over-the-counter smoking cessation products to the list of Medicaidreimbursable products. Filing date: January 13, 2003. Effective date: January 13, 2003. See N.Y. Register, January 29, 2003.

Communicable Diseases

Notice of emergency rulemaking. The Department of Health gave notice of its intent to amend section 2.1(a) of title 10 N.Y.C.R.R. to enable the Department to monitor for complications among persons receiving smallpox vaccinations and request treatment from the CDC to be used to treat adverse reactions on a timely basis. Filing date: January 28, 2003. Effective date: January 28, 2003. *See* N.Y. Register, February 12, 2003.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health repealed section 703.6, amended section 710.1 and added a new section 703.6 to title 10 N.Y.C.R.R. to clarify and enhance the requirements that apply to part-time clinics and to require prior limited review of all part-time clinic sites. Filing date: January 27, 2003. Effective date: January 27, 2003. *See* N.Y. Register, February 12, 2003.

Treatment of Opiate Addiction

Notice of emergency rulemaking. The Department of Health added a new section 80.84 to title 10 N.Y.C.R.R. and amended section 80.86 of title 10 N.Y.C.R.R. to permit the treatment of opiate addiction in an office-based setting. Filing date: February 4, 2003. Effective date: February 4, 2003. See N.Y. Register, February 19, 2003.

Newborn Screening

Notice of emergency rulemaking. The Department of Health amended section 69-1.2 of title 10 N.Y.C.R.R. to add three conditions (cystic fibrosis, medium-chain acylcoA dehydrogenase deficiency and congenital adrenal hyperplasia) to the current list of eight genital/congenital disorders that comprise New York State's newborn screening panel. Filing date: February 4, 2003. Effective date: February 4, 2003. *See* N.Y. Register, February 19, 2003.

Reportable Communicable Disease List and Quarantine Authority

Notice of emergency rulemaking. The Department of Health amended sections 2.1 and 2.5 of title 10 N.Y.C.R.R. to expand the list of potential bioterrorist agents in the communicable disease reporting system which permits local authorities to utilize quarantine measures in the event of a bioterrorist disease outbreak in New York State. These new bioterror agents include: glanders, melioidosis, Q Fever, smallpox, staphylococcal enterotoxin B poisoning and viral hemorrhagic fever. Expiration date: February 4, 2003. Effective date: February 19, 2003. *See* N.Y. Register, February 19, 2003.

Insurance Department

Healthy NY Standardized Applications

Notice of emergency rulemaking. The Department of Insurance amended sections 362-2.3 and 362-4.3 of title 11 N.Y.C.R.R. to simplify the Healthy NY standard application process by requiring health maintenance organizations and participating insurers to accept simplified, standardized Healthy NY applications. The use of such applications seeks to facilitate the appropriate enrollment in the program and to ease administrative processes. Filing date: November 12, 2002. Effective date: November 12, 2002. See N.Y. Register, November 27, 2002.

Physicians and Surgeons Professional Insurance Merit Rating Plans

Notice of emergency rulemaking. The Department of Insurance amended part 152 of title 11 N.Y.C.R.R. in order to establish guidelines and requirements for medical malpractice merit rating plans and risk management plans. Filing date: December 3, 2002. Effective date: December 3, 2002. See N.Y. Register, December 18, 2002.

Partnership for Long-Term Care Program

Notice of proposed rulemaking. The Department of Insurance gave notice of its intent to amend section 39.3(b)(1) of title 11 N.Y.C.R.R. in order to increase the minimum daily benefit dollar amounts for nursing home and home care services. *See* N.Y. Register, December 31, 2002.

Rules Governing Individual and Group Accident and Health Insurance Reserves

Notice of emergency rulemaking. The Department of Insurance repealed part 94 of title 11 N.Y.C.R.R. and added a new part 94 to prescribe regulations for the valuation of minimum individual and group accident and health insurance reserves. Filing date: December 31, 2002. Effective date: December 31, 2002. *See* N.Y. Register, January 15, 2002.

Compiled by Francis J. Serbaroli, Esq. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft's 20-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the New York Law Journal, and 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.

REQUEST FOR **A**RTICLES

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

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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.

In the Law Journals

By Dale L. Moore

Journal of Health Law Volume 35, Number 3

- William G. Kopit, Price Competition in Hospital Markets: The Significance of Managed Care.
- Stuart I. Silverman & Sidney Rocke, *Nursing Home Qualityof-Care Cases After* Mikes v. Straus.
- Mark H. Goran & Erin E. Fuller, Navigating the Minefield: Legal Ethics and Healthcare Law.
- HIPAA Standards for Privacy of Individually Identifiable Health Information: An Introduction to the Consent Debate.
- Kristen Rosati, DHHS Wisely Proposed to Remove the "Consent" Requirement from the HIPAA Privacy Standards.
- Geralyn A. Kidera, The Proposed Changes to the Final Privacy Rule Suggest a Disturbing Reduction in an Individual's Ability to Exercise a Right to Healthcare Privacy.
- Andrew M. Knoll, Mea Culpa, Mea Culpa: A Call for Privilege for Self-Disclosure of Error in the Setting of Primary Medical Education.

Journal of Health Law Volume 35, Number 4

• Brandy L. Glasser & Bryan A. Liang, *Hearing Without Understanding: A Proposal to Modify* Federal Translation Guidelines to Improve Healthcare for Citizens with Limited English Proficiency.

- Neil F. O'Flaherty, FDA's New Regulatory Scheme for Human Cell and Tissue Products.
- William A. Knowlton, Jeffrey D. Kahn, & Kelly Honohan, Negotiating Clinical Trial Agreements in a Scrutinized and Competitive Environment.
- Sarah Beatty Ratner, HIPAA's Preemption Provision: Doomed Cooperative Federalism.
- Jennifer A. Marsh, *Telefraud: The Inception of Fraud and Abuse Prosecutions Against Telemedicine Providers.*

Houston Journal of Health Law & Policy Volume 2, Number 1 Biotechnology Symposium

- Joan H. Krause, Foreword: The Promise and Peril of Biotechnology.
- James Sheehan, Address, Bio-Tech Fraud: Reality or Fantasy?
- Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development.*
- Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs.*

- Cynthia M. Ho, Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient Based Discoveries.
- Frederick R. Parker, William J. Winslade, & Charles J. Paine, Organ Procurement and Tax Policy.
- Jennifer L. Smith, Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn.
- Rachel Polinger-Hyman, Erecting Women: Contracting Parenthood from Marriage to Divorce.
- Jennifer N. Phan, The Graying of America: Protecting Nursing Home Residents by Allowing Regulatory and Criminal Statutes to Establish Standards of Care in Private Negligence Actions.

In Other Journals:

- Carl H. Coleman, *Conceiving Harm: Disability Discrimination in Assisted Reproductive Technologies*, 50 U.C.L.A. L. Rev. 17 (2002).
- Robin Fretwell Wilson, Rethinking The Shield of Immunity: Should Ethics Committees be Accountable for Their Mistakes? 14 HealthCare Ethics Committee Forum 172 (2002).

Dale L. Moore is Associate Dean of Academic Affairs and Professor of Law, Albany Law School, and co-editor of the NYSBA *Health Law Journal*.

For Your Information

By Claudia O. Torrey

On February 20, 2003, the Department of Health and Human Services (DHHS) issued two long-awaited pieces to the Health Insurance Portability and Accountability Act of 1996 (HIPAA): modifications to the Electronic Data Transaction Standards and Code Sets final rule,¹ and the final Security Rule (SR)² for electronic protected health information (EPHI). This column will give a brief overview of the SR.³

Subpart C of 45 C.F.R. § 164 is the new home of the SR. As a point of review, subpart A contains general provisions; subpart E contains the privacy standards for the privacy rule (PR), which has a compliance date of April 14, 2003! The SR effective date is April 21, 2003, but for enforcement purposes, the SR compliance date is April 21, 2005. An extra year is given for small health plans. One need not relax, however, because a "quasi-SR" exists within the PR at 45 C.F.R. § 164.530(c).⁴

Generally speaking, the SR is narrower in scope than the PR because it only pertains to EPHI,⁵ whereas the quasi-SR requires safeguards for both EPHI and non-EPHI. Some new word concepts are introduced within the SR, and changes in terminology are made for consistency with the PR.

The heart of the SR lies within 45 C.F.R. § 164.306. Among other things, this section mandates a covered entity $(CE)^6$ to:

- ensure the confidentiality, integrity, and availability of all EPHI the CE creates, receives, maintains, or transmits;
- (2) protect against any reasonably anticipated threats or hazards to the security or integrity of such information;
- (3) protect against any reasonably anticipated uses or disclosures of such information *not* permitted or required under the PR; and,

(4) ensure workforce compliance with the SR.⁷

Security implementation is to be flexible, and factor in items such as cost, CE capabilities, and potential risks to EPHI.⁸

Implementation specifications under the SR are listed primarily as "required" or "addressable."⁹ If no corresponding implementation is given for a particular security measure, then the stated security measure is the implementation specification. The SR appendix lists fourteen *required* implementation specifications,¹⁰ and all decisions are to be documented.¹¹

Readers may recall that the proposed SR required a chain of trust agreement, which sought to guarantee the secure transmission of all EPHI between contracting parties. The final SR does not require a chain of trust agreement, but uses business associate terminology (BA) to require CEs to have agreements with assurances from BAs that they are using reasonable and appropriate safeguards for EPHI.¹² The reader should also carefully review the SR regarding group health plans.¹³

Regarding research, the SR preamble asserts that the SR applies to researchers who are either part of a CE or part of the healthcare component of a hybrid CE. Thus, researchers who are neither part of the CE workforce nor themselves a CE are *not* subject to the SR. Only time will tell how well this will work.

In conclusion, the SR favors the CE who exercises prudent judgment and constant risk evaluation. Both the SR and the PR demand that CEs ensure the security of EPHI transmissions irrespective of whether or not the recipient is a BA. In particular, risk analysis and risk management will be critical ongoing processes for CEs. So, go forth and be a HIPAA hero!!

Endnotes

- Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets, 68 Fed. Reg. 8381 (Feb. 20, 2003). The modifications are to the Code of Federal Regulations (C.F.R.) at 45 C.F.R. part 162; Corrections, 68 Fed. Reg. 11445 (Mar. 10, 2003).
- 2. Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334 (Feb. 20, 2003) (to be codified at 45 C.F.R. parts 160, 162, and 164).
- "The wheel that squeaks the loudest is the one that gets the grease," Josh Billings, pen name for Henry Wheeler Shaw; John Bartlett, *Familiar Quotations* 561, #19 (1980). This statement is apropos of what occurred with the SR. According to the preamble, DHHS considered not issuing a final SR; however, those against the idea were very vocal.
- 4. The quasi-SR explicitly mandates reasonably appropriate, administrative, technical, and physical safeguards to protect the privacy and security of PHI from any intentional, unintentional, or non-incidental uses or disclosures.
- 5. See 45 C.F.R. §§ 160.102, 164.302.
- Id. § 160.103 (A CE is defined as a health plan, a health care clearinghouse, and/or a health care provider who transmits any health information in connection with a transaction covered by 45 C.F.R. part 162.).
- 7. 45 C.F.R. § 164.306 (a).
- 8. Id. § 164.306 (b).
- 9. Id. § 164.306 (d).
- 10. Appendix A to 45 C.F.R. part 164.
- 11. 45 C.F.R. § 164.306 (d); see also 45 C.F.R. § 164.316.
- 12. *Id.* § 164.314 (a). The SR incorporated the PR definition of a BA.
- 13. *Id.* § 164.314 (b).

Claudia O. Torrey, Esq. is a member of the American Health Lawyers Association, the American Bar Association, and a sustaining member of the New York State Bar Association (NYSBA). From 1998–1999, as a member of the Health Law Section of the NYSBA, she chaired the year-long study group project that led to the creation of the current Special Committee on Medical Information.

Special Edition: The New York State Attorney General's Role in Health Care Issues

The New York State Attorney General's Role in Health Care Issues

By Eliot Spitzer

I want to thank the editors of the NYSBA *Health Law Journal* for dedicating the Spring 2003 edition to a discussion of the role of the Attorney General's Office (OAG) in health care issues. The OAG plays an integral role in a wide variety of health care matters, and it is important that lawyers and other health care practitioners are aware of the functions and duties of this office.



Many different OAG bureaus are involved in aspects of the health care industry, and attorneys from five of these bureaus provide their perspectives in this issue. Health Care Bureau Chief Joseph Baker and Assistant Attorney General David Sharpe discuss the general activities of the Health Care Bureau and provide a detailed description of one particular issue—the bureau's investigation into allegations that several health plans were violating the Utilization Review Law. William Comiskey, the Deputy Attorney General in charge of the Medicaid Fraud Control Unit (MFCU), and MFCU Public Information Officer Kevin Ryan co-author an article that provides an excellent overview of MFCU's activities, including discussions of several important cases.

Charities Bureau Chief William Josephson provides insight into the essential role that the OAG plays in the oversight of not-for-profit health care organizations. The article by Antitrust Bureau Chief Jay Himes and the Bureau's Director of Litigation Robert Hubbard discusses our efforts to preserve and foster competition in the health care marketplace. Finally, Consumer Protection Bureau Chief Thomas Conway and Assistant Attorney General Rose Firestein provide an excellent description of one of our most recent initiatives—the lawsuits filed against three pharmaceutical companies, alleging fraud in the reporting and use of "average wholesale prices" of prescription medication. This investigation required the expertise and participation of attorneys in numerous bureaus, and the article shows the coordinated and cooperative effort that was used to develop this important case.

Although these five articles give some idea of the breadth of issues addressed by the OAG, they still do not encompass the entire picture. For example, our office not only brings affirmative lawsuits on health care issues, it also plays an important role in defending such cases in its capacity as litigation counsel for SUNY, OMH, OMRDD and other agencies that operate health care facilities. This defensive side of our operations is every bit as important to the state and its residents, and it provides us with a broad perspective on virtually all health care issues that arise.

Finally, it is important to note that the OAG works very closely with DOH and other state agencies in many initiatives. We have forged a strong working relationship with these agencies, as well as our counterparts at the federal and local level, and these cooperative efforts are very important to our joint role in protecting the health and well-being of all New York residents.

I believe that all health care lawyers and practitioners will find these articles to be enlightening. I again want to thank the *Health Law Journal* for compiling this issue, as well as the OAG personnel who worked so hard to put together these excellent summaries of our activities in the health care area.

The Health Care Bureau: Empowering Health Care Consumers

By Joseph Baker and David Sharpe

This article provides an overview of the principal functions of the Attorney General's Health Care Bureau (HCB), the kinds of consumer complaints it helps to mediate, and a more detailed description of a particular enforcement action undertaken by its attorneys: the HCB's investigation into several health plans' utilization review procedures. This 18-month investigation revealed that several health plans in New York State had been violating important consumer-protection provisions contained in Article 49 of the Public Health Law and Article 49 of the Insurance Law (together, the Utilization Review Law or UR Law) concerning the way in which health plans conduct utilization review (UR)that is, how they decide whether to deny coverage of health services as medically unnecessary. The investigation concluded with seven of the plans signing agreements under which they promised to bring their UR practices into compliance with the law and to have their compliance monitored by the HCB for the following two years.

1. The Health Care Bureau's Mission

The HCB is part of the Attorney General's Division of Public Advocacy. The HCB's principal mandate is to protect and advocate for the rights of health care consumers statewide, through:

- Operation of the Health Care Helpline. This tollfree telephone hotline provides assistance to New York health care consumers by employing mediators who provide helpful information and referrals, investigate individual complaints, and attempt to mediate a resolution that will help to ensure that each consumer obtains access to the health care to which the consumer is entitled.
- **Investigations and Enforcement Actions**. These activities target health plans, providers and other individuals and entities that engage in fraudulent, misleading, deceptive or illegal practices in the health care market.
- **Consumer Education.** Through education initiatives, the HCB seeks to acquaint New Yorkers with their rights under health and consumer protection laws.
- Legislation and Policy Initiatives. Such projects are aimed at enhancing the rights of health care consumers and their ability to obtain good, affordable health care in New York State.

2. Enforcement Actions

Helpline complaints and inquiries often spark investigations of and enforcement actions against health plans, providers and other entities operating in the health care market. The HCB's objective in these enforcement actions is to protect consumers' health care rights, to rectify systemic problems and to provide restitution to affected consumers. Over the last several years, the HCB has brought more than 45 enforcement actions to protect consumer health care rights and provide restitution to aggrieved consumers.

3. The UR Investigation

The HCB's investigation into several health plans' UR procedures examined the process whereby health insurers monitor doctors, hospitals and other health professionals to ensure that they are providing to plan members only those health services that are medically necessary.

UR can lead to approvals of coverage or denials of coverage. A denial of coverage on the grounds that a health service is not medically necessary is called an adverse determination. When a plan issues an adverse determination, it must provide written notice to the consumer, his or her provider, or both. This written notice must: include a statement of the reasons and clinical rationale, if any, for the adverse determination;¹ inform the consumer and/or provider of his or her right to appeal the adverse determination and provide instructions on how to initiate an appeal;² and inform the consumer and/or provider that he or she may request a copy of the clinical review criteria on which the determination was based.³

In retrospective situations (when a health plan refuses to pay for care that has already been provided), an adverse determination will be of concern mostly to the provider, since care has already been provided and the only outstanding issue is payment. In prospective and concurrent situations, however, an adverse determination can mean that the care in question will not be received. Thus, in these situations, a consumer's right to appeal an adverse determination is most important.

(a) Investigation

Based on anecdotal evidence and a number of consumer complaints, the HCB decided to investigate whether certain health plans were allowing only qualified personnel to make adverse determinations, providing adequate statements of the reasons and clinical rationale for their adverse determinations and including in denial notices to consumers and providers complete and accurate information on how to appeal adverse determinations. The HCB investigated eight health plans (Aetna/U.S. Healthcare, Inc.; Prudential Health Plan of New York, Inc.; HMO-CNY, Inc.; Group Health Incorporated; Health Insurance Plan of Greater New York, Inc.; Oxford Health Plans, Inc.; United Healthcare of New York, Inc.; and Vytra Health Plans Long Island, Inc.) and one company hired by plans to conduct UR (Green Spring Health Services, Inc.) (to be known hereafter as the "Investigated Companies").

(b) Findings

The most consistent problem uncovered by the investigation was the failure of the Investigated Companies to provide adequate statements of the reasons and clinical rationale for their adverse determinations.⁴ The HCB could arrive at this finding, however, only after it had reached a considered position on the meaning of the phrase "clinical rationale."

While there is no definition, in either the UR Law or the relevant regulations, of the phrase "clinical rationale,"⁵ the Investigated Companies argued that the statements contained in their letters constituted clinical rationales and thus met the requirements of the UR Law. In a majority of cases, the HCB strongly disagreed. The HCB's position derives from a purposive reading of the clinical rationale requirement. In order for a consumer and his or her provider to make effective use of their appeal rights, they must first have a clear understanding of why the health service in question was found to be medically unnecessary, and this requires a clinical rationale that is case-specific and grounded in clinical information.

Rather than provide this kind of case-specific, clinically grounded explanation, however, the Investigated Companies repeatedly relied on stock phrases, such as: "care could have been provided in a setting of lesser intensity" and "the requested care was found to be not medically necessary." Some of the Investigated Companies' denial letters also stated that the case did not meet the "criteria" contained in manuals, published by companies such as Milliman & Robertson and Interqual, that list standards of care for thousands of conditions. While these listings are offered merely as guidelines, the HCB investigation found that the Investigated Companies would occasionally, or even regularly, treat them as bright-line rules.

The HCB's investigation revealed that the clinical peer reviewers making adverse determinations consistently provided clinical rationales, but the plans did not share these rationales with patients and providers who might have wanted to appeal such denials. This failure undermined both the members' and their providers' appeal rights, since only an individualized clinical rationale offers an opportunity to argue the merits of a specific case.

The investigation also revealed problems in the health plans' record keeping. Some of the plans' patient files were so consistently incomplete that it was possible in only a fraction of the cases to determine whether or not they had complied with the UR Law.

In a small though not insignificant number of cases, health plans failed to meet statutory time-frames for making initial UR determinations, providing notice of initial adverse determinations, acknowledging requests for appeals of initial adverse determinations, issuing decisions on those appeals and providing notice of the results of those appeals. The HCB might have found that this problem was more widespread if it had not been faced with so many incomplete patient files.⁶

The Investigated Companies were in almost total compliance with the requirement that only properly qualified "clinical peer reviewers" issue adverse determinations.

(c) Negotiation of the Assurances of Discontinuance

The HCB conducted its investigation pursuant to provisions in the Executive Law and the General Business Law that authorize the Attorney General to investigate and prosecute fraudulent business practices and illegal acts in the carrying on, conducting or transaction of business.⁷ After presenting our findings to the Investigated Companies, we were able to settle each case by signing an Assurance of Discontinuance (AOD).

At the heart of the AODs is the requirement that each Adverse Determination Letter contain a meaningful statement of the reasons and clinical rationale for the adverse determination. The AODs therefore contained the following definition:

> "Reasons and Clinical Rationale" means the individualized medical basis for an Adverse Determination. A statement of Reasons and Clinical Rationale must demonstrate that the UR Agent made an individualized medical assessment of the Enrollee by referring to the specific medical data relating to the Enrollee, which the Clinical Peer Reviewer took into consideration when making the Adverse Determination. Merely stating that the service at issue is not medically necessary is not sufficient, nor is a statement that the proposed service does not meet the UR

Agent's criteria. A statement of Reasons and Clinical Rationale must be sufficiently specific to enable the Enrollee and/or the Enrollee's health care provider to make an informed decision about whether or not to appeal the Adverse Determination and to determine the issue or issues to address in the appeal.

