NYSBA WINTER 2000 | VOL. 5 | NO. 1

Health Law Journal

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

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

NYSBA

HEALTH LAW JOURNAL

WINTER 2000

Vol. 5, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

in cooperation with

PACE UNIVERSITY SCHOOL OF LAW
HEALTH LAW AND POLICY PROGRAM

A Message from the Section Chair

To Law Students and Young Lawyers:

At our most recent Executive Committee meeting, several members argued that we need to do more to reach out to law students and young lawyers. My colleagues said we need to attract these newly and nearly minted lawyers to the practice area of health law, and to the Health Law Section as well. I couldn't agree more. Accordingly, I'd like to direct my column today to those law students or young lawyers who might come across this issue of the *Journal*.

First let me say—and I admit that this is somewhat subjective—that health law simply is the most exciting, most professionally rewarding and overall the coolest area of law to practice in.

If you are business-oriented, as a health lawyer you might find yourself forming and advising all sorts of health care enterprises, or structuring health care mergers, joint ventures or transactions. If you are public policy-oriented, as a health care lawyer you can help government, associations or health care clients develop and promote policy positions on the key policy issues of the day—issues like the rights of managed care enrollees, or the effort to secure health care coverage to the uninsured, or the need to protect the privacy of medical information in the Internet age.

If you take pride in mastering intricate and technical legal knowledge, you can enter the valued priesthood of Medicare or Medicaid reimbursement law experts. If you are a technophile, health care clients need your help with the legal aspects of telemedicine, or their obligations regarding genetic testing and genetic information.

If you want to litigate, unfortunately the area of health law provides ample opportunity for you to indulge that peculiar inclination.

Those of you who, like me, are intrigued by ethical issues posed by medical advances will find that clinicians and institutions regularly encounter clinical situations that are legally complex as well as ethically and medically challenging, and they will greatly value sound legal counsel.

As these examples illustrate, the practice of health law encompasses a broad and diverse range of issues. Moreover, the field is growing and sprouting new subspecialities. To help you understand the terrain better, this issue of the *Journal* carries a reprint of a recent article by Frank Serbaroli that describes what health lawyers do.

But while there are many rewarding aspects of practicing health law, there is one that is paramount—and I think most of my colleagues would agree with me on this. We tend to see ourselves not just as lawyers, but as participants in health care—and health care is special. It is special because of the enormous and fundamental importance of extending life and restoring health. But it is also special because our clients tend to be motivated by missions beyond the desire for commercial success, and tend to be bound by values beyond just fair dealing with customers. Their mission generally includes improving quality of care, promoting access to care and preserving the cost-effectiveness of care. Their values include respect for patient autonomy, dignity and confidentiality. As health care lawyers we have to be supportive of that mission and protective of those values in providing our services.

Accordingly, health lawyers draw a special sense of satisfaction from our work; a sense that we are part of a meaningful, valuable endeavor.

Perhaps you're intrigued, but unsure how to become a health lawyer. Let me offer a few suggestions.

- Join the Health Law Section. (You knew I was going to say that, right?) There are special rates for students and young lawyers. Even more important, join one or two of the committees within the Section. This is a great way to meet other health lawyers, learn from them and make valuable professional connections.
- Don't just be a member of a committee, be an active member. Volunteer to draft a report, organize a conference, research an issue under discussion. You will gain substantive knowledge and make a favorable impression on your colleagues.
- Write an article on a health law topic for the *Health Law Journal* or some other periodical. A well-written article on a topic of interest to the field will establish your credentials as the authority on that topic.
- Attend professional education programs. Our upcoming CLE Program "Health Law Primer" provides a particularly useful way for law students or young lawyers to learn the basics of this topical area.

I hope this column has piqued your interest in becoming a health lawyer, or strengthened your existing intention to do so. We need your talent and energy in this field. I also hope you'll join the Section and participate on our committees.

I have one final request: if this column helped you decide to join us, let me know. I'd like to welcome you.

Robert N. Swidler

Robert Swidler can be reached at swidlerr@nehealth.com.

In the New York State Courts

No Cause of Action for Wrongful Denial of Hospital Staff Privileges

Moallem v. Jamaica Hospital, 694 N.Y.S.2d 653 (1st Dep't September 16, 1999). Jamaica Hospital summarily suspended plaintiff's clinical privileges based on allegations that he had been verbally abusive and had failed to follow hospital policy regarding scheduling. After providing the physician with a due process hearing under its Medical Staff bylaws, the Hospital adopted the hearing committee's recommendation that the physician remain suspended until he apologized for his behavior and promised to follow Hospital policies. The physician sued the hospital for breach of contract, intentional interference with contract, and *prima facie* tort.

The Appellate Division (reversing the motion court) granted the Hospital's motion for summary judgment and dismissed the complaint. The Court reaffirmed the well-established principle that there is no common law cause of action based on an allegedly wrongful denial of staff privileges by a private hospital. Thus, a common law action for damages cannot be maintained and the only statutory relief available is injunctive relief under Public Health Law (PHL) § 2801-c. The Court ruled that the physician's claims should have been dismissed for two reasons. First, the physician did not exhaust his mandatory administrative remedy with the New York State Public Health Council. Second, because the physician had no contract or bylaws claims independent of the privileges suspension, his claims for damages could not be maintained.

HMO Advertising Did Not Violate Consumer Fraud Statute

Maltz v. Aetna U.S. Healthcare, Inc., New York County Index No. 605474/98 (August 26, 1999) (Lehner, J.). Plaintiffs are members of a health maintenance organization (HMO) operated by Aetna. In this suit, plaintiffs alleged that Aetna engaged in deceptive trade practices by print, television and Internet marketing that misled consumers about available HMO benefits. Plaintiffs claimed that Aetna aired advertisements showing a boy suffering from Crohn's disease being flown to and treated at Cleveland's Mayo clinic. However, Aetna refused to authorize treatment at the Mayo Clinic for plaintiffs' son, who also had Crohn's disease. The plaintiffs also alleged misrepresentation as to the detrimental impact on the quality of medical care that results from HMO's use of the capitation payment system.

The Court held that plaintiffs' allegations failed to state a cause of action under General Business Law § 349 (GBL). The Court found that Aetna's advertising did not suggest that treatment at the Mayo Clinic was a specific HMO benefit, and thus was not a misrepresentation under the GBL. Second, the Court held that plaintiffs had not shown any injury, since plaintiff's son was receiving care in New York; that Aetna was paying for that care; and that such care was not alleged to be inferior to the care provided at the Mayo Clinic. As to plaintiffs' GBL claim based on capitation, the Court held that plaintiffs could not use a GBL action to challenge the Department of Health regulations that govern the capitation system.

Physician Convicted of Medicaid Fraud Must Pay Restitution and Treble Damages

Vacco v. San Juan, 10/21/99 N.Y.L.J. 30 (col. 2) (Sup. Ct., Bronx Co. October 21, 1999). Defendant physician was convicted of Medicaid fraud, and was ordered to pay restitution to the state in the amount of $110,000. The state commenced an action for civil forfeiture and treble damages under Social Services Law § 145-b, which permits a crime victim to recover as treble damages three times the amount of any restitution. The doctor opposed the state's request for relief, arguing that his obligation under the restitution order precluded the state from also seeking treble damages. The Court disagreed since SSL § 145-b states that its remedies are in addition to any other remedies provided by law. Accordingly, the court granted judgment to the state in the amount of $330,000. The Court also granted the state's motion for forfeiture of the physician's motor vehicle on the ground that it was acquired with proceeds of a crime. (The court credited the physician with $23,000 towards the treble damage judgment for his Z-3 BMW convertible.)

Federal Courts Continue to Reject New York Peer-Review Confidentiality Laws

Syposs v. United States, __ F. Supp. __, 1999 WL 705107 (W.D.N.Y., August 31, 1999). In this medical malpractice suit brought under the Federal Tort Claims Act, plaintiffs subpoenaed physician peer-review records from non-party hospitals. The non-party hospitals moved to quash the subpoenas based on New York's peer-review privilege found at Public Health Law § 2805-m and Education Law § 6527(3). The Court denied the hospitals' motions on the ground that there is no federal peer-review privilege and that the federal courts are not required to recognize state law privileges. In reaching its conclusion, the Court rejected the hospitals' argument that confidentiality and non-disclosure of peer-review information was essential for the delivery of quality health care. Instead, the Court concluded that immunity from liability for damages was all that Congress and the New York legislature believed was required to encourage effective peer review.

Franzon v. Massena Memorial Hospital, ___ F.R.D. ___, 1999 WL 809819 (N.D.N.Y., August 12, 1999). The physician plaintiff alleged that the Hospital used the peer review process to violate his First Amendment right to free speech. To support his claim, the physician sought discovery of peer review discipline concerning all other physicians in the Hospital. The Hospital objected to the discovery request on several grounds, including the New York's peer-review confidentiality laws. The court held that there is no federal peer review privilege, and that the state law privilege must yield to permit plaintiff to search for evidence that might exist to support his First Amendment claim.

Federal Court Abstains from Exercising Jurisdiction Over State Disciplinary Proceedings

Selkin v. State Board for Professional Medical Conduct, ___ F. Supp.2d ___, 1999 WL 692043 (S.D.N.Y. Sept. 3, 1999). Plaintiff's license to practice medicine was revoked by a Committee of the State Board for Professional Medical Conduct (BPMC). Plaintiff obtained a temporary restraining order (TRO) from the Appellate Division that stayed the revocation, but lost the TRO when the state appealed to the Administrative Review Board (ARB). (Presumably, the state was not appealing the revocation, but the Committee's dismissal of most of the misconduct charges). Pursuant to Public Health Law § 230-c(4), (5) (PHL) , the ARB appeal divested the Appellate Division of jurisdiction, and thus extinguished the stay. The physician commenced a federal action under 42 U.S.C. § 1983, alleging that PHL § 230 deprived him of his Constitutional right to due process, since he could not obtain injunctive relief from the license revocation pending the ARB appeal.

In addition to finding that plaintiff could not establish a likelihood of success on the merits, the Court declined to exercise jurisdiction and dismissed the complaint on abstention grounds. Applying the Younger Abstention doctrine, the Court held that "state disciplinary proceedings contemplating the revocation of a physician's medical license" are judicial in nature, implicate an important state interest, and that the physician can raise his constitutional claims with the ARB and in later court proceedings.

Radiologist's Age Discrimination Claim Dismissed for Lack of Proof

Maniatas v. The New York Hospital-Cornell Medical Center, ___ F. Supp. ___, 1999 WL 553831 (S.D.N.Y., July 26, 1999). In *Maniatas*, a radiologist alleged that a hospital's termination of her part-time employment was motivated by age discrimination. In support of her claim, the radiologist demonstrated that three out of the four radiologists hired after her termination were younger than she. The Court held that the radiologist had established a *prima facie* case of discrimination, but that the hospital had articulated legitimate reasons for the termination: the radiologist was part-time and her hours were inflexible; she was not contributing to the Hospital Department's teaching and research mission; and she was not adequately trained in technologies the Hospital now requires for employment in its newly organized radiology department. The Court found that plaintiff's statistical evidence (her only proof) was insufficient to show that the Hospital's reasons were a pretext for discrimination, and therefore granted summary judgment dismissing the complaint.

Exclusive Contract Holder's Status as Independent Contractor Requires Dismissal of Federal and State Employment Discrimination Claims

Moon v. Southside Hospital, 98 Civ. 3772 (E.D.N.Y., September 14, 1999). The plaintiff in this action had an exclusive contract to provide radiation oncology services at the Hospital. The plaintiff alleged that the Hospital's decision to not renew his exclusive contract was motivated by race, national origin and age discrimination.

The Court granted summary judgment dismissing the complaint on the ground that plaintiff was not a hospital employee, but an independent contractor (to which Title VII, the ADEA and the New York Executive Law do not apply). The Court noted that, unlike an employee, the plaintiff was independently responsible for determining patient treatment plans and for hiring—and paying—the assistant radiation oncologists who worked under him. The radiation oncologist also billed patients directly for his services, rather than receiving a salary from the hospital. Finally, the radiation oncologist did not work exclusively at the hospital, but also provided radiation oncology services at three competing hospitals, as well as his own free-standing radiation oncology facility.

Case Update: ***Rotwein v. Sunharbor Manor Residential Health Care Facility***: This case (in which the Court dismissed a podiatrist's "whistleblower" claim under Labor Law § 740 and awarded attorney's fees to the defendants) was summarized in this column in the 1999 Summer/Fall issue of the *Health Law Journal*. The decision has been published at 695 N.Y.S.2d 477.

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

In the New York State Legislature

The New York State Senate returned to Albany on October 7th and passed several bills that had been passed by the Assembly on the last night of the legislative session. The bills passed by the Senate included the clinic access and anti-stalking act of 1999, defining criminal interference with health care services (A9036A/S6146). In addition, the bill addresses criminal interference with religious worship and expands upon stalking laws. The Senate also passed legislation increasing penalties for school violence, expanding the state's DNA databank and easing restrictions on building power-generating plants.

The full legislature will need to return by the end of the year as well to address Health Care Reform Act (HCRA), which expires at the end of the year. It is likely that a number of managed care reforms will be part of the discussions, including establishing a guarantee fund for unpaid claims, mandating new payment practices and reducing HMOs' ability to make health care decisions. There have been rumblings among legislative staff that the legislature might simply do an extension of HCRA rather than make substantive changes. However, advocates on behalf of business, plans, providers and consumers have been putting pressure on the legislative leaders from all sides to make significant amendments to the law. Although the Assembly introduced their HCRA proposal at the end of the session, the Senate and the governor have not yet expressed their priorities for amending HCRA. Any serious debate on the issue awaits the issuance of a governor's proposal. With the arrival of the new commissioner, Antonia Novello, it is expected that the Department of Health will be finalizing an administration proposal before long.

The Assembly Health and Insurance Committees scheduled several hearings for the end of October to discuss their HCRA proposal. The hearings were held October 27th in Buffalo, October 28th in Syracuse, October 29th in Utica and November 12th in New York City. Any questions can be directed to the offices of Assemblyman Richard Gottfried (518) 455-4941 or Assemblyman Alexander Grannis (518) 455-5676. These hearings may serve as the springboard for further HCRA discussions.

A special session devoted to HCRA will undoubtedly open the door for other health-related issues to be considered. It is likely that advocates will be lobbying strongly for the bills requiring coverage for infertility, mental health parity and HMO liability. We will be watching these issues closely and will keep you apprised of any developments in subsequent *Journal* issues.

REQUEST FOR ARTICLES

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

Professor Barbara L. Atwell or Professor Audrey Rogers
Pace University School of Law
78 North Broadway
White Plains, NY 10603

Articles should be submitted on a 3 1/2" floppy disk, preferably in WordPerfect 5.1 or 6.1 or Microsoft Word, along with a printed original and biographical information, and should be spell checked and grammar checked.

In the New York State Agencies

Rules published in the New York State Register from mid-July 1999 until October 31, 1999 include the following:

- Patient Review Instrument (PRI) Instruction. This emergency rule amends 10 NYCRR 86-2.30 to allow for a new admission qualifier in claiming medical treatments and for the use of a nurse practitioner or physician assistant where a physician is currently required. Filing date: June 30, 1999.
- Medicare Supplement Insurance. This emergency/proposed rule amends 9 NYCRR Part 52 to bring the standards for Medicare Supplemental Insurance into compliance with federal requirements. Filing date: June 30, 1999. Effective date: July 20, 1999. See NYS Register: August 4, 1999.
- Poison Control Center Operations. This emergency rule establishes a methodology to distribute money from the HCRA health care incentives pool for Poison Control Centers. Filing date: July 26, 1999. Effective date: July 26, 1999. See NYS Register: Aug. 11, 1999.
- Medicaid Ratesetting Consenquences for Overutilization by Alcoholism/Substance Abuse Providers. The Office of Alcoholism and Substance Abuse Services adopted this amendment to Part 840 of Title 14 NYCRR to impose Medicaid ratesetting consequences for unlawful excess utilization. Filing date: Sept. 14, 1999. Effective date: Sept. 29, 1999. See NYS Register: Oct. 1, 1999.
- External Appeals of Adverse Determinations of Health Care Plans. This emergency rule provides guidance to insurers, insureds, and external appeal agents for the implementation of Chapter 586 of the Laws of 1998, which establishes the right of health care insurance subscribers to an external appeal of final determinations rejecting claims on the grounds that the service is not medically necessary or is experimental. Filing date: Sept. 15, 1999. Effective date: Sept. 15, 1999. See NYS Register: October 6, 1999.
- Hematopoietic Progenitor Cell (Stem Cell) Banks. The Council on Human Blood and Transfusion Services adopted this rule which amends 10 NYCRR Subpart 58-5 to update the requirements for hematopoietic progenitor cell banks. Filing date: Sept. 24, 1999. Effective date: Oct. 13, 1999. See NYS Register: Oct. 13, 1999.

In the Law Journals

1. Patricia I. Carter, *Health Information Privacy: Can Congress Protect Confidential Medical Information In the Information Age?*, 25 Wm. Mitchell L. Rev. 223 (1999).

2. Christine E. Brasel, *Managed Care Liability: State Legislation May Arm Angry Members With Legal Ammo to Fire at the MCOs for Cost Containment Tactics. . . . But Could It Backfire?*, 27 Cap. U. L. Rev. 449 (1999).

3. Becky M. Brooks, *Local Health Care Districts Can Now Play Ball: Chapter 18 Levels the Playing Field for Asset Transfers to Nonprofit and For-profit Corporations*, 30 McGeorge L. Rev. 769 (1999).

4. Frank M. McClellan, *Is Managed Care Good for What Ails You? Ruminations on Race, Age, and Class*, 44 Vill. L. Rev. 227 (1999).

5. Arti K. Rai, *Reflective Choice In Health Care: Using Information Technology to Present Allocation Options*, 25 Am. J.L. & Med. 387 (1999).

6. Alan B. Cohen, *Hitting the "Target" In Health Care Cost Control*, 24 J. Health Pol. Pol'y & L. 697 (1999).

7. Adams Dudley & Harold S. Luft, *Goals, Targets, and Tactics: Making Health Care Policy Decisions Explicit*, 24 J. Health Pol. Pol'y & L. 705 (1999).

8. Joseph White, *Targets and Systems of Health Care Cost Control*, 24 J. Health Pol. Pol'y & L. 653 (1999).

9. Mark Stephen Bishop, *Crossing the Decisional Abyss: An Evaluation of the Surrogate Decision-making Statutes as a Means of Bridging the Gap Between Post-*Quinlan *Red Tape and the Realization of An Incompetent Patient's Right to Refuse Life-Sustaining Medical Treatment*, 7 Elder L.J. 153 (1999).

10. Bethany J. Spielman, *Managed Care Regulation and the Physician-Advocate*, 47 Drake L. Rev. 713 (1999).

11. Kerrie Webb, *Access to Specialists for Managed-Care Patients With Chronic, Disabling, or Life-Threatening Illnesses, or Conditions*, 30 McGeorge L. Rev. 675 (1999).

12. Susan O. Scheutzow, *State Medical Peer Review: High Cost but No Benefit . . . Is It Time for a Change*, 25 Am. J.L. & Med. 7 (1999).

