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Act now to prevent suits against hospital ethics committees, experts advise

Although lawsuits against hospital ethics committees and their members are not prevalent, it is worth taking the time now to prevent legal problems in the future, according to experts who spoke during an American Bar Association teleconference on January 23, 2008.

The role of an ethics committee. Ethics committees review ethical or moral questions that may arise in the course of a patient's care. Membership is diverse, typically including physicians, nurses, and social workers, as well as attorneys, chaplains, medical ethics professionals, and community members. Up to 95 percent of hospitals now have ethics committees, a figure that has doubled since the 1980's.

Robyn Shapiro, a partner with Drinker Biddle, Milwaukee, Wisconsin, said that to prevent legal problems, committees should identify and express in writing what their role is, what their responsibilities are, and who their members are. The members should keep up to date on medical literature. "Take the education of yourself seriously," Shapiro recommended. Committees that meet regularly should devote a portion of their meetings to education, she added.

Characteristics of an effective ethics committee. The committee should have clear guidelines for consultation that will help ensure consistency in how these consults happen. The guidelines should assure that there is a clear understanding on the part of all members about the medical facts of the case presented, Shapiro advised. "That is absolutely an essential requirement for people to have a good feeling for what the medical facts are before they start to analyze them from a medical perspective."

There also should be a process that assures that people are heard, Shapiro emphasized. "One of the significant values of an ethics committee is its multidisciplinary nature." She cautioned against "group think," in which particular members of a committee may not feel comfortable expressing their own perspectives if they go against the majority opinion. "There should be a process for making sure that all voices are heard," she added.

Documentation should be appropriate, including, but not limited to, documentation that notice was provided to the patient or the patient's family that care is taken to protect confidentiality, Shapiro explained. Finally, the committees and their work should be evaluated periodically to assure accountability and reduce possible exposure.

Accountability. Sharon Caulfield of Caplan and Earnest, Boulder, Colorado, said the ethics committee should be accountable to the governing

Wolters Kluwer Law & Business

Trends (cont.)

board of the institution about how the committee is fulfilling its charge, how many consults it has undertaken, what kinds of community involvement it has sought, and to whom it has been listening, so that when the committee does an accreditation review, it has information to demonstrate the activities in which it has been involved. That way, in the event of a legal challenge, the documentation will be there to demonstrate that the committee is fulfilling the role the case law suggests it should, Caulfield said.

Caulfield also stressed that hospitals should ensure that members of ethics committees spend time working out their differences before a lawsuit arises. "Deal with dominant personalities early," she suggested. ■

CCH Washington Bureau, Jan. 30, 2008.

Tax-Exempt Organizations

Practitioners recommend "test run" of revised Form 990

Tax-exempt hospitals should do a practice run before they have to file a new tax schedule, according to practitioners who spoke during a February 6, 2008, teleconference presented by the American Health Lawyers Association (AHLA). When the IRS revised Form 990, the annual reporting form for tax-exempt organizations, it developed Schedule H for hospitals. Although the revised Form 990 generally will take effect in 2008 (for the 2009 filing season), Schedule H will not apply until 2009 (for the 2010 filing season).

Mary Rauschenberg of Deloitte Tax LLP recommended that organizations prepare a "mock-up" of Schedule H using 2008 information. James King of Jones Day suggested taking a "test drive" and filling out the schedule for 2008.

The previous Form 990 did not provide for the reporting of community benefit activities. King noted that Schedule H still does not answer the question of how to identify community benefit. The revised form has sections on community benefit, billing and collections, management companies and joint ventures, and facility information.

While the Internal Revenue Services' (IRS') goal was to reduce the reporting burden on exempt organizations, it conceded that most of the information requested in Schedule H was not required in the previous Form 990 and that the additional burden could be substantial for many hospitals, particularly in the first year of reporting.

Draft instructions. Ronald Schultz, Senior Technical Advisor to the IRS Commissioner of Tax Exempt and Government Entities, indicated that the IRS is focused on issuing instructions for the revised form. The IRS anticipates releasing a draft set of instructions in the spring of 2008 and expects to issue final instructions by the summer of 2008. Some instructions may be released as soon as they are completed, possibly for Schedules H and K, governance and compensation. There will be a period for submitting comments.

A few regulatory changes will be needed so that the regulations are consistent with the new Form 990 reporting, Schultz stated. This may only be in three or four areas, he said. An important instruction will be the definition of a hospital. The IRS is considering licensed facilities under state law, and is looking to see whether a second category might be needed. It may review prior IRS determination letters involving medical organizations, Schultz noted.

Another important definition will be for a material diversion of assets, Schultz indicated. This phrase was added to the final draft of Form 990 but is undefined. Schultz said the IRS will look to state law and wants to avoid too broad a definition. It will be looking for abusive transactions and not, for example, a transfer of assets for value to a joint venture.

Other issues. According to King, the most important aspect of Form 990 for 2008 is Schedule J on compensation. He noted that the IRS performed a compliance check on compensation of executives for exempt organizations and may take further action in this area. This is a hot topic, he commented, and subject to demagoguery. King also suggested that whistleblower attorneys may be pouring over the Form 990s looking for items to report. ■

CCH Washington Bureau, Feb. 6, 2008.

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Senate committee examines private MA plans

In response to complaints that Medicare Advantage (MA) plans are inefficient, unaccountable, and cumbersome, the Senate Finance Committee examined private fee-for-service MA plans at a hearing on January 30, 2008.