In order to protect the right of providers to appeal retrospective adverse determinations, the AODs also require that, in all retrospective situations, the health plan send a copy of the adverse determination letter to the provider.⁸

The AODs also contain requirements concerning the contents of so-called Acknowledgment Letters. UR Agents are required by law to send such letters to an enrollee or provider who has requested an appeal of an adverse determination, but the law says nothing about what information these letters should contain. The AOD requires that each Acknowledgment Letter contain a statement that: (1) the UR Agent is required by law to determine the appeal within 60 days of receipt of information necessary to conduct the appeal; (2) the UR Agent is required by law to notify the Enrollee, the Enrollee's designee and, where appropriate, the Enrollee's health care provider, in writing, of the determination within two business days of rendering such determination; and (3) the UR Agent shall automatically reverse its decision if it misses the deadline for determining the appeal.9

Finally, the AODs contain detailed requirements aimed at ensuring that each Investigated Company's files are complete and accurate enough that the Investigated Company's own staff, the HCB and other regulatory bodies can determine with confidence whether the Investigated Company was in compliance with the AOD and the UR Law.

(d) Monitoring of Compliance

The AODs stipulate that, for two years after the signing of the AOD, the HCB will conduct quarterly examinations of each Investigated Company. The examinations completed to date demonstrate that all of the Investigated Companies have shown a marked improvement in their UR practices, with particularly strong improvement in the completeness and quality of the statements of reasons and clinical rationale contained in their adverse determination letters. Recordkeeping has also noticeably improved.

4. Legislative Proposal: Providing a Right to an External Appeal of Denials of Out-of-Network Referrals

In investigating and resolving the UR case, we identified a serious gap in the UR Law. Health plan enrollees sometimes ask their plans to cover the cost of a visit to an out-of-network provider on the grounds that their health plan's network of providers does not contain someone with the necessary experience and expertise to meet the enrollee's particular health needs. Section 4403(6)(a) of the Public Health Law requires that, where the plan's network lacks an appropriate provider, the plan must allow the enrollee to go out-ofnetwork at no additional cost. Enrollees who wish to challenge a health plan's refusal to authorize out-of-network treatment under this provision can do so only according to the plan's grievance procedures, which do not include the right to an independent external review of the denial. If such decisions were treated as medicalnecessity determinations, however, enrollees would have access to external appeals.

In order to protect consumers' rights to seek medically necessary out-of-network care, the Attorney General has proposed legislation that would make decisions by health plans under PHL § 4403(6)(a) medical-necessity decisions subject to the UR Law, with access to external review.

Endnotes

- 1. N.Y. Public Health Law § 4903(5)(a) (PHL); N.Y. Insurance Law, § 4903(e)(1) ("Ins. Law").
- 2. PHL § 4903(5)(b); Ins. Law § 4903(e)(2).
- 3. PHL § 4903(5)(c); Ins. Law § 4903(e)(3).
- 4. The UR Law requires that every notice of an adverse determination sent by a UR Agent to a consumer or provider contain "the reasons for the determination including the clinical rationale, if any." PHL § 4903(5)(a); Ins. Law § 4903(e)(1).
- 5. There is also no definition of the phrase "medically necessary."
- 6. Where important dates could not be determined due to missing records, the HCB did not assume that the applicable deadline had been missed.
- 7. N.Y. Executive Law § 63(12); N.Y. General Business Law § 349(a).
- The UR Law is silent with respect to who should receive notice of adverse determinations in retrospective situations and how notice is to be provided in retrospective situations: PHL § 4903(4); Ins. Law § 4903(d).
- 9. PHL § 4904(5); Ins. Law, § 4904(e).

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Fostering Competitive Health Care Markets

By Jay L. Himes and Robert L. Hubbard

The Antitrust Bureau of the Attorney General's office seeks to further competition in health care markets. Because competition is a "public policy of the first magnitude,"¹ and because health care costs represent about one-seventh of the economy, antitrust issues frequently arise in health care markets. The increasing importance of competition in health care markets is illustrated by New York's Health Care Reform Act of 1996.² That Act changed a health care system that regulated many aspects of hospital services, including the prices charged, to one in which hospitals set their own rates by negotiating with third party payers. In short, the legislature further extended market competition as the rule of trade in determining how health care markets, including hospitals, operate.

The Basis for the Attorney General's Antitrust Enforcement Authority

The work of the Antitrust Bureau in health care markets is best understood in the context of antitrust matters generally and the Attorney General's corresponding antitrust enforcement authority. Briefly, antitrust law prohibits direct competitors from agreeing on the price they will charge their customers, from divvying up the territories, customers, or services that the agreeing competitors will cover, and from adopting other unreasonable restraints of trade.³ Antitrust law also prohibits mergers or acquisitions that are anticompetitive, or an abuse of monopoly power.⁴

The Attorney General's authority under the antitrust laws is extensive, and focused on protecting New York consumers and New York public agencies. The Attorney General, under state and federal law, represents the people of New York State and may recover antitrust damages and other monetary or equitable relief on their behalf. This representation, called *parens patriae* authority, is most likely to be exercised when the impact of an antitrust violation is on consumers' pocketbooks and where the damage caused by the violation is, in the aggregate, significant.

Section 4C of the Clayton Act establishes a statutory basis for the New York State Attorney General to recover damages on behalf of state residents under the federal antitrust laws.⁵ His right under federal law to secure equitable relief is established by case law.⁶ No New York statute expressly confers *parens* authority to the Attorney General under state antitrust law. However, under N.Y. Executive Law section 63(12), the Attorney General may seek "restitution and damages" for "repeated, fraudulent or illegal acts." The Attorney General has often invoked section 63(12) authority in antitrust cases to provide remedies to consumers.⁷ Equally important, *parens patriae* authority exists as a matter of common law because the "prerogation of parens patriae is inherent in the supreme power of every state."⁸

The Attorney General also represents the state of New York, including state agencies and other public entities, as purchasers of good or services.⁹ This authority extends to public authorities besides the state itself, and includes, for example, the New York Convention Center Development Corp.¹⁰ In addition, the Attorney General may sue under the federal antitrust laws for injury in its proprietary capacity.¹¹

State purchases in health care markets are extensive, and the Attorney General seeks damages when the state pays more than it would have but for antitrust violations. The Attorney General does not generally focus on the antitrust claims of businesses, which have the right to assert their own antitrust claims, except to the extent that restraints on business injure New York consumers or otherwise affect the public interest.¹² In sum, competition in health care markets is a core concern for the Attorney General—both because the state and other public bodies make significant health care purchases, and because health care markets have a dramatic pocketbook impact on the people and businesses of the state.

The Attorney General's Efforts to Promote Competition

The Antitrust Bureau commits significant resources to promoting competition in health care markets. Many of these activities may not result in litigation. For example, the Antitrust Bureau reviews mergers and other transactions in health care markets, the vast majority of which either raise no antitrust concerns or raise concerns that are addressed without resort to litigation. Activities that have significant implications for competition are often altered or abandoned in light of concerns expressed by the Attorney General.13 The Attorney General further advocates competition in legislative efforts and opposes protectionist legislation that shields some businesses from competition without offering corresponding benefit to consumers or otherwise promoting the public interest.¹⁴ As part of its competition advocacy program, the Attorney General also prepares amicus curiae briefs, such as that supporting a challenge to a hospital merger by the Antitrust Division of the United States Department of Justice.¹⁵

Of course, from time to time litigation has been necessary for the Attorney General to vindicate the rights of the state and its citizens to competitive health care markets. The Attorney General sued and recovered over \$4.4 million from pharmacies that allegedly boycotted the Empire Plan, the health care plan for state employees.¹⁶ The Attorney General similarly sued and was granted summary judgment in an action alleging that the two hospitals in Poughkeepsie were engaged in *per se* illegal price fixing and market allocation.¹⁷ After the court's ruling, the hospitals abandoned the challenged activities in a consent judgment.¹⁸

The Antitrust Bureau has prosecuted significant health care antitrust cases in conjunction with other states, often taking a leadership role in such multi-state efforts. In the Disposable Contact Lens Antitrust Litigation,¹⁹ 32 states, led by New York, and a certified class alleged that major contact lens manufacturers, the American Optometric Association, and others illegally colluded to inflate the price, and to limit the supply, of replacement contact lenses. Plaintiffs charged that the illegal agreement made it more costly and difficult for consumers to buy replacement contact lenses from mail order firms or pharmacies. After years of litigation, settlements with many of the defendants, and five weeks of trial to a jury in Jacksonville, Florida, the states and class settled with the last remaining defendant. As a result of the case, manufacturers agreed to sell to mail order firms and pharmacies on a non-discriminatory basis, and to pay cash and rebate coupons to consumers worth over \$100 million.²⁰

New York also participated in a multi-state action, litigated together with the Federal Trade Commission, which challenged as illegal monopolization a drug company's cornering of the supply of the active pharmaceutical ingredients in various drugs—conduct that increased prices twenty-fold. That action was settled for over \$100 million in cash and injunctive relief.²¹ New York further led a multi-state investigation and litigation against a drug manufacturer that tied the purchase of its breakthrough drug for the treatment of mental illness to the monitoring for possible side effects from that drug, an arrangement that the states alleged was an illegal tying arrangement.²²

Recent significant multi-state antitrust litigations in health care markets have focused on efforts by brandname drug manufacturers to delay or prevent competition from generic drug manufacturers. Although the means to hinder generic competition have varied, each case involved brand-name drug manufacturers manipulating the procedures under the federal Hatch-Waxman Act (HWA) to keep cheaper generic drugs off the market, and maintaining monopoly pricing long after expiration of the brand-name drug's patent.

The first of these cases, the *Cardizem CD Antitrust Litigation*,²³ concerns the anti-hypertension drug Cardizem CD[®] and its bioequivalents. The litigation challenges an agreement between brand-name manufacturer Hoechst Marion Roussel, Inc. (HMRI) and generic drug manufacturer Andrx Corporation (Andrx), under which HMRI paid Andrx over \$89 million in exchange for Andrx's agreement to keep its cheaper alternative to HMRI's Cardizem CD heart medication off the market. As part of the agreement, Andrx agreed to stay off the market while still prosecuting its rights under HWA. This enabled Andrx to maintain its right to the 180-day exclusivity period granted the first-filer under the HWA. Andrx further pledged not to transfer or to sell its HWA exclusivity rights. As a result, the agreement effectively barred any generic entry. Only after private suits challenged this arrangement, and after the FTC opened an investigation, did the parties terminate the agreement and Andrx enter the market, removing the block against generic competition. A federal district court held the HMRI/Andrx agreement was a per se violation of the antitrust laws.²⁴ In another case challenging the agreement, the Court of Appeals for the District of Columbia Circuit reinstated a generic manufacturer's claim challenging the HMRI/Andrx agreement.25

The states, along with counsel seeking to certify a national class of end-users of Cardizem CD, recently reached a proposed settlement requiring HMRI and Andrx to pay \$80 million, which will be used to pay claims of consumers (indirect purchasers), state agencies, and third party payers, along with notice costs, settlement administration costs, litigation expenses and fees. The court preliminarily approved the settlement on January 29, 2003. The states expect consumer participation in the settlement process to start this summer. HMRI and Andrx also settled a case brought by private plaintiffs on behalf of direct purchasers for an additional \$110 million.

The Taxol Antitrust Litigation²⁶ concerns the efforts by Bristol-Myers Squibb Co. (Bristol) to preserve its monopoly on Taxol, an important anti-cancer drug used to treat breast cancer and other tumors. The federal government developed Taxol and thereafter licensed it to Bristol for five years. The states' action alleges that Bristol unlawfully maintained a monopoly by fraudulently obtaining follow-on patents for Taxol, and listing them in the FDA's Orange Book. Bristol also filed litigation for the sole purpose of delaying generic entry into the market, exploiting a provision in HWA that automatically stays generic entry upon the filing of patent litigation. The states and Bristol have entered into a settlement agreement calling for a \$55 million recovery for state government purchasers and consumers, together with injunctive relief that prohibits certain patent practices. An additional settlement covers direct purchasers other than state agencies.

The *BuSpar Antitrust Litigation*²⁷ is another multistate monopolization case against Bristol. This action concerns the anti-anxiety drug BuSpar® and Bristol's effort to extend its patent monopoly for the profitable buspirone medication. As its patent for buspirone was about to expire, Bristol received a patent for a metabolite that Bristol claimed the body naturally produces when buspirone is ingested. Bristol then had the FDA list the metabolite patent in the Orange Book barely 11 hours before the FDA was scheduled to approve the first generic buspirone alternative, with generic alternative shipments loaded on trucks ready to be delivered. Although Bristol explicitly stated to the United States Patent Office that its new metabolite patent did *not* cover buspirone, its Orange Book entry made precisely the opposite claim. The Orange Book listing effectively barred generic makers of buspirone from the market, and consumers paid hundreds of millions of dollars more than they would have paid had a generic alternative been available.

In an action brought by an excluded generic entrant, a federal judge in the District of Columbia found that Bristol's conduct before the FDA was improper, and ordered the patent de-listed, thereby permitting the sale of generic alternatives. On appeal, the Federal Circuit held that, as a matter of procedure, the generic entrant could not sue to obtain de-listing from the Orange Book, and vacated the order without evaluating Bristol's behavior before the FDA.28 Last year, a federal judge in the Southern District of New York found Bristol's Orange Book filing to be "objectively baseless" and an effort to "justify taking property that belongs to the public."29 Again, the states and Bristol have reached a settlement, under which Bristol will pay \$100 million to state governmental purchasers and consumers. Injunctive relief indentical to that in the Taxol litigation also has been agreed to. Bristol also has agreed to settle a case brought by private direct payers.

Endnotes

- LaRossa v. Abrams, 62 N.Y.2d 583, 589 (1984) (quoting Aimcee Wholesale Corp. v. Tomar Products, Inc., 21 N.Y.2d 621, 625 (1968)).
- 2. 1996 N.Y. Laws ch. 639 § 1.
- 3. 15 U.S.C. § 1; N.Y. General Business Law § 340 (GBL).
- 4. 15 U.S.C. §§ 2, 18; GBL § 340.
- 5. Clayton Act § 4C, 15 U.S.C. § 15c.
- See Georgia v. Pennsylvania Railroad Co., 324 U.S. 439 (1945) (upholding federal antitrust action by state seeking equitable relief).
- 7. See, e.g., New York v. Feldman, 210 F. Supp. 2d 294 (S.D.N.Y. 2002) (upholding use of section 63(12) to sue on behalf of consumers harmed by bid-rigging, including consumers outside of New York); In re Lorazepan & Clorazapate Antitrust Litigation, 205 F.R.D. 369, 386-87 (D.D.C. 2002) (upholding use of section 63(12) to recover damages for consumers for abuse of monopoly power, and characterizing section 63(12) as providing the Attorney General with the "functional equivalent" of parens patriae authority under state antitrust law). See also N.Y. Executive Law § 63(1) ("Exec. Law").

- 8. Late Corporation of the Church of Jesus Christ of Latter Day Saints v. United States, 136 U.S. 1, 57 (1890). See generally Alfred L. Snapp & Sons, Inc. v. Puerto Rico, 458 U.S. 592 (1982). See also Finger Health Agency v. St. Joseph's Hospital, 81 A.D.2d 403, 407 (3d Dep't 1981) ("A State has inherent power to sue as parens patriae on behalf of its citizens to prevent harm to its sovereign interests such as the health, comfort and welfare of its people"); New York v. New York City Conciliation and Appeals Board, 123 Misc. 2d 47, 49 (N.Y. Co. Sup. Ct. 1984).
- 9. Exec. Law § 63; GBL § 342-b.
- 10. New York v. Julius Nasso Concrete Corp., 202 F.3d 82 (2d Cir. 2000) (construction bid rigging).
- 11. See, e.g., Georgia v. Evans, 316 U.S. 159 (1942).
- 12. *Compare New York v. Feldman*, 210 F. Supp. 294 (S.D.N.Y. 2002) (where bid-rigging scheme injured both consumers and auction houses handling consumers' transactions, the Attorney General sued on behalf of both).
- 13. For example, the Attorney General's office investigated contractual provisions of a major third party payer in upstate New York, which required health care providers to give their best deals to that payer. These provisions are sometimes referred to as "most favored nation" clauses. By letter agreement with the Attorney General's office, the payer agreed to stop using such clauses, to stop enforcing such clauses already in its contracts, and to notify health care providers of that change.
- Letter dated July 24, 2002, from Eliot Spitzer to Senator Edward Kennedy and Senator Judd Gregg (*available at* http:// www.oag.state.ny.us/press/2002/jul/jul24b_02_attach1.pdf).
- Brief of Twenty-four-States as Amici Curiae on Behalf of the United States in *United States v. Mercy Health Services*, Nos. 95-4253, 95-1051 (8th Cir. Feb. 29, 1996).
- 16. New York v. Brooks Drugs, Inc., 90 Civ. 4330 (S.D.N.Y.).
- 17. *New York v. St. Francis Hospital,* 94 F. Supp. 2d 399 (S.D.N.Y. 2000).
- New York v. St. Francis Hospital, 2000-2 Trade Cas. (CCH) ¶ 72,960 (S.D.N.Y. 2000).
- 19. M.D.L. No. 1030, 97-861-Civ-J-20A (M.D. Fla.).
- Order Granting Final Approval of the Settlements, *Disposable* Contact Lens Antitrust Litigation, M.D.L. 1030 (M.D. Fla., Nov. 1, 2001).
- 21. In re Lorazepam & Clorazapate Antitrust Litigation, 205 F.R.D. 369 (D.D.C. 2002).
- In re Clozapine Antitrust Litigation, M.D.L. No. 874, No. 91 C 2431 (N.D. Ill. filed Apr. 16, 1991) (resulting in a 50-state, \$20 million settlement); see Antitrust & Trade Reg. Rep. (BNA), Vol. 68, No. 1712.
- 23. M.D.L. No.1278, Case No. 01-CV-71835 (NGE) (E.D. Mich.).
- 24. In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682 (E.D. Mich. 2001).
- 25. Andrx Pharmaceuticals, Inc. v. Biovail Int'l Corp., 256 F.3d 799 (D.C. Cir. 2001).
- 26. Civ. No. 1:02 CV 01080 (EGS) (D.D.C.).
- 27. M.D.L. Nos. 1410, 1413, 01 Civ.11401 (JGK) (S.D.N.Y.).
- Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1 (D.D.C.), rev'd, 268 F.3d 1323 (Fed. Cir. 2001).
- 29. In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002).

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Charities Bureau Oversight of Not-For-Profit Health Care Organizations

By William Josephson

The New York State Attorney General supervises organizations and individuals that administer and/or solicit charitable funds or charitable assets in New York State. The Attorney General works to protect donors to charity, charities and the beneficiaries of charities. The Attorney General's supervisory authority over charities is rooted in the common law of charitable trusts and corporations, as well as the *parens patriae* power of the state to protect the interest of the public in assets pledged to public purposes. In addition, the Attorney General has broad authority under state statutes to regulate not-for-profit organizations and charitable trusts, and to commence investigations and legal actions to protect the public interest.

The Charities Bureau's jurisdiction is more fully described in a pamphlet, *The Regulatory Role of the Attorney General's Charities Bureau*, available on its Web site at www.oag.state.ny.us/charities/charities.html.

Unlike for-profit corporations, not-for-profit corporations do not have shareholders with the incentive and opportunity to protect their own economic interest. Charitable trusts without specific beneficiaries also lack checks on management. Both can hold endowments and other restricted funds that may need protection from invasion or waste. It falls to the courts, and to the Attorney General, in his *parens patriae* capacity and by statute,¹ to protect charitable assets for the benefit of New Yorkers generally.

Significant corporate transactions that, for for-profit corporations require shareholder approval under the Business Corporation Law, require, in the case of a notfor-profit corporation, court approval on notice to the Attorney General under the Not-for-Profit Corporation Law (N-PCL): merger and consolidation (N-PCL Article 9), voluntary and involuntary dissolution (N-PCL Articles 10 and 11), amendment of corporate purposes (N-PCL section 804(a)) and the sale or other disposition of "all or substantially all" assets (N-PCL sections 510-511).

When charitable purposes become impossible of fulfillment, judicial *cy pres*, and *quasi cy pres* relief require participation of the Attorney General.

The Attorney General's Charities Bureau welcomes requests for guidance. The public and practitioners should consult the Attorney General's Web site. It contains forms, publications and substantive guidance. Telephone inquiries and meetings are welcome.

Health Care Cases Involving Dispositions of Substantial Assets

Under N-PCL section 511(d), the disposition of "all or substantially all" of a not-for-profit corporation's assets will be approved only if the court finds that the consideration and the terms of the transaction are fair and reasonable to the corporation and that the purposes of the corporation or the interests of any members will be promoted thereby. On December 3, 1999, New York County Supreme Court Justice Bernard Fried denied a petition filed by the Manhattan Eye, Ear & Throat Hospital (MEETH) pursuant to N-PCL sections 510-511 for court approval to sell, for \$41 million, "all or substantially all" of its assets to Memorial Sloan Kettering Cancer Center (MSK) and a private real estate developer.² The MEETH board had decided to terminate the MEETH's residency programs, sell its facilities, close the hospital and transform the MEETH's Harlem Center and planned Brooklyn Center from extension centers of the MEETH to free-standing Diagnostic and Treatment (D&T) Centers without first obtaining either judicial approval on notice to the Attorney General or state Department of Health (DOH) approval.

"[T]he Attorney General has broad authority under state statutes to regulate not-for-profit organizations and charitable trusts, and to commence investigations and legal actions to protect the public interest."

The Attorney General not only filed papers in opposition to the MEETH's petition, but successfully cross-moved for a preliminary injunction, and obtained a temporary restraining order, enjoining the closing of the hospital *pendente lite*. After a thirteen-day evidentiary hearing, Justice Fried concluded that the MEETH had not satisfied either of the statutory criteria for court approval under N-PCL section 511(d).