13. Elizabeth B. Cooper, *Testing for Genetics Traits: The Need for a New Legal Doctrine of Informed Consent*, 58 Md. L. Rev. 346 (1999).

14. Jennifer E. Gladieux, *Medicare+Choice Appeal Procedures: Reconciling Due Process Rights and Cost Containment*, 25 Am. J.L. & Med. 61 (1999).

15. Scott Forehand, *Helping the Medicine Go Down: How a Spoonful of Mediation Can Alleviate the Problems of Medical Malpractice Litigation*, 14 Ohio St. J. on Disp. Resol. 907 (1999).

16. Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 Am. J.L. & Med. 327 (1999).

17. Patricia C. Keszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 Am. J.L. & Med. 297 (1999).

18. Megan Cleary, *ERISA: Denial of Benefits On Experimental Procedure Affirmed In Tenth Circuit . . .* Healthcare America Plans, Inc. v. Bossemeyer, 25 Am. J.L. & Med. 175 (1999).

19. Alison M. Sulentic, *Crossing Borders: The Licensure of Interstate Telemedicine Practitioners*, 25 J.Legis. 1 (1999).

20. Julia Anastasio, *Legislative Developments In the Regulation of Insurance Coverage: Will These New Regulations Benefit Women With Breast Cancer*, 7 Am. U.J. Gender Soc. Pol'y & L. 55 (1999).

21. John C. Render & James B. Hogan, *Health Care Law: A Survey of Significant 1998 Developments*, 32 Ind. L. Rev. 841 (1999).

22. Elizabeth I. Mitchell, *The Potential for Self-interested Behavior By Pharmaceutical Manufacturers Through Vertical Integration With Pharmacy Benefit Managers: The Need for a New Regulatory Approach*, 54 Food & Drug L.J. 151 (1999).

23. Symposium, *The Influence of the Minnosota Tobacco Trial On the Healthcare Community and Tobacco Regulation*, 25 Wm. Mitchell L. Rev. 455 (1999).

24. Anthony L. Osterlund, *The Unequal Balancing Act Between HIV-positive Patients and Physicians*, 25 Ohio N.U. L. Rev. 149 (1999).

25. Dennis P. Saccuzzo, *Legal Regulation of Behavior Modification for Developmentally Disabled and Other Handicapped Persons*, 25 Ohio N.U. L. Rev. 27 (1999).

26. Timothy J. Vinciguera, *Symposium on Twenty-Five Years of Roe v. Wade: The Legal Evolution of Reproductive Freedom and Parental Rights Notes of a Foot-Soldier*, 62 Alb. L. Rev. 1167 (1999).

27. Robert D. Hayes, Nancy G. Boyd & Kenneth W. Hollman, *What Attorneys Should Know About Long-term Care Insurance*, 7 Elder L.J. 1 (1999).

28. Stacey M. Schwartz, *Beaten Before They Are Born: Immigrants, Their Children, and a Right to Prenatal Care*, 1997 Ann. Surv. Am. L. 695 (1999).

29. Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 Am. J.L. & Med. 149 (1999).

30. Andrew P. Czajkowski, *The Making of a Lawsuit: A Health Plan Perspective*, 25 Wm. Mitchell L. Rev. 379 (1999).

31. Heather Burghardt, *Fraud & Abuse: RICO Cause of Action Against MCOS . . . Humana v. Forsyth*, 25 Am. J.L. & Med 178 (1999).

Compiled by Joe DaBronzo. Joe DaBronzo is a second-year student at Pace University School of Law. He received a Doctor of Pharmacy degree from SUNY Buffalo and a B.S. degree in Pharmacy from St. John's University. Mr. DaBronzo served as Clinical Coordinator for Neurology in the National Institute of Neurological Disorders and Stroke of the National Institutes of Health. He also has 11 years of experience in the pharmaceutical industry. He was Assistant Director in the International Medical Department for American Cyanamid's International Pharmaceutical Division Lederle International, and with Merck Pharmaceuticals serving in the positions of Director of Clinical Policy and Director of Health Utilization Management in Merck's managed care division Merck-Medco Managed Care L.L.C.

'Net Worth

By Margaret R. Moreland

Law has always been a very collegial profession. Bar associations existed almost as long as the profession. In addition to performing a social function, they have been a vehicle for the exchange of knowledge and information. Now most are a presence on the Internet. Their web sites are well worth a visit. As usual, if you know of a source that you think should be included in a future column, please send the Internet address to:
mmoreland@law.pace.edu

American Bar Association, Health Law Section
http://www.abanet.org/health/home.html

This web site is mainly devoted to the business of the association, such as announcements of meetings and CLE programs. A link to BNA Health Care Daily is restricted to members only. However, the "Job Opportunities" area can be browsed by anyone and "Health Law Links" is a comprehensive list of health law web sites.

The American College of Legal Medicine
http://www.aclm.org/

This organization of physicians, attorneys, health care professionals, administrators, scientists, and others focuses on the "issues where law and medicine converge." Its web site includes abstracts of selected papers presented at its conferences. The stated intent is to make these papers available in their entirety.

American Health Lawyers Association
http://www.healthlawyers.org

This Association claims to be the nation's largest, nonpartisan, educational organization devoted to legal issues in the health care field. As part of its educational mission it has developed this excellent web site. Its strengths are its currency and the primary materials it presents. "Today in Health Law" provides daily health law news from BNA's *Executive Briefing* (along with an offer for a free trial of its *Health Care Daily Report*). Past issues of *Executive Briefing* are archived and may be browsed by date. "Ask Health Lawyers" includes current health law documents in full-text format that can be downloaded or ordered for a fee. Some recent documents are the October 20th HRSA revised final rule on the organ procurement and transplantation network, DHHS OIG inspection reports on "Early Effects of the Prospective Payment System on Access to Skilled Nursing Facilities," "Beneficiary Awareness of Medicare HMOs," and "Effects of the Prospective Payment System on Access to Skilled Nursing Facilities for Patients with End-Stage Renal Disease," OIG correspondence on discount arrangements between clinical laboratories and SNFs, and on a nephrologist-home dialysis supplies joint venture, an OIG Advisory Opinion on a proposed contractual arrangement between a self-insured employer health plan and a single-specialty managed care organization to provide managed podiatry benefits for the employer's retirees, OIG Compliance Guidance on "Compliance Program Guidance for Hospices," an OIG Special Advisory Bulletin, "The Effect of Exclusion From Participation in Federal Health Care Programs," and an FTC/DOJ draft "Antitrust Guidelines for Collaborations Among Competitors." Certain of these documents are highlighted on the home page under "Of Note." Recently they included the OIG Nursing Facility Guidance and information on the OIG Healthcare Integrity and Protection Data Bank and the notice of proposed rule making that would exempt the HIPDB from privacy act provisions. The Association also uses this forum to announce upcoming programs, such as those on fraud and abuse, managed care liability, and the use of e-mail in peer review, and to market its publications.

The American Society for Bioethics and Humanities
http://www.asbh.org

This web site has its focus on serving as a source of information about ASBH for members and prospective members. However, it also links to selected articles from *ASBH Exchange*, a quarterly Society publication covering clinical, research, and public policy issues, and has organized links to other related information on the Internet under about a dozen topic headings.

The American Society of Law, Medicine & Ethics
http://www.aslme.org

The ASLME has posted information about their two peer-reviewed journals, *The Journal of Law, Medicine & Ethics* and *The American Journal of Law & Medicine*. Hundreds of articles have been archived here and can be searched. They also offer access to their funded research projects on pain undertreatment and pain management. The entire text of a special edition of JLME devoted to appropriate pain management will be made available at no cost to those interested. In the "News" section users can find *Recent Developments in Health Law*, a scholarly review of important health law developments compiled by Harvard Law School and Boston University Law School students. Also in this section is a list of employment and fellowship opportunities. Under "Connections" the Society has begun to gather links to other relevant sites for research

and study. ASLME has also posted information on this web site regarding their upcoming educational conferences.

Bazelon Center for Mental Health Law
http://www.bazelon.org/

This site was created by a leading national advocate organization for people with mental illness and mental retardation. It contains a wealth of information in this area. "What's New" covers recent Supreme Court ADA decisions and the Center's position on involuntary commitment. "Action Alerts" relate to pending federal legislation on issues such as medical records privacy, mental health services, the ADA, and SSI benefits. "Advocacy Resources" are gathered for ADA, Aging, Children's, and Fair Housing Issues, Mental Health Care and Advance Directives. In these areas you will find numerous items, such as general background articles, publications, transcripts, information on current activities, links to statutes, and links to other sources of information. Finally, there are "Announcements" of meetings, courses and conferences. This is a valuable resource for mental health law.

Margaret R. Moreland is Lawyer/Librarian for Research Services at Pace University School of Law. Her e-mail address is mmoreland@law.pace.edu

For Your Information

By Claudia O. Torrey

When Congress enacted the 1996 Health Insurance Portability and Accountability Act,[1] they mandated themselves to enact legislation on the subject of health information privacy by August 21, 1999.[2] If they default, the Department of Health and Human Services is required to have regulations in place by February 21, 2000 regarding the privacy and confidentiality of electronic health information records.[3] Not surprisingly, Congress *did not* meet the August 21, 1999 deadline.

"Not surprisingly, Congress did not *meet the August 21, 1999 deadline."*

During the Winter of 1999, a national survey on the confidentiality of medical records was released by the California HealthCare Foundation ("Foundation").[4] Some of the key findings in the Foundation survey were quite revealing: of the 1,000 adults surveyed, 54% believe electronic oriented health information, or the computerization of medical records, from paper record-keeping systems will make it more difficult to keep personal medical information private and confidential; the Foundation survey also reflects that 70% of those surveyed are not comfortable with allowing drug companies to have access to their medical records for the purposes of marketing new drugs and other health care products. Particularly noteworthy in the Foundation survey is the fact that three specific policies were rated highest in perceived effectiveness: establishing fines and punishments for violations of medical privacy; requiring someone's permission to release personal health information and requiring providers to set up security systems like passwords and encryption.

As we all know, privacy lost is not necessarily regained (consider the ever-eroding Fourth Amendment "reasonable expectation of privacy"). All of us will need medical care at one time or another; indeed, a critical test of the fundamental fairness of a society is the manner in which it provides its citizens with such services.[5]

From Spring, 1998, to Spring, 1999, 19 members of the New York State Bar Association/Health Law Section were involved in a project concerning the topic of health information privacy/confidentiality. The project participants were known as the Health and Human Services Study Group ("Study Group"). The task was daunting, but your colleagues rose to the occasion with the exertion of time, talent and endurance. The Study Group report is reproduced on page 24 in this issue of the *Health Law Journal*. (A state law appendix is also available upon request.)

"All of us will need medical care at one time or another; indeed, a critical test of the fundamental fairness of a society is the manner in which it provides its citizens with such services."

Endnotes

1. 42. U.S.C. §§ 1320d-1320d-8.
2. *Id.*
3. *Id.*
4. *See* California HealthCare Foundation, *National Survey: Confidentiality of Medical Records*, 1999.
5. *See* Dworkin, 41 N.Y. Rev. of Books at 23.

Claudia O. Torrey, Esq. can be reached at Post Office Box 150234, Nashville, Tennessee 37215.

Navigating a Fraud and Abuse Concern: Skilled Nursing Facility Arrangements With Ancillary Providers

By Ari J. Markenson, J.D, M.P.H. and Patrick Formato, Esq.

I. Introduction

The enactment of the Balanced Budget Act of 1997[1] dramatically changed the financial arrangements by which Medicare Skilled Nursing Facilities (SNFs) are reimbursed under the Medicare system. The BBA has also changed the landscape in which SNFs can associate with outside (independent contractor) ancillary providers. This dramatic change came in two parts, the prospective payment system (PPS) and Consolidated Billing. The changes have forced most SNFs to renegotiate their agreements with ancillary providers. As a result of cost containment incentives inherent in PPS and the potential profit opportunities for SNFs associated with consolidated billing SNFs have sought new contractual arrangements for ancillary services. These arrangements typically involve discounts and differential charges based upon payor source. However, such arrangements have raised serious fraud and abuse concerns. In particular these type of contractual arrangements may constitute violations of the anti-kickback statute 42 U.S.C. § 1320a-7b. These fraud and abuse implications are evidenced most clearly by the recently released Department of Health and Human Services, Office of the Inspector General (OIG) advisory opinion (99-2) concerning an arrangement between a SNF and an ambulance provider.

II. Medicare PPS for SNFs

The PPS legislation is contained in § 4432 of the BBA. The corresponding regulations were published on July 30, 1999, as a final rule in the Federal Register, at 64 Fed. Reg. 41644. This legislation has changed SNF reimbursement so that SNFs are no longer reimbursed on a cost based system but rather via a prospectively determined per diem rate. Beginning January 1, 1999 Medicare Part A reimburses a SNF a fixed per diem or daily fee based on a SNF resident's classification within the Medicare RUGS III guidelines. RUGS is an acronym for Resource Based Utilization Groups. These guidelines are a measure of the type of care the resident requires and what it costs the SNF to provide that care to the resident. The SNF evaluates a resident's health condition based on a standardized assessment form (called the MDS 2.0 or Minimum Data Set) provided by the Health Care Financing Administration (HCFA). Information from the MDS 2.0 is then used to assign the resident a RUGS III category.

Under PPS, the facility is financially responsible for all Medicare Part A and B services (with some limitations)[2] provided to a resident while in a so-called Part A stay. Thus, most outside providers who may have previously provided services to a Part A resident and billed directly must now look to the facility for payment.

Many SNFs are finding the cost pressures of PPS to be an enormous burden. SNFs are finding that the rates paid to facilities are wholly inadequate to cover the cost of services that they are now required to provide under a per diem rate. SNFs have argued, to no avail, that the intention of the PPS legislation is not being carried out and the rate cuts are simply too deep. In fact, in the early legislative history to the PPS legislation, Senator Hatch remarked that "it would be unfortunate for HCFA to put into effect a system that did not adequately account for the medical services offered to residents within a skilled nursing home. I urge HCFA to implement and include all ancillaries only when the data and the information are adequate."[3] It does seem on many levels that Senator Hatch's words went completely ignored in HCFA's implementation of PPS for SNFs. HCFA included almost all ancillary services, with few exceptions, in the PPS rates. The American Health Care Association (the trade association for SNFs) has vehemently argued that there is no question HCFA had inadequate cost data for ancillary services provided to SNF residents when they calculated the Medicare Part B ancillary portion of the PPS rates. As a result, SNFs are looking for the best deal on ancillary services they can find. However, the inadequate calculations that brought about the PPS rates and associated headaches are only a part of the picture.

III. Medicare Consolidated Billing for SNFs

The consolidated billing legislation is contained in § 4432(b) of the BBA. Its corresponding regulations were published on July 30, 1999, as part of a final rule on PPS in the Federal Register, at 64 Fed. Reg. 41644. The consolidated billing provision mandates that the SNF be responsible for billing for essentially all services (with some limitations)[4] a resident receives at the SNF while in a Medicare Part A stay (up to the first 100 days of skilled services, provided the resident meets the applicable technical and clinical eligibility requirements) and following the end of a Part A stay for all Part B services. Certain services are excluded from the consolidated billing provisions, such as physicians services, certain services performed under physician's supervision, services of nurse practitioners, qualified psychologists, nurse anesthetists, dialysis services and supplies, cer-

tain radiology services, hospice care, and certain ambulance services. The regulations regarding the exclusions from consolidated billing can be found at 42 C.F.R § 411.15(p)(2). According to the Health Care Financing Administration (HCFA), "if a particular type of service does not appear on the excluded list, it is included within the overall package of services that is subject to consolidated billing when furnished to an SNF resident."[5]

Under consolidated billing, the SNF is financially responsible for almost all services covered by Medicare provided to residents whether in a Part A stay or not. Thus, all of the SNFs outside ancillary providers [excluding those providers listed in 42 C.F.R § 411.15(p)(2)] who may have previously provided services to residents and billed directly must, under consolidated billing, look to the facility for payment. However, providers and their attorneys should be aware that HCFA has acknowledged that its current systems cannot effectively manage consolidated billing and has delayed implementation of consolidated billing for residents not in a Part A stay indefinitely.[6] Consolidated Billing for services provided to Part A residents took effect on January 1, 1999.

IV. Agreements between SNFs and Ancillary Providers

The requirements of PPS have led SNFs and ancillary providers to the bargaining table in order to renegotiate their agreements. SNFs who are currently financially responsible to ancillary providers for services rendered to Medicare Part A patients are looking for the best possible deals they can achieve. The delay in implementation of consolidated billing for residents not in a Part A stay means that ancillary providers can continue to bill for Part B services provided to those residents. Within this framework SNFs and ancillary providers are considering and, in some cases, entering into arrangements for differential pricing. The differential pricing arrangements are most commonly either capitated arrangements or discounts applicable to the Part A and other all inclusive payor arrangements (i.e. managed care) in which the facility is paid an all inclusive fee and thus responsible for payment to the ancillary provider.

For example, with regard to discounting arrangements, a SNF may negotiate an arrangement with a clinical laboratory to provide a CBC test for its Part A and managed care patients (billable to the facility) at a discounted fee of 30% below the Medicare fee schedule. In turn, the clinical laboratory will provide CBC tests to the SNFs non-Part A or managed care patients and bill the payors (i.e., Medicare Part B, private insurers, etc.) directly at the applicable Medicare allowable fee.

With regard to capitated arrangements, suppose an ambulance trip can be charged to Part B at $150 a trip. The facility only has 1 Part A patient and 1 Part B patient during the year. The Part B patient had ten trips during the year (total of $1500 billed to Part B). The Part A patient also had ten trips during their 100 days of Part A benefits. The facility is paying its ambulance provider $2 a day to provide all services to its Part A residents. Thus, the facility paid a total of $200 dollars to the ambulance company for all services rendered to its Part A patient. The same amount of services was provided to each patient. All things being equal, the facility saved (or received a discount of) $1300.

Examples such as the two above concerning capitated and discounted differential pricing arrangements represent the most common arrangements that SNFs and ancillary providers are considering. However, the OIG's recent advisory opinion is testament to the notion that these arrangements present serious concerns with regard to potential violations of the Medicare anti-kickback statute.

V. The Recent Advisory Opinion and Navigating the Fraud and Abuse Concerns

On March 4, 1999, the OIG released an Advisory Opinion (99-2) relevant to the arrangements discussed above. The opinion discusses a contractual arrangement between a SNF and an ambulance provider. The arrangement between the parties provided a significant discount (up to 50%) to the SNF for services that the SNF was required to pay the ambulance provider for under PPS and other all inclusive arrangements. The agreement also provided that the ambulance provider would service the SNFs other patients on a fee-for-service basis. The ambulance provider would bill Medicare Part B, private insurance and private pay individuals at its normal rates.

