One of the most pressing problems for hospitals today is covering costs for the provision of care to indigent patients, whether it be through the state’s Medicaid program, charity care, or some other state or local assistance program (such as General Assistance). Medicare providers who also provide a large volume of indigent care may be eligible for additional reimbursement through federal Medicare disproportionate share hospital (“DSH”) payments. Both eligibility for, and the amount of, Medicare DSH payments are determined by federal statute, based partly on the number of days of care provided by the hospital in a particular fiscal year to patients “eligible for medical assistance under” the state’s Medicaid Plan. For those hospitals that qualify, Medicare DSH payments related to low income patient care can amount to millions of dollars of additional reimbursement.

There is an ongoing disagreement between the Health Care Financing Administration (“HCFA”) and hospitals regarding which patients meet the criteria of being eligible for medical assistance under the state’s Medicaid Plan. HCFA recently issued a Program Memorandum (the “PM”) and Interim Final Rule (the “Rule”), in which HCFA sets forth its position as to the types of patient days that may be counted and the circumstances under which hospitals may receive Medicare DSH payments related to these days. Many hospital representatives have construed the PM and the Rule as limiting their procedural or substantive rights to additional reimbursement. This is not the case. The PM and the Rule merely describe certain scenarios under which HCFA will agree to payment of Medicare DSH.

A brief review of this issue should help hospital representatives understand the narrow parameters of the PM and the Rule.

**Background**

In 1998, this firm successfully argued before the Provider Reimbursement Review Board (the “PRRB”) that a New Jersey hospital was entitled to include charity care days in its Medicare DSH calculation. The PRRB, in a 5-0 decision, agreed with this New Jersey hospital that the days related to “Charity Care,” a program incorporated in New Jersey’s Medicaid State Plan,
medicare dsh reimbursement: opportunities for additional payment
continued from page 1

Medicare DSH Reimbursement: Opportunities for Additional Payment
continued from page 1

constituted days that were includible in the hospital’s Medicare DSH calculation pursuant to the federal statute. See Jersey Shore Medical Center v. Blue Cross and Blue Shield Association / Blue Cross and Blue Shield of New Jersey, PRRB Case No. 95-0907 (8/26/98). This decision was reversed by the HCFA Administrator and then appealed to federal district court on procedural grounds. The PRRB rejected HCFA’s argument that only days related to Title XIX Medicaid were includible in a Medicare DSH calculation.

In fact, hospitals in some other states had already been receiving Medicare DSH payments based on similar types of patient days. For example, Pennsylvania hospitals had received such payments in connection with patient days related to that state’s General Assistance program. Similarly, New York hospitals had received payments in connection with patient days related to that state’s Home Relief program.

However, HCFA had started to recoup monies from Pennsylvania hospitals, positing that the Medicare DSH payments were made by mistake. In the Fall of 1999, HCFA threatened to recoup billions of dollars of payments from New York hospitals on that same basis. These three developments—the threatened recoupment from New York hospitals, the incomplete recoupment from Pennsylvania hospitals, and the successful appeal on this issue by a New Jersey hospital (with dozens of other appeals pending for other New Jersey hospitals)—led to HCFA’s issuance of the PM and Rule.

The Program Memorandum

The PM was issued as a result of what HCFA has termed its “unclear Medicare DSH policy.” In the first part of the PM, HCFA sets forth the types of days it believes should be included in the Medicare DSH calculation (essentially Title XIX Medicaid eligible days), and days that should be excluded (various types of non-traditional Medicaid days). HCFA does not present a concise definition of non-traditional Medicaid days addressed by the PM, but one can infer that HCFA regards the following as representative of such days: charity care, state or county General Assistance or Medical Assistance, state only or county only health program, low income or indigent care, uncompensated care or bad debt, Medicaid DSH, and/or Section 1115 waiver / demonstration project or population days.