Under the *MEETH* decision, the factors a nonprofit board and its counsel must consider in a transaction subject to sections 510-511 include whether or not: (1) the board exercised due diligence in deciding to sell, selecting the purchaser, and negotiating the terms and conditions of the disposition; (2) the procedures used by the seller in making its decision, including whether appropriate expert assistance was used, were fair; (3) any conflict of interest was disclosed, including but not limited to conflicts of interests of board members and experts retained by the sale; and (4) the seller will receive fair value for its assets.

The court found the MEETH board process flawed because (1) the board's decision to abandon the MEETH mission was not based on an independent evaluation, study or business plan demonstrating that there was a basis for changing the MEETH's corporate purposes; (2) the board failed to consider in good faith expressions of interest by other New York City hospitals to continue the MEETH; and (3) the board's percentage fee arrangement with its financial/strategic advisor did not ensure disinterested advice and "resulted in a situation where the board relied upon an advisor that had an actual interest in the recommendation of its strategic study."

Recent years have seen an increasing number of complex health care restructuring transactions in the form of mergers pursuant to Article 9 of the N-PCL and disposition-like transactions involving transfers of control, as exemplified by the court's approval of Lenox Hill Hospital's becoming the sole member of the MEETH, subsequent to the decision described above.

In *In re Kaiser Foundation Health Plan of New York and Community Health Plan*,³ Kaiser Foundation Health Plan of New York (Kaiser) and Community Health Plan (CHP) filed a petition pursuant to N-PCL section 907(a) for court approval of their proposed merger. After being served with statutorily required notice of the petition, the Attorney General filed objections, asserting, among other things, that (a) Kaiser had previously acquired control over CHP's operations without court approval through an affiliation agreement, and (b) Kaiser intended, after the merger, to sell CHP, but not through a transaction for which it would seek court approval.

The court acknowledged the potentially adverse effect of a sale of CHP on the 600,000 New Yorkers who depend on CHP for their health care. Relying on the condition for court approval of mergers under N-PCL section 907(e) that "the public will not be adversely affected," the court conditionally approved the Kaiser-CHP merger, subject to the condition that any "future non-merger transfers of operational and managerial control of CHP" be subject to the requirement of, and standards for, court approval of mergers under N-PCL section 907(e).

In contrast, in *Nathan Littauer Hospital Association v. Eliot Spitzer*⁴ the Third Department affirmed an order of the Fulton County Supreme Court that rejected the Attorney General's arguments in a declaratory judgment action that proposed amendments to Littauer's certificate of incorporation to effectuate the creation of a new sole member required court approval under N-PCL section 804(a)(ii) and the transfer of Littauer board powers to its new sole member was a disposition of substantial assets, i.e., control. There, Nathan Littauer Hospital was proposing to give to a new sole corporate member powers that its board now exercised itself. Conceding that the "distinction that exists between a corporation's power and purposes and the services that it actually provides" is "subtle," the Third Department held:

Under the restated certificate of incorporation at issue here, TCH, as Littauer's [new] 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 Littauer'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.

The First Department's recent application of N-PCL section 804(a)(ii) seems inconsistent.⁵ The issue was whether or not amendments to the Herbert H. Lehman College Foundation's (the "Foundation") by-laws were inconsistent with provisions of the Foundation's certificate of incorporation that gave the Herbert H. Lehman College ("the College") control of the Foundation's Board. The Board amended by-laws increasing the number of directors so that the majority became outside directors.

The Supreme Court granted an Article 78 petition brought by the new majority to stop the president of the College from reconstituting the board in accordance with its certificate of incorporation and directed the Foundation to amend its certificate to conform to the amended by-laws. On appeal, the Appellate Division, First Department, held that Supreme Court's direction to amend the Foundation's certificate of incorporation "in effect approved fundamental changes in the life of the Foundation without following the procedures prescribed by law." The court, according to the First Department, "may have underestimated the impact of the by-law amendments on the powers and purpose of the Foundation." The First Department concluded:

> By thus diluting the influence of the College and its president on the governance of the Foundation, in effect transforming the Foundation into an independent entity unaccountable to the College, the by-law amendments changed the Foundation's powers and purposes as enumerated in its certificate of incorporation. *There can be no doubt that any like amendment to the certificate would require judicial approval on notice to the Attorney General* [pursuant to NPCL section 804(a)(ii)].(emphasis added)

If documentation of the transfer of controlling powers from representatives of Lehman College to others requires Supreme Court approval, on notice to the Attorney General, as the First Department held, so also, it would seem, would a certificate that transferred controlling powers from the sole member or the board of one not-for-profit to a new sole member.

In the *Littauer* case the Third Department also rejected the Attorney General's argument that a disposition of control of a not-for-profit corporation was subject to N-PCL section 511, notwithstanding the fact that subsequent to the reported *MEETH* decision, New York County Supreme Court by order under N-PCL section 511 made Lenox Hill Hospital the MEETH's new sole member. This issue of disposition of membership control, arising out of a purported sale of control of a notfor-profit corporation to an individual who then misappropriated funds from the corporation, may be litigated in *Spitzer v. Lev.*⁶

A postscript to the Littauer decision is in order. Before the hospitals brought their declaratory judgment action against the Attorney General, the Attorney General attempted to negotiate with counsel to Littauer, St. Mary's Hospital and the parent of St. Mary's, Carondelet (a large hospital system which would control the new sole not-for-profit corporate member of both hospitals), an agreed approach to the affiliation for submission to Fulton County Supreme Court. The negotiations foundered when the parties refused the Attorney General's request for up-to-date financial statements for St. Mary's, which was rumored to be in marginal financial condition, and Carondelet, which was also reported to be in financial trouble.⁷ The new sole corporate member of both hospitals had no assets and would have to be financed by Littauer and St. Mary's. The Attorney General was specifically concerned with potential upstreaming of Littauer's and St. Mary's revenues or

proceeds of sales of assets to the new sole member and Carondelet, which would raise issues regarding the general prohibition against distributions or dividends to the members of a not-for-profit corporation under N-PCL sections 508 and 515. The Attorney General also requested an unwinding provision should the affiliation not work as the parties expected.⁸ Many of these affiliations have unwound, and the unwinding can be costly and difficult.⁹ Subsequently, Carondelet's financial situation required it to sell hospitals and then to affiliate or merge with Ascension, another large health system.¹⁰ Ultimately, on November 8, 2002, St. Mary's and Littauer announced that they had called off the affiliation.¹¹

Cy Pres

Many New York State hospitals are experiencing financial difficulties. When they merge with others the Attorney General is concerned to preserve endowments and reviews each restricted fund. Many of them are old endowments of beds for indigents that can be consolidated as part of the merger proceedings. If a hospital ceases operations, *cy pres* proceedings with respect to its use of its endowments are in order as in the pending proceedings involving Genesee Hospital in Rochester. When such endowments are held in a separate not-forprofit entity, *cy pres* proceedings are also in order.

Use of *cy pres* proceedings to continue hospital operations is illustrated by a *cy pres* proceeding for the 140-year old Long Island College Hospital (LICH) in Brooklyn. It had received roughly \$135 million in endowment bequests from Dr. Donald F. Othmer and his wife, Mrs. Mildred Topp Othmer.

Subsequently, LICH found itself in financial difficulty, yet could not access the principal of the Othmer endowment funds. LICH proposed to the Attorney General's Charities Bureau that a *cy pres* proceeding be commenced seeking court approval of invasions of principal. In the belief that such a proceeding would be unlikely to succeed or fundamentally assist the hospital, the Charities Bureau suggested that LICH develop a financial plan that included simplifying, consolidating and stretching out its debt so that debt service hopefully could be funded from current revenues. The Othmer endowment funds could be one of the security interests behind the consolidated debt, if the court so authorized in a *cy pres* proceedings.

In *In re Donald F. Othmer*¹² and *In re Mildred Topp Othmer*,¹³ Acting Kings County Surrogate Leonard Scholnick granted *cy pres* relief to LICH, which permitted LICH to use the restricted principal of the Othmer endowment funds as collateral to secure almost \$90 million of new financing for necessary capital improvement projects and immediate working capital. The purpose of the *cy pres* doctrine, codified in section 8-1.1 (c) of the Estates, Powers & Trusts Law, is to effectuate the general charitable intention of a donor where, because of changed circumstances, literal compliance with the donor-imposed restrictions is impracticable or impossible. The court applied the following three-part test to determine if LICH met the standard for *cy pres* relief: (1) the gift must have been charitable; (2) the language of the gift instrument must indicate that the donors demonstrated a general, rather than specific, charitable intent, and (3) the particular purpose for which the gift was created has failed or has become impossible or impracticable to achieve.

"The purpose of the cy pres doctrine, codified in section 8-1.1 (c) of the Estates, Powers & Trusts Law, is to effectuate the general charitable intention of a donor where, because of changed circumstances, literal compliance with the donor-imposed restrictions is impracticable or impossible. "

The court found that all three requirements were met: (1) because the Othmers' bequests were to an institution that promotes health and provides medical services, they were clearly charitable in nature; (2) the Othmers had a general charitable intent to benefit LICH, as evidenced by their long record of LICH support, the facts that the Othmers' gifts were to be used by LICH for general purposes and there was no gift over of the bequests after LICH received them; and (3) the restriction on the use of the principal of the Othmer endowment funds had become impossible or impracticable, because LICH was facing a life-threatening financial situation, due to unforeseen changes in the health care industry, not because of any misconduct.

If and when LICH's new debt is repaid, the principal of the Othmer endowment funds will cease to be security and will revert to endowment status. Meanwhile, as long as LICH does not default on its financing, the Othmer endowment funds should continue to produce income and appreciation to be used by LICH for general purposes.

Endnotes

1. See e.g., N-PCL §§ 112(a), 720(b); N.Y. Estates, Powers & Trusts Law 8 1.1(f), 8-1.4 (EPTL).

- Manhattan Eye, Ear & Throat Hospital v. Spitzer, 186 M.2d 126, 715 N.Y.S.2d 575 (Sup. Ct., N.Y. Co. 1999). The MEETH case, as it has become known, was discussed in my September 12, 2000, New York Law Journal article and has been the subject of several other articles, e.g., L.T. Crowley, Hospital Care. Significant Governance Justice, N.Y.L.J. (Feb. 10, 2000), of which the most comprehensive is Scott M. Himes, The Collision of Health Care and Corporate Law in a Hospital Closure Case, 34 J. Health L. 335 (2001).
- 3. Index No. 2068-99 (Sup. Ct., Albany Co. 1999).
- 287 A.D.2d 202, 205, 734 N.Y.S.2d. 671, 674 (3d Dep't 2001), motion for leave to appeal denied, 98 N.Y.2d 602, 771 N.E.2d 835 (2002).
- Herbert H. Lehman College Foundation, Inc. v. Ricardo R. Fernandez, 292 A.D.2d 227, 739 N.Y.S. 2d 375 (1st Dep't 2002), motion for leave to appeal withdrawn.
- 6. Sup. Ct. N.Y. Co. Index No. 400989/02, June 8, 2002, granting the Attorney General's motion for injunctive relief *pendente lite* enjoining further misappropriations by the individual who had acquired control of the corporation and others and holding, among other things, "When the Attorney General is authorized by statute to seek injunctive relief to enjoin fraudulent or illegal acts, no showing of irreparable harm is necessary."
- 7. Modern Health Care, June 11, 2001 at 6.
- The question of "breakup fees" in an unsuccessful N-PCL section 510/511 transaction is being litigated in 64 The Associates, L.L.C. v. Manhattan Eye, Ear & Throat Hospital, et al., Index No. 600639/01 (Sup. Ct., N.Y. Co.), where Justice Gammerman invalidated the breakup fee provision in the MEETH/Memorial Sloan Kettering and Downtown Associates sales agreement. On Jan. 28, 2003, the Appellate Division in a brief but important opinion affirmed. 301 A.D.2d 462, 753 N.Y.S.2d 504 (1st Dep't 2003).
- 9. N.H. Dep't of Justice, New Hampshire Attorney General's Report on Optima Health (1998), available at http:// www.state.nh.us/nhdoj/charitable/optima.html. In New York, a number of these affiliations appear to have been successful so far, but a number have not. In Syracuse alone, for example, Crouse and Community Fund Health Alliance of Central New York are scrapping their partnerships, and Crouse and SUNY upstate have called off their "virtual merger." Amsterdam Hospital's affiliation with a hospital in Schenectady has ended. The affiliation through a holding company of Rochester General Hospital and Genesee Hospital ended in Genesee's ongoing receivership. The current policy of the State Health Department and Public Health Council is not to oversee most of these affiliations under the so-called "passive parent rule." See Public Health Law § 2801-a[2]; N.Y. Comp. Codes R. & Regs. tit. 10, § 405.1 (N.Y.C.R.R.); cf. Francis J. Serbaroli, Court Curbs Attorney General's Foray into Health Care, N.Y.L.J., May 30, 2001, p. 3 and my response which appeared in N.Y.L.J., July 26, 2001, p. 2.
- 10. See Modern Health Care, June 11, 2001, at 6; *id.*, April 9, 2001, at 4; *id.*, Jan. 15, 2001, at 6; *id.*, Sept. 25, 2000, at 9; *id.*, Dec. 9, 2002 at 4.
- 11. See Modern Health Care, Nov. 25, 2002, at 12; *St. Mary's Urged End of Hospitals' Plan*, Times Union (Albany, NY), Nov. 12, 2002, at E1.
- 12. 185 Misc. 2d 122, 710 N.Y.S.2d 848 (Sur. Ct., Kings Co. 2000).
- 13. N.Y.L.J., June 8, 2000, p. 32 (Sur. Ct., Kings Co. 2000).

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An Interdisciplinary Approach to Protecting Health Care Consumers

The Average Wholesale Price Litigation: A Case Study

By Thomas Conway and Rose Firestein

Much of the affirmative litigation of the Office of the Attorney General (OAG) is undertaken by bureaus within the Division of Public Advocacy. These bureaus include some that are explicitly concerned with health care issues and others that are not. In 2002, three of these bureaus, Antitrust, Health Care, and Consumer Frauds and Protection, came together with the Medicaid Fraud Control Unit (MFCU) (collectively "the bureaus") to address a health care issue that injures millions of New Yorkers and the state itself but cuts across the legal disciplines the bureaus typically practice.

From various sources, the OAG became aware that the confluence of the following factors was injuring consumers and the state:

- Medicare, Medicaid and EPIC (Elderly Pharmaceutical Insurance Coverage Program) are statutorily required to pay a set percentage of the average wholesale price to physicians and pharmacists for drugs covered by these programs;
- pharmaceutical manufacturers routinely report as the average wholesale price of some of their prescription drugs amounts that greatly exceed the drugs' actual cost to physicians and pharmacists;
- the pharmaceutical companies influence physicians and pharmacists to administer and dispense their products over those of competitors by marketing the guaranteed profit, called the "spread," that the drug company creates by fraudulently reporting the inflated average wholesale prices; and
- individuals who participate in these health care programs are responsible for paying a portion of the reimbursement amount, which is based on the inflated average wholesale price.

The drug manufacturers benefit from this scheme by increasing or maintaining their market share in the face of increasing competition from generics and new alternative therapies.

In February 2003, this cross-bureau collaboration generated civil litigation to stop manufacturers from engaging in these practices and to obtain restitution for the state-funded health care programs and injured Medicare beneficiaries, Medicaid recipients, and EPIC participants. The litigation also seeks civil penalties, including additional civil penalties for fraud directed against the elderly, and treble damages for the state's overpayment for Medicaid- and EPIC-covered drugs. The Attorney General brought three actions simultaneously in state Supreme Court, Albany County, against GlaxoSmithKline, Pharmacia Corp., and Aventis Pharmaceuticals, Inc. These actions allege that each company engaged in fraudulent business practices prohibited by N.Y. General Business Law section 349, repeated and persistent fraud and illegal conduct in violation of Executive Law section 63(12), commercial bribery in the second degree in violation of Penal Law section 180.00, and Medicaid fraud in violation of Social Services Law sections 145-b and 366-f and 18 N.Y. Comp. Codes R. & Regs. section 515.2.

Development of the Litigation

At the outset of the OAG's investigation, the bureaus had a shared basic understanding of the drug companies' fraudulent scheme, based in large part on reports of the Office of the Inspector General (OIG) of the federal Department of Health and Human Services and work done jointly by the federal Department of Justice and the National Association of MFCUs. The OIG's reports, going back a decade, had shown truly gargantuan spreads for some Medicare-covered drugs administered by physicians in their offices. The group of these drugs with particularly large spreads was dominated by chemotherapy agents and anti-emetics given to control the nausea and vomiting caused by chemotherapy drugs.

In a 2001 report,¹ the OIG found, for example, that if drug manufacturers had reported accurate average wholesale prices instead of the inflated ones they in fact reported, Medicare would have saved \$21.3 million on Doxobrubicin HCl, a chemotherapy drug, and a total of \$37 million on three anti-emetics in 1999. Medicare beneficiaries were responsible for paying 20 percent of these amounts that were fraudulently charged to Medicare, over \$11 million on just these four drugs. GlaxoSmithKline, Pharmacia, and Aventis manufacture these and other high-spread physician-administered drugs covered by Medicare, as well as high-spread pharmacist-dispensed drugs covered by Medicaid and EPIC. The creation and marketing of the spread on all of these drugs defraud the state and the affected consumers.

While none of the bureaus had expertise in all the diverse subjects involved in this scheme, each bureau brought critically important knowledge and experience to the investigation: Antitrust brought its understanding of the pharmaceutical industry's practices gained through litigation of generics' entry into the marketplace; MFCU had extensive experience with pharmaceutical pricing and the Medicaid Program; Health Care was knowledgeable about all the government health care programs; and, as the name indicates, the Consumer Frauds and Protection Bureau is the expert in civil litigation of consumer fraud. Overseeing and facilitating this collaborative process were members of the Attorney General's executive team. Together, this varied group compiled a complete picture of the scheme and how the state's judicial system could be invoked to stop these illegal practices and to make the victims whole.

As the investigation proceeded, the scheme appeared both more complex and simpler. It was simpler because its basic operation is the same regardless of which drugs or which government program is involved. The essence of the fraud, as well as the illegal conduct, is the misrepresentation of the average wholesale price, the guaranteed profit based on the statutory obligation to use the average wholesale price to set reimbursement levels, and the process of marketing this guaranteed profit to influence providers to use one drug over another to further the provider's financial self-interest, not the best interests of the patient.

The details of the scheme, however, were shown to be more complex than originally thought. For example, drug manufacturers use a variety of methods to create the spread. Some sell drugs directly to the health care provider at a discount. Others use specialized middlemen called "distributors," who list the drugs in their catalogs at deeply discounted prices. Still others use non-specialized middlemen called "wholesalers," who do not list discounted prices in their catalogs but instead participate in a charge-back arrangement. Under this system, the manufacturer agrees to sell the drug to the health care provider at a deeply discounted price. The provider, however, actually buys the pharmaceuticals from the wholesaler, which often has purchased the drugs at a price higher than the one the manufacturer promised to the provider. The manufacturer then compensates the wholesaler for the difference between the two prices, often in the form of a credit memo.

Regardless of the particular scenario employed by a manufacturer for a particular drug and a particular middleman-provider dyad, the law requires that the average wholesale price reflect the price physicians and pharmacists pay for the drugs. But the manufacturers both report average wholesale prices that far exceed any price any health care provider pays for the drug and conceal the real cost of the drugs. For example, Aventis' Anzemet[®], one of the anti-emetics cited above, was reimbursed by Medicare at \$14.82; its median catalog price, which does not reflect charge-backs, rebates and other discounts that lower the physician's actual cost, was \$8.29 (a 44 percent discount off the reported average wholesale price)²; and the Medicare beneficiary paid \$2.96, over 35 percent of the catalog price.

It will take the judicial process with its enforceable discovery mechanisms to unmask the full range of drugs for which the manufacturers report fraudulent prices and the amount by which they inflate those prices. It has, moreover, become quite clear that only judicial intervention will achieve meaningful relief from these practices by stopping them in the future, punishing past fraudulent and illegal acts, and providing restitution to the victims.

Conclusion

The cases filed by the Attorney General confront a scheme rooted in the recondite practices of an industry that wraps itself in the mantle of public service and the sometimes not-so-veiled threat that without excessive profits, manufacturers will no longer develop new lifesaving drugs and doctors will not provide life-saving treatments to Medicare, Medicaid, and EPIC participants. This litigation requires coordination and collaboration by lawyers whose expertise covers a multitude of diverse subjects, and it will provide both consumers and the financially strapped state health care programs with significant relief. The cross-bureau approach the Attorney General has initiated, which will continue throughout this and other litigation, provides precisely the mix of knowledge and skill needed to proceed against this type of widespread fraud that targets our most vulnerable citizens.

Endnotes

- 1. DHHS, Office of Inspector General, "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310 (Jan. 2001).
- Id. Using physicians' actual expenditures rather than median catalog prices, the General Accounting Office found that a discount of 65 percent off average wholesale price was widely available for Anzemet[®] in 2000-01. General Accounting Office, "MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost," GAO-01-1118 (Sept. 2001), at 12.

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Fighting Medicaid Fraud in New York State

By William J. Comiskey and Kevin R. Ryan

More than two hundred years ago, Benjamin Franklin observed, "There is no kind of dishonesty into which otherwise good people more easily and frequently fall than that of defrauding the government."

Today, Franklin's insightful words still ring true. Fraud is big business—especially in America's \$1 trillion health care arena where government, through its funding and administration of the Medicare and Medicaid programs,¹ is the biggest player.

Medicaid is the primary government health-care program for many of America's poorest citizens, and New York is home to the largest Medicaid-funded health care system in the country. Established by federal statute and regulations, Medicaid is funded in New York by contributions from federal, state and local governments. Last year, the New York State Department of Health, the state agency that administers the Medicaid program in New York, processed more than 200 million Medicaid claims for payment and paid out over \$28 billion in claims to health care providers.