The OIG advised in this opinion that this arrangement could represent prohibited remuneration under the federal anti-kickback statute 42 U.S.C. § 1320a-7B or Social Security Act § 1128B(b) provided that the requisite intent to induce referrals of federal health care program business were present in the arrangement. The federal anti-kickback statute prohibits the offering, giving, receiving or solicitation of illegal remuneration (kickbacks or bribes). Anyone who knowingly and willfully solicits, pays, offers or receives any remuneration, in cash or in kind, directly or indirectly, overtly or covertly, to induce, or in return for arranging for or ordering items or services that will be paid for by Medicare or Medicaid may be guilty of a felony, fined or imprisoned for not more than five years, or both. Essentially, the OIG opined that the possibility of a vio-

lation of the anti-kickback statute exists where the SNF provides the ancillary provider with access to the Part B business in exchange for a low or discounted rate on the Part A business.

The anti-kickback statute does provide certain exceptions or safe harbors.[7] One of the safe harbors to the statute is the "discount" safe harbor. The discount safe harbor generally provides that certain properly disclosed discounts would not be deemed illegal remuneration under the statute if they meet the regulatory framework. However, the discount safe harbor specifically excludes differential pricing arrangements where the discount is "a reduction in price applicable to one payor but not to Medicare or a state health care program."[8] The OIG also addresses the inapplicability of the safe harbor in the opinion.

An interesting issue that has arisen with the release of this opinion is that it seems the OIG has in one way unraveled the goals of the PPS legislation in the BBA and, in effect, "shot itself in the foot." One of the primary goals of the legislation was to control costs by reimbursing SNFs a prospectively determined per diem payment and allow SNFs to be prudent purchasers of the services and supplies that would be covered under that payment to the facility. PPS envisions putting the SNF on the negotiating front line in order to save the Medicare program money overall. An anticipated goal of PPS was that SNFs would negotiate good deals and thus the prospective payments would be readjusted downward to correct for the cost savings the SNFs were achieving.[9] However, as a result of this advisory opinion SNFs will find it difficult to adequately control costs for ancillary services and in effect will have a difficult time negotiating for anything less than the applicable Part B fee schedule amounts. This result will arguably increase costs to the program (provided Medicare would adjust for the increased SNF costs in the future) or send many SNFs out of the program completely. Irrespective of these inconsistent policy concerns, many SNFs are going to continue to enter into arrangements to provide the best possible cost savings while attempting to steer clear of potential fraud and abuse concerns.

As SNFs—and their attorneys—inevitably look to negotiate new agreements with ancillary providers, and they should, prior to entering into any such arrangements, review the OIG opinion in order to become familiar with the issues involved. One scenario that has been suggested would be that SNFs should seek out separate ancillary providers in order to provide services to the Part A/managed care population and the Part B/private insurance population. However, depending on how each ancillary provider provides its services, using different entities has the potential to violate Medicare prohibitions on discrimination and restrictions applicable to one payor class and not the other.[10] Even so, the discounts may still have the potential to violate the anti-kickback statute. Additionally, as many SNFs have seen, using different entities may not actually be possible. Some SNFs in suburban and rural areas only have a single provider of a particular service in its locality. Others who have choices have had significant resident care or other issues with the other ancillary providers that are available that would dissuade them from using those additional providers. For whatever reason, it simply is not an easy solution to find two separate ancillary providers, nor is it necessarily an advisable solution given its own inherent and additional risks.

Therefore, at the very least, if an SNF is going to enter into an arrangement with one ancillary provider, the SNF should undertake the following with regard to any negotiations with the ancillary provider:

- Review the prevailing Medicare Part B rates, the ancillary provider's usual and customary charges and the rates they intend to charge the SNF in order to determine the discount amount, if any, provided to the SNF.
- Ensure that the negotiated and agreed-upon rates provided the facility reflect fair market value for the supplies and/or services from the ancillary provider.
- Compare the discounts provided by the ancillary provider to the actual and/or anticipated savings the ancillary provider may achieve in billing the SNF for certain types of residents (i.e., Part A, managed care, etc.) rather than preparing separate bills for each resident.

Additionally, in order to address the fraud and abuse concerns certain contractual provisions should be included in the actual agreement. However, please note that if what practically occurs violates that statute, what is on paper will not insulate the parties to an agreement from criminal and/or civil liability. While not intended, nor guaranteed, as a shield against potential liability, the following suggestions may be helpful with regard to contractual arrangements between SNFs and ancillary providers:

- Include a provision that specifically delineates the fees for services and supplies and in what situations the services or supplies are to be billed to the SNF or to third party payors and/or the resident directly by the ancillary provider.
- Include a provision that explains correctly and precisely that once consolidated billing is fully implemented the SNF will be billed for all Medicare services.

- Include a provision that states that once consolidated billing is implemented, the rates billed to the SNF must be agreed to in writing and will in no event exceed the Medicare Part B reimbursement rate in effect at that time.
- Include a provision stating that both parties will cooperate in the provision of information to one another which is necessary for billing third party payors.
- Include a provision which states that in the event the ancillary provider bills a third party and it is subsequently determined that the facility should have paid for the service, the ancillary provider will immediately withdraw any claim to the third party payor and/or refund any monies paid by the third party payor and will bill the facility for the service.
- Include a provision stating that the arrangement is a non-exclusive arrangement and the SNF is free to contract for some or all of the services with other ancillary providers.
- Include provisions describing how the discounts were arrived at and how they can be substantiated.
- Include a provision that states the fees provided in the agreement have been negotiated through good faith arms length bargaining and represent the fair market value of the services to be rendered or provided. In addition, the fees provided to the SNF are not in any way conditioned upon the referral of, or arrangement for, the provision of any item or service, to any other residents including, but not limited to, residents with Medicare Part B coverage, private insurance residents, etc.

VI. Conclusion

While there is no guarantee that the OIG will not construe a particular agreement to be in violation of the anti-kickback prohibition, in order to prevent an SNF from falling prey to potential OIG inquiry, the issues in the recent Advisory Opinion should be adequately addressed in any agreement with an ancillary provider. It is clear that these arrangements may be highly suspect as many SNFs have found it extremely difficult to contract at a discount with one ancillary provider for its Part A and managed care business and another ancillary provider for its Part B and private insurance business. As mentioned earlier, other SNFs are simply constrained by locality or other issues to using only one ancillary provider. The end result is that SNFs and ancillary providers need to be careful and do a thorough cost and savings analysis in order to determine whether differential pricing is worth the risk, if it is, whether it can be provided and under what circumstances. It is also clear that enactment of the BBA and in turn PPS presupposed that SNFs would negotiate good deals on their own behalf as they became responsible to provide and bill for all Medicare services. In that regard, monetary pressures have necessitated hard bargaining. However, SNFs cannot ignore the fraud and abuse implications inherent in certain types of arrangements that may very well represent the best negotiated deals.

Endnotes

1. BBA, P.L. § 105-33.
2. *See* 63 Fed. Reg. 26252 and 64 Fed. Reg. 41644, HCFA Medicare Program Memorandums (PM) Transmittal Nos. A-98-45, A-98-37, AB-98-63, AB-98-45, AB-98-35, A-98-20, A-98-16, AB-98-18.
3. *See* Testimony of Senator Hatch, Skilled Nursing Facilities Prospective Payment Act of 1997, Congressional Record S6094-5, June 23, 1997.
4. *See* 63 Fed. Reg. 26252 and 64 Fed. Reg. 41644, HCFA Medicare Program Memorandums (PM) Transmittal Nos. A-98-45, A-98-37, AB-98-63, AB-98-45, AB-98-35, A-98-20, A-98-16, AB-98-18.
5. *See* 63 Fed. Reg. 26252.
6. *See* HCFA Medicare Program Memorandum (PM) Transmittal No. AB-98-35.60.
7. *See* 42 U.S.C. § 1320a-7b and the regulatory safe harbors 42 C.F.R. § 1001.952.
8. *See* 42 C.F.R. § 1001.952(h)(3)(iii).
9. *See* Testimony of Senator Hatch, Skilled Nursing Facilities Prospective Payment Act of 1997, Congressional Record S6094-5, June 23, 1997.
10. *See* 42 C.F.R. § 489.54.

Ari J. Markenson received his B.A. from Syracuse University, his J.D. from Brooklyn Law School and his M.P.H. from Columbia University School of Public Health. He is an associate with the Law Offices of Robert Abrams, P.C. His areas of practice focus on issues in health law, corporate compliance in the health care industry, federal and state legal and regulatory issues affecting acute care and long-term care providers.

Patrick Formato is an associate of the Law Offices of Robert Abrams, P.C. who chairs the firm's Health Law Department. Mr. Formato received his B.A. from the State University of New York at Albany and a J.D. degree from Albany Law School. Presently, Mr. Formato counsels health care facilities with respect to a variety of issues including fraud and abuse, the implementation of corporate compliance programs and a variety of transactional matters.

Brain-Dead Patient or Live Organ Donor? Hidden Pitfalls in Implementing the Donor's and Family's Intentions

By Patrick L. Taylor

While lawmakers have promoted advance planning for health care decision making, through proxies[1] and laws addressing organ donation and procurement organizations,[2] counsel must plan to avoid hidden pitfalls that can frustrate the declared intentions of the brain-dead donor and family.

When a person suffers "irreversible cessation of all functions of the entire brain, including the brain stem," the person is "dead" in accordance with regulations and accepted medical standards.[3] The death must "be registered immediately. . . by filing with the registrar [of vital statistics] of the district in which the death occurred . . . a certificate of such death."[4] Generally, the death certificate must be signed by "the physician, if any, last in attendance on the deceased," except when the death occurs in a hospital, where it can be signed by either the attending physician "or a physician acting in his behalf."[5]

Once death has been declared, the body cannot be moved to a non-adjacent county without the consent of the local registrar.[6] (For purposes of this rule, counties within New York City are considered one county.[7]) That consent may be obtained verbally, but only "upon request by telephone of a licensed funeral director or undertaker who holds a certificate of death signed by the attending physician showing the death resulted from natural causes, and was not the result of accidental, suicidal, homicidal or other external causes."[8]

"A potential recipient's life may depend on immediate action."

If the brain-dead deceased provided for organ donation, or the family legally consents, the death is certified by "the physician who attends the donor at his death and one other physician, neither of whom shall participate in the procedure for removing or transplanting the part."[9] Organ procurement organizations (OPOs)—regulated specialists in organ removal and transport—then become involved in ascertaining whether the donated organs are usable based on screening protocols and the medical record. If an organ is usable, then OPOs—helped by specialist physicians and competent hospitals—attempt to identify a suitable transplant recipient, and arrange for organ retrieval and transport to a transplant center.[10]

These legal rules break down in practice. First, the hospital may not have diagnostic technology or specialists necessary for screening and organ retrieval; the deceased must therefore be transported to a higher order hospital. This is particularly true for heart donations. It will be increasingly true as OPOs obtain more donations from patients requiring more screening, such as older patients, and as OPOs boost organ donation in rural areas where hospitals, however capable, may lack specialist staff or required technology.

"The only current alternative to obtaining registrar consent is to treat the deceased as alive, provided the attending physician at the time of brain cessation has not yet certified death."

But donating patients do not schedule their decease—and the need for transport to a higher order hospital—within the weekday office hours of the local registrar. It may be impossible to wait until the office is open. The patient may be clinically unstable, or the family may agree to donation only if a ventilator is swiftly removed. A potential recipient's life may depend on immediate action.

In addition, verbal registrar authorization is permitted only if requested by the undertaker or funeral director, and the death certificate, on its face, "show[s]" that the death was not a "result of" accidents or other "external causes."[11] The undertaker may be unavailable. It may be impossible to rule out external contributing causes from information known at the time of brain death; external causes may not be definitively excluded until after a pathologist's report from a post-donation autopsy, a coroner's or medical examiner's report, or a hospital's internal root-cause analysis of potential malpractice. Some of these options may take weeks or longer.

The only current alternative to obtaining registrar consent is to treat the deceased as alive, provided the attending physician at the time of brain cessation has not yet certified death. Taking an adventurous view of the law, one might argue that the attending physician who must certify death is the physician attending at the time death is declared, and allow a transplant physician to make that determination post-transport at the higher

order hospital. But then the transplant physician would be barred from participating in the removal or transplant. In addition, the receiving hospital would have to treat the clinically dead patient as an "admission," which means that (1) the death may be reportable to the Department of Health or accrediting bodies, which treat certain deaths as reportable and all deaths as potentially significant, and those regulatory bodies may then count the death as the receiving hospital's mortality; (2) the receiving hospital may be implicated in malpractice or wrongful death litigation or regulatory investigations as the site of death; (3) the "admission" of the patient can automatically trigger inappropriate procedures generally applicable to admitted patients, such as procedures to obtain consents to treatment, generation of a "patient" record, or automated registration and billing procedures; and (4) there may be confusion among the registrars, the physicians and the funeral director over where a death certificate has been filed—there may even be two competing death certificates, with the potential for financial affairs being held up until the confusion is resolved.

". . . the law treats brain-dead persons as dead for some purposes, and incompletely recognizes donor's and families' desire to provide for organ donation."

In short, the law treats brain-dead persons as dead for some purposes, and incompletely recognizes donor's and families' desire to provide for organ donation. Counsel must be aware of logistical issues and to the extent possible mitigate them in advance to carry out the donor's intent; if brain death is clinically likely, advance coordination with the physicians, the funeral director and the registrar may facilitate the eventual process. In addition, lawmakers have shown real leadership in promoting organ donation in this state. Donors, families, recipients, physicians and hospitals need them to exercise that leadership again, so that laws affecting these donations match the realities of transplants from brain-dead donors.

". . . lawmakers have shown real leadership in promoting organ donation in this state."

Endnotes

1. *See* Public Health Law, article 29-C (PHL).
2. *See* PHL, §§ 4301, 4302(5), 4306, 4308.
3. *See* 10 N.Y.C.R.R. § 400.16.
4. *See* PHL, § 4140.
5. *See* PHL, §§ 4141, 4141-a.
6. *See* PHL, § 4144.
7. *See* PHL, § 4144(7).
8. *Id.*
9. *See* PHL, § 4306. Re organ donation procedures generally, *see* PHL, articles 43, 43-A, 43-B. *See* article 43 for procedures by which persons make post-decease organ donations of their own organs, including for transplant, and article 43-B for the authority of family members and guardians to consent to organ donation on behalf of a deceased who has not previously executed a organ donation document.
10. *See* PHL, articles 43-A, 43-B; 42 C.F.R. Part 486.
11. PHL, § 4414(2).

Patrick L. Taylor, Senior Vice President and General Counsel, Albany Medical Center, Albany, New York.

An Overview of the Specialty

By Francis J. Serbaroli

The health care industry is the largest sector of the United States economy, accounting for $1 trillion in annual expenditures and representing about 15% of gross domestic product. Like any other industry of size and complexity, health care generates myriad legal issues and, consequently, a large volume of work for lawyers.

Two commonly encountered questions asked of health lawyers (frequently at the same time) are "What is health law?" and "How do I get into it?" After five years of writing this column, we have covered only a fraction of the many topics that make up the health law specialty. Perhaps this is a good time to return to fundamentals and to explain briefly just what it is that health lawyers do. A later column will address careers in health law.

"The key to understanding the health law specialty is in understanding that health care is probably our most heavily regulated industry . . ."

What the Law Is Not

At the outset it may be helpful to clarify what health law is not. It is not medical malpractice, which is a specialty area of tort law. That is not to say that health lawyers do not become involved in medical malpractice issues. An injury to or the wrongful death of a patient because of a failure to abide by acceptable standards of professional practice not only may involve a malpractice lawsuit against the hospital, physician, resident or intern, nurse or other personnel, but also often triggers a review of the circumstances of the case by regulatory agencies such as the Health Department (which licenses and regulates most non-federal health facilities), the Education Department (which licenses physicians, nurses and other medical professionals) and other government agencies.

It is not the law governing drugs, pharmaceuticals or medical devices, which is mainly the province of the intellectual property bar. After a drug or device is approved by the Food and Drug Administration, however, health lawyers may be called on for assistance in obtaining approvals of the Medicare or Medicaid programs or commercial health insurers and HMOs, to pay for the drug or device.

Health law is also not representing individuals to assist them in qualifying for Social Security, Medicare or Medicaid benefits, disability benefits and the like. Although health lawyers can and do specialize in Medicare and Medicaid payment issues, most often they do so on behalf of providers, who depend on those payors for much of their revenue.

What the Law Is

A health lawyer's clients can span a broad range of industry players, from a single doctor to a multi-state hospital chain and everything in between: nursing homes, clinics, certified or licensed home health agencies, pharmacies, clinical laboratories, physician groups, ambulatory surgery centers, state or municipal health departments, health insurers, health maintenance organizations and managed care organizations.

Clients are also senior residences, assisted living facilities, rehabilitation centers, nurse practitioners, health care-related trade associations, durable medical equipment suppliers, alcohol and substance abuse facilities, physician practice management companies, medical, dental, nursing, pediatric, chiropractic and other training schools.

Also included are ambulance and ambulette companies, ophthalmic dispensers, peer review organizations, hospital medical staffs, medical record transcription services, blood banks, medical billing services, accrediting commissions and agencies, psychologists, mental health programs and facilities and many more.

In representing these types of clients, a health lawyer may become involved in a variety of specialty areas of the law: corporate, regulatory administrative, securities, contracts, commercial, tax, litigation and other areas. Health lawyers sometimes have to deal with ethical and bioethical issues such as violations of professional ethics, the propriety of and protocols for human research and experimentation in health facilities and medical schools, death and dying issues, and so on.

The key to understanding the health law specialty is in understanding that health care is probably our most heavily regulated industry and also in understanding the underlying economic (i.e., reimbursement), regulatory and policy issues that permeate and affect it on a daily basis.

When, for example, a software company is sold, among the many issues that may arise are intellectual property and licensing, securities, tax, corporate, commercial, real estate, etc. When a corporation owns a health care provider and is sold, among the issues that may arise are most of those just mentioned, plus regula-

tory approval of the license transfer (an often lengthy, complex and cumbersome process depending on the state in which the facility is located); Medicare, Medicaid and other third party payor liabilities; transfer or termination of affiliations with other health care providers; residual malpractice, tax and ERISA liabilities; labor matters and a host of other complex issues.

A merger of non-profit hospitals in New York, for example, will involve not only regulatory approvals by the state Health Department, but review and approval by the Attorney General's Charities Bureau, a possible Hart-Scott-Rodino filing with the U.S. Justice Department, filings with the Internal Revenue Service relative to maintaining the facility's tax exemption, negotiating with the Medicare and Medicaid programs and third party payors over new reimbursement rates, and governmental approvals if the facility has debt that is state or federally guaranteed.

Aside from regulatory approvals, such a merger may also involve the negotiation or re-negotiation of medical school or other academic affiliations if the combined facility has teaching programs, the possible creation (and licensing) of a corporate parent, liability insurance or self-insurance issues and many other substantive legal issues.

Fraud and Abuse

With the federal government's massive attack on fraud and abuse (Attorney General Janet Reno has repeatedly stated that health care fraud is the Justice Department's second-highest priority after violent crime) health care attorneys are focusing their attention on the prevention and correction of violations of the so-called fraud and abuse laws: the anti-kick back law[1] the Stark anti-referral law[2] and the federal False Claims Act.[3] Virtually every transaction involving health care providers can have fraud and abuse implications that otherwise knowledgeable non-health lawyers often miss.