It is important to emphasize that hospitals’ procedural rights to appeal this issue are not affected by the PM and its listing of so-called excluded days. The hospitals’ substantive rights are not strictly governed by HCFA’s opinion on this issue, but rather depend upon the meaning of the federal statute. HCFA’s opinion may be entitled to some deference under the law, but not to the extent that its opinion contravenes the plain meaning of the Medicare statute.
In the second part of the PM, HCFA designates the circumstances under which it will “hold harmless” certain hospitals that have historically received Medicare DSH payments based on what HCFA now terms as excluded days and other hospitals which have properly appealed the issue. Those hospitals that already received payments may keep those payments (with monies already recouped to be returned to the hospitals), and those hospitals with properly pending appeals may obtain additional reimbursement. In general, the hold harmless provisions apply only to cost reporting periods beginning prior to January 1, 2000, and to practices followed or appeals filed on this issue before October 15, 1999 (the date on which HCFA first announced it would issue clarification of its policy). Hospitals should read the PM very carefully to determine whether they are covered by the hold harmless provisions.

If hospitals are not covered by these hold harmless provisions, they may still be entitled to additional reimbursement in accordance with the federal Medicare statute, which establishes rights that may be pursued through an appeal. Indeed, in a Memorandum dated March 13, 2000, HCFA agreed that the purpose of the PM and its hold harmless provisions is “to have the intermediaries resolve appeals,” and not to otherwise preclude appeals. Thus, hospitals in New Jersey, Pennsylvania, and many other states that benefit from the PM, will have to appeal to have these days included in their Medicare DSH calculation for years subsequent to 2000 and for years for which they did not raise the issue until after October 15, 1999 (the cut-off date for automatic relief). For example, while Jersey Shore Medical Center qualifies for payment under the hold harmless provisions of the PM for the year 1992, the PM would not entitle the hospital to payment for the year 2000. Yet, the Jersey Shore PRRB decision indicates that Jersey Shore is entitled to the inclusion of its charity care days for the year 2000 and going forward.

**The Interim Final Rule**

In the subsequently issued Rule (which is still subject to comments), HCFA has focused on one type of patient day it previously considered to be excluded: Section 1115 waiver expansion days. These days relate to care for certain non-Medicaid populations that have been incorporated into a state’s Medicaid program (usually, if not always, a managed care program) by way of a waiver granted pursuant to Section 1115 of the Social Security Act. The Rule provides that such days should be counted in the Medicare DSH formula for discharges occurring on or after January 20, 2000. The Rule identifies the following states as currently having such Section 1115 expansion waivers: Delaware, Hawaii, Massachusetts, Missouri, New York, Oregon, Tennessee, and Vermont.

Again, it is important to note that the Rule does not affect hospitals’ procedural rights to appeal, and hospitals’ substantive rights are ultimately governed by the federal Medicare statute. Thus, hospitals not deemed eligible by the Rule may still be entitled to additional reimbursement based on discharges occurring prior to January 20, 2000, and those hospitals may pursue an appeal on this issue.

**Conclusion**

Hospitals’ rights to Medicare DSH payments based on the days they provide care to low income patients depend on whether those days properly constitute eligible patient days under the federal Medicare statute. The PM and the Rule issued by HCFA will benefit many hospitals. However, the converse is not true—hospitals’ procedural and substantive rights to additional reimbursement are not and cannot be cut off by the PM or the Rule. As a result, Medicare hospitals may still be able to seek relief for the high costs of indigent care by adding non-traditional Medicaid days to their Medicare DSH calculation.

---

*Murray J. Klein, Esq.*
*Steven M. Ziolkowski, Esq.*

In addition to handling the Jersey Shore case, Messrs. Klein and Ziolkowski are currently representing hospitals from many different states in a national group appeal to secure additional DSH reimbursement for non-traditional Medicaid days.
Telemedicine—medical services provided remotely through electronic communication—offers potential as a low-cost alternative to traditional health care. Despite its promise, telemedicine has been successful only in locations where legal and financial obstacles have been removed or never existed.

Despite substantial growth, … telemedicine still faces substantial legal obstacles, including licensure, [FDA] regulation, reimbursement, fraud and abuse, and health information security issues.

Internationally, telemedicine has flourished where physician licensure issues do not exist and centralization of health care is well-established. In December 1999, Johns Hopkins and Lucent Technologies agreed to develop international telemedical offerings, suggesting that there will be growth of this industry overseas.

In the U.S., telemedicine has experienced steady growth. The Association for Telemedicine Service Providers (“ATSP”) reports an increase of 19% in active U.S. telemedicine programs from 132 to 157, with 100 of these programs based in academic medical centers or hospital-based care networks.

These U.S. telemedicine programs, as reported in the 1998 Report on U.S. Telemedicine, Association for Telemedicine Service Providers (February 5, 1999), are operating at more than 1,345 sites, and conducted more than 58,000 patient consultations in the survey period.