Given the magnitude of these expenditures, it is not surprising that the nation's public health care delivery system has proven ripe for fraudulent activity. According to the U.S. General Accounting Office, fraud and abuse can account for up to 10 percent of total health care costs.² While assigning a precise dollar amount to fraud is impossible, even a small percentage loss to a program such as Medicaid represents billions of dollars.

New York has been in the forefront of the fight against health care fraud since the 1970s when, following the revelation of egregious and widespread abuses plaguing the state's nursing home industry, it became the first state in the nation to establish an office—The Office of the Special Prosecutor for Nursing Homes, Health and Social Services³—to investigate those engaged in health care fraud and abuse. The exposure of those scandals in late 1974 drew national attention to the devastating impact of fraud and abuse, and the pressing need to ensure that public funds earmarked for the care of indigent and elderly patients were being used for that purpose and not to line the pockets of greedy providers. Consequently, as a result of New York's advances in the war on nursing home fraud, the Special Prosecutor's Office was used as the model for the State Medicaid Fraud Control Units (the "Units") nationwide, mandated by Congress in the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977.4 Today, the Special Prosecutor's Office, which has since

become known as the Medicaid Fraud Control Unit (MFCU), is the largest statewide operation in the nation dedicated exclusively to the investigation and prosecution of health care crime.

The Units, which are monitored by the U.S. Department of Health and Human Services, are annually certified by the Secretary as adhering to eligibility mandates that include the operation of a statewide program for: investigating and prosecuting providers using all applicable state laws encompassing Medicaid fraud; recouping overpayments discovered in the course of the Unit's activities; reviewing and, where appropriate, prosecuting allegations of patient abuse and neglect in health care facilities receiving Medicaid funds; and investigating and prosecuting fraud in the administration of the program.⁵

"[T]he Medicaid Fraud Control Unit (MFCU), is the largest statewide operation in the nation dedicated exclusively to the investigation and prosecution of health care crime."

In accordance with these mandates, the New York MFCU exercises broad civil and criminal authority,⁶ derived from grants of power by state commissioners and other officers under Executive Law sections 63(3) and 63(8)⁷ and from the power vested in the Attorney General under Executive Law section 63(12) and Social Services Law section 145-b.⁸

Since its creation, the New York MFCU has fulfilled its mandate by securing more than 2,400 convictions against individuals who have defrauded the Medicaid program and nearly 300 convictions against individuals who have engaged in patient abuse or neglect. In addition, the Unit has instituted, through both criminal restitution and aggressive civil process, the recovery of more than \$400 million in Medicaid funds stolen or diverted from the program. The Unit focuses on substantial cases of Medicaid fraud and abuse and endeavors to protect the state's vulnerable nursing home population by criminally prosecuting egregious cases of abuse and neglect.

The investigation of substantial health fraud cases is difficult and requires specialized audit and investigative skills. In many cases, plowing through mountains of claims and looking for patterns that might indicate fraud is the only way to detect a crime. The investigation of the Parkshore Adult Health Care Center and its owner—charged with committing the nation's single largest Medicaid fraud—illustrates the challenges faced by the New York MFCU.

The Parkshore was an adult day care center that operated in Brighton Beach, Brooklyn, the heart of New York's Russian immigrant community. Adult day care centers such as Parkshore were intended to serve as cost-effective alternatives to nursing home care for individuals who could still live independently in their own homes. They were designed to provide medically necessary care and services for this elderly population.

In contrast, Parkshore was operated more like a "social club" than a health care facility. To carry out his elaborate fraud, Parkshore's owner, Lawrence Friedman, aggressively marketed his day care center to the community's elderly Russian population, enticing new clients with offers of free ambulette service to and from their homes with no regard for actual medical need. He served familiar foods, such as herring, gefilte fish, and borscht, and offered such social diversions as dancing, movies, English lessons, and the services of a beauty parlor.

At its peak, elderly Russian immigrants made up 99 percent of the Medicaid patient population at Parkshore, and the facility operated with assembly-line efficiency—running three shifts daily and billing Medicaid for nearly 1,000 people per day, well in excess of its authorized capacity. Because of Friedman's aggressive efforts, Parkshore's Medicaid billings mushroomed from \$500,000 in 1996 to more than \$42 million in 1999, when it accounted for 25 percent of all adult day care billings in the state.

In December 1999, Friedman was charged with billing taxpayers for meals, social activities and unnecessary transportation instead of approved medical care. Friedman pleaded guilty as charged to fifteen felony counts, and was sentenced in January 2002 to one to three years in state prison and ordered to pay more than \$48 million in restitution.

The Friedman/Parkshore case has had a significant impact on the adult day health care industry in New York, leading not only to systemic changes in the way such providers are reimbursed but also to the enactment of emergency regulations by the state Department of Health.⁹

The successful prosecution of the Friedman/Parkshore case occurred at a time when, under the leadership of New York Attorney General Eliot Spitzer, the MFCU determined to curtail its investigation and prosecution of low-level drug diversion cases and place greater emphasis on identifying and prosecuting substantial fraud cases. This shift in priorities has produced dramatic results. Between 1999 and 2002, the Unit recovered more than \$98 million in Medicaid dollars that had been wrongfully obtained by providers. That amount represents a 249 percent increase in restitution collected by the Unit when compared to the previous four-year period. Similarly, total restitution ordered between 1999 and 2002 as a result of MFCU cases reached \$153 million—a 286 percent increase over the restitution ordered between 1995 and 1998.

This enhanced recovery effort can also be attributed, in part, to a greater use by staff of a groundbreaking computer system-the MFCU Data Warehousewhich contains records of all Medicaid claims filed and paid in New York State. The Data Warehouse provides the Unit with instant access to billing information regarding every provider and every recipient within the state system. As a result, once a billing irregularity is discovered during an investigation, an audit can be quickly expanded statewide to determine if other Medicaid providers have similarly abused the system. The importance of the Data Warehouse as an effective fraudfighting tool became abundantly clear in September 1999 when the MFCU announced a record \$84 million settlement with Staten Island University Hospital (SIUH) for overbillings to the state Medicaid program. This monetary settlement is believed to be the largest recoupment by a state in the history of the Medicaid program. In addition, while many health care settlements require the establishment of a compliance program, this was the first time that a state Medicaid Fraud Control Unit imposed an outside monitor to review the future conduct of a hospital in an attempt to ensure that the wrongful billings are not repeated.

The Unit's investigation revealed that Staten Island University Hospital had been paid for approximately 1.6 million improper claims for outpatient services that had occurred in more than 500 "part-time clinics." Beyond the billing problems, the Unit found that the services were unsupported by evidence of genuine medical necessity; consisted more often of recreational activities than therapy; were characterized by inadequate hospital supervision; and included social work services, which were not billable to Medicaid as hospital outpatient services. In the face of these allegations, SIUH settled with MFCU by agreeing to pay, in payments over time and in free services to the indigent, \$84 million to the state.

Following the SIUH case, the Unit analyzed similar billings by other hospitals across the state and found similar widespread problems with outpatient billings. As in the Parkshore case, our investigation led to the state Health Department issuing a directive re-emphasizing the rules governing outpatient billings.¹⁰ As a result of the directive, it is estimated that Medicaid

billings were reduced by as much as \$10 million per month.

As the Parkshore and Staten Island University Hospital cases reflect, New York's specialized audit teams have uncovered fraud and abuse in virtually every aspect of the Medicaid program. Medicaid managed care plans, once thought to be a remedy to fraud, have proven to be equally susceptible to fraud.

In 2000, the Unit initiated a landmark investigation, focusing on both Managed Healthcare Systems of New York, Inc. (MHS), an HMO under contract with the City of New York to provide primary health care services to Medicaid recipients, and its subcontractor, Jean Millien, a physician's assistant who operated two medical clinics in Brooklyn. What the Unit found in this case was disturbing. Millien's clinics were inadequately staffed and often failed to provide necessary medical services. Those recipients "lucky enough" to get any medical care were often treated by medical personnel other than doctors—in violation of the city's contract, and violating the subcontract that MHS had with Millien.

Under the contract, physicians were required to be available 20 hours a week, and the clinics were to provide 24-hour coverage. One of the more troubling aspects of this investigation was the failure on the part of MHS to remediate and correct problems, which had been brought to its attention.

In June 2000, MHS repaid more than \$2 million, including interest, to the Medicaid program for services that the state funded but recipients never received. In February 2001, Millien was sentenced to one to three years in state prison and ordered to make restitution of \$275,000 to the Medicaid program.

While the Unit's success in prosecuting Medicaid provider fraud is widely recognized, it is perhaps less well known—though no less important—that the nation's MFCUs are the only law enforcement agencies in the country specifically charged with investigating patient abuse and neglect in nursing homes and other Medicaid-funded health care institutions. Traditionally, the Unit has prosecuted individual health care workers who committed isolated acts of neglect or abuse. Recognizing that these episodes of neglect and abuse may be manifestations of institutional problems, such as chronic understaffing, the Unit has begun aggressively examining whether owner/management policies or practices have created an environment where elderly residents are at risk.

Our focus on institutional responsibility bore fruit in September 2002 when the Briar Crest Nursing Home, in Ossining, and its former owner pleaded guilty to charges resulting from their failure to provide an adequate level of skilled nursing care to patients. As a result of this unprecedented prosecution, Briar Crest, which did business as Chandler Care Center, pled guilty to grand larceny in the second degree, a class C felony. By its plea, Chandler Care was convicted of stealing \$400,000 from the Medicaid program by misrepresenting that it had provided adequate care to its patients. Additionally, Samuel Klein, the facility's owner, pled guilty to the crime of wilful violation of the public health laws based on his admission that he willfully failed to employ sufficient nurses to provide adequate care. Significantly, the two defendants were ordered to return every Medicaid dollar received during the time deficient services were provided.

The Chandler prosecution illustrates the Unit's resolve to hold facilities accountable for creating conditions that compromise patient care. When facilities, driven solely by a desire to maximize profit, are so grossly understaffed that patient care is jeopardized, the Unit will use every resource, including resort to the criminal courts, to remedy the situation. Such swift and appropriate intervention underscores our commitment to protecting the more than 120,000 individuals who reside in New York's 667 nursing homes.

"While the Unit's success in prosecuting Medicaid provider fraud is widely recognized, it is perhaps less well known—though no less important that the nation's MFCUs are the only law enforcement agencies in the country specifically charged with investigating patient abuse and neglect in nursing homes and other Medicaidfunded health care institutions."

Our commitment is also revealed in our vigorous prosecutions of those individual care providers who violate, mistreat or neglect these citizens. Last year, for example, a nurse's aide was prosecuted for physically attacking an 85-year-old female patient on New Year's Day. In another case, a registered nurse neglected a terminally ill patient by not irrigating or changing the dressing on her gangrenous foot for three days. Unfortunately, these cases are but a small snapshot of the reported assaults, neglect and mistreatment confronted by the Unit.

One of the most appalling cases involved Arthur Wallace, a certified nurse's aide who was formerly employed at the Oneida City Hospital Extended Care Facility. In July 2000, Wallace was sentenced to 25-50 years in state prison for repeatedly raping a 92-year-old female resident at the facility over a two-month period. While one can hardly imagine a crime more horrible than sexually violating an elderly person, it is disheartening to think that a simple background check may very well have prevented such a tragedy as this from occurring.

What the Oneida nursing home did not know when it hired Wallace was that the U.S. Army had court-martialed him for having had sexual contact with a threeyear-old girl. In another case, Wallace was later convicted for illegally possessing a weapon. Yet, in filling out his employment application, Wallace simply left blank the box asking about prior criminal convictions.

"As the Unit moves forward, we are committed to creatively using every investigative and prosecutorial tool available to identify, prosecute and eliminate Medicaid fraud and patient abuse."

A comprehensive analysis of the approximately 360 patient abuse prosecutions brought by the Unit since its inception reveals that 25 percent of those health care workers charged have had prior arrests for crimes, including the sale of drugs, sexual abuse, and felony assault. Given this compelling evidence, Attorney General Spitzer has worked with the New York State Department of Health in the development of regulations requiring criminal background checks for health care workers.

As the Unit moves forward, we are committed to creatively using every investigative and prosecutorial tool available to identify, prosecute and eliminate Medicaid fraud and patient abuse. We will collaborate with other units within the Attorney General's Office and with other public agencies to bring affirmative civil proceedings under Executive Law section 63(12) to force institutions to deliver quality services to Medicaid patients and to secure additional restitution for the Medicaid program.¹¹ We will employ, where appropriate, investigative techniques and remedies traditionally used in organized crime investigations to pursue those who engage in systemic and organized fraud upon the Medicaid system. In a time of shrinking resources, our efforts to curb the theft of Medicaid resources and to protect vulnerable patients will be redoubled.

Endnotes

1. Title XVIII and Title XIX, respectively, of the Social Security Act. 42 U.S.C. § 1395 *et seq.* and § 1396 *et seq.* Together these two

major health care systems finance an estimated \$390 billion in health care services—about one-third of the country's total health care bill and almost three-fourths of all public spending on health care.

- 2. GAO Report (GAO/HRD 92-69 Health Insurance Fraud).
- The office was created on Jan. 10, 1975, by then-Governor Hugh L. Carey, at the behest of then-Secretary of State Mario M. Cuomo.
- See 42 U.S.C. § 1396b. On May 2, 1978, Governor Carey authorized the certification of the Office of the Special Prosecutor as the Medicaid Fraud Control Unit for New York State by the U.S. Department of Health and Human Services under sec. 17 of P.L. 95-142.
- 5. 42 U.S.C. § 1396b(q); 42 C.F.R. § 1007.11.
- See St. Francis Hospital-Poughkeepsie v. Spitzer, 284 A.D.2d 629 (3rd Dep't 2001); Virag v. Hynes, 80 A.D.2d 382 (2d Dep't 1981).
- 7. See Mann Judd Landau v. Hynes, 49 N.Y.2d 129, 134–138 (1979).
- See State of New York v. Estate of Ben Z. Frankel et al., 65 A.D.2d 788, 788–789 (2d Dep't 1978).
- 9. The new regulations shift reimbursement rates to a cost-based schedule (current provider rates are subject to a statutory ceiling of 65% of the sponsoring nursing facility's rate) 10 N.Y.C.R.R. § 86-2.9 *et seq.* DOH has convened a work group to develop a new system for reimbursement of transportation costs. Most significantly, DOH imposed a retroactive rate adjustment for similar facilities, which will save millions in taxpayer dollars. In Parkshore's case alone, the retroactive rate adjustment translates to a savings of more than \$23 million.
- 10. The directive, which amended 10 N.Y.C.R.R. §§ 703.6 and 710.1, stressed the need for a more detailed description of the types of services permitted in part-time clinics; explicit exclusion of certain types of locations and premises as acceptable sites for part-time clinics; a requirement that part-time clinics be in sufficient proximity to the sponsoring hospital or diagnostic and treatment center to ensure adequate supervision; and enhanced operating standards, including requirements for quality assurance and improvement and for credentialing of staff. The rules also guard against the unnecessary expenditures of Medicaid funds for unneeded or duplicative services—thereby making funds available for needed care.
- 11. In December 2002, Attorney General Spitzer, as a result of the collaborative efforts of multiple parts of his office and the Department of Health, filed a lawsuit against the former operators of Seaport Manor Home for Adults, an adult home for the mentally ill in Brooklyn. The lawsuit accuses Seaport's operators of neglecting residents, distributing medication carelessly, and forcing them to live in deplorable and unsanitary conditions, that included rooms infested with mice, cockroaches, and flies. The suit seeks \$12 million in compensatory damages and to permanently bar the operators from owning or administering a state-licensed facility serving the elderly, mentally ill, or homeless. The suit also seeks restitution from the defendants to compensate hundreds of former Seaport residents whose disability checks paid their room and board.

William J. Comiskey is the Deputy Attorney General in charge of the Medicaid Fraud Control Unit (MFCU) within the New York State Attorney General's Office. Kevin R. Ryan is the MFCU Public Information Officer.

Other Views on the Role of the AG in Health Care

By Robert Wild, Edward Kornreich, Pat Formato, Harold Iselin, Ben Golden and Mark Thomas

On the Role of the Antitrust Bureau

Robert Wild

Not too many years ago, antitrust issues played little, if any, role in the analysis of transactions among health care providers. However, with the proliferation of mergers, acquisitions and provider networks in the 1990s (both in the for-profit and not-for-profit sectors), antitrust issues rose to a far more prominent place on the legal "radar screen."

The Antitrust Bureau of the New York State Office of the Attorney General has been particularly active over these years in enforcing both federal and state antitrust laws.¹ The federal and state antitrust laws are quite similar although there are some differences. The state law (The Donnelly Act) prohibits price fixing, bid rigging, monopolization, boycotts, tying arrangements and other similar practices. Violators may be subject to fines or imprisonment and private individuals may bring lawsuits to enjoin unlawful practices and obtain treble damages for provable injury.

Federal law (Hart-Scott-Rodino)² provides a mechanism for notification to federal regulators of a transaction that meets the thresholds and standards contained within the Act. State law, however, does not contain a similar provision. Nevertheless, notification to the New York State Attorney General of health care transactions that may raise antitrust issues has become both the policy of the New York State Health Department (DOH) and good practice. Transactions that come before DOH which are in the nature of merger, network formation, acquisition or membership changes (in the case of notfor-profits) are generally referred to the Attorney General's Antitrust Bureau by DOH for review. In the alternative, the sponsor of the proposed transaction may be required to seek an appropriate antitrust review (federal and state where applicable, or state only where the federal thresholds are not met).

Health lawyers in New York are reminded that there have been significant cases brought by or with the participation of the New York State Attorney General³ and, therefore, early interaction with that office is often necessary and certainly recommended in most cases.

Experience shows that when the Attorney General is advised early on in the transaction of its nature, significance and importance to those participating, the Antitrust Bureau will be responsive in providing indications as to whether it views the transaction as one which is problematic under federal and state antitrust laws or one which does not appear so.

While a refusal by the Antitrust Bureau to seek to enjoin a given transaction is not an assurance that the transaction may not be challenged in the future, it does provide a significant degree of comfort and often the process of securing such refusal will provide reasonable guidance as to essential elements of the transaction impacted by the antitrust laws.

Recently, the Federal Trade Commission announced an initiative to re-review transactions that had previously been submitted (generally under Hart-Scott-Rodino) to determine whether the transactions have, after implementation, had an adverse impact on commerce. Apparently, in New York State, the Antitrust Bureau is either participating in this initiative with respect to New York state transactions or has implemented its own review of such transactions to determine whether or not these transactions do present potential antitrust issues now that they have been in effect for some time. Apparently such review includes some of the major network transactions that have been in effect for some years in New York State. As recently as Monday, March 10, an article appeared in Crain's *Health Pulse* indicating that the Long Island Health Network (an affiliation of 11 Long Island hospitals) was under investigation by the Attorney General.

Clearly, antitrust issues must be at the forefront of consideration in applicable health care transactions. In many instances, it may be both appropriate and expedient to seek out the Attorney General's Antitrust Bureau in such transactions to anticipate potential issues and hopefully resolve them before they negatively affect the proposed transaction.

Endnotes

- Sherman Antitrust Act, 15 U.S.C. § 1 et seq.; Clayton Act, 15 U.S.C. § 12 et seq.; Federal Trade Commission Act, 15 U.S.C. § 45 et seq.; and Donnelly Act, N.Y. Gen Bus. Law § 340 et seq.
- 2. Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a.
- United States v. Long Island Jewish Medical Center and North Shore Health System, Inc., 983 F. Supp. 121 (E.D.N.Y. 1997); and State of New York v. St. Francis Hospital, Vassar Brothers Hospital and Mid-Hudson Health, 94 F. Supp. 2d 399 (S.D.N.Y. 2000) and 94 F. Supp. 2d 423 (S.D.N.Y. 2000).

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On the Role of the Charities Bureau

Edward Kornreich

In 1816, the state of New Hampshire passed legislation to effect a change in the charter of Dartmouth College, pursuant to which the Governor would appoint a majority of the College's board. The trustees of Dartmouth College challenged the statute as an impairment of contract prohibited by the newly established United States Constitution. Ruling in favor of the trustees, Justice Marshall noted the intent of those who created the College for self-governance by a self-perpetuating board of trustees, which was deemed preferable to government operation. This understanding, as adopted in the College's original Charter, created a binding contract between the state of New Hampshire and those donors and creators (and their successors, the trustees bringing the suit) that the legislation at issue impermissibly impaired. In holding for the trustees, the Court stated:

> When, then, the argument assumes, that because the charity is public, the corporation is public, it manifestly confounds the popular, with the strictly legal sense of the terms. . . . When the corporation is said at the bar to be public, it is not merely meant, that the whole community may be the proper objects of the bounty, but that the government have the sole right, as trustees of the public interests, to regulate, control, and direct the corporation, and its funds and its franchises, at its own good will and pleasure. Now, such an authority does not exist in the government, except where the corporation is in the strictest sense public; that is, where its whole interests and franchises are the exclusive property and domain of the government itself. . . . Yet who ever thought before, that the munificent gifts of private donors for general charity became instantaneously the property of the government; and that the trustees appointed by the donors, whether corporate or unincorporated, might be compelled to yield up their rights to whomsoever the government might appoint to administer them? If we were to establish such a principle, it would extinguish all future eleemosynary endowments; and we should find as little of public policy, as we now find of law to sustain it.1

Indeed, Justice Marshall's judgment and instinct were correct. It is not likely that Dartmouth College

would have achieved or maintained its prominence had it become a state-controlled institution. Importantly, this country's great private, not-for-profit universities and renowned academic medical centers serve the public interest (either broadly or as specifically defined by the mission of the not-for-profit). These institutions, and others striving to join their ranks, are entitled to substantial self-governance in the absence of fraud, gross error of judgment or self-dealing.