Because of the extraordinarily broad wording of the anti-kickback law, arrangements that in any way involve the referral of patients among independent providers raise potential anti-kickback issues. Creative accounting or even innocent billing errors can result in massive penalties to a provider under the False Claims Act.

Providers are not alone in this spotlight: insurers such as Blue Cross and Blue Shield plans that function as carriers or intermediaries for the Medicare program are often investigated and fined for improperly collecting payments from Medicare. The importance of creating effective internal compliance programs cannot be over-emphasized, and the input of experienced health care lawyers is virtually indispensable in the process.

Managed care has spawned the development of many new delivery structures, an alphabetical maze of entities such as the MCO (managed care organization), IPA (independent practice association), PPO (preferred provider organization), PHO (physician-hospital organization), PSO (provider service organization), IHS (integrated health system), MSO (medical service organization, sometimes referred to as a PPM, for physician practice management), IDS (integrated delivery system) and others.

". . . Attorney General Janet Reno has repeatedly stated that health care fraud is the Justice Department's second-highest priority after violent crime . . ."

Managed care's legal issues range from the corporate structures of these provider entities, to licensing, regulatory and professional ethical issues, to negotiating payment arrangements with HMOs and other MCOs. In representing HMOs, health lawyers may deal with such issues as denial of payment for necessary treatment, possible malpractice liability, negotiating capitated payment arrangements with providers, compliance with applicable provisions of the Public Health Law and Insurance Law governing an HMO's finances, payment policies, marketing practices, quality and utilization review procedures.

Hospitals and some other types of facilities, such as large diagnostic and treatment centers, have organized medical staffs responsible not only for the medical care provided by the facility, but for many internal procedural functions as well: reviewing and approving the admission of new members to the staff and renewals of the privileges of existing staff members, peer review and quality assurance functions corrective and disciplinary actions, and so on.

Health lawyers play an important role in advising medical staffs on how their bylaws are worded and enforced, assisting the staff in compliance with the bylaws' due process provisions in disciplinary cases and in carrying out the many other functions and procedures required by the bylaws, as well as by law, regulation and the standards of various accrediting organizations.

Rights of Patients

The area of patient rights has become increasingly important in health care law. Obtaining the proper consents for medical treatment and/or conducting medical research has raised many justifiable concerns over the years, as have the more recent issues involving right-to-

die and assisted suicide. The appointment of guardians for incompetent patients often involves many clinical and legal issues, particularly where invasive procedures such as surgery may be necessary.

A patient's reasonable expectation that the confidentiality of his or her medical information will be respected and protected is another issue that has come to the forefront, particularly with the advent of computerized medical records and the electronic transmission of medical information to and among providers, insurers, clearinghouses and other interested recipients. Both the federal government and many states are currently working to increase confidentiality protection, and it is likely that we will see an increase in regulatory enforcement actions as well as private suits when breaches in confidentiality occur.

"Health law's burgeoning growth stems not only from the expanding demand for legal services in a rapidly evolving marketplace, but also from the range of interesting and challenging legal, financial and policy issues that health lawyers face on a daily basis."

Since the vast majority of American hospitals are nonprofit and tax-exempt, the tax issues facing health facilities can be a subspecialty of both tax lawyers and health lawyers. The IRS recently has been pressing nonprofits to justify their tax-exempt status by demonstrating the levels of uncompensated services and benefits that they provide to their communities. Entrepreneurial hospitals can jeopardize their tax-exempt status by engaging in too many for-profit activities and joint ventures.

Among other areas under active scrutiny by the IRS are private inurement in the form of excessive executive compensation, use of tax-exempt premises and resources for profit-making activity, self-dealing by officers, directors/trustees and key employees and improper recruitment incentives for physicians. Not only are many of these a concern from a tax point of view but they raise serious issues under the fraud and abuse statutes as well.

Institutional health care providers are both capital-intensive and labor-intensive, and handling labor matters for a health care provider requires familiarity with, among other things, those employed professionals who fall under collective bargaining classifications and those who are exempt. Disciplinary actions against employees of health care facilities often involve such clinical issues as deficiencies in rendering patient care, failing to follow medical protocols and procedures, etc.

The employment of individuals with disabilities such as HIV, physical handicaps and the like can raise complicated legal issues, for example, if their job responsibilities place them in a clinical workplace. The ability to draft hospital-physician employment agreements properly is a health law staple.

The foregoing barely skims the surface of this specialty area of the law. Health law's burgeoning growth stems not only from the expanding demand for legal services in a rapidly evolving marketplace, but also from the range of interesting and challenging legal, financial and policy issues that health lawyers face on a daily basis.

Those interested in learning more about health law should consider joining the American Health Lawyers Association ((202) 833-1100), which sponsors numerous educational programs during the year and distributes to members a newsletter, useful articles and case digests on a monthly basis. (Membership in the AHLA is not restricted to lawyers.)

Membership in the New York State Bar Association's Health Law Section ((518) 463-3200) offers access to New York-specific programs and a periodic newsletter, as well as the opportunity to get to know other New York lawyers who practice in the field. Local bar associations, such as the Association of the Bar and the New York County Lawyers' Association, also have health and health-related committees.

Endnotes

1. 42 U.S.C. § 1320a-7b.
2. 42 U.S.C. § 1395nn.
3. 31 U.S.C. §§ 3729 et seq.

Francis J. Serbaroli is a partner at Cadwalader, Wickersham & Taft.

This article is reprinted with permission from the July 30th issue of the *New York Law Journal.*

Committee Report

Who Needs to Know?—The Search for a Balance Between Health Information Privacy and Confidentiality

A Compilation of Suggestions Presented to Selected Members of Congress Health Law Section, New York State Bar Association, June, 1999[1]

The Study Group of the New York State Bar Association/Health Law Section

Executive Summary

During the Winter of 1998, the Chair, at that time, of the Health Law Section ("HLS") of the New York State Bar Association ("NYSBA") requested the chair of the HLS's Legislative Committee to form a subcommittee that would review recommendations submitted to Congress by the Secretary of Health and Human Services ("Secretary" or "Secretary Shalala;" "HHS") on the issue of health information privacy. Submitted on September 11, 1997, the recommendations are entitled *Confidentiality of Individually – Identifiable Health Information: Recommendations of the Secretary of Health and Human Services pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996* ("Recommendations;" "HIPAA").

The subcommittee, consisting of seven members with various backgrounds and very busy schedules, started conference call meetings in the Spring of 1998. The subcommittee called itself the HHS Study Group ("Study Group"). The complexity of the issues regarding health information privacy became apparent very quickly—to wit, how would such a voluminous issue be approached?

The commitment of time from people who had very little of it to spare was a constant motivator. As the Study Group progressed, it tripled in size; however, the vicissitudes of life were a constant, several members had to drop out due to circumstances beyond their control.

The Study Group decided that its final product would not be a "definitive report" on health information privacy, but instead would be a submission of suggestions based upon group discussions of the Recommendations. The Study Group also created eight guiding objectives (listed on page one) that served as a foundation for its suggestions.

This work product consists of the Study Group's guiding objectives, suggestions, and conclusion, which has been submitted to the chairperson of several committees. They are the committee on: Health, Education, Labor and Pensions of the Senate (including the committee members); Finance of the Senate; and both the Committee on Commerce; and, Ways and Means of the House of Representatives. Since the Secretary's Recommendations were sent to these committees, it was deemed wise for the Study Group to do the same. The work product has also been sent to the Majority and Minority Leaders of the Senate and the House of Representatives; the Speaker of the House of Representatives; and, the entire New York State delegation.

It is hoped that you will find these suggestions useful as Congress embarks on the daunting task of developing a legislative framework for the issues regarding health information privacy, as mandated by the HIPAA legislation.

Claudia O. Torrey, Esq.
Chair
The Study Group of the
NYSBA/HLS

I. Guiding Objectives

1. The patient's privacy must be protected.
2. The patient has an absolute right to review his/her records, except in enumerated circumstances; the patient should also have a right to append comments.
3. There should be efficient procedures for maintenance and delivery of medical records.
4. Utility – every suggestion must address a specific concern.
5. There must be clarity without redundancy in the suggestions.
6. The suggestions must be practical and workable.
7. Except for a patient's right of access, the right of access only follows the need for access.
8. Federal law should preempt State law, *but only if* Guiding Objectives 1 through 7 are incorporated into final legislation.

The report reflects a consensus after much discussion. Thus, the reader should be aware that while each Study Group member may not *personally* agree with

every objective and/or suggestion within this work product, common ground was found with concepts that will hopefully be for society's greater good in the long term.

II. General Comments and Suggestions Regarding Recommendations on Disclosure and Certain Special Areas

A. General Comments

Until relatively recently, an individual's health/medical record was maintained at a physician's private office or at a hospital. There was minimal review of this record, just the occasional inquiries by insurers and hospital quality reviewers. Individuals could reasonably maintain the belief that their records were held with a significant degree of confidentiality.

The health/medical record as we once knew it (paper document) is fast diminishing in our technologically oriented world. The "paper medical record" is becoming an electronic wire or concept that has varying dimensions depending on the software and the database with which it interfaces.

Because the "protection" of the medical record has largely been based on its location (and thereby the type of provider or end-user), the legal protections have been slim (particularly in private sector or non-governmental settings). Literally, a medical record located in a physician's office file (with some legal controls) could become a different animal (free of some legal controls) located in an insurance company file. The health data itself (i.e. the medical record), and *not* its location, needs to be secure. In today's society, the therapeutic relationship may not always be with a physician. This is particularly true within the framework of managed care. As one's health information is collected, electronically transmitted, and linked, virtually anyone in the health care system (physician and non-physician alike) can "bring up" one's medical record on a computer screen.

Medical/health record information travels interstate, as well as intrastate. Indeed, the European Union has a Directive on Data Protection[2] that forbids members from transferring data to nations that do not have sufficient data protection(s). This would necessarily impact upon the United States.

As a threshold matter, within the Recommendations, the Secretary has separated "disclosure" proposals into two parts: (i) disclosures with patient authorization[3] and (ii) other disclosures – those without patient authorization.[4] The latter, which recommends express and implied disclosures under certain circumstances, including disclosures to payors and their "service organizations," is troublesome.

To justify certain automatic disclosures to payors, the Secretary explains that the patient authorization process is ritualistic, inefficient and cumbersome, ultimately resulting in higher costs to patients.[5] The Secretary also observes that the patient authorization process offers little utility because the individual authorization forms are often meaningless to the patient. Because payors often need to review medical records to cover treatment, the Secretary expresses a concern that the current patient authorization requirement could impair care by delaying treatment.[6]

We are troubled by the Secretary's broad stroke elimination of the patient authorization process for payors. While we agree that the patient authorization process may be ritualistic, the Secretary has offered no empirical evidence indicating that the patient authorization process is "inefficient" or "cumbersome." Also, there is no offering of any empirical evidence that the patient authorization process results in a delay in treatment. Indeed, because the patient authorization process is pro forma,[7] most payors and other healthcare entities obtain individual authorization as a matter of course at the time an individual enrolls in a health plan, or obtains treatment. The Secretary neither offers nor presents any evidence indicating that the authorization process, which has been in use in one form or another for most of this century, results in a burden to payors or providers.

More importantly, the patient authorization process offers important benefits. At the very least, it reminds the patient on different occasions that his/her medical records will be reviewed by third-party payors. It also offers patients a window of opportunity to prevent such a release of information for any reason the patient so desires.

Given that we question whether patient authorizations truly result in higher costs and inconveniences, and that we find that patient authorizations not only serve as an important recitation of patient rights, but also offer patients clear opportunities to prevent disclosures, we submit that Congress should not promote the Secretary's general approach to express and implied disclosures.

B. Suggestions Regarding Recommendations on Disclosure and Certain Special Areas

1. Recommendation D—Disclosures Authorized by the Patient[8]

This proposal sets forth recommendations regarding the disclosure of information pursuant to an authorization signed by a patient. Specifically, it describes conditions under which a third-party may request medical

records pursuant to a patient authorization, and regulates the content of the patient authorization.

As previously discussed, we support the notion of requiring patient authorizations. We also support regulating the content of patient authorization forms. We believe that such regulation can help ensure that patient authorizations are obtained knowingly and voluntarily.

Indeed, we believe that the Secretary should go further than simply regulating the content of patient authorization forms—she should draft a model form which can be used universally by all third-parties. A model uniform form will accomplish two of the objectives that the Secretary identified—efficiency and clarity. It will allow third-parties and patients alike to become familiar with a single form. Moreover, a uniform form will allow providers and payors operating in multistates to simplify their operations by using one authorization form, instead of a myriad of forms.

Notwithstanding our general support of Recommendation D, we find one particular recommendation counterproductive. Recommendation D (2) requires third-parties, who request medical information, to give patients a copy of their authorization. If the patient is executing a written authorization to release her/his information, why should the patient not be expected to retain a copy? Recommendation D (2) would undoubtedly increase bureaucracy, without providing any measurable benefit to patients.

We further suggest that Recommendation D(1), regarding revocations of patient authorization, deserves more clarity. The recommendation fails to specify whether the revocation is directed to the provider, the payor, or both. Similarly, it is not clear if a revocation must be in writing or communicated orally. Recommendation D(1) also fails to specify when and how a revocation is to be effectuated.

2. Recommendation E—Other Disclosures[9]

This section describes circumstances under which medical records may be disclosed without patient authorization(s). It would allow payors (and their service organizations), health oversight entities, and research entities to obtain individually-identifiable medical information from a provider directly and automatically.

As discussed above, we have fundamental concerns regarding the elimination of the patient authorization form for payors. Related to those concerns, we are troubled that the Recommendations contemplate that "payors" and "service organizations" include a panoply of entities that may be involved in only tangential or peripheral aspects of reviewing/paying a claim.[10]

Another area of concern is health oversight.[11] The Study Group submits that the Recommendations refer to examples of oversight activities, but do not define, with precision, the term "health oversight activities." Such is a fundamental deficiency because, as an exception to the general rule requiring patient authorizations, access by health oversight entities should be confined to clear and finite activities. Without a clear limitation, countless entities, government and private, are likely to claim access to records under the rubric of health oversight—a result that could flout patient privacy.

Assuming the term "health oversight activities," as utilized in the Recommendations, covers customary, traditional governmental, and private oversight activities, we would support the health oversight exception. Such an exception would be consistent with both Federal and State laws.

We also believe that a health oversight entity should receive redacted medical records (eg. names, social security numbers, etc.). For example, law enforcement[12] should not only be required to have a court order *prior* to obtaining a person's medical records, they should also be prohibited from redisclosing information for any purpose unrelated to their oversight activity. Oversight entities operating in one capacity, should not be permitted to share medical records with oversight entities operating in other capacities—such unfettered sharing "chills" the cooperative efforts of patients and providers with oversight entities.

With respect to research,[13] we support the Recommendations. We believe that these recommendations are consistent with current law, and contain adequate safeguards to protect patients. However, it is suggested that potential federal health privacy legislation extend such safeguards to privately funded research that utilizes individually, identifiable information.

3. Recommendation F (7)—Disclosures Relating to Banking and Payment Processes[14]

The Secretary recommends that providers and payers be permitted to make disclosures without the patient's consent in connection with payment, and that anyone directly involved in payment or billing transactions be permitted to use or disclose health information only for purposes directly related to payment transactions. The failure to clarify or define "minimum amount of health information necessary" could, theoretically, allow those involved in payment or billing transactions the opportunity to define for themselves the minimum amount of information needed, and to obtain more information than is appropriate.

In general, financial institutions do not access, or have a reason to access, medical records and other spe-

cific patient information. There may, however, be a concern that the mere identity of a provider (eg. ABC reproductive clinic; XYZ mental health clinic; etc.) could reveal certain sensitive information. If that is the type of concern at issue, we strongly suggest that Congress expressly identify what type of health information may and may not be given to a financial institution (perhaps 42 U.S.C. § 1320d-8 should be re-evaluated).

In many instances, the information provided to a debit or credit card issuer to obtain payment would be unlikely to constitute medical record information, for which consent would be necessary before the disclosure could be made.[15] In those instances where it could be argued that confidential information is being sought or disclosed, implementation of this recommendation would enable the provider to avoid having to approach the patient. In areas of particular sensitivity, patient rights should be respected, and the patient should be directly involved in the decision to disclose the information. We believe the *onus* should be on the provider—the provider should either obtain authorization from the patient, or ensure that there is no disclosure of sensitive information that could be construed as confidential.

4. Recommendation F (1) and F (2)—Deceased Persons[16]

There appears to be no compelling reason or justification for limiting the confidentiality otherwise accorded to medical records to a two-year period following the death of the patient. The considerations which give rise to the privilege are no less persuasive in the third and subsequent years following death than they are during the patient's life time, or within two years after his or her death. We suggest that no such two-year limitation be imposed.

We further contend that the portion of the Secretary's Recommendation F (1) which gives "control of the patient's health information" to the decedent's executor or administrator, or, in *under specified* conditions, to the next-of-kin, or, to the "holder of the health information," is unwise. We suggest, instead, that any waiver of the privilege with respect to a decedent's medical records or history, be subject to approval of an appropriate court, which, acting upon a simple petition, and upon notice to appropriate interested parties, would be required to balance the relative merits of continuing the privilege against some alleged public good or necessity.

Being of the mind that all medical records and communications should be accorded the widest privilege against disclosure, with exceptions being limited to those created by well considered statute, we conclude that the proposed two year limitation is unwise and unacceptable. There seems to be no logical support for a two year limitation on the confidentiality of medical records of a deceased person. Reputation and privacy are prominent factors in the lives of most human beings, and it cannot be assumed arbitrarily that any one of them would freely release the benefits of confidentiality after the two year period recommended. This is particularly true of public figures, whose confidential, personal history will long be of interest to the public. The prospect of hordes of media personnel awaiting the two year anniversary of the death of prominent citizens suggests the unreasonableness of placing any limit on the blanket of confidentiality which is generally accorded to medical records and communications. There appears to be no reason which justifies the recommended time limitation. It should be kept in mind that involved in this question is not only the reputation of the deceased, but also the peace of mind of possible surviving spouse and family. In passing, it should be noted that even the two year period of limitation may be, under the recommendation, avoided by including waiver by an executor or administrator, or in their absence by next-of-kin, or in the absence of all of those, by the holder of the information.

Of real significance on this subject of the effect of death on the confidentiality privilege, is the recent decision of the Supreme Court of the United States in *Swidler & Berlin v. Hamilton*.[17] This case deals with the attempt of Independent Prosecutor Starr, during the days of the "Travelgate Investigation," to obtain the notes taken by the attorneys who were consulted by Vincent Foster, a few days before he committed suicide. The Federal District Court[18] granted the petition whereby the attorneys sought to quash the subpoena by which the Special Prosecutor sought to obtain the notes, finding that they were privileged by virtue of the attorney-client relationship, and by the attorneys work product rule. The Circuit Court of Appeals,[19] applying a "balancing test," reversed, holding that there is a posthumous exception to the privilege for communications whose relative importance to a particular criminal litigation is substantial. It was also held that the notes sought were not protected by the attorney work product rule.