Despite substantial growth, however telemedicine still faces substantial legal obstacles, including licensure, the Food and Drug Administration (“FDA”) regulation, reimbursement, fraud and abuse, and health information security issues.

Licensure
As a general rule, physicians may not treat patients unless they are licensed in the state where patients are treated. Licensure is a hurdle that interstate telemedicine has so far failed to completely overcome, despite numerous attempts.

Physicians generally oppose relaxed licensure requirements, fearing a negative impact on the quality of care as well as financial competition from large, national providers. In contrast, health care organizations and the government favor removal of the licensure impediment to stimulate telemedicine as a low-cost health services alternative.

Several attempts have been undertaken nationally to address this licensure issue. First, a Model Act was authored by the Federation of State Medical Boards in 1995, but this was rejected by the American Medical Association Board of Trustees in 1996.

Second, in 1998, ATSP drafted an interstate telemedicine licensure compact to permit physicians holding a full license in good standing in their home state to be recognized as eligible to practice telemedicine in participating states. The compact would utilize the National Practitioner Data Bank maintained by the Department of
Health and Human Services ("HHS") to establish physician standing.

Currently, two bills addressing the issue are pending in the U.S. Senate, S.980 (Promoting Health in Rural Areas Act of 1999), and S.770 (Comprehensive Telehealth Act of 1999), and one bill is pending in the House of Representatives, H.R.1344 (Triple-A Rural Health Improvement Act of 1999). Chances for passage are not considered high.

To date, at least 20 states have enacted legislation requiring interstate telemedicine practitioners to carry a full license to practice telemedicine in their state. These states include: Arizona, Arkansas, Connecticut, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Massachusetts, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania and Texas.

FDA and Software in Telemedicine Devices

For more than four years, FDA has considered how it should regulate medical devices containing software. While FDA has still not finalized its position, current regulations set difficult standards. FDA has drafted guidelines for customer and “off-the-shelf” software and is considering a proposed policy governing “stand-alone medical software products” submitted by the Health Industry Manufacturers Association. Key affected telemedicine components include imaging devices and Picture Archiving Communications Systems that are critical to teleradiology.

Reimbursement

Most telemedicine projects are supported by federal, state or private demonstration grants. Grants fund capital costs and provide reimbursement for telemedicine. In October 1996, HHS established a $42 million Medicare demonstration project to provide primary care telemedicine services to 57 rural locations administered by the Health Care Financing Administration (“HCFA”). The Balanced Budget Act of 1997 (“BBA”) extended Medicare eligibility to telehealth providers in so-called Health Professional Shortage Areas (“HPSAs”).

The BBA has been narrowly construed to limit Medicare reimbursements to:

a) teleradiology;
b) remote patient monitoring; and
c) live (interactive) consultations with patients residing in HPSAs.

In order to be covered, referral may be made only by a prescribed group of mid-level professionals. Moreover, reimbursements are subject to “fee-splitting,” in which the provider receives 75% and the referring provider 25%.

The financial incentives established by current Medicare regulations disfavor telemedicine. Several bills pending in Congress seek solutions by broadening coverage and simplifying processes for telemedical treatments. These include H.R.1344, S.980, and S.770. Although any of these bills would reduce reimbursement obstacles, each provides only a partial solution and will not make telemedicine a paying proposition anytime soon.

Medicaid regulations treat telemedicine as a health care delivery method, and defer to states to set eligibility requirements. Despite this wider discretion, states permitting Medicaid telemedicine reimbursements (with the exception of Kansas) restrict reimbursements to physician video consultations.

Fraud and Abuse

Anti-kickback issues present another obstacle to telemedicine operations. The federal anti-kickback law imposes criminal penalties for knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce referrals of items or services reimbursable by Medicare and Medicaid. Telemedicine operations by their nature involve fee splitting and a “hub” through which consultation requests are received and referred. The hub provides equipment and telecommunications services to health care providers. Such activities may implicate the federal anti-kickback law.

Continued on page 6
In a recent Office of Inspector General (“OIG”) Advisory Opinion, the OIG ruled that one such “hub” organization operating under a federal telemedicine grant would not be prosecuted for anti-kickback violations after expiration of the grant period for continuing these types of funding activities. While this Advisory Opinion can only be directly relied upon by the parties who requested it, the Advisory Opinion indicates that the OIG may be willing to insulate from anti-kickback scrutiny telemedicine operations focused on rural health care.