Not-for-profit corporations are entitled to a presumption of regularity, and the government, by law, intervenes where there is evidence of impropriety or a fundamental change in the corporation (but not the identity or the manner of appointment of the trustees), such as the sale of substantially all of the assets, a merger, dissolution or a change in the power or purposes of the corporation. By limiting the Attorney General's power to intervene in not-for-profit corporate affairs to the foregoing circumstances, the law assures the free exercise of judgment by these not-for-profit entities, independent of politics and with due consideration of the long-term best interests of the not-for-profit. Those New Yorkers who support Attorney General Spitzer's intervention in not-for-profit affairs might have regarded interventions by the Vacco administration problematic, and vice-versa. Management of not-for-profit entities cannot turn on the political passions of the moment.

New York State hospitals are heavily regulated at the state and federal level and are among the most regulated entities in this country. The New York State Department of Health is very aggressive in its review of hospital activities, and the hospitals are also subject to oversight by notoriously intrusive and powerful governmental and quasi-governmental bodies. These include the United States Department of Health and Human Services and its Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, Office of the Inspector General and Office for Civil Rights, and Food and Drug Administration (regarding research), and the Medicare fiscal intermediaries, the New York State Attorney General's Charities Bureau, the United States Internal Revenue Service (regarding federal tax exemption), peer review organizations, the Joint Commission on Accreditation of Health Care Organizations, and health maintenance organizations and insurance companies (that often have their own anti-fraud bureaus). Given this plethora of oversight, there is simply no justification for further extending existing regulations or interpreting them broadly.

With this right to self-governance and the benefits of tax exemption that not-for-profits enjoy comes the responsibility to exercise those rights in accordance with law. There is no doubt that the Attorney General, representing the people of the state of New York, has full authority to intervene in any circumstance of fraud or abuse. But like the responsibility of not-for-profits to exercise their independence responsibly, with the Attorney General's authority comes a heavy responsibility to exercise judgment and discretion in using that authority to protect the independence that is the hallmark of the American not-for-profit corporation.

Endnote

 The Trustees of Dartmouth College v. Woodward, 17 U.S. (4 Wheat.) 518, 671–72 (1819).

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On the Role of the Medicaid Fraud Control Unit

Patrick Formato

The New York State Attorney General's Medicaid Fraud Control Unit is charged with investigating and prosecuting health care provider fraud and abuse in New York's Medicaid program. Since its creation in 1975, the Medicaid Fraud Control Unit's investigations have resulted in over 3,000 arrests with an overall conviction rate of ninety-one percent and the recovery of more than \$422 million in overpayments, penalties and restitution.¹ Moreover, its continued prosecutions have "deterred the theft of more than \$1 billion from the state Medicaid program."2 One of its renowned cases involved an owner and operator of an adult day care facility. As a result of its investigation of an elaborate fraud scheme where the operator billed Medicaid for adult day care registrants' meals, social activities, and unneeded transportation from 1996 to 1999, the Unit recovered \$23.4 million and the operator was sentenced to one to three years in state prison.³

In addition to its stepped-up efforts to uncover Medicaid fraud, the Medicaid Fraud Control Unit has continued its long-standing endeavors to improve the quality of care for nursing home residents. As part of its effort to improve nursing home residents' quality of care, the Unit has intensified its commitment to investigating and prosecuting resident abuse and neglect. The first case to result from Attorney General Spitzer's statewide nursing home initiative to examine nursing homes for quality of care issues was the Townhouse case. In this highly publicized case, the Unit was successful in prosecuting the Director of Nursing at the Townhouse Extended Care Center, a Long Island nursing home, on felony charges of tampering with evidence and directing staff to cover up the circumstances surrounding a resident's death.4

The Medicaid Fraud Control Unit should be commended for vigorously investigating allegations of neglect or abuse of nursing home residents. However, the decision to investigate any complaint of abuse or neglect imposes a difficult balancing act and the Unit must exercise reason and judgment in making such a decision. The Unit has the challenge of weeding out the legitimate claims of abuse and neglect from frivolous claims made by disgruntled facility employees or distraught guilt-ridden family members. If not properly evaluated, allegations without merit may trigger unnecessary and costly investigations. Such investigations require facilities to spend inordinate amounts of time and resources in responding to the demands of the Unit's investigations. The time and resources expended on responding to and defending frivolous claims rather than focusing on care rendered to nursing home residents can often serve to undermine one of the stated goals of the Medicaid Fraud Control Unit of ensuring quality of care and life for nursing home residents.

Endnotes

- 1. N.Y.S. Office of the Attorney General (NYSOAG), *supra*, at 33.
- 2. Ia
- 3. NYSOAG News: Brooklyn Adult Care Provider Pleads Guilty in Nation's Largest Criminal Medicaid Fraud Case, Apr. 6, 2001.
- 4. NYSOAG News: Nursing Home Official Convicted of Covering Up Patient Abuse at Long Island Facility, Apr. 11, 2001.

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On the Role of the Health Care Bureau Harold Iselin

The Attorney General's Health Care Bureau is a fairly recent addition to the health care landscape and focuses on enforcing consumer rights. While the Health Care Bureau advocates on behalf of consumers experiencing problems from all sectors of the health care industry, in recent years it has focused increasingly on consumer issues relating to health plans (health insurers and HMOs). Although this scrutiny has generally been fair and balanced, there are times when the Bureau's enforcement duplicates the work of other oversight bodies and overlooks the real-world operational issues confronting health plans.

Health plans are perhaps the most heavily regulated entities in New York State. In addition to the Departments of Health and Insurance, health plans are subject to oversight by the federal government (CMS), consumer watchdog groups, employer organizations, accrediting bodies and others. There are at least three different managed care report cards in New York State alone while no comparable report cards exist for hospitals, physicians or other health care providers. Thus, the actions of the Health Care Bureau represent an additional layer of oversight and enforcement. This creates the potential for duplicative and conflicting compliance standards, as well as possible jurisdictional issues between all of the oversight bodies.

To its credit, the Health Care Bureau has generally used its enforcement powers in a targeted and judicious fashion. When it receives a complaint, the Bureau contacts the health plan in an effort to ascertain the plan's perspective and to seek an informal resolution of the complaint. As initially developed by the first head of the Bureau, Jeff Gold, and as now practiced by the current head, Joseph Baker, the Bureau's approach has produced positive results for consumers and health plans because the majority of complaints are resolved to the satisfaction of both sides. What is more, the Bureau recognizes that there are instances where the grievance of a consumer or provider is not valid, and the Bureau has been willing to uphold the position of the health plan.

There are, however, occasions where the Bureau can seek an end that it could achieve through less adversarial methods. In one investigation, the Bureau issued a subpoena that generated hundreds of thousands of documents, which resulted in a settlement that could have been achieved through a less burdensome approach. The investigation also threatened to hold health plans to a different compliance standard than had been established by the Departments of Health and Insurance.

The Health Care Bureau is now carrying out its mission as an ombudsman for consumers in a way that produces fair results for both sides. Having refined its enforcement approach, it is important for the Bureau to apply it to other sectors of New York's health care system. Too often, consumers are victimized by inappropriate balance billing or illegal price-fixing that makes health care unaffordable. All of the consumer protection developed by the Bureau means little if consumers cannot afford health insurance. Working with the Antitrust Bureau and other offices of the Attorney General, the Health Care Bureau can and should tackle these other challenges.

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On the Role of the AG in Life-Sustaining Treatment Decisions Ben Golden

"There's the law and there's what's right," said state Supreme Court Justice James Tormey, when despite the law—he decided to order a stop to futile life-sustaining treatment for Sheila Pouliot, a Syracuse woman with profound mental retardation.¹

However, state Attorney General Eliot Spitzer appealed Judge Tormey's ruling and treatment continued before Pouliot, her body described by physicians as "devour[ing] itself" and "d[ying] by millimeters," expired.² The Attorney General was subsequently sued by the family for assault and practicing medicine without a license but a federal court ruled that Spitzer's actions were consistent with state law.³

Judge Tormey's comments reflected a much broader tendency to quietly try to do the right thing despite the law, thereby hiding its defects from public view.⁴ But that's not easy for individuals with mental retardation. Many are never competent to meet New York's high standard for refusal of heroic end-of-life medical interventions. And further, like Sheila, many live and work in state-regulated programs, making them especially susceptible to a strict application of the New York law, regardless of how inhumane. It is this "state connection" which brought Spitzer into the case.

Fortuitously, while the Pouliot case was in the news, advocates of individuals with mental retardation were drafting legislation to avoid just such catastrophes. When the Attorney General was later sued by Pouliot's family, other families of individuals with mental retardation, through NYCARC, Inc. (formerly The New York State Association for Retarded Children), deplored the prosecutorial decision that prolonged this woman's suffering.⁵ Thus, Spitzer's enforcement not only helped highlight problems with New York's endof-life standard, but darkly characterized—to the chagrin of state officials—the state's role in enforcing it.

The Attorney General's office indicated that its actions in *Pouliot* were merely to obtain enforcement "guidance." Regardless, while it can be argued that the Attorney General deserves blame for adding to the burden of Sheila Pouliot's suffering, it can also be argued that his very visible enforcement helped provide advocates with critical political ammunition to change a law which resisted any change for nearly a decade.⁶ That change was approved on September 17th when Governor Pataki signed the Health Care Decisions Act for Persons with Mental Retardation (HCDA).⁷ The HCDA carves out an exception to New York's standard for refusing life-sustaining treatment by giving courtappointed guardians the authority to withhold or withdraw such treatment for individuals with mental retardation.

However that exception is limited: advocates outside the mental retardation field are still seeking passage of the Family Health Care Decisions Act or some other initiative to relieve the harshness of New York's rule that restricts end-of-life decisions for other patients.⁸

"Though Sheila was considered by the state to be 'its ward,' she cast a welcome light on the shortcomings of its humanity," said her attorney, Martha Mulroy, who gave Pouliot's eulogy.⁹ While it can't be determined if the Attorney General intentionally helped shine that light, the illumination helped advocates give the legislature a view from which it could not turn away.

And advocates needed all the help they could get since the HCDA "was extraordinarily difficult to do because it brings into consideration what is the role of government when it comes to the basic question of life," said the bill's Senate sponsor, Kemp Hannon (R-Westbury), who perservered for three years crafting the HCDA and is credited by advocates for individuals with mental retardation as central to its passage. The Assembly sponsor, Martin Luster (D-Ithaca), argued that the HCDA granted a basic "civil right"—one previously denied in cases like *Pouliot*.

Endnotes

- 1. Michael D. Goldhaber, *The Law vs. What's Right*, Nat'l L.J., Mar. 27, 2000.
- Jim O'Hara, End Woman's Treatment, Judge Orders, The Post-Standard, Mar. 2, 2000, at B-3.
- 3. Blouin v. Spitzer, 213 F. Supp. 2d 184 (N.D.N.Y. 2002).
- Ben Golden, New Law Gives Guardians Authority To End Futile Treatment For Adults With Retardation, N.Y. St. B.J. (Feb. 2003).
- Letter from Mary Ellen Murphy, Chairperson, Governmental Affairs Committee, to the National Abortion and Reproductive Rights Action League (Jan. 2, 2002) (on file with author).
- 6. Family Health Care Decisions Act, A.5523, 2201 Leg. 224th Sess. (N.Y. 2001), memo.
- 2002 N.Y. Laws ch. 500, S4622B, A8466D, signed on Sept. 17, 2002.
- Robert Swidler, Harsh State Rule on End-of-Life Care Remains in Need of Reform, N.Y. L.J., Jan. 26, 2000, p. S-4.
- 9. Goldhaber, *supra* note 1.

Ben Golden is the director of governmental affirs for NYSARC, Inc. (Formerly The New York State Association for Retarded Children).

On the Role of the AG in Health Care: A Hospital Community Perspective Mark Thomas

The Department of Law, under Attorney General Spitzer's stewardship, continues its strong tradition of representing consumers. In recent years, the Department has especially distinguished itself, particularly regarding coverage and related issues with health insurers and HMOs. Many former payer abuses have been corrected as a direct result of intervention from the Department.

With regard to oversight of not-for-profit health providers, the hospital community is concerned that the Department is seeking to supplant traditional regulatory agencies to impose new review and approval mandates on provider transactions. The recent *Littauer* litigation is but a single example of the Department's attempt, thwarted by the judiciary, to intervene in a process that had already been the subject of extensive review by regulatory agencies. Perhaps as a result of the Appellate Division decision in *Littauer*, a review of policies and initiatives will be undertaken by the Attorney General.

Hospitals would further encourage the Attorney General to examine the effects of oligopolistic health insurer and HMO markets, their effect on the delivery of care and on access to services in both urban and rural settings. Similarly, near-monopolistic markets for insurance and blood supplies leave providers in some areas exposed to anticompetitive pressures that call for review by the Department. At the same time, sound health policy may require something less than "pure" competition among providers if efficiencies across the health care system are to be maximized.

The Department of Law's vital role in enforcement, consumer protection and assuring a thriving competitive environment presents several challenges in the health field. From the hospital perspective, the Department more than meets these challenges and has generally been responsive to provider concerns.

Mark Thomas is General Counsel to the Healthcare Association of New York State.

The Attorney General's Formal Opinion: Futility-based DNR Orders

April 3, 2003

D. Andrew Edwards, Jr. Formal Opinion University Counsel No. 2003-F1 The State University of New York The Capitol Albany, New York 12224-0341

Dear Mr. Edwards:

You have asked whether a physician who is treating a legally incapacitated patient and who concludes that administration of cardiopulmonary resuscitation would be "medically futile"¹ has the authority to enter a do-not-resuscitate order over the objection of the patient's surrogate or health care agent. We conclude that in these circumstances entry of a do-not-resuscitate order would violate Public Health Law § 2965 and is therefore not authorized.

Your question arises from an apparent conflict between the governing statutes and a pamphlet issued jointly in 1992 by the New York State Department of Health, the New York State Task Force on Life and the Law, the Medical Society of the State of New York, and the Hospital Association of New York State. *See* New York State Department of Health, et al., *Do-Not-Resuscitate Orders: Questions and Answers for Health Care Professionals* (2d ed. 1992) [hereinafter *Questions and Answers*]. The pamphlet says that where cardiopulmonary resuscitation would be "medically futile," the attending physician may enter a do-not-resuscitate order without the consent of the patient's surrogate or health care agent where the judgment of futility is confirmed by a second physician.²

To the extent this advice indicates that a physician may enter a do-not-resuscitate order without obtaining the consent of a reasonably available health care agent or surrogate, in our view, it is inconsistent with Public Health Law § 2965 and with regulations promulgated by the Department of Health. Though the views reflected in this aspect of the *Questions and Answers* publication have support within the medical community, they have been explicitly rejected by the Legislature.

PUBLIC HEALTH LAW §§ 2960, 2961, 2962, 2964, 2965, 2966, 2970, 2972, 2973; 10 N.Y.C.R.R. 405.43(f).

Where a patient is incapacitated and did not consent to the entry of a do-not-resuscitate order prior to becoming incapacitated, a physician must obtain the consent of the patient's surrogate or health care agent before entering a do-not-resuscitate order, even if the physician concludes that administration of cardiopulmonary resuscitation would be "medically futile." Only where no health care agent was appointed and no competent surrogate is reasonably available and willing to make a decision may the physician enter a do-not-resuscitate order based on medical futility without obtaining consent, and then only with the concurrence of another physician that resuscitative efforts would be medically futile or by obtaining a court order. To dispute the decision of the health care agent or surrogate, the physician must proceed to mediation and, if the dispute remains unresolved, commence a court action.

Statutory Framework

In New York, do-not-resuscitate orders are governed by article 29-B of the Public Health Law, entitled "Orders Not to Resuscitate." As defined by that article, an "order not to resuscitate" is an order instructing medical personnel "not to attempt cardiopulmonary resuscitation in the event a patient suffers cardiac or respiratory arrest." Pub. Health Law § 2961(17). The order must be included in writing in the patient's chart, *id.* § 2962(2), and is subject to periodic review, *id.* § 2970. As the statutory definition suggests, an order not to resuscitate ordinarily is entered in anticipation of a future cardiac or respiratory arrest.³

The Legislature enacted article 29-B "to clarify and establish the rights and obligations of patients, their families, and health care providers regarding cardiopulmonary resuscitation and the issuance of orders not to resuscitate." *Id.* § 2960 (legislative findings and purpose). To this end, the article is exhaustive; that is, it identifies all the circumstances in which a physician is authorized to enter an order not to resuscitate a patient.⁴ *See id.* § 2962(2) ("It shall be lawful for the attending physician to issue an order not to resuscitate a patient, *provided that the order has been issued pursuant to the requirements of this article.*") (emphasis supplied). Article 29-B makes the consent of the patient or the patient's agent or surrogate the principal source of the physician's power to enter an order not to resuscitate. Indeed, in its statement of "Legislative findings and purpose," the Legislature summarized its intent as follows: "The Legislature finds that . . . it is appropriate for an attending physician, in certain circumstances, to issue an order not to attempt cardiopulmonary resuscitation of a patient *where appropriate consent has been obtained.*" *Id.* § 2960 (emphasis supplied); *see also id.* § 2962(1) ("Every person admitted to a hospital shall be presumed to consent to the administration of cardiopulmonary resuscitation . . . *unless there is consent to the issuance of an order not to resuscitate as provided in this article.*") (emphasis supplied).

Where a patient has the capacity to consent to entry of a do-not-resuscitate order, it is, of course, the patient whose consent is required. *Id.* § 2964. The patient's consent is effective even if the patient later becomes incapacitated. *Id.* § 2965(1)(b) (consent of surrogate or agent is not required for incapacitated patient where patient had consented to order not to resuscitate prior to losing capacity).

If the patient has not consented, a do-not-resuscitate order can be entered based upon the consent of a "health care agent." *See id.* § 2961(8).⁵ A decision by a health care agent, duly appointed by the patient, takes "priority over decisions by any other person, except the patient or as otherwise provided in the health care proxy." *Id.* § 2965(1)(c). Where the patient is incapacitated but has previously appointed a health care agent to make medical decisions on his or her behalf, the health care agent stands in the patient's shoes. *See id.* §§ 2962(5), 2982(1). Accordingly, in this setting, the consent of the health care agent, if one is available, "must be obtained prior to issuing an order not to resuscitate the patient." *Id.* § 2965(1)(a).

Where a patient is incapacitated and has not appointed a health care agent, the decision whether to consent to the entry of a do-not-resuscitate order falls next to a "surrogate." *Id.* §§ 2961(21), 2965(2). The categories of persons permitted to act as a surrogate are identified in section 2965(2) of the Public Health Law. A surrogate can be a committee or guardian appointed pursuant to article 17-A of the Surrogate's Court Procedure Act (concerning individuals with developmental disabilities); otherwise, it must be a near relative or close friend of the patient. Pub. Health Law § 2965(2). The person chosen to serve as the surrogate must be reasonably available, willing to make a decision about the issuance of an order not to resuscitate, and competent to make the decision. *Id.*

In keeping with the fact that the patient has not granted the surrogate the power to make decisions on

his or her behalf, the surrogate plays a somewhat different role in the process than does the patient or the patient's health care agent. The patient or the patient's health care agent may consent to the entry of a do-notresuscitate order without any particular medical finding by the physician. *See id.* §§ 2964, 2965(1). In contrast, a surrogate may only consent to the entry of a do-notresuscitate order if there has been a determination by an attending physician, with the concurrence of another physician, that either: (1) the patient has a terminal condition; (2) the patient is permanently unconscious; (3) administration of cardiopulmonary resuscitation would be medically futile; or (4) resuscitation would impose an extraordinary burden on the patient given the patient's condition. *Id.* § 2965(3).

Although the statute makes the existence of one of these four circumstances a prerequisite to the entry of a do-not-resuscitate order where the order is based on the consent of a surrogate, none of these circumstances provides an independent basis for the entry of a do-notresuscitate order over the objection of or without consent of the surrogate. If a surrogate is reasonably available and is willing and able to make a decision, the physician cannot dispense with the surrogate's consent, any more than the physician can dispense with the consent of a competent patient or health care agent; the surrogate's consent "must be obtained." *Id.* § 2965(1)(a).

Section 2966 does provide limited authority for the issuance of a do-not-resuscitate order for an incapacitated adult who did not consent to a do-not-resuscitate order prior to losing capacity, and for whom no health care agent or surrogate is reasonably available. In this, and only this, circumstance, section 2966 permits the attending physician to enter a do-not-resuscitate order without consent, either on the basis of a determination by two physicians that resuscitative efforts would be medically futile, or as directed by court order. Pub. Health Law § 2966(1). But if a health care agent has been appointed, or a surrogate is reasonably available, then the consent of the health care agent or surrogate "must be obtained prior to issuing an order not to resuscitate." *Id.* § 2965(1)(a).

It is clear from these statutes that article 29-B does not permit physicians who conclude that resuscitative efforts would be "medically futile" to independently override the refusal of the surrogate or the health care agent to give consent or to enter an order without consulting (and obtaining the consent of) a reasonably available health care agent or surrogate. Public Health Law § 2965 specifically requires the consent of the agent or surrogate and makes "medical futility" one of four medical determinations that will justify giving effect to the consent of a surrogate; it does not make medical futility an independent basis for the entry of a do-notresuscitate order. Public Health Law § 2966 makes medical futility the basis for entry of a do-not-resuscitate order only where no health care agent or surrogate is reasonably available. Regulations promulgated by the Department of Health are fully consistent with this statutory scheme. *See* 10 N.Y.C.R.R. 405.43(f).

Moreover, the statutory scheme contemplates frank discussion between the physician and health care agent or surrogate about the patient's diagnosis and prognosis and the foreseeable risks and benefits of cardiopulmonary resuscitation. See Pub. Health Law § 2962(3) (requiring the attending physician to provide such information to the person giving consent). In most cases, such open discussion should result in agreement regarding issuance of an order not to resuscitate. Where it does not, a physician seeking to enter a do-not-resuscitate order over the objection of a health care agent or surrogate has two options. The physician must first bring the dispute before the hospital's dispute mediation system, pursuant to Public Health Law § 2972. However, persons appointed to participate in the dispute mediation system do not have the authority to determine whether a do-not-resuscitate order shall be issued. Pub. Health Law § 2972(5). If mediation does not resolve the dispute and the physician wishes to persist in his or her efforts to enter a do-not-resuscitate order over the objection of a health care agent or surrogate, the physician must commence a court action. Id. § 2973.