The dissent,[20] by Judge Tatler of the Circuit Court of Appeals, asserts that the attorney-client privilege found its first expression in the courts of Elizabethan England, and was accepted in the earliest days of our republic.[21] He observed that since "at least the mid-nineteenth century, the common law has protected the attorney-client privilege after a client's death,"[22] and that both "state and federal courts have consistently followed the common law rule."[23]

In reversing the Circuit Court of Appeals, the Supreme Court, which accepted Judge Tatler's philoso-

phy on the subject, noted that the attorney-client privilege is one of the oldest recognized privileges for confidential communication.[24] The Court's interpretation "of the privilege's scope" is guided by the principles of the common law, as interpreted by courts in the light of reason and experience.[25]

Any pleasure or hope that the advocates of the physician/patient privilege might initially feel upon reading *Swidler* quickly dissipates upon reflection. That favored privilege is not founded in the common law, is not substantive in nature, and finds its origin in a procedural statute, which merely specifies what a physician or nurse be "allowed" or "required" to state in a pending litigation. Moreover, even if the privilege were based on the common law, it is subject to modification or limitation by statute, which is what New York State has expressly done in providing that the stated health personnel "shall be required" to disclose otherwise privileged material about a deceased patient, unless someone bothers to object, or unless the memory of the decedent would be disgraced by the proposed revelation.[26]

Whereas rejection of the proposed two year limit specified in the Recommendation is compelling, more difficult is the wisdom of vesting in the various persons or entities enumerated in the proposal the right or power of waiving the confidentiality privilege with which the decedent was blessed. Given the reverence with which the privilege is held, various considerations present themselves.

With hospitals, laboratories, physicians, nurses, and public officials as possible holders of sensitive information about what may be to them an anonymous decedent, one can hardly expect any thoughtful consideration to a request for waiver of the privilege.

Given the various conflicts which often arise in the administration of estates, particularly between children, surviving spouse, legatees, next-of-kin, and what are sometimes institutional executors or administrators, the proposal gives little assurance that the reputation of the decedent, or even the surviving family, will be accorded proper weight in arriving at the decision as to whether or not the privilege should be waived under particular circumstances. It is easy to conceive of a host of scenarios where an unfeeling executor is motivated by the personal gain which might be had by agreeing to a requested waiver: a vindictive surviving spouse, eager to harm the reputation of the decedent; an executor or administrator who sees as attractive the increase of estate assets which may result from sale of the waiver to some biographer or member of the media. On the other hand, children or other issue of the decedent, desperately needing DNA or other medical evidence available in the decedent's medical records, may well be thwarted by the holders of the waiver power.

With regard to Recommendation F (2), it is obvious that the realities of life, and sound public policy, requires that where the identity of a body, or the investigation of a possibility of crime by coroner or medical examiner is involved, release of otherwise confidential medical information is appropriate. It is apparent, however, that both aspects of the Recommendation go much further than is necessary.

First, it must be clear that implicit in the identification inquiry is the concession that at the point of the request for release of information, it is not certain that the person whose records are sought is the deceased whose identity is in question. It is possible that there is no relationship between the person whose records are sought and the unidentified deceased. Several limitations on any released medical information should be imposed: (a) release of only such information as is required to complete a physical identification should be required; and (b) the release should be only to a coroner or medical examiner, not to the police department or other investigation unit, and then only under the legal obligation to treat the released medical information under continued confidentiality.

Second, if the phrase, "or to aid a medical examiner's or coroner's investigation" is intended to relate solely to identification of the deceased, then nothing further need be said. If it relates to the investigation other than that involved in identifying a body, such as the investigation of possible crime, or settling the question of cause of death, then the point should be made that any release of medical information or communications should be with the legal obligation on the part of the recipient to treat as confidential all matter received.

Therefore, the Study Group puts forth the following suggested modification to recommendation F (2):

> We recommend that health information be permitted to be disclosed to a coroner or medical examiner, but only to the extent that such information is necessary to identify a dead person, or to aid said officials in the investigation of a suspected crime. Information so disclosed, shall be treated as confidential by such recipients, and released only to the extent required to further such identity process or investigation.

5. Recommendation F (3)—Correctional and Detention Facilities[27]

This recommendation smacks of gross insensitivity. Its inherent vice is that it assumes that inmates in correctional institutions, as well as any person detained under provisions of law, have no rights whatsoever. Rather than deal with the realities of prison life, the proposal strips persons in custody, for any reason, of

any rights with respect to their medical history, whether or not that history is necessary for the conduct of institutional living, and without any assurance that the information obtained by wardens, guards or even other prisoners, will not be misused. It fails to make any distinction between classes of inmates, civil prisoners, or temporary detainees. What is particularly egregious about this is that it is unnecessary. To the extent that medical information about a person or person in custody is necessary, it should be available to prisons and other like institutions. There is no reason to strip that information of the intended benefits of confidentiality, and relieve officials of all responsibility for the handling and disposition of that information. Particularly is that true, where many states and municipalities have already, or are in the process of, privatizing correctional institutions. Therefore, we suggest Congress consider the following wording with regard to Recommendation F (3):

> Where medical information and/or records are required by any correctional facility, prison or other institution of detention, the same shall, upon written request of a physician, or other health care provider, employed by, or working for or with the same, be furnished to such facility, prison or institution. Upon receipt, such information shall be kept confidential, except where necessary for the evaluation or treatment of the prisoner involved, and shall not be admissible in any action or proceeding, except wherein such health information is relevant to the condition, classification, punishment or treatment of such prisoner by the institution.

6. Recommendation F (4)—Minors[28]

We suggest that the Secretary's Recommendation F (4) be disapproved in its entirety. The said Recommendation injects the Federal Government into a very sensitive area of the relationship between children and their parents, and impacts upon the right of parents, or persons in loci parentis to have access to medical information which concerns the physical, mental and emotional health of their children or wards. The profound, and sometimes violent, disagreement generated by this subject suggests that it should be left to the wisdom of the various states, and should not be pre-empted by federal regulation.

7. Recommendation F (5)—Powers of Attorney[29]

This recommendation is an excellent example of why the preemption issue is *so* important. The Study Group Guiding Objectives reflect ceiling preemption *if and only if* certain conditions are met. If Congress considers adopting ceiling preemption in the area of federal health privacy legislation, we, the Study Group, *strongly* suggest(s) mirroring New York State's Health Care Proxy statute.[30]

Through the allowance of health care proxies and their corollary, "living wills," New York law provides ample means to ensure that an incompetent patient's previously expressed desire to have certain decisions regarding his or her health care, such as whether to accept artificial life support, is effectuated. Thus, federal legislation affording protection along the same lines, as recommended in the second part of Recommendation F (5), would merely be superfluous. Moreover, federal legislation which affords protection along different or inconsistent lines could only serve to muddy the relatively clear waters created by Article 29-C's statutory health care proxy prescription and the state judiciary's recognition of "living wills," creating controversy, and the potential need for litigation, at a sensitive time when neither is in the patient's or his family's best interest.

The New York State General Obligations Law[31] ("GOL") recognizes the elective creation of a "durable" power of attorney which will remain effective from the date of its execution by a competent principal even though that principal subsequently becomes disabled, incapacitated or incompetent. Moreover, the GOL also provides for the creation of a "springing" power of attorney, which becomes effective only upon the occurrence of a defined future event.[32] Accordingly, the power of attorney, as it is recognized by New York law, may be securely relied upon for protection, management and disposition of the principal's assets, and like its health care counterpart, the health care proxy, provides sufficient protection to the principal so that federal legislation governing those instruments would only serve to be detrimental.

If Congress adopts floor preemption in the area of federal health information privacy legislation, we suggest that federal law be enacted and preempt a State's law regarding health care proxies and powers of attorney (presumably regarding the disclosure of otherwise confidential information) only in the following circumstances; (i) where the state law that is being preempted is *less protective* than the preemptive federal law; or (ii) where the proxy or power of attorney is sought to be used in a state different than that state in which, and pursuant to whose law, it was prepared. State law which is equally, or more, protective than federal law on the issues of health care proxies and/or powers of attorney should, other than in the foregoing limited circumstances, control.

8. Recommendation F (6)—Patients Unable to Make Choices for Themselves[33]

Irrespective of whether or not Congress adopts floor or ceiling preemption in the area of federal health privacy legislation, we suggest that language similar to the following be added to the first part of recommendation F (6):

> These rights may also be exercised by a person appointed as the patient's surrogate or health care agent, or such other person as is designated by applicable state law for appointment to make healthcare decisions on behalf of the patient, or in the absence of such person.

Such language could be quite useful if floor preemption is adopted, particularly for those states that do not provide for the appointment of a "healthcare power of attorney."

Suggested language for the second part of recommendation F (6) reads as follows:

> Anyone exercising these rights should be required to consider the patient's wishes with respect to the disclosure of protected health information and, only if such wishes cannot be reasonably known with reasonable diligence, should the agent make a decision that he/she believes to be in the patients best interests. The agent's decisions should be carried out without the need for an independent investigation into the patient's wishes or best interests, so long as the decisions of the agent are reasonable under the circumstances and there is no evidence of the patient's contrary wishes, or of a decision that would have a materially greater chance of advancing the patient's best interests.

We further suggest that any federal health privacy legislation that tackles this area should fully describe the procedure(s) for determining patient incapacitation, when said patient has not been legally adjudicated incompetent, or has not been appointed a legal representative. Suggested language reads as follows:

> (a) A determination that the patient is not capable of exercising his or her rights under the legislation shall be made by the patient's attending physician to a reasonable degree of medical certainty. The determination shall be made in writing and shall contain such attending physician's opinion regarding the cause and nature of the patient's inability to exercise his or her rights, as well as its extent and probable duration. The determination shall be included in the patient's medical records.
>
> (b) If an attending physician of a patient in a general hospital or mental hygiene facility determines that a patient is incapable of exercising his or her rights under the legislation because of a mental illness, the attending physician who makes the determination must be, or must consult with, for the purpose of confirming the determination, a qualified psychiatrist. A record of such consultation shall be included in the patient's medical records.
>
> (c) A physician who has been appointed as the patient's health care agent or who is the patient's next-of-kin shall not make the determination of whether the patient is capable of exercising his or her rights under the legislation.
>
> (d) A request for the determination of whether a patient is capable of exercising his or her rights under the legislation shall be made by an attending physician if requested by the patient's healthcare agent or next-of-kin. The attending physician may also make such a determination without such a request if the patient has not appointed a health care agent and has no next-of-kin.
>
> (e) The attending physician shall promptly give notice of a determination that the patient is not capable of exercising his or her rights under the legislation (i) to the patient, orally and in writing, where there is any indication of the patient's ability to comprehend such notice; (ii) to the agent, next-of-kin or health care provider , as applicable; (iii) if the patient is in or is transferred from a mental hygiene facility, to the facility director; and (iv) to the conservator for, or committee of, the patient.
>
> (f) A determination that a patient is not capable of exercising his or her rights under the legislation shall not be

deemed a determination that the patient lacks capacity for any other purpose.

(g) Notwithstanding a determination pursuant to this provision that a patient is not capable of exercising his or her rights under the legislation, where the patient objects to the determination that he or she is not capable of exercising his or her rights, or where the patient objects to a particular decision of the health care agent, next-of-kin or health care provider, as applicable, under the legislation, the patient's objection or decision shall prevail, unless the patient is determined by a court of competent jurisdiction to be incapable of exercising his or her rights under the legislation.

(h) The person or entity disclosing protected health information shall confirm the patient's continued inability to exercise his or her rights under the legislation prior to accepting the authority of the health care agent, next-of-kin or the patient's health care provider, as applicable, to disclose such information, other than those disclosures made at or about the time of the initial determination made pursuant to this provision. The confirmation shall be stated in writing and shall be included in the patient's medical records. The notice requirements set forth in subsection (e) of this provision shall not apply to the confirmation required by this sub-section (h).

(i) In the event the attending physician determines that the patient has regained his or her ability to exercise his or her rights under the legislation, the authority of the health care agent, next-of-kin or health care provider, as applicable, shall cease, but shall recommence if the patient subsequently loses his or her ability to exercise his or her rights under the legislation, as determined by this provision.

Such language could be very useful, yet not run afoul of mandatory reporting laws as outlined in Recommendation G (1).[34]

III. Commentary Suggestions Regarding Enforcement Issues

The Secretary states that the ability to seek redress for violations is an important element of confidentiality protection.[35] There have been, and will continue to be, improper disclosures of health information through negligence or deliberate choice.[36] We agree with the Secretary's Recommendations covering both civil and criminal enforcement.[37]

It is noted that the federal "wiretap laws,"[38] which prohibit the unauthorized interception of, or access to, wire, electronic, or oral communications, did contemplate computer to computer communication of medical records between hospitals and/or physicians offices.[39] Such a breach allows for imprisonment up to five years,[40] or civil action for money damages and other appropriate relief.[41]

The recommended enforcement proposals also serve to further enhance federal law(s) regarding: fraud and related activity in connection with identification documents and information,[42] fraud and related activity in relation with access devices,[43] and fraud and related activity in connection with computers.[44] In particular, 18 U.S.C.A. § 1030 (8)(B) expressly includes any impairment to the integrity or availability of data, a program, a system, or information that modifies or impairs, or potentially modifies or impairs, the medical examination, diagnosis, treatment, or care of one or more individuals.[45]

The Secretary has recommended that, where civil liability arises, alternative dispute resolution procedures be made available to individuals whose rights to confidentiality of health information have been violated[46]

Alternative Dispute Resolution ("ADR") includes a variety of different methods for resolving disputes, other than through litigation. Some of the more common processes of ADR are arbitration, mediation, early neutral evaluation, and summary jury trials.

Arbitration is a process in which a dispute is submitted to a neutral third party who makes decisions after hearing arguments and reviewing evidence. This process is often more formal than mediation, may be mandatory as provided by contract, and may be binding on the parties.

Mediation is an informal, voluntary process involving a neutral party who assists parties in communicating the issues of their dispute, and attempts to bring the parties to a mutually acceptable agreement. The resolution achieved in mediation is often not binding on the parties.

Early neutral evaluation involves presentation of each side's case to a neutral third party, who assists the parties in identifying the strengths and weaknesses of their respective positions, and advises them on the decision that a judge or jury would likely render.

Summary jury trial is an evaluation by a panel of jurors who are not informed in advance that they are serving in an advisory capacity only. The parties' attorneys present a summary of their evidence to this jury, which renders a decision, but the decision is advisory only and has no binding or legal effect.

The recommendation of the Secretary regarding the use of ADR for violation of a federal confidentiality law where civil liability arises fails to address such issues as (a) the types of cases or circumstances where ADR would be used; (b) whether ADR would be voluntary or mandatory, and if mandatory, whether it would be based on certain monetary threshold amounts; (c) who would pay for ADR expenses; and (d) whether ADR would be available only in a civil action brought by an aggrieved individual or in civil actions brought by the Secretary.

The federal Administrative Dispute Resolution Act[47] ("The ADR Act") provides for various forms of ADR in federal courts and requires that each agency adopt a policy that addresses the use of ADR in managing its cases. Arbitration is one of the means of ADR available, but only if all of the parties consent to the arbitration proceeding in a written agreement. The agreement must specify the maximum award that may be issued by the arbitrator and may specify other limitations on the outcome. The arbitration award becomes final and binding on the parties 30 days after it is served on all parties, unless a person adversely affected brings an action for judicial review pursuant to the Federal Arbitration Act[48] ("Federal Arbitration Act"). The initial decision by an agency to use or not to use ADR to resolve a controversy is left entirely to the discretion of the agency.

The ADR Act was enacted because Congress found that ADR (a) offers a prompt, expert and inexpensive means of resolving disputes as an alternative to litigation in federal courts; (b) is faster, less expensive and less contentious; and (c) can lead to more creative, efficient, and sensible outcomes.

The Federal Arbitration Act, enacted in February 1925 and amended repeatedly thereafter, permits a court to stay the trial of an action where it is referable to arbitration due to a written agreement between the parties.

In view of the foregoing, the concept of ADR being utilized for health information privacy issues is supported. However, we suggest the following modifications:

(i) prescribe the types of cases or circumstances where ADR will be available;

(ii) address whether ADR will be available as a voluntary option if the parties agree; and

(iii) address whether payment for ADR will be borne by the losing party, or as otherwise agreed to by the parties

These suggested modifications serve to enhance an otherwise good and unique idea.

IV. Conclusion

The medical community's Hippocratic Oath mandates that physicians keep confidential patient information "which ought not to be spread abroad."[49] Needless to say, adhering to this objective or principle evolves with modern societal changes. Moving toward the twenty-first century requires America to have a comprehensive and consistent protection scheme in place for health information. The rising influence of managed care, along with increasing advances in computer technology, has created wider access to, and many users of, health information.[50]

Congress has grappled with the issue of health information privacy for well over twenty years. The HIPAA mandate gives Congress both the exciting opportunity and the awesome responsibility to legislatively maintain the principle(s) of the Hippocratic Oath, while simultaneously keeping America in step with modern health technologies.

The concepts of health care quality and health information privacy need not be in conflict. Issues pertaining to the confidentiality and privacy of health care information should neither impede upon, nor be a barrier to health care access. Indeed, respect for these issues will necessarily promote health care access. The American people *need* to be able to trust in their health care system's ability to protect their personal health information.

It is hoped these suggestions have been helpful and useful. Thank you in advance for considering the Study Group's point(s) of view.

Respectfully submitted,
The Study Group of the
NYSBA/HLS

Endnotes

1. The Health Law Section Executive Committee approved this Report at its October, 1999 meeting. Unless and until adopted in whole or in part by the Executive Committee or the House of Delegates of the New York State Bar Association, no part of this report should be attributed to the Association.
2. Council Directive 95/46 EC, art.24, October 1995 O.J. (L.281) 31-50 ("European Directive"); *See also*, European Directive, art. 25.
3. Recommendation D at 38.
4. Recommendation E at 42.
5. *Id*. at 42-44.
6. *Id*. at 42-43.
7. *See* New York State Public Health Law § 17 and 18 (McKinney's 1991, Supp. 1999).
8. *Supra*. n.2.
9. *Supra*. n.3.
10. Recommendation A at 19-20.
11. *Supra* n.19 at 44-48.
12. *Id*. at 59-62.
13. *Id*. at 51-55.
14. Recommendation at 68.
15. We recognize the value of the Recommendation in so far as it limits information from being disclosed to others, such as direct marketers. Nevertheless, in many circumstances, those paying by debit or credit cards have the option, when signing up with the card issuer, of not being included on direct market lists.
16. Recommendations at 65-66.
17. 524 U.S. 399, 118 S.Ct. 2081, 141 L.Ed.2d 379 (1998).
18. *In Re Sealed Case*, 326 ADC 317 (Fed.Dist.Ct. 1997).
19. 124 F.3d 230 (D.C.Cir. 1997).
20. *Id*. at 237.
21. *Id*., citing *Chirac v. Reinicker*, 24 U.S. (11 Wheat.) 280, 294, 6 L.Ed.474 (1826).
22. *Id*. at 238.
23. *Id*.
24. *Ante*. n.16 at 2087-88.
25. *Id*. at 2088, citing *Funk v. United States*, 290 U.S. 371, 381, 54 S.Ct. 212,215, 78 L.Ed.369 (1933).
26. *See* New York State Civil Practice Law and Rules §4504 (c) (McKinney's 1993, Supp. 1999); ("Article 29-C").
27. Recommendations at 66.
28. *Id*.
29. *Id*. at 67.
30. *See* New York State Public Health Law, Article 29-C, §§ 2980-2992 (McKinney's 1993, Supp. 1999); ("Article 29-C").
31. *See* §§ 5-1501–5-1506 (McKinney's 1989, Supp. 1999).
32. *Id*. § 5-1506.
33. Recommendations at 67.
34. *Id*. at 70-71.
35. *Id*. at 76.
36. *Id*.
37. *Id*. at 76-78.
38. 18 U.S.C.A. §§ 2510–2522 (1970, Supp. 1999).
39. *See* 1986 U.S.C.C.A.N. 3555, 3562.
40. *Ante*. n.37 § 2511.
41. *Id*. § 2520.
42. 18 U.S.C.A. § 1028 (1970, Supp. 1999).
43. *Id*. § 1029.
44. *Id*. § 1030.
45. *Id*.
46. Recommendations at 78.
47. 5 U.S.C. §§ 571–584(1994, Supp. III 1997).
48. 9 U.S.C. §§ 9-13 (1994).
49. Stedman's Medical Dictionary, 26th ed., Baltimore: Williams & Wilkins, 1995.
50. *See* Appendix, American Health Information Management Association, *Patient Health Information: Where does it go?*, 1998.