Health Information Security
Health information security regulations proposed by HHS pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”) will have a dramatic impact on telemedicine. Electronic access to patient charts is a central concept of telemedicine. Proposed HIPAA security regulations will require, at a minimum, security measures adequate to prevent unauthorized access to patients’ charts. Security measures such as user authentication (e.g., digital signatures/public keys managed by certificate agencies and biometric identifiers such as fingerprints) and internet transmission security (e.g., encryption and managed firewall intrusion detection) will add to the already high costs of operating telemedicine networks.

Conclusion
Legal obstacles to telemedicine, while significant, are not fatal. Internet pharmacies, for example, have already adapted to their own licensure problems by obtaining licenses in all applicable states. Growing public and political interest in reimbursement and government regulation promise to drive related telemedicine issues to resolution regardless of how long and painful the path may be.

While the greatest challenge is likely to be economic—balancing the costs of legal compliance and technology requirements—steady industry growth combined with strong public demand for reasonably-priced health care indicates that obstacles will be overcome. Moreover, internet market forces have already demonstrated that creative solutions will prevail. Health care clients should study remote patient care as one important option and an emerging opportunity to cut costs and serve new patient populations.

Kerry A. Kearney, Esq.
Celia M. Santander, Esq.
FEDERAL QUESTION LITIGATION MAY DEFEAT PEER REVIEW PRIVILEGE

By Decision and Order dated August 9, 1999, Judge Thomas J. McAvoy of the United States District Court, Northern District of New York, reaffirmed the fundamental dichotomy between state and federal law concerning the existence of a peer review privilege, at least in those cases in which there is federal question jurisdiction. Olof Franzon, M.D. et ano. v. Massena Memorial Hospital, et. al., 97-Civ-0150 (TMJ). Thus, while recognizing the state law privilege under N.Y. Education Law Section 6527(3) and N.Y. Public Health Law Section 2805(m), Judge McAvoy held that “there is no federal counterpart to these state law privileges.” It is a distinction of critical import to parties in actions brought against hospitals or physicians in which the discovery requested includes the peer review files of particular physicians.

In Franzon, the plaintiff-physician alleged that he was denied reappointment of staff privileges at the defendant-hospital in retaliation for his exercise of speech protected under the First Amendment. The hospital sought to justify the denial of plaintiff’s privileges based on, among other things, its concerns about his competence to practice medicine. In his request for production of documents, plaintiff sought the peer review files of all other physicians in the hospital in order to demonstrate that the hospital’s defense was pretextual, i.e., that the peer review process at the hospital was operated in a corrupt manner, designed not to improve patient care, but to protect physicians throughout the hospital with worse records than plaintiff.

Affirming the Magistrate Judge’s denial of defendants’ motion for a protective order, Judge McAvoy held that “as a matter of comity federal courts accord deference to state-created privileges, that these privileges serve important purposes, but that, in the present case, they must yield so that plaintiff may pursue his federal cause of action and enforce his First Amendment rights.” Judge McAvoy continued, “[b]ecause plaintiff alleges that the defendants have used the peer review process to retaliate against him for exercising his First Amendment rights, plaintiff must present evidence that other physicians with comparable or worse records than his were not treated similarly. Such evidence, if it exists, would likely be found in the records of disciplinary proceedings against other doctors.”

For physicians and hospitals, the decision is significant. Relying on the oft-held belief that hospitals and physicians can insulate themselves from the repercussions stemming from denial of a physician’s privileges by relying on the state law peer review privilege becomes particularly dangerous. For attorneys that represent physicians who have lost their privileges, the ability to invoke federal question jurisdiction may well create significant leverage against hospitals and physicians that are loathe to disclose their own peer review files.

Mitchell G. Mandell, Esq.
Last November in the Boston Medical Center case, the National Labor Relations Board overruled twenty years of precedent and concluded for the first time that medical interns and residents at hospitals are not “students,” but rather are “employees” under federal labor law.

As employees, they are entitled to the full protection of the National Labor Relations Act, including the right to organize a union and elect one to bargain on their behalf. Before we take a look at what the decision means, a little history first.