Legislative History

With respect to the question you pose, the plain meaning of article 29-B is consistent with the policies and purposes underlying its enactment. *Cf. Insurance Co. of N. Am. v. ABB Power Generation, Inc.,* 91 N.Y.2d 180, 186 (1997) ("the literal meaning of the [statute's] text should not be followed where it is patently inconsistent with the policies or purpose of the statute or where the result would be absurd"). Responding to "a need to clarify the rights and obligations of patients, their families, and health care providers," Pub. Health Law § 2960 (legislative findings and purpose), the Legislature, in enacting article 29-B, sought to balance the risk of medically inappropriate resuscitation with the need to safeguard the patient's interest in continued treatment.

There are divergent views in the medical community as to how best to accommodate these two interests. The view that physicians should be permitted to override the surrogate or health care agent in cases of medical futility has substantial support. *See, e.g.,* American Medical Association, *Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders* (1990) ("if, in the judgment of the treating physician, CPR would be futile, the treating physician may enter a do-not-resuscitate order into the patient's record"). Indeed, some commentators have argued that it is absurd to deny physicians the power to decide unilaterally whether to enter do-not-resuscitate orders in cases involving medical futility. *See, e.g.,* Rita T. Layson & Terrance McConnell, *Must Consent Always Be Obtained for a Do-Not-Resuscitate Order?*, 156 Archives Internal Med. 2617, 2619-20 (Dec. 9/23, 1996). However, other commentators have argued cogently that decisions about resuscitation should be left to the patient or her surrogate. *See, e.g.,* Stuart J. Youngner, *Who Defines Futility?*, 260 JAMA 2094 (Oct. 14, 1988); Paul C. Sorum, *Limiting Cardiopulmonary Resuscitation*, 57 Alb. L. Rev. 617, 622-23 (1994).

The Legislature was cognizant of the concerns underlying these competing views when it adopted Public Health Law § 2965. In a report issued in April 1986 containing the proposed legislation that eventually became article 29-B of the Public Health Law, the New York State Task Force on Life and the Law⁶ identified "medically inappropriate resuscitation" and the entry of do-not-resuscitate orders without consent as the two principal problems driving the need for legislation. New York State Task Force on Life and the Law, Do-Not-Resuscitate Orders: The Proposed Legislation and Report of the New York State Task Force on Life and the Law 6-7 (1st ed. 1986). The report explained that where medical personnel attempt to resuscitate a patient who is certain to suffer repeated arrests in a short period before death occurs, the "outcome may be a more traumatic death rather than a prolongation of life." Id. at 7-8.

In spite of the Task Force's concerns about medically inappropriate resuscitation, the legislation proposed by the Task Force made the surrogate's consent a prerequisite to the entry of a do-not-resuscitate order. See *id.* at 37, 80-81. The Task Force's report explicitly stated: "If the attending physician believes that CPR is not medically appropriate for the patient, he must identify the proper surrogate to make a decision on the patient's behalf." Id. at 37. The report emphasized, "[w]hile the physician's advice and guidance to the surrogate are critical, the surrogate must act as an independent decision maker," and explained that "[t]he independence of the surrogate and physician provides greater protection for the patient." Id. Although the Task Force recognized that the proposed legislation "does not resolve the dilemma of resuscitation which yields greater pain or discomfort than benefit," it concluded that its proposed compromise appropriately reflected a presumption in favor of resuscitation "where the decision making process cannot adequately safeguard against the risk of a decision which does not serve the patient's interests in continued treatment." Id. at 45.

The Legislature subsequently adopted a statutory scheme that closely followed that recommended by the Task Force in its report. As the Task Force proposed, the surrogate's consent was made a prerequisite to the entry of a do-not-resuscitate order, even in cases of medical futility. Pub. Health Law § 2965(1)(a). Because the Legislature plainly considered the concerns that militate in favor of permitting physicians to override the surrogate in cases of medical futility, these concerns provide no grounds for overriding the careful compromise it reached in enacting article 29-B.

Conclusion

We conclude that where a patient is incapacitated and did not consent to the entry of a do-not-resuscitate order prior to becoming incapacitated, the Public Health Law requires the physician to obtain the consent of the patient's health care agent or surrogate before entering a do-not-resuscitate order, even if the physician concludes that administration of cardiopulmonary resuscitation would be "medically futile." Only where no health care agent was appointed by the patient and no competent surrogate is reasonably available and willing to make a decision may the physician enter a do-notresuscitate order based upon medical futility without obtaining an agent's or surrogate's consent, and then only upon the concurrence of another physician that resuscitative efforts would be medically futile or after obtaining a court order. To dispute the decision of the health care agent or surrogate, the physician must proceed to mediation and, if the dispute remains unresolved, commence a court action.

Very truly yours,

Eliot Spitzer Attorney General

Endnotes

- For purposes of the statutory scheme governing orders not to resuscitate, "cardiopulmonary resuscitation" is defined as "measures... to restore cardiac function or to support ventilation in the event of cardiac or respiratory arrest" and "medically futile" means either situations in which such measures will not be successful in restoring cardiac and respiratory function or situations in which "the patient will experience repeated arrest in a short period before death occurs." Pub. Health Law § 2961(4),(12).
- 2. *Q: When can the attending physician enter a DNR order based on medical futility?*

If the physician determines that CPR would be medically futile, the physician may enter a DNR order on that basis provided that he or she takes the following steps:

- The physician must discuss the DNR order with the patient, agent, or surrogate, if possible;
- The judgment of futility must be confirmed by a second physician authorized by the hospital to render concurring opinions on DNR matters; and
- The physician must enter the order in the patient's chart and inform the patient, agent, or surrogate. The order will not require the consent of the agent or surrogate.

Q: What if the health care agent or surrogate refuses to consent to a DNR order and the physician believes that CPR would be futile for the patient?

The attending physician must seek a second opinion. If the second physician concurs that CPR will be futile, as futility is defined by the law, and the concurrence is written in the chart, the attending physician may enter the order on grounds of futility, but must inform the agent or surrogate.

Questions and Answers, supra, at 28.

- 3. This opinion does not address whether, in the absence of a donot-resuscitate order, a decision to forego or terminate resuscitative efforts made after an arrest occurs could ever be considered the legal equivalent of an order not to resuscitate under Public Health Law article 29-B. The Questions and Answers publication advises physicians that a decision made after an arrest occurs to forego resuscitative efforts is governed not by the statutes in article 29-B, but "by evolving standards of care, professional guidelines, and, when applicable, Health Department regulations." Questions and Answers, supra, at 1-2. The publication also instructs physicians that, in this post-arrest setting, a finding of "futility" will justify a decision to forego resuscitation. Id. at 2. You have advised that you do not seek an opinion on the accuracy of this aspect of the publication. Your exclusive concern is the situation where a physician enters a do-not-resuscitate order in anticipation of a *future* cardiac or respiratory arrest.
- Article 29-B establishes enforceable standards of conduct for issuance of do-not-resuscitate orders, not merely recommended guidelines or a "safe harbor." *See* Pub. Health Law §§ 12, 12-b, 2973(3).
- 5. Appointment of and decisionmaking by a health care agent are governed by article 29-C of the Public Health Law.
- 6. The New York State Task Force on Life and the Law was established by Executive Order in 1984 with a mandate to study and recommend public policy on a number of issues arising from medical advances, including the decision-making process involved in the issuance of do-not-resuscitate orders. *See* Executive Order No. 56, 9 N.Y.C.R.R. 4.56 (Dec. 20, 1984). The Task Force was established with the Commissioner of Health as its chair and members from the medical, ethical, legal and religious communities, as well as interested laypersons. *See id.*

Horn v. The New York Times

February 25, 2003

Bernard M. Plum, for appellant. Pearl Zuchlewski, for respondent. New York City Partnership; New York State Psychiatric Association, Inc. et al.; National Employment Lawyers Association/New York; Medical Society of the State of New York, et al.; The Business Council of New York State, Inc., *amici curiae*.

READ, J.: At issue in this appeal is whether the narrow exception to the at-will employment doctrine adopted in *Wieder v. Skala* (80 N.Y.2d 628 (1992)) encompasses a physician employed by a non-medical employer. For the reasons that follow, we conclude that it does not and decline to expand the *Wieder* exception to do so. Accordingly, we reverse.

I.

In her complaint, Sheila E. Horn, D.O., formerly the Associate Medical Director of the Medical Department of *The New York Times*, alleges that her "primary responsibilities" in this position "were to provide medical care, treatment and advice to employees of the *Times*. Among other things, * * * determining if injuries suffered by *Times* employees were work-related, thus making the employees eligible for Worker's Compensation payments." She worked at the *Times*' main building in midtown Manhattan, along with the Medical Director, a physician's assistant, two nurses and three professional social workers.

According to Horn, on "frequent occasions" personnel in the *Times*' Labor Relations, Legal and Human Resources Departments directed her to provide them with confidential medical records of employees without the employees' consent or knowledge. She also claims that personnel in the *Times*' Human Resources Department instructed her to misinform employees whether their injuries and illnesses were work-related so as to curtail the number of workers' compensation claims filed against the newspaper.

Horn "consulted with the New York State Department of Health and other authorities" about "the propriety and legality" of these directives. The Department of Health supposedly advised her that "if a physician releases patient information and/or medical records without the consent of the patient, except under certain narrowly-defined circumstances, the physician is violating several provisions of state law, the Code of Ethical Conduct of the American College of Occupational and Environmental Medicine, the Americans With Disabilities Act, and various federal regulations." Accordingly, Horn disregarded her employer's orders and refused to share patient information or records with non-medical *Times* personnel without patient consent or knowledge.

In April 1999, the *Times* decided to restructure its Medical Department, resulting in the "phas[ing] out" of the positions occupied by Horn and the Medical Director and physician's assistant with whom she had worked, but not those of other professional personnel in the Medical Department. Horn contends that this restructuring and the *Times*' outsourcing of certain medical services were mere pretexts; that the *Times*, in fact, undertook these actions in order to get rid of her because she was viewed as a troublemaker.

Horn contends that her contract of employment with the *Times* "implied the fundamental understanding, which requires no written expression, that the physician will conduct her practice *on the employer's behalf* in accordance with the ethical standards of the medical profession (emphasis added)." She alleges that the *Times* terminated her employment because she resisted management's entreaties to trench upon patient confidentiality in violation of unexpressed but commonly understood ethical standards, and seeks compensatory and punitive damages for breach of contract.

The *Times* made a pre-answer motion to dismiss Horn's complaint for failure to state a cause of action. Supreme Court denied the motion as to the first cause of action for breach of contract. Characterizing the issue presented as "whether the exception enunciated in *Wieder v. Skala* (80 N.Y.2d 628 (1992)) to New York's rule relating to employment at-will should be extended to a physician employed by a non medical entity," Supreme Court concluded that it should (186 Misc. 2d 469, 470 (2000)).¹ The Appellate Division affirmed, with two Justices dissenting (293 A.D.2d 1 (2002)), and subsequently certified the following question to this Court: "Was the order of (the Appellate Division), which affirmed the order of the Supreme Court, properly made?"

II.

The traditional American common law rule undergirding employment relationships, which we adopted in *Martin v. New York Life Ins. Co.* (148 N.Y. 117 (1895)), is the presumption that employment for an indefinite or unspecified term is at will and may be freely terminated by either party at any time without cause or notice. While the twentieth century featured significant statutory inroads into the presumption of at-will employment, most notably with passage of the National Labor Relations Act in 1935 and Title VII of the Civil Rights Act of 1964, American courts have proved chary of creating common law exceptions to the rule and reluctant to expand any exceptions once fashioned (*see* Summers, *Employment at Will in the United States: The Divine Right of Employers*, 3 U Pa J Lab & Emp L 65 (2000)). Our own jurisprudence reflects this pattern, as a brief examination of our major cases over the last twenty years illustrates.

In Weiner v. McGraw-Hill, Inc. (57 N.Y.2d 458 (1982)), plaintiff Weiner alleged that he was induced to leave his former employer for McGraw-Hill by assurances of job security. He claimed that he signed and submitted a McGraw form job application specifying that his employment was subject to McGraw's handbook on personnel policies and procedures, which represented that McGraw would "resort to dismissal for just and sufficient cause only, and only after all practical steps toward rehabilitation or salvage of the employee have been taken and failed" (id. at 460); that he relied on these undertakings in good faith when he left his former employer to work for McGraw, thereby forfeiting accrued fringe benefits and foregoing a promised salary increase; that he routinely rejected other offers of employment to remain at McGraw because of these assurances; and that he was instructed by his supervisors to adhere strictly to the handbook's procedures when considering the dismissal of subordinates. When Weiner was subsequently dismissed without just cause or an opportunity for rehabilitation, we found these cumulative factors sufficient to state a cause of action for breach of contract.

A scant four months later in *Murphy v. American Home Prods. Corp.* (58 N.Y.2d 293 (1983)), we considered whether a long-tenured corporate employee allegedly discharged in part² for reporting accounting improprieties to top management had stated a cause of action in tort for abusive discharge, or in contract for breach of an implied covenant of good faith and fair dealing. Plaintiff Murphy, an assistant treasurer in a corporation, urged us to recognize the tort of abusive or wrongful discharge of an at-will employee, pointing out that other jurisdictions had done so where employees were dismissed in retaliation for employee conduct protected by public policy.

Judge Jones, writing for the majority, emphatically turned down Murphy's invitation, "being of the opinion that such a significant change in our law is best left to the Legislature," which is well-situated "to discern the public will, to examine the variety of pertinent considerations, to elicit the views of the various segments of the community that would be directly affected and in any event critically interested, and to investigate and anticipate the impact of" any major change in the atwill employment rule (*id. at* 302). In short, if this rule were "to be tempered, it should be accomplished through a principled statutory scheme, adopted after opportunity for public ventilation, rather than in consequence of judicial resolution of the partisan arguments of individual adversarial litigants" (*id.*).

Murphy further argued that the law implies a covenant of good faith and fair dealing in all contracts, including employment contracts of indefinite duration; that he was required to disclose accounting improprieties by virtue of his terms of employment; and therefore that his employer's discharge of him for having done so constituted a breach of contract. Citing the venerable case of Wood v. Duff-Gordon (222 N.Y. 88 (1917)), Judge Jones acknowledged that New York recognizes an implied and enforceable obligation of good faith and fair dealing on the part of a party to a contract in appropriate circumstances; however, "[i]n such instances the implied obligation is in aid and furtherance of other terms of the agreement of the parties. No obligation can be implied, however, which would be inconsistent with other terms of the contractual relationship. * * * [U]nder New York law as it now stands, absent a constitutionally impermissible purpose, a statutory proscription, or an express limitation in the individual contract of employment, an employer's right at any time to terminate an employment at will remains unimpaired" (58 N.Y.2d at 304-305 (emphasis added)).

We next visited at-will employment in *Sabetay v. Sterling Drug* (69 N.Y.2d 329 (1987)). Plaintiff Sabetay asserted that he was discharged on account of his refusal to participate in certain improper, unethical and illegal financial activities in violation of contractual obligations derived from the corporate personnel policy manual and the corporation's accounting codes. We reiterated that a covenant of good faith and fair dealing "can be implied only where the implied term is consistent with other mutually agreed upon terms in the contract" (*id. at* 335); and again observed that "significant alteration of employment relationships * * * is best left to the Legislature (citations omitted), because stability and predictability in contractual affairs is a highly desirable jurisprudential value" (*id. at* 336).

In *Weiner, Murphy* and *Sabetay,* we thus exhibited a strong disinclination to alter the traditional rule of atwill employment. It was in this context that we decided *Wieder v. Skala* (80 N.Y.2d 628 (1992)), the case upon which Horn pins her faith.

Plaintiff *Wieder*, an associate in a law firm, asked the firm to assign another associate to represent him in a real estate transaction. This associate neglected the project and then lied to Wieder in order to cover up his inattention. When Wieder asked the firm's partners to report the associate's misconduct to the Appellate Division's Disciplinary Committee, as required by DR 1-103 (A) of New York's Code of Professional Responsibility (22 NYCRR 1200.4), they balked. When the firm subsequently dismissed Wieder, he sued, claiming retaliatory discharge and breach of implied contract. Supreme Court dismissed his complaint on account of the employment-at-will doctrine and the Appellate Division affirmed.

We rejected Wieder's argument that "the dictates of public policy in DR 1-103 (A) have such force as to warrant * * recognition of the tort of abusive discharge" (80 N.Y.2d at 638-639). Moreover, we relied upon *Murphy* and *Sabetay* for the proposition that major alterations in employment relationships are best left to the Legislature, pointing out the Legislature's enactment of the Whistleblower's Law (Labor Law 740; Civil Service Law 75-b). Although we reinstated the cause of action for breach of contract, we were careful to limit the reach of the exception to the at-will employment doctrine thus created and to preserve *Murphy* and *Sabetay*.

Critically, we observed that the plaintiffs in *Murphy* and *Sabetay*, employees working in the financial departments of large companies, provided professional accounting services in furtherance of their corporate responsibilities. By contrast, Wieder's provision of professional services to the firm's clients as a member of the Bar "was at the very core and, indeed, the *only* purpose of his association with [the law firm] * * * [his] duties and responsibilities as a lawyer and as an associate of the firm [are] so closely linked as to be incapable of separation" (*id. at* 635 (emphasis added)).

We also considered the particular ethical rule at issue in *Wieder* to be indispensable to the unique function of attorney self-regulation, a judgment that we are best-situated to make since the regulation of lawyers in New York has been delegated by the Legislature to the Judiciary (*see* Judiciary Law 90(2); *see also People v. ex rel. Karlin v. Culkin*, 248 NY 465, 480 (1928) ("If the house is to be cleaned, it is for those who occupy and govern it, rather than for strangers, to do the noisome work")). Further, Wieder's failure to comply with DR 1-103 (A) put him at risk of suspension or disbarment.

We accordingly concluded that "these unique characteristics of the legal profession in respect to (DR 1-103 (A)) make the relationship of an associate to a law firm employer intrinsically different from that of the financial managers to the corporate employers in *Murphy* and *Sabetay*," which "call[ed] for a different rule regarding the implied obligation of good faith and fair dealing" (*Wieder*, 80 N.Y.2d at 637). We were careful to point out, however, that we did not mean to "suggest that each provision of the Code of Professional Responsibility should be deemed incorporated as an implied-in-law term in every contractual relationship between or among lawyers" (*id.*).

Finally, and at the heart of our holding, we observed that Wieder and the law firm were engaged in a "common professional enterprise," the practice of law. Because of their common endeavor, Wieder and his firm were mutually bound to follow DR 1-103(A). We specifically quoted the passage in *Murphy* (reprised in *Sabetay*) warning that in order for any condition to be implied in a contract, that condition must aid and further the agreement's underlying terms, and held that DR 1-103(A) did so because "[u]nlike Murphy and Sabetay, giving effect to an implied understanding-that in their common endeavor of providing legal services [Wieder] and the firm would comply with the governing rules and standards and that the firm would not act in any way to impede or discourage [Wieder's] compliancewould be 'in aid and furtherance of [the central purpose] of the agreement of the parties'" (id. at 638 (quoting Murphy, 58 N.Y.2d at 304) (fourth alteration in original)).

III.

We determined that the plaintiff in *Wieder* stated a cause of action for breach of an implied-in-law obligation in an at-will employment relationship because of the unique confluence of specific, related factors. Although Horn "strikes a sympathetic, and even a seductive, chord" (*Horn v. The New York Times,* 293 A.D.2d at 12), she has failed to plead facts that place her claim for breach of contract within the *Wieder* exception to the at-will employment rule.

First, Horn was employed as the Associate Medical Director of the *Times'* in-house Medical Department, where whatever medical care and treatment she rendered was provided only to fellow employees and only as directed by her employer. Moreover, while Horn alleges that, in fact, her "primary responsibilities" "were to provide medical care, treatment and advice to employees of the *Times*," the sole concrete example of these "primary responsibilities" offered in her complaint is the "determin[ation] if injuries suffered by *Times* employees were work-related, thus making the employees eligible for Worker's Compensation payments."

When Horn made assessments as to whether a *Times* employee had suffered a work-related illness or injury, she was surely calling upon her knowledge as a physician, but not just for the benefit of the employee. Rather, she was applying her professional expertise in furtherance of her responsibilities as a part of corporate management, much like *Murphy* and *Sabetay* and unlike Wieder. Concomitantly, to the extent that Horn, in fact, treated *Times* employees as part of her job responsibilities, her provision of these professional services did not occupy "the very core" or "the only purpose" of her employment with the *Times*, unlike Wieder's provision of legal services for his firm's clients.

Next, the commonly understood ethical standards that the *Times* allegedly directed Horn to violate at the risk of losing her professional license include CPLR 4505 (the physician-patient privilege, an evidentiary rule) and provisions in the Education Law and the Rules of the Board of Regents.³ These provisions were not central to Horn's "conduct [of] her practice on her employer's behalf."

We by no means intend to deny or belittle the importance of physician-patient confidentiality, which we just recently affirmed in *Matter of Grand Jury Investigation in New York County v. Morgenthau* (98 N.Y.2d 525 (2002)). Nonetheless, the principle of physician-patient confidentiality—unlike DR 1-103(A)—is not a self-policing rule critical to professional self-regulation. More importantly, because of the absence of a common professional enterprise between Horn and the *Times*, the Education Law provisions cited by Horn do not impose a mutual obligation on the employer and the employee in this case.

Our dissenting colleague would compensate for the absence of a mutual obligation flowing from a common professional enterprise by substituting the notion that the *Times* knew or should have known about Horn's professional responsibility to protect patient confidentiality. By loosing *Wieder* from its analytical moorings, however, the dissent would create a broad new exception to the presumption of at-will employment, applicable to hosts of professional employees.