Participant List

The following people are current members of the Study Group:

Linda S. Beck, Esq.
Robert W. Corcoran, Esq.
Tina Eskreis-Nelson, Esq.
Joy A. Feldman, Esq.
James G. Foussier, Esq.
Jennifer Goldman, Esq.
Joseph K. Gormley, Esq.
Craig B. Greenfield, Esq.
Mark A. Hartman, Esq.
Deborah A. Hodys, Esq.
Ellen F. Kessler, Esq.
Anne Maltz, Esq.
Philip Rosenberg, Esq.
Claudia O. Torrey, Esq.
Robert A. Wild, Esq.

The following people were contributors to the Study Group:

Jeffrey S. Gold, Esq.
Margaret M. Johnson, Esq.
Kelly Mercure, Esq.
Martin Schaum, Esq.

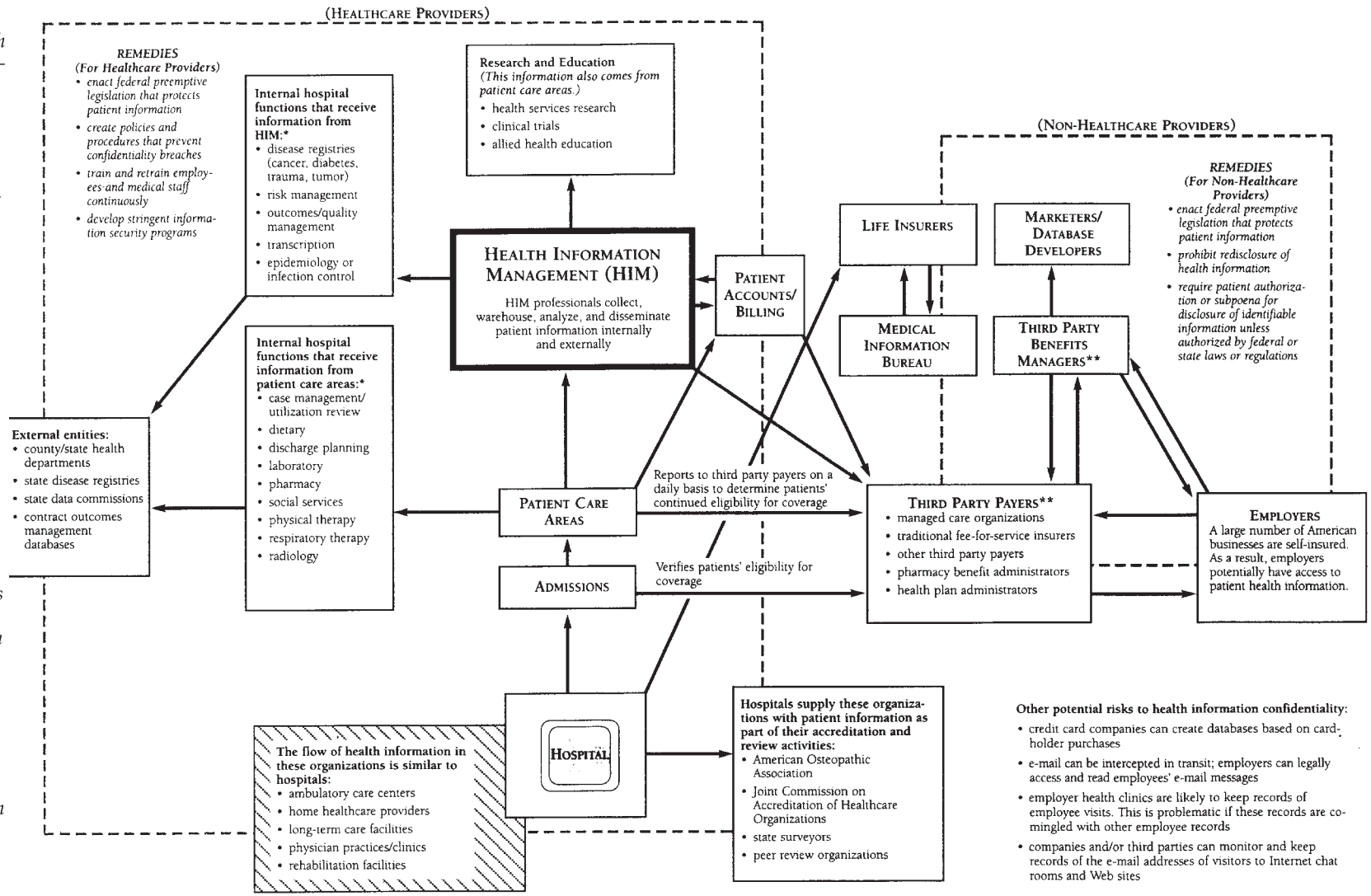
We sincerely and gratefully acknowledge the diligent assistance of Ms. Lisa Bataille, Ms. Kathy Plog, and the Graphics Department, all of the NYSBA.

Flow of Patient Health Information Inside and Outside the Healthcare Industry

The American Health Information Management Association (AHIMA) is a national association of 38,000 medical record and health information management (HIM) professionals, who handle hundreds of thousands of medical records each day. Based on the collected experience of its members, AHIMA developed this diagram, which delineates exactly who, both inside and outside the health care industry, has access to patient health information. The number of individuals and organizations that have access to these records makes a strong case for federal preemptive confidentiality legislation that protects all patient information equally.

For more information contact:
AHIMA
919 N. Michigan Avenue, Su. 1400,
Chicago, IL 60611
(312) 787-2672
fax (312) 787-9793

http:www.ahima.org



Committee Report

Opinion of Counsel Letter Required to Establish Rebuttable Presumption Under Intermediate Sanctions Law

Committee on Fraud, Abuse and Compliance

Following the February, 1998, publication of the Office of Inspector General's Compliance Program Guidance for Hospitals ("OIG Compliance Program"), many hospitals have embarked upon the development and implementation of compliance programs.

Unfortunately, there is no "cookie cutter" hospital compliance program. Each institution must obtain commitment by the highest bodies, beginning with the Governing Board, ("Board") the CEO and senior management. Each institution must evaluate its own situation, assess its high risk areas, and target these areas in a methodical and realistic manner using the OIG Compliance Program as a guide. There must be the appointment of a compliance officer and dedication to institution-wide education, audits and ongoing monitoring. Even though there is no uniform model, compliance programs share common components and published model compliance plans can assist in the development of an institution's compliance program. Publicly available corporate integrity agreements (CIA(s)) can also provide guidance. CIAs are basically mandatory compliance programs put in place as components of OIG settlement agreements with providers.

Every compliance program should include the substantive areas of fraud and abuse emphasizing attention to the billing and coding areas and include such important areas as physician, other provider and vendor relationships. For those hospitals that have been granted Internal Revenue Code § 501(c)(3) (I.R.C.) status, another important component of a compliance program is attention to both protection of the hospital's tax exempt status and compliance with the intermediate sanctions law.[1]

A Board's relationship to its institution's compliance program begins with a resolution for its creation. If the compliance program is to be effective, it must have ongoing Board involvement. Board involvement includes receipt of periodic progress reports from its compliance officer and may require board approval for certain management proposals.

In 1996, the Taxpayer Bill of Rights II was passed into law. With this passage and the promulgation of the proposed intermediate sanction regulations,[2] Board involvement has become critical to assure compliance with the intermediate sanctions law.

In brief summary, I.R.C. § 4958 imposes a penalty tax on any disqualified person who engages in an excess benefit transaction with an "applicable tax-exempt organization." An organization manager may be subject to a first tier tax if the manager participates in an excess benefit transaction knowing that it is an improper transaction.

The tax on organization managers applies only to an individual who knowingly participated in the excess benefit transaction. Under the proposed regulations, a person knowingly participated if he or she has "actual knowledge of sufficient facts" regarding the transaction, and (1) is aware that the transaction may constitute excess benefit, and (2) is either aware that the transaction does constitute excess benefit or negligently failed to make reasonable attempts to determine whether it was.

A significant provision in the proposed regulations permits managers to rely on a reasoned written legal opinion by either in-house or outside counsel that a transaction is not an excess benefit transaction. The reliance on such opinion establishes that the manager did not knowingly participate in an excess benefit transaction.

The legislative history to § 4958 specifies that a rebuttable presumption that a compensation arrangement is reasonable arises where (1) the arrangement was approved by an independent board or board committee composed entirely of non-disqualified persons; (2) appropriate comparability data was used in reliance on the decision; and (3) adequate documentation exists to ascertain the basis of the determination.

The regulations specify the written elements that must be included in any approval, they are as follows:

- terms of the transaction;
- the date of approval;
- the members of the board or committee who were present during debate and those who voted on it;
- the comparability data obtained, relied upon and how the data was obtained;
- the actions taken by anyone who is a member of a body or a committee but who had a conflict of interest with respect to the transaction.

The decision must be documented "concurrently" with the action. In other words, minutes must be provided at the next scheduled meeting and approved within a "reasonable time period thereafter."

Although the "Opinion of Counsel"on page 36 is used primarily to comply with the Intermediate Sanctions law, it also addresses necessary elements for compliance with both the anti-kickback and Stark laws. This publication of the "Opinion of Counsel" by the Fraud, Abuse and Compliance Committee is intended to provide guidance with respect to these issues and solicit comment from attorneys representing health care clients. The Committee welcomes your comments and looks forward to the participation of the membership of the Health Law Section.

Endnotes

1. I.R.C. § 4958 included in the Taxpayer Bill of Rights 2 (H.R. 2337) and signed into law on July 30, 1996.
2. Published in the Federal Register on August 4, 1998. Prop. Treas. Reg. (53-4958-1, et seq.).

JOHN LAW
ATTORNEY AT LAW
MAIN STREET
ANYTOWN, N.Y.

Board of Directors
Community Hospital
Union Street
Anytown, New York

CONFIDENTIAL

ATTORNEY/CLIENT COMMUNICATION

Re: Physician Contracts

To the Community Hospital Board of Directors:

This document is intended to advise the Board of Directors that it is the author's legal opinion that the transactions described below do not constitute excess benefit transactions within the meaning of the intermediate sanctions law, section 4958 of the Internal Revenue Code (ISL), and are legal within the meaning of 42 U.S.C. § 1395nn ("Stark"), and § 1128B(b) of the Social Security Act ("anti-kickback statute").

Professional Services Agreement

Coverage Agreement with PLLC

In 1998, Hometown Health Center in Anytown, New York (HHC) became an affiliate of Anytown Health Services, Inc., parent corporation of Anytown Hospital (ATH). HHC currently is staffed by physicians who do not cover inpatient admissions at ATH. For the past six or so months, ATH has been assisting HHC in the recruitment of a primary care physician to assist HHC and to provide inpatient treatment should the need arise. To date, the recruitment has been unsuccessful. ATH desires to enter into a contractual relationship with a primary care practice to provide inpatient evening and night on-call services for HHC on a temporary basis while the recruitment efforts continue.

Hometown Family Practice (HFP) is a primary care physician professional limited liability company that is willing to enter into an interim contract with ATH to provide HHC inpatient evening and night on-call services.

Contract Objectives

In entering into the HFP contract, ATH desires to provide service and assure continuity of care and treatment to those HHC patients who may require inpatient treatment at ATH.

Intermediate Sanctions Law Analysis

Not a Disqualified Person; Reasonable Compensation

The ISL sets forth categories of *disqualified persons*. If a person is not described in a specific category, the proposed regulations provide that whether the person is deemed to exercise *substantial influence* over the affairs of the corporation and thus be considered a *disqualified person*, is "based on all relevant facts and circumstances" of the transaction as described in 26 CFR § 53.4958-3(e)[1].

Since none of the HFP physicians is "related" to ATH by virtue of managerial or supervisory responsibility; membership on the Board of Directors; authority to control or determine capital expenditures, operating budget or compensation; or is related to any other disqualified person, it is my opinion that neither HFP nor any of its physicians can be considered a *disqualified person*. Assuming, however, that HFP were a *disqualified person*, and for purposes of both the

anti-kickback and Stark legislation, it is nevertheless important that the compensation paid to HFP be both reasonable and constitute fair market value for the services provided.

Reasonableness of Compensation

The contract provides that HFP will provide six (6) months of evening and night on-call services for the sum of Five Thousand Dollars ($5,000). This translates to less than thirty dollars ($30) per day. Were this amount translated to an hourly basis, it would fall well within and indeed well below ranges typically provided for medical record review.[2] Although it is true that being "on-call" in and of itself could be considered unproductive time, it has long been accepted that being on-call is necessary and has intrinsic value which requires the on-call individual to be at all times ready to be engaged should the need arise. We have investigated comparable positions at similarly situated hospitals but have received no responses. Although no comparable compensation has been found,[3] it is my opinion that the calculated hourly rate falls well within the range of reasonable compensation for the services provided.

Stark and Anti-kickback Statute Analysis

Stark prohibits physicians ordering "designated health services" for Medicare/Medicaid patients from entities with which the physician (or an immediate family member) has a "financial relationship." Inpatient and outpatient hospital services are included in the definition of "designated health services." The proposed contract between ATH and HFP constitutes a "financial relationship." Stark is a statute of exception. Since this arrangement is governed by Stark, unless one of the Stark exceptions applies, the prohibition attaches. This contract has been drafted to satisfy one of the Stark exceptions.[4]

The anti-kickback statute prohibits payments, solicitations or receipt of remuneration in order to induce business for which payment may be made under a federal health care program. The prohibition includes, but is not limited to, kickbacks, bribes and rebates. This contract has been drafted to fit within the personal services safe harbor.[5]

Conclusion

Based on the foregoing, it is my opinion that the proposed compensation agreement does not constitute excess compensation or violate either Stark or the anti-kickback statute.

Physician Recruitment

The following proposed recruitment package is brought to the Board for its assurance that the recruitment furthers the hospital's charitable purposes and for its approval as to the reasonableness of the proposed package.

Jane Hill, M.D.

Dr. Hill is an active candidate for board certification in family practice and will be relocating to the Anytown region from Pennsylvania. She will be joining the Southern County Family Practice (SCFP). The hospital was approached by a representative of the SCFP practice who requested assistance for the recruitment of a family practitioner. The partial retirement of Dr. Brown, a long-time member of the SCFP practice, together with the closing of a local HMO staff model practice, has resulted in a significant increase in the number of new patients seeking admission to the SCFP practice. To accommodate this increased need, SCFP believes a new practitioner is warranted. The belief that more primary care physicians are needed to service this region is bolstered by a recent Anytown University public health report ("Report") which concluded that "[t]here is an immediate need for 3 to 4 additional primary care practitioners in the region."[6] The difficulty ATH has experienced in recruiting a primary care physician (PCP) to service HHC highlights the importance of taking advantage of the opportunity to bring a new PCP to the region.

The total value of the proposed recruitment package will not exceed _____ Dollars ($_____). The package consists of a one-time _____ Dollars ($_____) recruitment bonus and relocation reimbursement not to exceed _____ Dollars ($_____). In consideration of this package, Dr. Hill agrees to "serve the entire community within GFH's service area including care to the indigent." Additionally, Dr. Hill is required to practice medicine within the service area for one (1) year. Failing that, Dr. Hill is required to pay back the lump sum bonus. In compliance with the anti-kickback statute, there is no requirement that Dr. Hill refer patients or services to ATH.

IRS Issue

The issue of physician recruitment raises special IRS concerns. As the recruited physician will not be considered a disqualified person, the issue is one of *inurement* and not one of excess compensation.[7] A recent IRS ruling provides guidance regarding what types of recruitment packages are considered acceptable.[8] The ruling focuses on demonstrated community need and on the reasonableness of the amount and terms of the recruitment package.

Stark and Anti-kickback Statute Issues

The proposed Stark II regulations include a physician recruitment exception. The contract has been drafted to satisfy the elements of this exception.[9]

In 1993, a proposed safe harbor under the anti-kickback statute for physician recruitment for rural hospitals was published. It has not yet been adopted. The ATH/Hill contract, however, has been drafted to comply with the proposed safe harbor and with the terms of the Office of Inspector General settlement with Kennestone Hospital at Windy Hill.[10]

Conclusion

It is my opinion that the SCFP assessment of need, the report and the hospital's difficulties in recruitment of a PCP for HHC, satisfies the IRS' requirement of demonstrating that the proposed remuneration furthers the hospital's charitable purpose of providing health care services in furtherance of addressing community need.

It is my further opinion, that the Hill recruitment contract is legal within the meaning of the Stark and anti-kickback laws.

Directorship

Diabetes Management—William Philip, M.D.

ATH desires to enter into a one-year directorship contract with Dr. Philip. The proposed compensation is in the amount of _____ Dollars ($_____) per year in consideration of an average of four (4) hours per week on a 45-week per year basis. It is proposed that the new contract run for a two (2) year term, expiring December 31, 2001 at the annual rate of _____ Dollars ($_____) per year.

Contract Objectives

ATH has made a long term commitment to its Diabetes Management program ("Program"). A medical director is required to participate in the overall planning of the Program, to provide clinical assistance in the development of policies, procedures and departmental goals, engage in and assist in utilization and quality review.

IRS Issues

As Dr. Philip has no managerial responsibility, is not a supervisor, is not related to any other disqualified person, is not on the Board of Directors, has no authority to control or determine capital expenditures, operating budget or compensation, it is my opinion that he is not a disqualified person.

Even were he considered a disqualified person, Dr. Philip has represented that he spends an average of four (4) hours per week in performance of these responsibilities. On the basis of a 46-week year, this translates to a rate of some $82 per hour. We have investigated comparable positions at similarly situated hospitals but have received no responses. Although no comparable compensation is available, it is my opinion that the calculated hourly rate falls well within the range of reasonable compensation for the services provided as noted in footnote 2.