**Background**

The health care industry was not covered by the federal labor laws until 1974. When Congress amended the law to include the health care industry, it cautioned the NLRB to ensure that this did not result in an “over-proliferation” of bargaining units in American hospitals. Congress’ concern was, for example, that if each unit of a hospital’s nursing staff had its own union, the facility could be faced with unending labor disputes and work stoppages. After trying to figure out what “over-proliferation” meant in thousands of different cases, the NLRB in 1989 finally adopted a rule for eight different bargaining units at acute care hospitals: registered nurses, physicians, all other professionals, technical employees, skilled maintenance, business office clerical, guards, and finally, all other non-professional employees.

The NLRB, therefore, has recognized “physicians” as a discrete bargaining unit since at least 1989. Union organizing by physicians, however, was largely a non-issue in the health care field before the Boston Medical Center decision for three reasons. First, under established NLRB precedent, interns and residents were considered “students” and, therefore, were not “physicians” in the eyes of the NLRB. Second, up until a few years ago, most physicians were self-employed or worked for other physician groups and, therefore, were not employees of a hospital. Third, those attending physicians who were employed by a hospital were often “supervisors” and therefore, like any other supervisor, were not eligible to vote for a union.

**Impact of Boston Medical Center**

Now that interns and residents are included within the ranks of “physicians” for union organizing purposes, what does that mean, particularly in light of a changing medical profession?

*Physicians Who Are Not Employees.* The NLRB’s ruling does not affect physicians who are independent contractors, rather than employees, of their hospitals. The NLRB has continued to affirm that physicians,

As physicians lose more control over the delivery of health care services, organized labor will step in to fill the void.
like other professionals, who maintain their own practices and do not work directly for another employer are not “employees” and, therefore, are not free to organize into a union for collective bargaining purposes.

Physicians As Supervisors. Those physicians who continue to exercise supervisory authority (e.g., direct the work of other employees, evaluate and discipline them, or hire and fire them) will remain supervisors and are not eligible to unionize. As a practical matter, attending physicians who supervise other professional staff, or supervise residents and interns, will likely be considered supervisors and unable to unionize.

Status of Staff Physicians. The NLRB still recognizes only one appropriate unit of “physicians.” This means that to the extent the interns and residents at a hospital are interested in organizing a union, any staff physicians who are not supervisors would also have to be included in the bargaining unit.

Staff Who Work For More Than One Hospital. The NLRB did not address the question of interns and residents who rotate or work at more than one hospital. In that situation, the hospitals may very well be considered “joint employers.” Under the current state of the law, it is difficult for employees who work for joint employers to organize into a single union.

Strikes and Collective Bargaining. Hospitals need to be aware that if their physicians do organize into a union, there are no special rules governing collective bargaining or strikes by physicians. Although the American Medical Association and other doctors’ groups say that physicians will not strike, legally doctors would have the same right to strike as any other hospital employee.

Similarly, doctors would be free to raise at the bargaining table the same kinds of issues which are of concern to other employees in the industry. For example, a common complaint for nurses is that non-licensed staff are encroaching upon their work. In an effort to control costs, hospitals reduce the number of RNs and, on the margin, replace them with technicians. Interns and residents may raise the same issue at the bargaining table in reverse and insist that some of their more mundane tasks be assigned to other personnel. The chief resident and the co-president of the house staff at Boston Medical Center made this point immediately after the decision came out: “We won’t have to endure 80 to 100 hour work weeks consumed by grunt work such as drawing blood and transporting patients.” The chief resident, of course, was referring to his expectation that as a result of the contract negotiations, house staff would obtain a provision in their agreement which presumably would require the nursing staff or other individuals to perform this type of work.

Organized Labor Reacts
The prospect of disgruntled physicians seeking union representation is not lost on organized labor. Before the Boston Medical Center decision, the United Food and Commercial Workers Union tried to persuade the NLRB that physicians who worked under contract with an health maintenance organization were employees and, therefore, eligible to form a union. After the Boston Medical Center decision, the Service Employees International Union, another AFL-CIO affiliate, provided the Committee on Interns and Residents with $1 million in cash, as well as in-kind support, to help organize the medical profession. The SEIU, for example, is currently attempting to unionize the entire University of California medical system, starting with the Davis campus. Even the AMA has jumped into the fray in favor of unionization and argued in support of the residents and interns in the Boston Medical Center case. As physicians lose more control over the delivery of health care services, organized labor will step in to fill the void. Unionization helped teachers retain some control over the educational system, will it work for physicians too?
Most health care entities are keenly aware of impending regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") that will require implementation of numerous safeguards to protect personal health information. Because of the comprehensiveness of the proposed rules, their expected effects on information technology ("IT") used in the health care industry, and the limited time that will be given for compliance, HIPAA has frequently been called Y2K "on steroids." (Under HIPAA, covered health care entities must comply with final rules within approximately 2 years after issuance of the relevant final rule).