The only exceptions to the employment-at-will rule ever adopted by this Court have involved very specific substitutes for a written employment contract: in Weiner, the employer's express, unilateral promise on which the employee relied; in Wieder, the parties' mutual undertaking to practice law in compliance with DR 1-103(A), a rule so fundamental and essential to the parties' shared professional enterprise that its implication as a term in their employment agreement aided and furthered the agreement's central purpose. We have consistently declined to create a common law tort of wrongful or abusive discharge, or to recognize a covenant of good faith and fair dealing to imply terms grounded in a conception of public policy into employment contracts, as the dissent would have us do, and we again decline to do so. The good and sufficient reasons underlying this forbearance, so eloquently expressed by Judge Jones in Murphy, have not changed,⁴ and Horn has presented us with no compelling reason in the facts of this case to expand the Wieder exception to the at-will employment rule.

Accordingly, the order of the Appellate Division should be reversed, with costs; defendant's motion to dismiss the first cause of action granted; and the certified question answered in the negative.

Horn v. The New York Times No. 20

*

Smith, J. (dissenting): Because I believe that plaintiff Sheila Horn has stated a claim for breach of an implied contract between herself and defendant *The New York Times*, I dissent. I would affirm the order of the Appellate Division.

Plaintiff began her employment as a physician with The Times in 1995. In 1996, she became the full-time Associate Medical Director of the Times' Medical Department. Sometime in April 1999, however, Dr. Horn was terminated. In April 2000, she commenced an action, alleging breach of contract (first cause) and an entitlement to punitive damages (second cause). In May 2000, The Times filed a pre-answer motion to dismiss the complaint for failure to state a cause of action. Supreme Court denied the motion as to the first cause, finding that Dr. Horn had stated a claim for breach of an implied contract of employment. Supreme Court reasoned that the strictures imposed upon those in the medical profession, and the resulting responsibility to the public, warranted extension of the principles set forth in Wieder v. Skala (80 N.Y.2d 628 (1992)). Supreme Court granted the motion as to the second cause which asserted only a claim for punitive damages. The Appellate Division affirmed, with two justices dissenting (293 N.Y.2d 1 (2000)). The Appellate Division certified to this Court the question of whether it had correctly affirmed Supreme Court.

"On a motion to dismiss pursuant to CPLR 3211, we must accept as true the facts as alleged in the complaint and submissions in opposition to the motion, accord plaintiffs the benefit of every possible favorable inference and determine only whether the facts as alleged fit within any cognizable legal theory" (*Sokoloff v. Harriman Estates Dev. Corp.*, 96 N.Y.2d 409, 414 (2001)(citations omitted)). If the motion is denied, defendant has the right to submit an answer and address the merits.

Dr. Horn's complaint alleged that her primary responsibilities were to provide "medical care, treatment and advice" to the company's employees and to examine employees seeking Workers' Compensation benefits to verify that their claims were work-related. She further alleged that on "frequent occasions" various named departments of the company directed her to provide them with confidential medical records of employees "without those employees' consent or knowledge," and that the vice president for human resources instructed her to "misinform employees regarding whether injuries or illnesses they were suffering were work-related so as to curtail the number of Workers' Compensation claims filed against The Times." After seeking advice from the New York State Department of Health, she was told "if a physician releases patient information and/or medical records without the consent of the patient, except under certain, narrowly-defined circumstances, that physician is violating several provisions of state law, The Code of Ethical Conduct of the American College of Occupational and Environmental Medicine, the Americans With Disabilities Act, and various federal regulations." Thereafter, she refused to comply with requests to turn over patients' medical records to other department heads without the patients' consent.

In April 1999, the human resources vice president announced that The Times was restructuring the medical department and as a result, the positions of Dr. Horn and Dr. DiPietro were eliminated. DiPietro had also failed to comply with requests from Labor Relations and other Times' departments for patient medical records without those patients' consent. Dr. Horn asserted that The Times thereafter contracted with Meridian Corporate Healthcare to provide a physician to work three days per week at The Times' main office, the place where she had worked. Dr. Horn asserted that she applied for the position but was not granted an interview. Human resources asserted economic reasons for the restructuring of the medical department. Dr. Horn alleged that she was terminated because she refused to comply with requests for confidential patient records and that her termination constituted a breach of the implied terms and conditions of the agreement between herself and The Times.

In hiring Dr. Horn, The Times impliedly committed to permitting her to perform her professional responsibilities in a manner not inconsistent with the ethical practice of medicine, and because Dr. Horn alleged in her complaint that The Times breached that agreement, she has stated a cognizable cause of action.

In its decision, the Supreme Court stated:

The conduct that plaintiff herein asserts resulted in her discharge is not merely "whistle blowing" type activity * * * but rather is affirmative conduct which defendant allegedly requested plaintiff to perform which could have an adverse affect on her patients and result in her losing her license to practice medicine, as well as the imposition of civil liability (*Horn v. New York Times*, 186 Misc. 2d 469, 474 (2000)).

The Appellate Division stated:

We cannot accept defendant's argument that nothing in the law prevents it from

firing the associate director of its medical department for refusing to divulge confidential patient information. Instead, we hold that a physician may claim an exception to New York's employment-at-will doctrine based on an implied-in-law obligation of her employer to, at the very least, do nothing to prevent her from practicing medicine in compliance with the ethical standards of the medical profession" (*Horn v. New York Times*, 293 A.D.2d 1, 3 (2002)).

Prior to the decision in Wieder v. Skala, the long settled rule in New York was that "where an employment [was] for an indefinite term it [was] presumed to be a hiring at will which [might] be freely terminated by either party at any time for any reason or even for no reason" (Murphy v. American Home Prods. Corp., 58 N.Y.2d 293, 300 (1983)(cases omitted)). Accordingly, the Murphy Court declined to "judicially engraft[]" a good faith limitation on "the unfettered right of termination lying at the core of an employment at will" (id. at 305 n. 2). Judge Meyer, on the other hand, noted in dissent that "[t]he at-will rule was created by the courts and can properly be changed by the courts but, more importantly, * * * , the rule ha[d] for at least a century been subject to the 'universal force' of the good faith rule. The Legislature, therefore, had no reason before the [*Murphy*] decision to believe that action on its part was required" (id. at 314).

In Wieder, however, this Court recognized that in certain contractual situations, an obligation of good faith and fair dealing arises which limits an employer's unfettered right to terminate at will. In Wieder, an associate who had been working for a law firm, brought a claim alleging that the firm in terminating him, breached an implied term of his contract—that the firm would do nothing to subvert the associate's ethical and lawful practice of law. The associate alleged that he had been wrongfully terminated because he insisted that the firm comply with Disciplinary Rule 1-103(A) of the Code of Professional Responsibility, which requires an attorney to report the professional misconduct of another attorney.⁵ In his complaint, the associate alleged that the firm had agreed to represent him in the purchase of a condominium apartment and had assigned a fellow associate to do everything that needed to be done. The fellow associate neglected the transaction for several months and made "false and fraudulent material misrepresentations" to conceal his neglect. When the associate learned of his fellow associate's neglect and false statements, he advised two senior partners. They conceded that they were aware of the fellow associate's having lied about pending legal matters on other occasions. The fellow associate admitted in writing that he had committed several acts of legal malpractice, fraud and deceit upon the associate and other clients. The associate alleged that the firm's partners refused to report the misconduct to the Appellate Division Disciplinary Committee as required under DR 1-103(A). The associate met with the Committee, but later withdrew his complaint, he alleged, because the firm had indicated that he would be terminated if he reported the misconduct of his fellow associate. Plaintiff alleged he was berated, and, after completing important litigation, was terminated.

This Court, in seeking to determine if an obligation of good faith and fair dealing could be implied in the contract, observed:

> It is the law that in "every contract there is an implied undertaking on the part of each party that he will not intentionally and purposely do anything to prevent the other party from carrying out the agreement on his part." The idea is simply that when A and B agree that B will do something it is understood that A will not prevent B from doing it. The concept is rooted in notions of common sense and fairness * * *. [It is] a recognition that the parties occasionally have understandings or expectations that [are] so fundamental that they [do] not need to negotiate about those expectations (id. at 637 (citations and quotations omitted)).

The Court also examined the nature of the relationship between the associate and the firm to see what could be implied in the contract. The Court observed that the relationship between the law firm and the lawyer hired as an associate was unique because (1) the associate was specifically hired to perform services for clients as a duly admitted member of the bar, but at the same time, the associate remained an independent officer of the court responsible to a broader public sense of professional obligations; (2) particularly critical to "survival of the [legal] profession" was the obligation of self regulation imposed by DR 1-103 (A); and finally (3) because the associate and the firm were engaged in a common professional enterprise each was governed by the same general "rules of conduct and ethical standards * * * in carrying out the sole aim of their joint enterprise, the practice of their profession." The Court recognized that "[i]ntrinsic to this relationship, of course, was the unstated but essential compact that in conducting the firm's legal practice both plaintiff and the firm would do so in compliance with the prevailing rules of conduct and ethical standards of the profession. Insisting that as an associate in their employ plaintiff

must act unethically and in violation of one of the primary professional rules amounted to nothing less than a frustration of the only legitimate purpose of the employment relationship" (*id. at* 637-638).

As in *Wieder*, a similar promise by The Times, to permit Dr. Horn to perform her professional responsibilities in a manner not inconsistent with the ethical practice of medicine, should be implied in its relationship with plaintiff. Dr. Horn alleges that The Times hired her to perform core medical duties for clients. Specifically, she alleges that she was hired to provide "medical care, treatment and advice" to the company's employees and to examine employees seeking Workers' Compensation benefits to verify that their claims were work related. Such duties required her to use the medical skills she had acquired through training and practice as a physician. Dr. Horn makes no allegation that can reasonably be read to assert that she was hired to do anything but perform as a physician. The Majority would distinguish Dr. Horn's duties at The Times as incorporating "corporate management" duties to be distinguished from "the very core" or "only purpose" attorney duties of the associate in Wieder. The associate in Wieder did not plead in his amended complaint that his attorney functions were his "sole functions;" rather, he pleaded that he "was associated with the law firm * * * and practiced solely in the area of commercial litigation."

As stated by the Majority at the Appellate Division, "Any employer who hires a physician to provide medical care knows, or should know as a matter of common knowledge, that the physician is bound by the patient confidentiality provision of the ethical code of the medical profession" (293 A.D.2d at 8). Like the associate in Wieder, Dr. Horn remained a duly admitted member of a professional body and was bound by its rules. The Code of Medical Ethics both requires the confidentiality of information obtained by a physician in plaintiff's position and the reporting of physicians who violate that confidentiality.⁶ In addition, section 6530 (23) of the Education Law defines as professional misconduct, the "[r]evealing of personally identifiable facts, data or information obtained in a professional capacity without the consent of the patient * * *." Section 6509 (9) of the Education Law defines professional misconduct to include "[c]ommitting unprofessional conduct as defined by the board of regents." Section 29.1(b)(8) of the Rules of the Board of Regents defines professional misconduct to include the "revealing of personally identifiable data or information obtained in a professional capacity * * *." The State of New York Department of Health has set forth a penalty of censure, reprimand, suspension of license, revocation of license, annulment of license, limitation on further license or fine for a person found guilty of professional misconduct (see Public Health Law 230-a). The Department has suspended the license of a physician who evidenced moral unfitness by engaging in sexual relations with his patients, who revealed patient information without consent, who harassed and/or intimidated a patient and who failed to maintain accurate information (see Matter of Dieter H. Eppel, M.D., Determination and Order No. 02-82 of the Professional Medical Conduct Administrative Review Board; see also Matter of James Y. Severinsky, M.D., Determination and Order No. BPMC 00-226 of the New York State Board of Professional Medical Conduct (suspending the licence of a physician who revealed patient's personally identifiable information obtained in a professional capacity without patient's consent and committed professional misconduct by practicing fraudulently and advertising falsely); Matter of James L. Duffy, M.D., Determination and Order No. BPMC 00-129 of the New York State Board of Professional Medical Conduct (suspending the license of physician who engaged in sexual relations with a patient, revealed personally identifiable facts, data, or information about patient without consent, was grossly negligent, negligent and failed to maintain accurate records).

The Department of Health, like the Departments of the Appellate Division, is responsible for maintaining standards and ethics of the profession and for enforcing those standards. In addition, the Principles of Medical Ethics of the American Medical Association states that physicians, including physicians employed by industry, have an ethical and legal duty to protect patient confidentiality and thus not to reveal confidential communications without the consent of the patient. The critical similarity between the rule governing Dr. Horn and the rule governing the associate in *Wieder* is not that the rule needs to reflect the profession's self-governing function—this is just a particular function of the legal profession. What is critical is that the profession regards the rule as intrinsic to its survival as a profession.

As to the third factor, the so called common enterprise factor, I agree with the Appellate Division that although Dr. Horn and the Times were not engaged in the same work, it is beyond cavil and universally known that a physician owes her patients a duty of confidentiality. Indeed, this Court observed in In re Grand Jury Investigation in New York County (98 N.Y.2d 524 (2002)) that the physician-patient privilege served three functions: (1) it "seeks to maximize unfettered patient communication with medical professionals, so that any potential embarrassment arising from public disclosure will not deter people from seeking medical help and securing adequate diagnosis and treatment;" (2) it "encourages medical professionals to be candid in recording confidential information in patient medical records, * * *;" and (3) it "protects patients' reasonable

privacy expectations against disclosure of sensitive personal information" (*id. at* 529 (citations and quotations omitted)). Just because the Times was "not a medical entity and therefore [was] not bound itself by the governing rules and standards of the medical profession [did] not negate the implied understanding in their relationship that the employer will not impede or discourage the physician's compliance with those particular rules and standards" (*Horn v. The New York Times*, 293 A.D.2d at 8, citing *Wieder* at 638).

This State's interest in protecting both the employer's and the employee's freedom of contract undergirds the employment-at-will doctrine. Nevertheless, even if the facts alleged in the complaint did not come within the Wieder rule, the strictures of the at-will doctrine itself, a judge-made doctrine, have been subject to a limited number of statutory exceptions (see Labor Law 741(2)(a) (preventing retaliatory discharge of healthcare employee making report of improper quality of patient care); Labor Law 740 (preventing retaliatory discharge against an employee who reports an employer's illegal activity creating a substantial and specific danger to public health and safety); Civil Service Law 75-b (preventing retaliatory discharge of public employee who reports violation of federal, state or local law); see also National Labor Relations Act of 1935, 29 U.S.C. 158, et seq. (defining unfair labor practices); Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e et seq. (stating that it shall be an unlawful employment practice to discriminate against members of named suspect categories)).

It should be emphasized, however, that Dr. Horn's claim comes within the limited exception to the at-will doctrine carved out in *Wieder*, legal professionals (here medical professionals) performing public duties, not corporate duties, whose employers take adverse action against them because they insist upon complying with an identifiable statutory duty or ethical principle which is at the core of their profession. The contention of the Majority that the dissent advocates a broad application of *Wieder* to all professionals is a misreading. Rather the dissent contends only that the rules and obligations which govern the conduct of doctors are similar to the rules applicable to lawyers. The most obvious of these rules is confidentiality.

No sound reason exists to preclude termination of a lawyer in *Wieder* while leaving without a remedy a doctor whose job it is to protect the physical and mental well-being of individuals. Even though the Times is not in the business of practicing medicine, "[i]t is significant * * * that the Times, a universally respected news organization, itself provides an essential service to the public that entails conforming to certain standards of truth, integrity and confidentiality of its news sources (*see e.g.* the Shield Law (Civil Rights Laws 79-h))" (Horn v. The New York Times, 293 A.D.2d at 11).

Accordingly, I would affirm.

* * *

Order reversed, with costs, defendant's motion to dismiss the first cause of action granted and certified question answered in the negative. Opinion by Judge Read. Judges Ciparick, Wesley, Rosenblatt and Graffeo concur. Judge Smith dissents and votes to affirm in an opinion. Chief Judge Kaye took no part.

Decided February 25, 2003

Endnotes

- 1. Supreme Court dismissed the second cause of action on the ground that there is no separate cause of action for punitive damages. Horn did not appeal this aspect of the order.
- Murphy also alleged that he had been fired because he was over 50 years old.
- These provisions include Education Law 6509 (9) (defining pro-3. fessional misconduct for those admitted to each of the 27 professions subject to licensure by the Department of Education to include "[c]ommitting unprofessional conduct, as defined by the board of regents," coupled with section 29.1 (b) (8) of the Rules of the Board of Regents, defining professional misconduct for those admitted to each of the 27 professions subject to licensure by the Department of Education to include "revealing of personally identifiable facts, data or information obtained in a professional capacity without the prior consent of the patient or client, except as authorized or required by law" (8 NYCRR 29.1 (b) (8); see also 8 NYCRR 29.4 (a)); and Education Law 6530 (23) (specifying professional misconduct for the commission of which a physician licensee is subject to those penalties prescribed in section 230-a of the Public Health Law (e.g., censure and reprimand, suspension, limitation or revocation of license) to include the "[r]evealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law"; cf. 8 NYCRR 29.1 (b) (8)).
- 4. We note that the Legislature remains active in this area, just last year having enacted a new Whistleblower Law to protect certain health care workers (*see* Labor Law § 741).
- DR 1-103 (A) provides: "A lawyer possessing knowledge, not protected as a confidence or secret, of a violation of DR 1-103 that raises a substantial question as to another lawyer's honesty,

trustworthiness or fitness in other respects as a lawyer shall report such knowledge to a tribunal or other authority empowered to investigate or act upon such violation."

6. Rule E-5.09 of the Code of Medical Ethics states in part:

"Where a physician's services are limited to performing an isolated assessment of an individual's health or disability for an employer, business or insurer, the information obtained by the physician as a result of such examinations is confidential and should not be communicated to a third party without the individual's prior written consent, unless required by law. If the individual authorized the release of medical information to an employer or a potential employer, the physician should release only that information which is reasonably relevant to the employer's decision regarding that individual's ability to perform the work required by the job.

When a physician renders treatment to an employee with a work-related illness or injury, the release of medical information to the employer as to the treatment provided may be subject to the provisions of worker's compensation laws. The physician must comply with the requirements of such laws, if applicable. However, the physician may not otherwise discuss the employee's health condition with the employer without the employee's consent or, in the event of the employee's incapacity, the appropriate proxy's consent."

Rule E-9.031 of the Code of Medical Ethics states in part:

"Physicians have an ethical obligation to report impaired, incompetent, and unethical colleagues in accordance with the legal requirements in each state and assisted by the following guidelines:

Unethical conduct. With the exception of incompetence or impairment, unethical behavior should be reported in accordance with the following guidelines:

Unethical conduct that threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service. Unethical behavior which violates state licensing provisions should be reported to the state licensing board or impaired physician programs, when appropriate. Unethical conduct which violates criminal statutes must be reported to the appropriate law enforcement authorities. All other unethical conduct should be reported to the local or state medical society."

DOM STATE OF NEW YORK DEPARTMENT OF HEALTH

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Antonia C. Novello, M.D., M.P.H., Dr.P.H. *Commissioner*

Dennis P. Whalen Executive Deputy Commissioner

October 15, 2002

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") gave the federal Department of Health and Human Services ("HHS") the authority to promulgate regulations containing standards with respect to the privacy of individually identifiable health information. HIPAA provided that such standards shall not supersede State law that imposes more stringent standards (P.L. 104-191, § 264(c)). HHS promulgated the federal standards, and they are now in Parts 160 and 164 of Title 45 of the Code of Federal Regulations (the "Privacy Rule").

Under the Supremacy Clause of the U.S. Constitution, federal law preempts State law when preemption is the clear and manifest purpose of Congress. In instances where the purpose of Congress is not clear, only the judicial branch of government can determine whether a federal law preempts a State law under the Supremacy Clause.

In enacting HIPAA, Congress clearly did not supersede State laws that impose more stringent standards with respect to the privacy of individually identifiable health information. Thus, the Department will continue to enforce such State laws that are within the Department's purview to enforce. The Department will enforce other State laws to the extent that the Privacy Rule does not preempt them. Under the provisions of the Privacy Rule, the Privacy Rule does not alter State laws that permit individuals greater rights of access to or amendment of their own individually identifiable health information (45 CFR § 160.202(More stringent)).

April 14, 2003, is the compliance date for most covered entities under the Privacy Rule. Unless the relevant federal or State laws or regulations are amended, the Department intends to enforce specified provisions of State law as outlined in the following charts.

HIPAA Privacy Rule	PHL § 17	Law That Will Prevail
A "covered entity" may generally disclose "protected health information" (PHI) to another covered entity for treatment, payment or health care operations without consent (164.506(a), 164.506(c)). A covered entity may use or disclose PHI without an authorization or opportunity to agree or object to the extent that such use or disclosure is "required by law" (164.512(a), 164.501(Required by law)).	"Upon the written request [of a patient, a provider] must release and deliver copies of all medical records regarding that patient to any other designated physician or hospital " (PHL § 17).	PHL § 17 prevails, because disclosures under PHL § 17 are "required by law."
"If, and to the extent, prohibited by an applicable provision of State law, a covered entity may not disclose, or provide access to, protected health information about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> " (164.502(g)(3)(ii)(B)).	" [R]ecords concerning the treatment of an infant patient for venereal disease or the performance of an abortion operation upon such infant patient shall not be released or in any manner be made available to the parent or guardian of such infant" (PHL § 17).	PHL § 17 prevails, because it is a provision of State law that prohibits a disclosure about an unemancipated minor to a parent, guardian, or other person acting in <i>loco parentis</i> . Also, PHL § 17 prevails, because HIPAA does not preempt State law that imposes privacy standards that are "more stringent than" the standards imposed under HIPAA (P.L. 104-191, § 264(c)(2)).