Stark and Anti-kickback Statute Issues

The proposed Stark II regulations include a *personal services arrangement* exception. The contract has been drafted to satisfy the elements of this exception and that of the *personal services contracts* safe harbor under the anti-kickback statute.

Conclusion

Based on the foregoing, it is my opinion that the Diabetes Management Medical Director compensation proposal does not constitute excess compensation. It is also my opinion, that the Diabetes Management director contract is legal within the meaning of the Stark and anti-kickback laws.

Very truly yours,

John Law

Endnotes

1. 26 CFR § 53.4958-3(a); Prior to the new legislation and proposed regulations, the IRS historically had taken the position that members of a hospital's medical staff were "insiders" for purposes of the inurement prohibition. Under the proposed regulations, physicians are not per se *disqualified persons*.
2. The following hourly rates serve as a benchmark for fair market value payment for professional medical/administrative services: non-medical staff administrative and management consultants retained by ATH ($125-$300 per hour); physician chart review for malpractice defense ($150-$300 per hour); physician chart review for peer review organizations ($100-$125).
3. The proposed regulations under the ISL describes key elements in the determination of reasonable compensation. An important element is that of appropriate comparability information. *Appropriate comparability information* includes compensation paid by similar organizations; the availability of similar services in the area; independent compensation surveys compiled by independent firms and actual written offers from similar institutions.
4. The proposed Stark II regulations were published in the January 8, 1998 Federal Register. One of the exceptions to the Stark prohibition is designated as *Fair Market Value Compensation* (FMVC). The proposed contract has been drafted to satisfy the six elements of the FMVC exception.
5. In 1991, the final *safe harbor* regulations were published in the Federal Register. The *safe harbor* regulations are intended to provide guidance on what types of arrangements are permissible and what types are prohibited. If each element of the safe harbor is satisfied, payments made and accepted will be deemed lawful. Failure to bring a transaction within a safe harbor does not mean, however, that the transaction violates the statute. The proposed contract has been drafted to satisfy the six elements of the Personal Services safe harbor.
6. *An Assessment of the Supply and Need for Primary Care Physicians in the Greater Anytown Area, A Report to The Anytown Health Network, Anytown, New York*, Prepared by The Center for Health Workforce Studies School of Public Health, Anytown University (December 15, 1998).
7. *Inurement* occurs when a transaction between a tax-exempt entity and an *insider* results in a dividend like distribution of the earnings of the tax-exempt organization. There is no de minimis inurement. Inurement can lead to either intermediate sanctions against the tax exempt entity's board and managers or in loss of tax exempt status.
8. Revenue Ruling 97-21 sets forth four examples of permissible recruitment incentives.
9. Remuneration provided to induce a physician to relocate to a hospital's service area is not a prohibited compensation arrangement provided that the physician is not required to refer patients to the hospital; the amount of remuneration is not determined in a way that takes into account the volume or value of referrals; the arrangement is in writing signed by both parties and the physician is not restricted from establishing privileges at another hospital or referring business to another entity.
10. The OIG Kennestone investigation involved a recruitment agreement between a hospital and a pulmonologist. The settlement agreement, in brief, required future physician recruitment efforts to be effected pursuant to a signed one-year contract with remuneration to be consistent with fair market value, no referral mandates and legal review for compliance with the anti-kickback statute.

Committee Report

Statement on Telemedicine

Committee on Ethical Issues in the Delivery of Health Care

Telemedicine, the use of telecommunications technology to deliver health care and related services at a distance from the provider, is rapidly increasing with significant implications for American health care delivery.[1] Although telemedicine has been available under limited circumstances for over 20 years, the past two years have seen tremendous growth in the practice of telemedicine. According to one national study, approximately 25% of internal medicine encounters are now managed with telemedicine.

At the simplest level, a nurse or physician providing advice over the telephone is telemedicine. As the term is generally used today, telemedicine is the provision of diagnosis or treatment at a distance in reliance upon technologies that range from high resolution still images (e.g., x-ray) to interactive teleconferencing. The most extensive application of telemedicine to date is teleradiology—radiologists review x-ray images, sonograms, CAT scans and MRIs sent from the patient's hospital or clinic to the physician who may be located at home or in another medical facility. Telemedicine is also used for mental health services, such as telepsychiatry, for pathology, and for home care services.

Telemedicine can significantly improve access to care, especially for patients in rural or underserved areas who do not have access to specialists or might have to travel long distances to obtain care. Telemedicine can also provide services in an emergency that would otherwise not be available to patients in remote areas. Currently used in the United States to improve access to medical specialists, telemedicine is also deployed internationally to link hospitals in developing countries with leading medical facilities in the United States and Europe.

In the United States, pilot projects are underway using telemedicine to improve access to care for patients who are homebound, allowing for more extensive monitoring of the patient's condition and follow-up. Other populations that are not readily mobile, including prisoners, could also benefit from the technology. Finally, telemedicine can offer a convenience to patients, giving them access to physician consultation from their homes or at times that physicians would otherwise not be available.

Along with these clear benefits, telemedicine presents a host of legal and social questions. Existing legal standards, especially with respect to licensure and professional discipline, are ill-equipped to respond to the burgeoning use of telemedicine. Built on the foundation of state jurisdiction and oversight, licensure and disciplinary standards and oversight practices must be revised in light of the changing reality of telemedicine practices that cross state boundaries. Telemedicine also raises legal questions about the standard of care for nurses, physicians and other practitioners engaged in telemedicine, and application of federal and state laws on fraud and abuse and antitrust.

In addition, telemedicine poses certain risks to patients, and raises basic questions about the long-term impact of the practice on the relationship of patient and physician. As the practice proliferates in New York and states around the nation, explicit protections for patients and clear guidance for health care professionals and providers are needed. In particular, concerns about informed consent, confidentiality and use of telemedicine to support rather than substitute for access to qualified medical professionals should be addressed.

Many other states have passed legislation that covers one or more aspects of telemedicine. By the end of 1998, 23 states and the federal government had proposed or enacted legislation addressing the practice of telemedicine. Among other initiatives, state legislation has (1) redefined the practice of medicine to clarify whether the various aspects of telemedicine constitute the practice of medicine, triggering application of existing laws on professional licensure and discipline; (2) changed requirements for licensure for physicians and other health care professionals to clarify whether telemedicine consultation provided across state lines requires licensure; (3) required insurers to cover treatment and diagnostic procedures rendered with the use of telemedicine; (4) protected the privacy of information transmitted through telemedicine; (5) set forth requirements for informed consent and (6) funded pilot and feasibility studies to evaluate telemedicine or to use telemedicine to promote access in rural areas.

New York State Law on Licensure, Practice of Medicine and Professional Discipline

The growing practice of telemedicine presents a pressing need to amend New York State law to provide guidance to physicians and regulators. At present, it is uncertain whether telemedicine constitutes the "prac-

tice of medicine" under New York State law. If it does, out-of-state practitioners providing a service in-state via telemedicine face civil and criminal penalties if they are not licensed in New York State. If telemedicine does not constitute the practice of medicine, the state lacks the authority to enforce professional standards to protect the well-being of patients in New York treated by out-of state practitioners.

New York Education Law § 6521 defines the practice of medicine as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition." The Education Law does not define "diagnosing" or "treating." The terms are not defined in the New York Public Health Law; the Mental Hygiene Law § 81.03 defines "major medical and dental treatment" solely in terms of psychiatric care.

The Office of the Professions in the New York State Education Department, responsible for interpreting the New York physician licensure statutes, has interpreted the practice of medicine and statutory exemptions for licensure broadly to preclude the practice of telemedicine unless out-of-state practitioners are fully licensed in this state. In April 1997, the Department of Education issued a memorandum explaining that the statutory exemption from licensure allowing consultation by out-of-state practitioners covers only occasional consultation and does not extend to the practice of telemedicine. In the absence of other statutory or judicial guidance, this regulatory interpretation carries substantial weight.

New York State should act to provide a streamlined licensure process that makes telemedicine feasible for out-of-state practitioners while subjecting them to New York's professional standards and enforcement powers. By acting responsibly, New York will position itself to pursue the same treatment for New York State health care professionals practicing outside the State via telemedicine.

Other states have created a streamlined licensure process for telemedicine that permits the practice with appropriate safeguards, including enforcement authority for professional misconduct in the state where the patient is located. As set forth in the Model Telemedicine Act proposed by the Federation of State Medical Board, the practice of telemedicine should be deemed to occur where the patient, not the practitioner is located. If a patient is harmed by telemedicine, it is significantly easier for a patient to file a complaint and pursue an enforcement action in his or her home state than in a distant location.

Protecting the Interests of Patients

Given rapid technological changes and dissemination of telemedicine, clinical practice guidelines and technical standards are either non-existent or under development. As telemedicine advances, policies are needed to protect patients in three areas: (1) continued access to face-to-face consultation when *reasonably available* and desired by patients, (2) informed consent and (3) patient confidentiality. In general, telemedicine should be practiced in accord with the same ethical principles and commitment to patient well-being that guide traditional medical consultation.

Telemedicine should be available to supplement, not substitute for, face-to-face consultation with providers when such consultation is *reasonably available* and desired by the patient. While telemedicine has the potential to extend access in fee-for-service health care delivery and to permit managed care coverage that is not feasible at the present time, it may also be used to steer patients to maximize the financial returns or convenience of health care providers and plans. *In particular, provider networks may be constituted to maximize financial return while diminishing the patient's access to providers in their geographic region.* These benefits and risks may be most pronounced for the Medicaid population as telemedicine expands in Medicaid managed care. For this reason, policies to preserve access to face-to-face consultation when such services are *reasonably available in geographic proximity* to the patient and preferred by the patient should be adopted. *Also significant is the need to extend insurance coverage to pay for medically appropriate use of telemedicine services. Overall, the use of telemedicine in New York State should be evaluated as the practice unfolds to determine how well it is meeting the needs of patients,* with particular attention to underserved and vulnerable populations.

Policies should also be adopted to assure that patient consent to use of the technology is informed. Specifically, informed consent should address three issues: (1) the risk, if any, that the technology is not as effective as traditional diagnosis or treatment, or disclosure of the fact that the comparative efficiency of telemedicine remains unknown; (2) the potential for reduced privacy because of the presence of technicians and others who may participate in the consultation but are not visible to the patient and (3) the potential risk for patient confidentiality because transmission of the medical information or consultation may not be secure, or because of the existence of a complete, verbatim record of the consultation. In addition, policies on informed consent should clearly delineate responsibility for seeking consent, placing that obligation on the primary care physician or specialist who triggers or requests the consult.

Practices and technical standards for telemedicine are evolving at the same time that studies of safety and efficacy are underway. Any known risk that a diagnosis or treatment is not as effective as face-to-face consultation should be presented to patients, except in an emer-

gency when consent is presumed. Patients should also be informed if it is not known whether diagnosis or treatment provided by telemedicine is as effective as traditional medicine. Second, the diminished privacy of any telemedicine consultation due to the presence of technicians or others should be disclosed. This is especially critical when telemedicine technologies are used for treating mental illness, drug abuse, and other illnesses that carry social stigma.

Third, concerns related to patient confidentiality should be disclosed. Patients should be informed that the transmission of information via the technologies might not be entirely secure. Finally, at times, records of telemedicine consultations are kept verbatim in their entirety, in contrast to notes in the medical record or test results from a traditional consultation. This leaves physicians in a mental health or other consultation less discretion about the content of a permanent record. Patients should be informed of this practice when applicable. In addition, policies should be devised regarding access to such records to protect the confidentiality and privacy of patients who use telemedicine and may often do so as their only means of access to care.

Studies are currently underway to examine patient satisfaction with telemedicine, the quality of patient-physician interaction, and the way in which patients access the services. As this information becomes available, it should inform the development of policies to respond to this rapidly evolving area of practice. *Also critical will be study of newly emerging practices on the Internet that do not involve a referring physician in New York or another state, but provide direct consultation, diagnosis, or treatment between patients and physicians who generally do not have a preexisting or ongoing patient-physician relationship. These practices provide expanded access to medical advice and treatments such as prescription medications that are desired by patients. At the same time, they pose serious risks because of the absence of an ongoing patient-physician relationship and the lack of clear professional and legal standards to guide practice and regulatory oversight.*

Endnote

1. For purposes of this paper, telemedicine does not include the transmission of information, diagnosis or treatment via the Internet.

News from the Health Law Section

Section Approves Telemedicine Report

In October, the Section adopted a *Statement on Telemedicine* that calls upon New York State to offer a streamlined licensure process to enable out-of-state practitioners to offer telemedicine services to New York patients. The Statement, reproduced on page 40 in this issue of the *Health Law Journal*, also recommends the adoption of policies to ensure that telemedicine is used only with the informed consent of the patient, and that such informed consent includes disclosure of the special risks telemedicine poses to patient privacy and confidentiality.

The Statement will be forwarded to the New York State Legislature, which will consider various bills regarding telemedicine in 2000.

New York Biotechnology Association Official Speaks to Biotechnology Committee

A representative of the New York Biotechnology Association (NYBA) met with the Committee on Biotechnology and the Law at its October committee meeting. Paula Olasciewicz, Director of Technology Development for NYBA, told the committee that her association's main legislative priorities were to promote economic development initiatives for biotechnology companies. She also explained that the organization tended to disfavor statewide efforts to regulate biotechnological advances, but were more receptive to the development of uniform federal policies.

The Biotechnology and the Law committee, chaired by James Lytle of Kalkines, Arky, Zall and Bernstein, has in recent years focused on genetic testing and new reproductive technologies. The committee is reviewing various new projects for 2000.

Volunteers Needed for Managed Care Hotline

The Consumer/Patients Rights Committee is seeking lawyers to willing to volunteer some of their time to help the NYS Attorney General respond to calls to his managed care hotline. Volunteer lawyers will be trained, and then assigned to those complaints or inquires that require legal assistance. This provides a great opportunity for lawyers to improve their health law knowledge and skills and provide a critically important service.

For more information, contact either Committee Co-chair Susan Slavin at (516) 942-9300 or Committee Co-chair Jeff Gold at (518) 474-8376.

Section Approves Report on Privacy of Medical Information

At a Fall meeting, the Health Law Section approved a report entitled "Who Needs to Know?—The Balance Between Health Information Privacy and Confidentiality." The report was prepared in June by a special Health Law Section Study Group and analyzes the recommendations of the Secretary of HHS regarding protecting the confidentiality of individually identifiable health information.

The report is critical of some of the HHS's recommendations such as its proposal to eliminate the need for patient authorization for the disclosure of information to payors and certain other entities. The report explains that the authorization process has not been shown to be unduly burdensome, and that it serves to remind patients that their medical information can be accessed by payors and the other entities.

The full report is set forth on page 24 in this issue of the *Health Law Journal*.

Travel Subsidy Policy Adopted

In October, the Health Law Section adopted a Travel Subsidy Policy, which is designed to encourage members from throughout the state to attend committee meetings. The rules are as follows**:**

Health Law Section Travel Subsidy Policy

Introduction. The Health Law Section, has established a Travel Subsidy Fund in the amount of $750 for the last quarter of FY 1999, and $3,000 for FY 2000, to help subsidize the cost that Health Law Section members incur in traveling long distances to attend committee meetings. The purpose of the fund is to encourage and support committee participation by members from throughout the State. This policy governs the operation of the Fund.

1. General Policy. From July 1, 1999 through December 31, 2000, Health Law Section members who take a plane or train for 100 miles or more solely to attend a meeting of a Committee of the Health Law Section are eligible for a subsidy toward the cost of their fare.

2. Non-subsidized Meetings. The subsidy is not available for travel to the NYSBA's Annual Meeting, professional education programs, or committee meetings held in conjunction with such Annual Meeting or professional education programs.

3. Application. A member can apply for the subsidy by sending the following to Health Law Section Liaison,

Lisa Bataille, within 30 days of the travel:

(a) The travel receipts.

(b) A signed letter, identifying the date of travel, the origin and destination, the plane or train fare, the committee meeting attended, and a statement that the travel was solely to attend a meeting of a committee of the Health Law Section.

4. Allocation. Shortly after the end of the last quarter of FY 1999 and each quarter of FY 2000, NYSBA shall allocate one-quarter of the annual Travel Subsidy Fund among those applicants who incurred travel costs that quarter, paying a proportionate share to each, not to exceed the costs each incurred.

5. Surplus. In the event that there is any surplus available after a quarterly distribution, the surplus shall be added to the amount available for the next quarterly distribution.

6. No separate account. The Travel Subsidy Fund is only a budgetary category, and does not need to be a separate account or to accrue interest.

7. Interpretation. The NYSBA reserves the right to interpret the terms of this policy, and to establish such other compatible policies as are necessary to avoid abuses and to make this policy operate fairly, efficiently and in furtherance of its purpose.

Section Starts Health Law Listserve

The Health Law Section has started an internet "listserve" focusing on the interests of New York State health lawyers.

The 1999 Health Law Section Executive Committee. Seated from left to right: Susan Slavin, Linda Nenni, Tracy Miller, Larry Palmer, Robert Abrams. Standing from left to right: James Lytle, Robert Swidler, Ross Lanzafame, Fred Bodner, Anne Maltz, Salvatore Russo, Peter Millock, Joseph Gormley, Audrey Rogers, James Horwitz. Not shown: Patrick Taylor, Jeffrey Gold, Robert Wild, Frank Serbaroli, Robert Corcoran, Barry Gold, Jerry Levy.

Subscribers to the List Serve can submit inquiries, comments and other messages, which will be instantly e-mailed to all other listserve subscribers. This is an enormously useful technique for obtaining advice and guidance from your health law colleagues.

There is no charge to subscribe to the listserve, and it is easy to do. Visit the Health Law Section website at http://www.nysba.org/sections/health and follow the instructions.

Section Bylaws Revisions Proposed

After receiving the recommendations of a Bylaws Revision subcommittee, the Executive Committee voted to propose significant changes to the Section's bylaws. Notably, the proposed amendments would limit the Section Chair to a one-year term, and generally would limit committee chairs to two one-year terms. These changes are responsive to comments from members that called for more rapid turnover of such positions.

The proposed amendments would also reduce the size of the nominating committee, and formalize the nomination process. They would also require that candidates for elected offices must have been Section members for at least three years.

Another proposed amendment would clarify that committees in the Section must secure Executive Committee approval before taking an action or transmitting their views outside the Section.

The bylaw amendments will be submitted to the membership at the Annual Meeting in January.

The proposed bylaws are set forth on the Health Law Section's website: http://www.nysba.org/sections/health.