HHS' Privacy and Security Standards

HIPAA provides for the development of both privacy and security standards and, to date, proposed regulations have been published for both standards. Both the privacy and security regulations have received extensive industry comment, and it is unlikely that the final rules will be forthcoming before the end of the year. Because the rules are not yet final, and are likely to change significantly before adoption, it might prove extremely wasteful to begin compliance efforts in advance of the final rules. On the other hand, waiting for the final rules invites a chaotic and costly effort to comply in accordance with the two-year timeframe. The proposed HIPAA rules have broad implications and potential effects both on health care entities themselves and on the health care entities' "business partner."

Indeed, one of the most controversial elements of the proposed privacy rules is the rule directed at "business partners." Many commentators have argued that the "business partner" rules exceed the scope of authority delegated to the Department of Health and Human Services ("HHS") by Congress. In the event that the "business partner" rules are ultimately adopted, therefore, a challenge in court is likely.

What Should Health Care Entities Be Doing About HIPAA Now?

Although there is no "right" answer that will fit the compliance requirements of all segments of the health care industry, health care entities would be wise to begin efforts to develop a comprehensive strategy for managing sensitive health care information collected or used as part of their operations.
strategy for managing sensitive health care information collected or used as part of their operations. Although the proposed HIPAA rules are not yet effective, a wide range of existing laws and regulations already govern disclosure of sensitive information such as state laws governing medical records, Federal Trade Commission regulations, the HCFA Internet Security Policy (which was adopted as stop-gap measure, until the HIPAA security rules take effect). In addition, HCFA has provided substantial guidance as to the major components likely to be included in the final rules.

Finally, health care organizations should be sure to manage their business relationships in a manner that allows for the flexibility that will be need to respond to the final rules.

By creating an architectural framework or roadmap of information flow before attempting to comply with HIPAA, a health care entity will be in a far better position to respond the challenges of the law. For example, a clear picture of information flow and requirements may enable an entity to decide to protect privacy by collecting less information, rather than undertaking procedures and technologies should focus on building a foundation that enables the health care entity to understand, for example:

- how the firm collects protected information;
- how the protected information is used internally;
- who receives or has access to protected information internally;
- who receives or has access to protected information externally;
- what, if any, security precautions are currently used;
- how HIPAA is likely to limit future uses of information by the firm; and
- the business ramifications of reduced flows of information.

A second suggestion then, given the uncertain future of the business partner rules, would be to delay implementing measures to comply with these rules until necessary. While these potential rules cannot be ignored because their adoption could force the renegotiation of innumerable business arrangements, the best course is to address the proposed rules in new agreements by expressly providing for termination and/or good faith negotiation in the event that regulatory changes eventually affect the parties’ respective rights and duties.

**Conclusion**

HIPAA is likely to impose substantial additional burdens on health care entities. Although final requirements are not yet clear, health care entities would be wise to begin to address the management of health care information as a discreet and significant element of their overall operations. ■

Gary L. Kaplan, Esq.

On February 24 and 25, Kevin Barry served as a Panel Moderator at a program at Georgetown University Law Center entitled “Federal Enforcement 2000: Health Care Fraud Criminal and Regulatory Investigation and Compliance Programs.”

Linda Baumann spoke on March 16 before the New Jersey Hospital Association in Princeton, New Jersey on “The New Safe Harbors and Other Legal Developments Impacting Hospital-Physician Collaboration.”

Linda Baumann authored an article entitled “Navigating the New Safe Harbors to the Anti-Kickback Statute” that was published in the February 2000 issue of the ABA Health Law Section’s The Health Lawyer.

Emily Boynton published an article in the April issue of the Physicians’ News Digest entitled “Unionization of Interns, Residents and Fellows.”