<u>PHL § 17</u>

PHL	, §	18

HIPAA Privacy Rule	PHL § 18	Law That Will Prevail	
General rule			
Applies to any "covered entity": health care provider, heath plan or health care clearinghouse (unless the entity transmits no health information in electronic form in connection with a transaction covered by the HIPAA Regulations) (160.102)	Applies to any "health care provider" as defined in New York law (18(2), 18(1)(b), 18(1)(c), 18(1)(d))	HIPAA prevails for health plans, health care clearinghouses and individuals who are health care providers under HIPAA but are not health care practitioners under State law. The remainder of this chart is confined to the law for "health care providers" under State law.	
Applies to all medical records and billing records and any other records used to make decisions about individuals (164.524(a), 164.501(Designated record set))	Applies to information concerning or relating to the examination, health assessment or treatment of an individual (18(2), 18(1)(e))	HIPAA prevails for billing records. <u>The remainder of this</u> <u>chart is confined to "patient</u> <u>information" under State law.</u>	
Exceptions to the general rule (when access can be denied)			
No exception	Does not apply to clinical records (maintained or possessed by an OMH, OMRDD or OASAS facility) access to which is governed under Mental Hygiene Law §§ 22.03 and 33.16 (18(1)(e)(i))	The law for clinical records maintained or possessed by an OMH, OMRDD or OASAS facility is beyond the scope of this chart.	
Does not apply to psychotherapy notes (164.524(a)(1)(i), 164.501(Psychotherapy notes)).	No exception	For psychotherapy notes as defined by HIPAA, PHL § 18 prevails.	
No exception	Does not apply to <u>practitioner's</u> <u>personal notes and observations</u> (18(1)(e)(ii))	For personal notes and observations other than psychotherapy notes as defined by HIPAA, HIPAA prevails	
No exception	Does not apply to information maintained by a practitioner, concerning or relating to the prior examination or treatment of a subject received from another practitioner (18(1)(e)(iii))	HIPAA prevails	
No exception	Does not apply to diagnostic services performed by a practitioner at the request of another practitioner (18(1)(e)(last sentence))	HIPAA prevails	

Does not apply to PHI obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information (164.524(a)(2)(v))	Does not include data disclosed to a practitioner in confidence by other persons on the basis of an express condition that such data would never be disclosed (18(1)(e)(iv))	HIPAA prevails
PHI does not make reference to another person, and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to <u>endanger the life</u> <u>or physical safety</u> of the individual or another person (164.524(a)(3)(i)), <u>e.g.</u> , when an individual exhibits suicidal or homicidal tendencies. This exception is intended to apply where disclosure is reasonably likely to result in the individual committing suicide, murder, or other physical violence. Under this reason for denial, covered entities may not deny access on the basis of the sensitivity of the health information or the potential for causing emotional or psychological harm (65 Fed. Reg. 82,555).	Provider may deny access to all or part of the information and may grant access to a prepared summary of the information if, after consideration of all the attendant facts and circumstances, the <u>provider</u> <u>determines that the request to</u> <u>review all or a part of the patient</u> <u>information can reasonably be</u> <u>expected to cause substantial and</u> <u>identifiable harm to the subject or</u> <u>others</u> which would outweigh the qualified person's right of access to the information (18(3)(d)(i)).	HIPAA prevails
<u>PHI makes reference to another</u> <u>person</u> , and a licensed health care professional has determined, in the exercise of professional judgment, that disclosure is reasonably likely to cause <u>substantial harm to such other</u> <u>person</u> (164.524(a)(3)(ii)). Substantial harm means serious harm (65 Fed. Reg. 82,555) and may be substantial physical, emotional, or psychological harm (65 Fed. Reg. 82,556).	Provider may deny access to all or part of the information and may grant access to a prepared summary of the information if, after consideration of all the attendant facts and circumstances, the provider determines that the request to review all or a part of the patient information can reasonably be expected to cause <u>substantial and</u> <u>identifiable harm to the subject or</u> <u>others which would outweigh the</u> <u>qualified person's right of access</u> to the information (18(3)(d)(i)).	HIPAA prevails if disclosure would cause substantial harm to the subject but not to the other person. PHL § 18 prevails if disclosure would cause substantial harm to the other person.

The request is made by the individual's personal representative, and a licensed health care professional has determined, in the exercise of professional judgment, that disclosure is reasonably likely to cause <u>substantial harm to the individual or</u> <u>another person</u> (164.524(a)(3)(iii)).	Provider may deny access to all or part of the information and may grant access to a prepared summary of the information if, after consideration of all the attendant facts and circumstances, the provider determines that the request to review all or a part of the patient information can reasonably be expected to cause <u>substantial and</u> <u>identifiable harm to the subject or</u> <u>others which would outweigh the</u> <u>qualified person's right of access</u> to the information (18(3)(d)(i)).	PHL § 18 prevails
General rule is that parent has access (164.502(g)(1)).	General rule is that parent has access $(18(2), 18(1)(g))$.	No conflict
Parents have no right of access if minor can lawfully obtain health care service without the consent of a parent (164.502(g)(3)(i)). "If, and <u>to the</u> <u>extent</u> , permitted or required by an applicable provision of State law, a covered entity may disclose, or provide access to, protected health information about an unemancipated minor to a parent, guardian, or other person acting in loco parentis (164.502(g)(3)(ii)(A)).	If a parent requests information concerning a child over 12 years old, the practitioner may notify the child and if the child objects to disclosure, may deny the request (18(3)(c)).	PHL § 18 prevails, because a covered entity may only disclose PHI to a parent to the extent permitted by State law. Also, HIPAA does not preempt State law that imposes privacy standards that are "more stringent than" the standards imposed under HIPAA (P.L. 104-191, § 264(c)(2)).
Parent has no right to access if the covered entity has a reasonable belief that the child has been or may be subjected to domestic violence, abuse or neglect by the parent or disclosure could endanger the child and the covered entity, in the exercise of professional judgment, decides that disclosure is not in the best interest of the child (164.502(g)(5)).	Provider may deny access to all or part of the information and may grant access to a prepared summary of the information if, after consideration of all the attendant facts and circumstances, the provider determines that disclosure would have a detrimental effect on the provider's professional relationship with an infant, or on the care and treatment of the infant, or on the infant's relationship with his or her parents (18(3)(d)(i), 18(2)(c)).	PHL § 18 prevails

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Fees		
Covered entity may impose a reasonable, cost-based fee (164.524(c)(4)).	The provider may impose a reasonable charge, not to exceed costs and not to exceed $75\notin$ per page, but the release of records cannot be denied solely because of inability to pay (18(2)(e)).	PHL § 18 prevails
Procedure		
Covered entity must provide the individual with access to the PHI in the form or format requested by the individual, if it is readily producible in such form or format, in a timely manner (30 or 60 days, with a possible 30 day extension) (164.524(c)(2), 164.524(b)(2)).	Provider must permit visual inspection within 10 days and furnish a copy within a reasonable time if the provider has space available to permit visual inspection, or must provide a copy within 10 days if the provider does not have space available to permit visual inspection (18(2)(a), (d), (g)).	PHL § 18 prevails
A licensed health care professional must be designated by the provider as a reviewing official to make a final determination (164.524(d)(4)).	A medical record access review committee appointed by the commissioner of the Department of Health (DOH) reviews appeals of denials of access (18(4)).	No conflict, because it is possible to comply with both the State and federal requirements. The reviewing official reviews HIPAA issues, and the medical record access review committee reviews PHL § 18 issues.
Individuals have a right to have a covered entity amend inaccurate or incomplete PHI about themselves created by a health care provider. Where a request to amend is denied, individuals may submit into the medical record a written statement of disagreement and the provider may submit a written rebuttal to such statement (164.526).	Individual may challenge the accuracy of information and may require that a brief written statement prepared by the individual concerning the challenged information be inserted into the medical record (18(8)).	HIPAA prevails

PHL § 206(1)(j)

HIPAA Privacy Rule	PHL § 206(1)(j)	Law That Will Prevail
Generally, a covered entity may not disclose PHI for research purposes without an authorization (164.508). A covered entity may disclose PHI without authorization to the extent that such use or disclosure is to a public health authority for public health oversight authority for health oversight authority for health oversight activities (164.512(d)) or if an IRB has waived the requirement to get an authorization, applying the specific criteria in 164.512(i). A covered entity must provide an accounting of a § 206(1)(j) disclosure if the subject did not authorize the disclosure and requests an accounting (164.528). PHI may only be disclosed in a manner consistent with a covered entity's Notice of Privacy Practices (164.502(i)). If disclosure is not pursuant to an authorization, covered entities must limit PHI disclosed for research to that which is reasonably considered to be the "minimum necessary" to accomplish the research (164.514(d)(3)(ii)). However, the covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for section 206(1)(j) research if DOH represents that the information DOH is requesting is the minimum necessary to do the research (164.514(d)(3)(iii)). PHI that is de-identified under HIPAA is no longer PHI and is no longer subject to HIPAA (164.514(a), (b), (c)). A covered entity may disclose a "limited data set" to DOH for research purposes if DOH executes a "data use agreement" (164.514(e)).	The Commissioner of DOH shall cause to be made scientific studies and research, and in conducting such studies and research, the commissioner is authorized to collect information, and such information shall be kept confidential and shall be used solely for the purposes of medical or scientific research or the improvement of the quality of medical care through the conduction of medical audits (PHL § 206(1)(j)).	Covered entities may disclose PHI to DOH under PHL § 206(1)(j): (1) if the subject authorizes the disclosure under HIPAA; or (2) if an IRB has waived the requirement to get authorization, applying the specific criteria in HIPAA. (A covered entity may disclose PHI to DOH without authorization for public health or health oversight activities, but such activities would not generally be considered PHL § 206(1)(j) research.) In addition, the disclosure must be: (1) accounted for by the provider if not authorized by the subject; (2) consistent with the provider's Notice of Privacy Practices; and (3) the minimum necessary to accomplish the research if not authorized by the subject. DOH could be asked to represent that the requested disclosure is the minimum necessary. Also, covered entities may disclose information that has been de- identified under HIPAA. Alternatively, a covered entity may disclose a "limited data set" to DOH for research purposes if DOH executes a "data use agreement."

<u>PHL § 2782</u>

HIPAA Privacy Rule	PHL § 2782	Law That Will Prevail
"If, and to the extent, permitted or required by an applicable provision of State law, a covered entity may disclose, or provide access to, protected health information about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> " (164.502(g)(3)(ii)(A)).	"No person who obtains confidential HIV related information in the course of providing any health or social service or pursuant to a release of confidential HIV related information may disclose or be compelled to disclose such information, except to an authorized agency in connection with foster care or adoption of a child" (PHL § 2782(1)(h)).	HIPAA does not preempt PHL § 2782(1)(h), but HIPAA may require an authorization to disclose confidential HIV related information to an authorized agency in connection with foster care or adoption of a child, if the agency is not a "person acting <i>in loco</i> <i>parentis</i> ."
A covered entity may use or disclose PHI without an authorization or opportunity to agree or object to the extent that such use or disclosure is "required by law" (164.512(a), 164.501(Required by law)) or if the disclosure is "for a law enforcement purpose to a law enforcement official [i]n compliance with and as limited by the relevant requirements of [a]n administrative request" (164.512(f)(1)(ii)).	"No person who obtains confidential HIV related information in the course of providing any health or social service or pursuant to a release of confidential HIV related information may disclose or be compelled to disclose such information, except to an employee or agent of the division of parole [or] an employee or agent of the division of probation and correctional alternatives or any local probation department [or] an employee or agent of the commission of correction" (PHL § 2782(1)(1), (m), (o)).	HIPAA does not preempt PHL § 2782(1)(l), (m) or (o). Nor would HIPAA require an authorization to disclose confidential HIV related information under these provisions, because such disclosures may be required by law or are for law enforcement purposes to law enforcement officials in compliance with and as limited by the relevant requirements of an administrative request.

Generally, a covered entity must treat a "personal representative" of a person who is the subject of PHI as though the personal representative were the person (164.502(g)).	Generally, a parent, legally appointed guardian or committee exercises rights on behalf of a child, ward or incapacitated person (<u>e.g.</u> , PHL § 18(2)(b), (c)).	Preemption of Mental Hygiene Law Article 81 and Surrogate's Court Procedure Act Articles 17 and 17-A is beyond the scope of this chart. This row of this chart is merely intended to preface the analysis of preemption of PHL § 2782(4) below.
If under applicable law a person has authority to act on behalf of an individual who is <u>an adult or an</u> <u>emancipated minor</u> in making decisions related to health care, a covered entity must treat such person as a personal representative with respect to PHI relevant to such personal representation (164.502(g)(2)). A covered entity may not disclose PHI about an <u>unemancipated minor</u> to a parent, guardian, or other person acting <i>in loco parentis</i> to the extent that an applicable provision of State or other law, including applicable case law, prohibits such disclosure (164.502(g)(3)(ii)(B)). A covered entity may elect not to treat a person as the personal representative of an individual if: (i) The covered entity has a reasonable belief that: (A) The individual has been or may be subjected to domestic violence, <u>abuse</u> , or <u>neglect</u> by such person; or (B) Treating such person as the personal representative could <u>endanger</u> the individual; <u>and</u> (ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual's personal representative (164.502(g)(5)).	"A physician may disclose <u>confidential HIV related information</u> pertaining to a protected individual <u>to a person</u> (known to the physician) <u>authorized pursuant to</u> <u>law to consent to health care</u> for a protected individual when the physician reasonably believes that: (1) disclosure is medically necessary in order to provide timely care and treatment for the protected individual; and (2) after appropriate counseling as to the need for such disclosure, the protected individual will not inform a person authorized by law to consent to health care; <u>provided, however, that the</u> <u>physician shall not make such</u> <u>disclosure if</u> , in the judgment of the physician: (A) the <u>disclosure would</u> not be in the best interest of the protected individual; or (B) the protected individual is authorized pursuant to law to consent to such care and treatment" (PHL § 2782(4)(e) [emphasis supplied]).	PHL § 2782(4)(e) prevails. A physician shall not disclose confidential HIV related information to a parent or guardian of a protected individual, if in the judgment of the physician, the disclosure would not be in the best interest of the protected individual, because HIPAA does not preempt State law that imposes privacy standards that are "more stringent than" the standards imposed under HIPAA (P.L. 104-191, § 264(c)(2)). Also, a physician shall not disclose confidential HIV related information to a parent or guardian of a minor who is a protected individual, if in the judgment of the physician, the disclosure would not be in the best interest of the protected individual, because State law prohibits such disclosure. There is no conflict between HIPAA and State law with respect to a disclosure of confidential HIV related information to a personal representative of a protected individual in abuse, neglect or endangerment situations, where, in the judgment of the physician, the disclosure would not be in the best interest of the protected individual.

HIPAA Privacy Rule	PHL § 2805-m	Law That Will Prevail
The HIPAA right of access to PHI applies to all medical records and billing records and any other records <u>used to make decisions</u> <u>about individuals</u> (164.524(a), 164.501(Designated record set)). Individual means the person who is the subject of PHI (164.501(Individual)).	Information required to be collected and maintained under PHL §§ 2805-j, 2805-k and reports required to be submitted under PHL § 2805-1 and any incident reporting requirements imposed upon diagnostic and treatment centers shall be kept confidential and shall not be released except to DOH or under PHL § 2805-k(4).	PHL § 2805-m prevails. None of the information that must be kept confidential under PHL § 2805-m is part of an individual's designated record set under HIPAA, because such information is not used to make decisions about the subject of the PHI.

<u>PHL § 2805-m</u>

<u>PHL § 4410</u>

HIPAA Privacy Rule	PHL § 4410(2)	Law That Will Prevail
A covered entity may use and disclose PHI for treatment, payment, or health care operations without consent (164.502(a)(1)(ii), 164.506). A covered entity may obtain consent of the individual to use or disclose PHI to carry out treatment, payment, or health care operations (164.506(b)(1)). Except in an emergency treatment situation, a provider must make a good faith effort to obtain a written acknowledgment of receipt of the provider's Notice of Privacy Practices, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained (164.520(c)(2)(ii)).	"Unless the patient waives the right of confidentiality, a health maintenance organization or its comprehensive health services plan shall not be allowed to disclose any information which was acquired by such organization or plan in the course of the rendering to a patient of professional services by a person authorized to practice medicine, registered professional nursing, licensed practical nursing, or dentistry, and which was necessary to acquire to enable such person to act in that capacity, except as may be otherwise required by law. A non- participating provider shall provide an enrollee's organization with such patient information as is reasonably required by the organization to administer its plan. In making such disclosure a provider shall comply with the provisions of subdivision six of section eighteen of this chapter concerning the disclosure of patient information to third parties provided, however, that with respect to a protected individual as defined in subdivision six of section twenty-seven hundred eighty of this chapter, disclosure shall be made only pursuant to an enrollee's written authorization and shall otherwise be consistent with the requirements of such section and rules and regulations promulgated pursuant thereto" (PHL § 4410(2)).	Health maintenance organizations must comply with both HIPAA and State law.

HIPAA Privacy Rule	Civil Rights Law § 79-1	Law That Will Prevail
A "covered entity" may generally disclose PHI to another covered entity for treatment, payment or health care operations without consent (164.502(a)(1)(ii), 164.506(a), 164.506(c)). A covered entity generally must have authorization to disclose PHI for other purposes (164.508). To be valid, an authorization must contain specified elements and comply with specified requirements (164.508(c)).	No person shall perform a genetic test on a biological sample taken from an individual without the prior written informed consent of such individual consisting of eight specific elements (Civil Rights Law § 79-l(2)).	Disclosures of genetic test information for treatment, payment or health care operations need only be in compliance with Civil Rights Law § 79-1. If not for treatment, payment or health care operations, a HIPAA-compliant authorization is also required.

Civil Rights Law § 79-1

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HIPAA Privacy Rule Education Law § 6530(23) Law That Will Prevail A covered entity may use and The following is professional Physicians, physician's assistants disclose PHI for treatment, misconduct for a physician, and specialist's assistants must physician's assistant or a payment, or health care operations comply with both HIPAA and State without consent (164.502(a)(1)(ii)), specialist's assistant: law. 164.506). A covered entity may "Revealing of personally obtain consent of the individual to identifiable facts, data, or use or disclose PHI to carry out information obtained in a professional capacity without the treatment, payment, or health care operations (164.506(b)(1)). Except prior consent of the patient, except in an emergency treatment as authorized or required by law." situation, a provider must make a good faith effort to obtain a written acknowledgment of receipt of the provider's Notice of Privacy Practices, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained (164.520(c)(2)(ii)).

Education Law § 6530(23)

The HIPAA Preemption Chart is also available on the Department of Health Web site at www.health.state.ny.us.



Annual Meeting Addressed Not-for-Profit Law, Mental Health Issues

The Health Law Section's 2003 Annual Meeting was well-attended and well-received. The morning's program, chaired by Edward Kornreich of Proskauer Rose, focused on not-for-profit healthcare systems—their history, structure and future. Among the many prominent presenters were William Josephson, Chief of the Charities Bureau of the New York State Attorney General's Office.

At lunch, Department of Health General Counsel, Donald P. Berens, Jr. spoke about the activities of the Health Department in 2002, and its new initiatives.

The afternoon meeting addressed emerging issues in mental disability law, including the state's experience under Kendra's Law, the innovative law that authorizes courts to order involuntary outpatient treatment. The program was co-chaired by David Seay of the National Alliance for the Mentally III, and Henry Dlugacz of the Law Office of Henry A. Dlugacz, Esq.

Over 150 people attended the meeting, which was held at the New York Marriott Marquis in Times Square.



At podium, Carolyn Reinach-Wolf speaks in support of Kendra's Law as it provides options for family members of mentally ill individuals. From left to right, John Gresham, John Carroll, Henry Dlugacz and J. David Seay listen.

Award Given to Former Chair of the NYSBA Committee on Public Health

During the luncheon at the Annual Meeting, the Chair presented an award to Hortense F. Mound, who headed the NYSBA Committee on Public Health (COPH) during the turbulent period of 1965-68. The COPH, later re-named as the Committee on Health Law, was the forerunner of the NYSBA Health Law Section, which was created in 1996.¹ Ms. Mound, the first female Chair of the COPH, described her experiences on the Committee in the 60s, particularly her role in creating the statute that authorized the creation of the state agency on alcoholism.

Endnote

1. See Claudia Torrey, "FYI," NYSBA Health Law Journal, Winter 2003, p. 22.



After the presentation to Hortense Mound. From left to right: Salvatore Russo, Hortense Mound, Claudia Torrey, James Lytle.

In-House Counsel Committee and Medical Society Co-Sponsor Program on Health Care Joint Ventures

On March 11, the In-House Counsel Committee and the Medical Society of the State of New York conducted a program on joint ventures in health care. The program was held at the offices of Proskauer Rose, LLP in New York City, and was quite well-attended. Speakers included Peter Millock of Nixon Peabody; Edward Kornreich of Proskauer Rose; Robert Belfort of Manatt, Phelps & Phillips; and Fred Miller of Garfunkel, Wild and Travis. The program was organized by Karen Gallinari, General Counsel to Staten Island Hospital.

New Section Officers Elected

At the Annual Meeting, the Section elected the following officers for 2003-2004. They take office in June 2003:

Chair:	James W. Lytle
Chair-Elect:	Philip Rosenberg
First Vice-Chair:	Lynn Stansel
Secretary:	Mark Barnes
Treasurer:	Peter Millock

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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		 Managed Care (HLS1800)
	Consumer/Patient Rights (HLS1200)	 Membership (HLS1040)
	Ethical Issues in the Provision of Health Care (HLS1300)	 Nominating
		 Professional Discipline (HLS2200)
	Fraud, Abuse and Compliance (HLS2400)	 Special Committee on By-Laws (HLS2900)
	Health Care Finance Issues (HLS2500)	 Special Committee on Medical Information (HLS2600)
	Health Care Internet (HLS2700)	 Special Committee on Mental Health Issues (HLS3000)

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