Current and Back Issues of *Journal* Now on Section Website

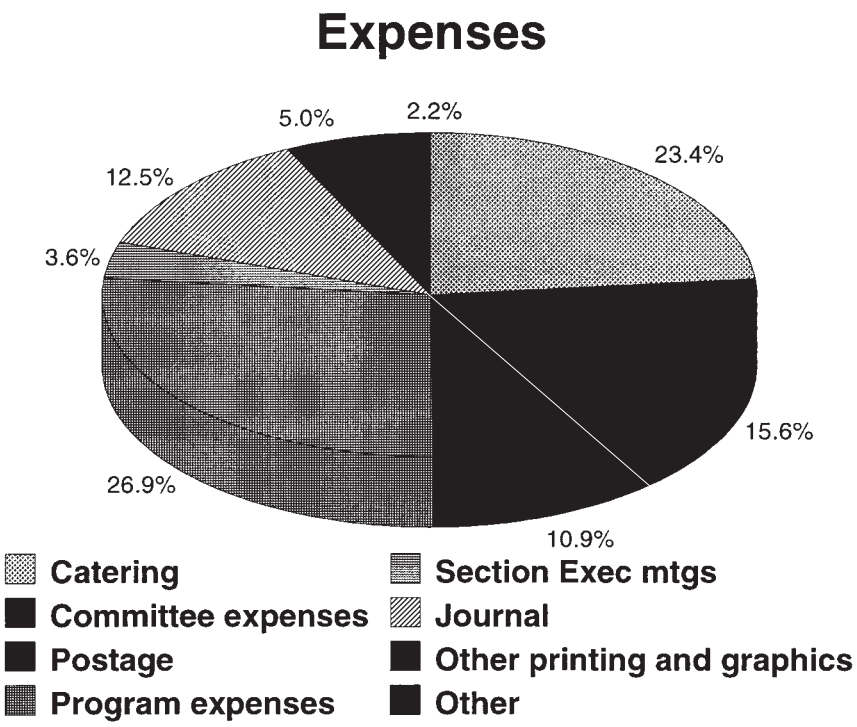
The Health Law Section website now includes the current issue of the *Health Law Journal* in a location for Section members only, and past issues of the *Journal* in a location that may be accessed by anyone.

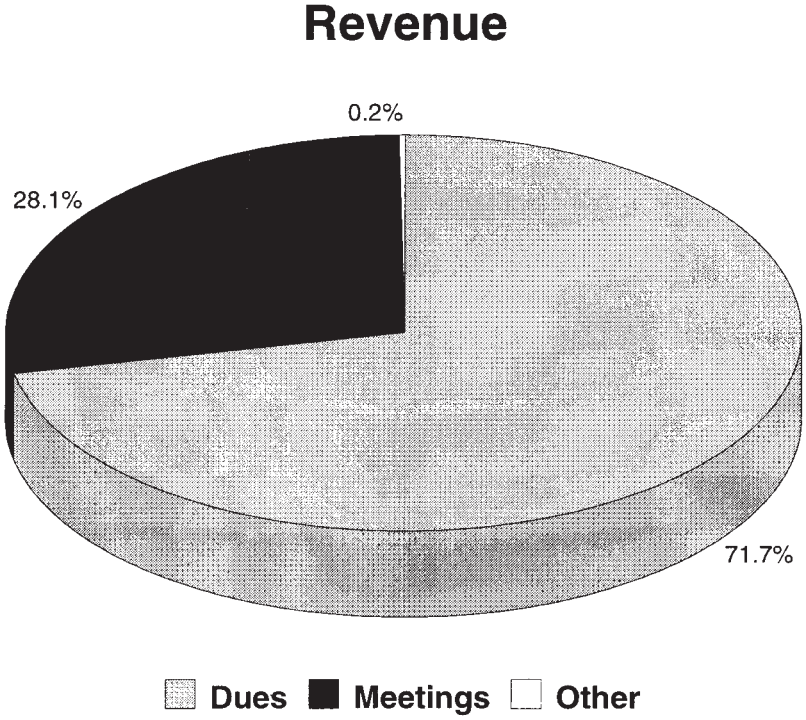
The Section took this approach to balance our interest in protecting the value of membership with our interest in providing a valuable resource to the profession and public at large.

The Health Law Section's website address is http://www.nysba.org/sections/health.

Health Law Section Year 2000 Budget

The Bar Association has approved the Section's budget for the year 2000. The budget is comprised of $32,075 in revenue and expenses, allocated as follows:





Fraud, Abuse and Compliance Committee

The Fraud, Abuse and Compliance Committee is a new committee, one of the goals of which is to share, through publication, programs, committee meetings, discussion and other resources, practical day-to-day tools for health care attorneys relating to fraud, abuse and compliance. Each of these practical tools may be used: (1) by health care attorneys in the representation of individuals and/or providers in fraud, abuse and compliance related matters, (2) to satisfy necessary components of a compliance program, or (3) to simply educate the attorney with respect to these issues. In that regard, the "Opinion of Counsel" is offered for your consideration on page 36 of this issue of the *Health Law Journal*. The Intermediate Sanctions legislation and proposed regulations are relatively new and whether a specific Opinion of Counsel letter satisfies the requirements necessary to establish the rebuttable presumption addressed by the law has yet to be tested. There have been many in-depth articles written addressing both compliance programs and the Intermediate Sanctions legislation.

I encourage you to join the Fraud, Abuse and Compliance Committee. As a new committee, there is a tremendous opportunity to take part in the establishment of goals, direction, publications and programs. If you are interested, please contact me at jhorwitz@glensfallshosp.org or the New York State Bar Association through Lisa Bataille at lbataille@nysba.org.

James D. Horwitz

The Professional Discipline Committee

The Professional Discipline Committee of the Health Law Section is one of its charter committees and one of its largest. The members include both (1) counsellors and defenders of licensed health professionals and (2) their adversaries, the NYS attorneys whose full-time job is the investigation and disciplinary prosecution of those health professionals.

Two administrative law judges of the NYS Department of Health's Bureau of Adjudication—Division of Legal Affairs are also committee members, one the director of the Bureau, the other in charge of the DH's OPMC Administrative Review Board. The Attorney General's staff and counsel to at least one health professional society are also repesented among the members.

Professional Discipline's meetings are held three or four times a year and, not surprisingly, are inevitably spirited, given the adversarial composition of the membership. Meetings are either face-to-face or by conference-telephone.

Guests are frequent at face-to-face meetings:

- Five guests attended the Fall, 1998, Meeting, including the Director of the NYS Medical Society's Committee for Physician's Health, a Deputy Counsel (one of only two) of the NYSDH's BPMC-Division of Legal Affairs and the Executive Coordinator of the NYS Department of Education's Office of Professional Responsibility.
- At our meeting as part of the NYSBA's 1999 Annual Meeting, our guest was Chief Counsel of Health's BPMC-Division of Legal Affairs, who waded heartily into an hour's crisp discussion and debate with the 20 PD Committee members present.

Joseph K. Gormley

Can Those Who Write Articles for Your Section Newsletter Get MCLE Credit? How Do They Do So? What About Editors of Newsletters?

Under New York's Mandatory CLE Rule, MCLE credits may be earned for legal research-based writing, directed to an attorney audience. This might take the form of an article for a periodical, such as your Section's newsletter. The applicable portion of the MCLE Rule, at Part 1500.22(h), says:

> Credit may be earned for legal research-based writing upon application to the CLE Board, provided the activity (i) produced material published or to be published in the form of an article, chapter or book written, in whole or in substantial part, by the applicant, and (ii) contributed substantially to the continuing legal education of the applicant and other attorneys. Authorship of articles for general circulation, newspapers or magazines directed to a nonlawyer audience does not qualify for CLE credit. Allocation of credit of jointly authored publications should be divided between or among the joint authors to reflect the proportional effort devoted to the research and writing of the publication.

Further explanation of this portion of the Rule is provided in the Regulations and Guidelines which pertain to the Rule. At Section 3.c.9 of those Regulations and Guidelines, one finds the specific criteria and procedure for earning credits for writing. In brief, they are as follows:

- the writing must be legal research-based
- the writing must be such that it contributes substantially to the continuing legal education of the author and other attorneys
- it must be published or accepted for publication
- it must have been written in whole or in substantial part by the applicant
- one credit is given for each hour of research or writing, up to a maximum of 12 credits
- only a maximum or 12 credit hours may be earned for writing in any one reporting cycle
- articles written for general circulation, newspapers and magazines directed at a nonlawyer audience don't qualify for credit
- only writings published or accepted for publication after January 1, 1998 can be used to earn credits
- credits (a maximum of 12) can be earned for updates and revisions of materials previously granted credit within any one reporting cycle
- **NO CREDIT CAN BE EARNED FOR EDITING SUCH WRITINGS** (this has particular relevance to Editors of Section newsletters)
- allocation of credit for jointly authored publications shall be divided between or among the joint authors to reflect the proportional effort devoted to the research or writing of the publication
- only attorneys admitted more than 24 months may earn credits for writing

In order to receive credit, the applicant must send a copy of the writing to the New York State Continuing Legal Education Board (hereafter, Board), 25 Beaver Street, 11th floor, NYC, NY 10004. A cover letter should be sent with the materials, and should include the following supporting documentation indicating:

- the legal research-based writing has been published or has been accepted for publication (after Jan. 1, 1998)
- how the writing substantially contributed to the continuing legal education of the author and other attorneys
- the time spent on research or writing
- a calculation of New York CLE credits earned and a breakdown of categories of credit (for the senior bar—those beyond the first 24 months of admission—there are two categories of credit: (1) ethics and professionalism; and (2) everything else (skills, practice management and traditional areas of practice)

After review of the correspondence and materials, the Board will notify the applicant by first class mail of its decision and the number of credits earned. Copies of the MCLE Rules and the Regulations and Guidelines can be downloaded from the Unified Court System web site (http://www.courts.state.ny.us/mcle.htm) or obtained by calling the New York State Continuing Legal Education Board at (212) 428-2105 (for calls outside of New York City, toll-free at 1-877-NYS-4CLE). Questions about MCLE requirements may also be directed to the Board by e-mail at: CLE@courts.state.ny.us.

Newsflash is a new column that offers Section members a way to keep up on the comings and goings of their colleagues and upcoming events of interest. Has there been a change in your practice? Any recent or forthcoming articles or lecture presentations? Won any awards recently? Please send submissions to Professor Barbara Atwell or Professor Audrey Rogers, Pace University School of Law, 78 North Broadway, White Plains, NY 10603.

Eugene Laks, health care law specialist and of counsel at Hiscock & Barclay, LLP, has been designated as a New York State Bar Association representative to the Finance Committee of the New York State Partnership to Improve End-of-Life Care. This Robert Wood Johnson Foundation grant program addresses patient care issues in hospices, nursing homes, hospitals and in the community. Over the next two years, Laks and the Partnership will review health care issues and develop a demonstration program to improve care, including health care insurance benefits. Laks, a graduate of Columbia College, Brooklyn Law School and New York University School of Law, joined Hiscock & Barclay, LLP in 1997 with an extensive background in health care law.

For the Spring 2000 semester, **Pace University Law School** will be offering via video-conferencing to its downtown Manhattan campus *Health Care Financing, Planning, and Management Tools*, a course that provides the analytical tools in accounting, finance, management, and strategic planning necessary to the successful representation of health care clients. The course meets Fridays, from 9:00 to 10:40 a.m., beginning January 14, 2000 and continuing through April 28. This two-credit course counts toward the Certificate in Health Law and Policy that Policy Pace University Law School offers to practicing attorneys, and also provides Continuing Legal Education (CLE) credits. For further information about the course, contact Professor Linda C. Fentiman, Director of the Health Law and Policy Program (914/422-4422, e-mail. To register, contact the Law School Registrar, Ms. Nilda Rodriguez (914/422-4214, e-mail nrodriguez@law.pace.edu).

The **Health Law and Policy Program at Pace** announces two programs for the new millenium: On January 13, 2000, a program, "The Supreme Court Takes an Interest in Health Law: The 1998-99 Term," will run from 5:00 - 7:00 p.m., and carries two CLE credits. On Thursday, April 6, 2000 a day long conference will be held, focusing on "Expanding Health Care Access: New Legal Remedies And New Payment Mechanisms." This program will provide 8 CLE credits. For further information about either of these programs, please contact Professor Linda C. Fentiman at Pace, or her assistant, Kathleen Lambert, at 914/422-4223, e-mail klambert@law.pace.edu.

Welcome New Members:

Michael Affleck
Adrienne J. Arkontaky
Jason B. Atlas
Eli Avila
Victoria Bach
Justyn P. Bates
Ursula Bender
Anna Boros
Susan J. Bouton
Linda Cahn
Linda L. Calzaretta
Georganne Chapin
Jeremy Chen
Laurie Cohen-Miller
Patricia A. Crawford
Marydale DeBor
Ralph DeRosa
John P. DiMascio
Kathleen Duffett
Michelle M. Faraci
Christopher D. Felker
Susan G. Fiske
Daniel Freidlin
Jeffrey C. Gerson
Thomas J. Giglio
Lambert L. Ginsberg
Maura R. Grossman
Louis J. Guida
Matthew F. Guilbault
Robert S. Holcombe
Jackie Huchenski
Stevens L. Ingraham
Miguel A. Irizarry
Jeffrey L. Kingsley
Marta Minc Klajman
Karina V. Lynch
Barbara Malach
Gary Marcus
Mark J. McCormick
Charles A. Mele
Stephen J. Meyer
Sheila J. Namm
Rebecca M. Neri
Larry I. Palmer
Karen Palumbo
Scot Phelps
Vasiliki Plytas
David M. Rothenberg
Eleanore Schenck
Kim M. Smith
Philip H. Stern
Randi Szalavetz
Lynn J. Taylor
Stacey L. Tishler
Mia D. Van Auken
Peter R. Vantyle
Jerri E. Walker
Eileen M. Wheeler
Maria K. Woods

Section Committees and Chairs

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

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

Consumer/Patient Rights
Jeffrey S. Gold (Co-Chair)
Health Care Bureau
332 Miller Road
East Greenbush, NY 12061
(518) 474-8376
Fax (518) 402-2163
e-mail: nuggett477@aol.com

L. Susan S. Slavin (Co-Chair)
Slavin Law Firm, PC
350 Jericho Turnpike, Suite 301
Jericho, NY 11753
(516) 942-9300
Fax (516) 942-4411
e-mail: ssesqs1@ix.netcom.com

Ethical Issues in the Provision of Health Care
Larry I. Palmer (Chair)
Cornell Law School
120 Myron Taylor Hall
Ithaca, NY 14853
(607) 255-3383
Fax (607) 255-7193

Fraud, Abuse and Compliance
James D. Horwitz (Chair)
Glens Falls Hospital
100 Park Street
Glens Falls, NY 12801
(518) 761-5208
Fax (518) 761-5273
e-mail: jhorwitz@glensfallshosp.org

Health Care Providers
Francis J. Serbaroli (Chair)
Cadwalader Wickersham & Taft
100 Maiden Lane, Room 703
New York, NY 10038
(212) 504-6001
Fax (212) 504-6666
e-mail: fserbaro@cwt.com

Health Care Delivery Systems
Robert A. Wild (Chair)
Garfunkel Wild & Travis, PC
111 Great Neck Road, Suite 503
Great Neck, NY 11021
(516) 393-2222
Fax (516) 466-5964
e-mail: rwild@gwtlaw.com

Inhouse Counsel
Patrick L. Taylor (Chair)
Albany Medical Center
43 New Scotland Avenue
Albany, NY 12208
(518) 262-3828
Fax (518) 262-4184
e-mail: taylorp@mail.amc.edu

Managed Care
Frederic L. Bodner (Chair)
Hinman, Straub, Pigors & Manning, P.C.
121 State Street
Albany, NY 12207
(518) 436-0751
Fax (518) 436-4751
e-mail: fredb@hspm.com

Membership
Robert W. Corcoran (Chair)
57 Wilton Road
Cold Spring Harbor, NY 11724
(516) 367-3336
Fax (516) 367-2626

Payment Issues
Ross P. Lanzafame (Chair)
Harter, Secrest & Emery
700 Midtown Tower
Rochester, NY 14604
(716) 232-6500
Fax (716) 232-2152
e-mail: rlanzafame@hselaw.com

Professional Discipline
Joseph K. Gormley (Chair)
225 Broadway, Suite 1201
New York, NY 10007
(212) 349-7100
Fax (212) 349-2764

Public Health
Salvatore J. Russo (Chair)
125 Worth Street, Room 527
New York, NY 10013
(212) 788-3300
Fax (212) 267-6905
e-mail: russos@nychhc.org

Securing Health Care for the Uninsured
Peter J. Millock (Chair)
Nixon Peabody, LLP
1 Keycorp Plaza
Albany, NY 12207
(518) 427-2650
e-mail: pmillock@nixonpeabody.com

Special Committee on Medical Information
Anne Maltz (Chair)
Stroock, Stroock & Lavan
180 Maiden Lane
New York, NY 10038
(212) 806-6673
Fax (212) 806-6006
e-mail: amaltz@stroock.com

Health Law Section

Committee Assignment Request

Please designate the Committee in which you are interested.

____ Biotechnology and the Law (HLS1100)

____ Consumer/Patient Rights (HLS1200)

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

____ Fraud, Abuse and Compliance (HLS2400)

____ Health Care Providers (HLS1400)

____ Health Care Delivery Systems (HLS1500)

____ Inhouse Counsel (HLS2300)

____ Managed Care (HLS1800)

____ Membership (HLS1040)

____ Payment Issues (HLS1900)

____ Professional Discipline (HLS2200)

____ Public Health (HLS2100)

____ Securing Health Care for the Uninsured (HLS2500)

____ Special Committee on Medical Information (HLS2600)

Name:_____

Firm:_____

Address:_____

City:_____ State:_____ Zip:_____

Phone:_____ Fax:_____

NYSBA

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

Publication and Editorial Policy

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

Publication Policy: All articles should be submitted to:

Professor Barbara L. Atwell
Pace University School of Law
78 North Broadway
White Plains, NY 10603
(914) 422-4257
batwell@law.pace.edu

or

Professor Audrey Rogers
Pace University School of Law
78 North Broadway
White Plains, NY 10603
(914) 422-4068
arogers@law.pace.edu

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

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

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

HEALTH LAW JOURNAL

Co-Editors
Professor Barbara L. Atwell
Pace University School of Law
78 North Broadway
White Plains, NY 10603
(914) 422-4257
Fax (914) 422-4229
e-mail: batwell@law.pace.edu

Professor Audrey Rogers
Pace University School of Law
78 North Broadway
White Plains, NY 10603
(914) 422-4068
Fax (914) 422-4229
e-mail:arogers@law.pace.edu

Section Officers

Chair
Robert N. Swidler
Northeast Health
2212 Burdett Avenue
Troy, NY 12180
(518) 271-5027
Fax (518) 273-3307
e-mail: rswidler@nehealth.com

First Vice-Chair/Committees
Tracy E. Miller
Mount Sinai School of Medicine
Department of Health Policy
Box 1077
New York, NY 10029
(212) 659-9567
Fax (212) 423-2998
e-mail: tracy_miller@smtplink.mssm.edu

Second Vice-Chair/Professional Education
Robert Abrams
Law Offices of Robert Abrams, P.C.
5 Dakota Drive, Suite 206
Lake Success, NY 11042
(516) 328-2300
Fax (516) 328-6638
e-mail: rabrams@abramslaw.com

Secretary
Linda J. Nenni
Kaleida Health
901 Washington Street
Buffalo, New York 14203
(716) 843-7502
Fax (716) 843-7595
e-mail: lnenni@kaleidahealth.org

Treasurer
Salvatore J. Russo
NYC Health & Hospital Corporation
125 Worth Street, Room 527
New York, NY 10013
(212) 788-3300
Fax (212) 267-6905
e-mail: russos@nychhc.org

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

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