Elizabeth Carder served on the Planning Committee for the American Health Lawyers Association’s annual conference on “Healthcare Fraud and Abuse,” held on November 11 - 12 in Washington, DC. Additionally, Ms. Carder presented, with Assistant United States Attorney James G. Sheehan, an “Industry Update on Home Health/DME/Hospice,” and presented a seminar on “Fraud and Abuse Enforcement Activities in the Pharmaceutical Industry.”

On January 21, the RSSM Health Care and Labor Groups jointly sponsored a teleconference seminar on the “Unionization of Interns and Residents—The Implications of the NLRB’s Boston Medical Center Decision.” Karl Fritton, John DiNome and David Weissman conducted the teleconference.

Thomas Greeson spoke on March 4 in San Antonio, Texas at a meeting sponsored by Fuji Medical Systems on “Legal and Regulatory Issues in Telemedicine.”

On March 20, Thomas Greeson spoke in Washington at the annual legislative conference of the American Society of Anesthesiologists on state and federal initiatives that permit physicians to collectively negotiate with third-party payors.

In the February 2000 issue of the ABA Health Law Section’s The Health Lawyer, Andrea Kahn-Kothmann published an article entitled “OIG/HCFA Special Advisory Bulletin on the Patient Anti-Dumping Statute—Obligations of Hospitals to Render Emergency Care to Enrollees of Managed Care.”
On March 3, Andrea Kahn-Kothmann spoke at the AHLA’s Hospital and Health System Law Institute in New Orleans regarding “Pitfalls in Medicare’s New Hospital Conditions of Participation.” Andrea Kahn-Kothmann served as a faculty member for the Pennsylvania Bar Institute’s 6th Annual Health Law Institute in Philadelphia and presented a workshop program on March 16 entitled “Fraud and Abuse Laws in Private Hands.”

On February 29, Kerry Kearney and Celia Santander spoke at the University of Pittsburgh on “Telemedicine and the Law.”

On March 23, Renee Martin presented a program in Princeton, New Jersey entitled “Medical Record Confidentiality.”

Renee Martin spoke in Atlanta on April 13 to the American Association of Managed Care Nurses on “Liability Issues for Managed Care Organizations.”


On January 27, Marc Scheineson spoke before the Washington, DC Center for Business Intelligence on “FDA Regulation of Dissemination of Information over the Internet.”

Marc Scheineson gave two presentations to Visions in Business, Ltd. in Nice, France. On March 28, he spoke about “Pushing Back the Legal Boundaries of the FTC Laws to Find Innovative Ways of Exploiting the Regulations,” and on March 30 he gave a speech entitled “Update on the View of the FDA: Can DTC Really Police Itself?”


On April 14, in Washington, DC, Marc Scheineson spoke to the Public Relations Society of America on “Off-Label Drug Information: The Impact of the WLF Case.”


In February, Brad Terry’s article entitled “HMO Liability Implications for the Use of Financial Incentive Arrangements in the Provision of Health Care” was published in The Health Care Law Monthly.

Karl Thallner is serving as an advisor for a chapter, entitled “Physician Financial Relationships - Provider Networks,” in the upcoming publication Health Care Compliance Guide: Medicare/Medicaid Risk Areas to be published by The Bureau of National Affairs, Inc.

Karl Thallner’s article “OIG Issues Report on Hospital Ownership of Physician Practices” was published in the December 1999 issue of the ABA Health Law Section’s publication The Health Lawyer.

Recent Reed Smith Client Memoranda Available

Below is a listing of Client Memoranda recently prepared by the Reed Smith Health Care Group. If you would like a copy of any of them, please contact any of the attorneys in our Health Care Group, and we would be happy to send one to you.

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/17/00</td>
<td>HOPPS Final Rule Part I: Outpatient Prospective Payment System</td>
</tr>
<tr>
<td>4/17/00</td>
<td>HOPPS Final Rule Part II: New Criteria For “Provider-Based” Facilities</td>
</tr>
<tr>
<td>3/20/00</td>
<td>OIG Final Compliance Guidance For Nursing Facilities</td>
</tr>
<tr>
<td>3/3/00</td>
<td>OIG Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which the Physician Refers</td>
</tr>
<tr>
<td>1/31/00</td>
<td>The Pennsylvania Department of Health’s Proposed Rulemaking on The Quality Health Care Accountability and Protection Act — “Act 68”</td>
</tr>
<tr>
<td>12/20/99</td>
<td>FDA’s Final Rule Implementing the Prescription Drug Marketing Act</td>
</tr>
<tr>
<td>12/17/99</td>
<td>New “Safe Harbor” Regulations Under The Anti-Kickback Statute</td>
</tr>
</tbody>
</table>
Congressional leaders still hope to make progress on a number of health care-related initiatives before the target adjournment date of October 6, 2000. Some of the more prominent issues now being debated include:

- **Medicare Reform**—In April 2000, the House and Senate approved a budget blueprint that essentially sets aside $40 billion over 5 years for Medicare reform initiatives, including funding for a Medicare prescription drug benefit (see below). While many lawmakers want comprehensive Medicare reform that extends the life of the Medicare trust fund, the short legislative calendar and the lack of consensus behind any single reform plan make it more likely that this issue will be held over until next year. Even without comprehensive reform, however, Congress could use a portion of the funds set aside in the budget resolution to add a prescription drug benefit and/or provide additional relief to providers—particularly hospitals and home health agencies—from the Medicare payment cuts included in the Balanced Budget Act of 1997.

- **Prescription Drug Coverage**—Congress is considering a wide variety of measures to expand Medicare coverage of prescription drugs. In recent weeks the debate in Washington has centered on whether a new drug benefit should be targeted at low-income beneficiaries, or if it should be universal. Republicans generally have endorsed targeting the benefit, at least initially, while Congressional Democrats and the Clinton Administration have launched a high-profile campaign to ensure that any prescription drug program is open to all beneficiaries. While Republican Congressional leaders have vowed to bring legislation to a vote this year, it is far from certain that the House and Senate could adopt a bill that the President will sign into law. If Congress fails to act, expect to see prescription drug coverage emerge as a high-profile issue in the fall elections, and a top candidate for action in 2001.

- **Managed Care Reform**—Lawmakers currently are negotiating to resolve major differences between House- and Senate-passed “Patients’ Bill of
Rights” legislation. While progress reportedly has been made on many smaller provisions, compromise has been elusive on some of the most significant items, including whether the new patient protections should apply to all privately-insured individuals or just those in self-insured plans, and how an external appeals process should work. Nevertheless, Congressional leaders have indicated that they still hope to enact broad patient protection legislation this year.

• Medical Records Privacy—Due to Congress missing its deadline under the Health Insurance Portability and Accountability Act of 1996 for adopting medical privacy legislation, the Department of Health and Human Services (“HHS”) issued a proposed rule in November 1999 to protect the confidentiality of certain individually-identifiable medical records are maintained or transmitted electronically. Many providers, insurers, and privacy advocates have raised a variety of concerns about the scope and potential implications of the regulation, including the potential exposure of individuals and businesses to significant civil and criminal penalties for violations of the new standards. In fact, HHS has received over 50,000 comments on the proposed regulation, which has pushed back the expected release date of the final rule until the end of this year or the beginning of 2001. In the meantime, some members of Congress still are attempting to craft privacy legislation that would supercede the Administration’s regulatory efforts—a development HHS has endorsed. The sheer complexity of the issue and lack of bipartisan solutions to questions such as whether individuals should be able to sue for damages related to privacy violations and whether the standards should preempt more stringent state laws makes the adoption of legislation unlikely in 2000.

• Medical Mistakes—Since release of a November 1999 Institute of Medicine report on the high level of deadly medical mistakes in the nation’s hospitals, various Congressional panels and members of Congress have been grappling with legislative initiatives to mitigate this problem. Some lawmakers, including the Chairman of the House Ways and Means Health Subcommittee, have argued that this issue should be included in patient protection bill, stating “isn’t the ultimate patient protection to prevent deaths from medical errors?” While a number of hearings have been held and several bills have been introduced to encourage reporting of medical errors, no consensus bill has yet emerged, nor has any panel proceeded to marking up legislation.

• Physician Collective Bargaining—In March 2000, the House Judiciary Committee approved legislation that would allow health care professionals in private practice to form collective bargaining units. According to the bill’s sponsor, Rep. Tom Campbell (R-CA), the Republican leadership has promised that the bill will be voted on in the House this year. It is likely that the measure will pass the House, since it has over 200 cosponsors. There has been no activity on this issue in the Senate, however, and it is unlikely that the Senate will take up the bill this year.

Any legislation that is not enacted before Congress adjourns in the fall would have to be reintroduced in 2001 to be subject to further action, since legislation does not carry over when this Congressional session ends.

Debra A. McCurdy