Background. Congress created the private fee-for-service plans in the 1998 Balanced Budget Act to address potential concerns that health maintenance organization (HMO) gatekeepers might ration care, Senate Finance Committee ranking member Charles Grassley (R-Iowa) said. Because private fee-for-service plans provide no quality data, however, beneficiaries cannot compare plans based on quality. Moreover, Grassley added, the plans do not have to coordinate care or help patients manage chronic illness, and they can force providers to accept the lower government-set Medicare payment rates instead of having to pay the market rate.

Relationships with providers. Unlike traditional fee-for-service plans, private fee-for-service plans are not required to have relationships with providers, nor must they ensure that the providers will serve the people enrolled in the plans, Senate Finance Committee Chairman Max Baucus (D-Mont.) noted. "Doctors and hospitals who do not have a contract with the plan can decide not to treat a patient in one of these plans at any time. And providers can deny treatment even if those providers participate in traditional Medicare," he said.

Quality reporting. Private fee-for-service plans also are not required to submit any data about the quality of the care their enrollees receive, unlike HMOs and preferred provider organizations, which are required to report quality data, according to Baucus. He added that CMS "cannot oversee and regulate the benefits of private fee-for-service plans as they do other Medicare Advantage plans. That means that private fee-for-service plans can require the beneficiary to pay more than traditional Medicare."

Transparency and accountability. Baucus said some providers have complained that private fee-for-service MA plans are more burdensome, less transparent, and pay less than traditional Medicare. These providers say the lack of a contractual relationship means that providers have little protection and recourse when these plans underpay or deny care. Baucus also has been told by providers that the private fee-for-service plans are confusing to beneficiaries.

Grassley commented that the plans have little accountability. "Providers are frustrated and oversight is difficult," he said. Moreover, while they advertise that enrollees can go to any doctor or hospital, the plans sometimes fail to explain that the hospital or doctor may refuse them, Grassley said, adding "I am disturbed that my constituents may have a hard time getting access to their doctors."

Rising enrollment. Grassley and others are concerned about the rapid growth of private fee-for-service plans. Grassley noted that in 2004 there were 50,000 people in the plans compared with about 1.9 million people this year.

Mark Miller, executive director of the Medicare Payment Advisory Commission, Washington, D.C., noted that enrollment in the plans has increased eightfold in the last two years. "Given that Medicare spends 17 percent more than it would if these beneficiaries had stayed in [traditional Medicare] fee-for-service, and [private MA plans] do not manage care, enrollment growth in private fee-for-service plans comes at an unacceptably high cost to Medicare," he said.

Other concerns. Miller also advised lawmakers to set the payment rate at an amount that will drive efficiency. "The Medicare program needs to exert consistent financial pressure on both the traditional fee-for-service program and the MA program," he said.

Senator Ron Wyden (D-Ore.) said the private fee-for-service product is "removed from the Medicare law," and complained about a lack of oversight.

Elyse Politi, State Health Insurance Program Coordinator for New River Valley Area Agency on Aging, Pulaski, Virginia asked for tighter marketing controls due to concerns about questionable marketing and sales tactics.

CCH Washington Bureau, Jan. 30, 2008.

OIG guidance on ED on-call arrangements: Structuring on-call arrangements to comply with the federal illegal remuneration statute

by Adam Robison, Esq. and Debbi Johnstone, Esq.

A number of hospitals currently are paying or considering whether to pay physicians for providing emergency department (ED) on-call coverage. Like most other compensation arrangements between hospitals and physicians, on-call arrangements can, if structured improperly, subject hospitals to liability under the illegal remuneration statute, §1128B(b) of the Social Security Act (Illegal Remuneration Statute), and the physician self-referral law, §1877 of the Social Security Act (Stark Law).

The requirements for structuring on-call arrangements to comply with the Stark Law are relatively straightforward. To avoid strict liability, the arrangement must be designed to fit squarely within a Stark Law exception, such as the personal service arrangements exception.[1] Knowing how to structure on-call arrangements to comply with the Illegal Remuneration Statute, however, has not been as clear. While the personal services and management contracts safe harbor (Personal Services Safe Harbor) is potentially applicable, hospitals have, in practice, had difficulty designing their on-call arrangements to comply with certain elements of the safe harbor.

On October 20, 2007, however, the HHS Office of Inspector General (OIG), issued Advisory Opinion 07-10 (AO 07-10), analyzing a hospital's on-call arrangement under the Illegal Remuneration Statute.[2] Prior to the issuance of AO 07-10, the OIG had not provided any formal guidance to hospitals on structuring on-call arrangements that do not meet all of the requirements of the Personal Services Safe Harbor.

While advisory opinions may not be relied upon by anyone other than the party requesting the opinion, AO 07-10 provides helpful guidance to hospitals that are in the process of:

(1) deciding whether or not to pay physicians for on-call coverage;
(2) implementing new on-call arrangements; and
(3) evaluating the adequacy of their existing on-call arrangements.

Difficulties meeting personal services safe harbor requirements

The OIG has promulgated a safe harbor to protect certain qualifying personal service arrangements, including on-call coverage arrangements, from liability under the Illegal Remuneration Statute. The Personal Services Safe Harbor requires that the following requirements be met:

(1) the personal services arrangement is set out in writing and signed by the parties;
(2) the agreement specifies the services to be provided;
(3) if the agreement is intended to provide for the services of a party on a periodic basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
(4) the term of the agreement is for not less than one year;
(5) the aggregate compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals for business between the parties that is reimbursed under the Medicare and Medicaid programs; and
(6) the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.[3]

On-call arrangements must comply with all the requirements set forth above to qualify for Personal Services Safe Harbor protection.[4]

In AO 07-10, the OIG commented that "in many cases, it should be possible to structure ED on-call coverage compensation to satisfy the [Personal Services Safe Harbor]."[5] While hospitals can, in theory, structure their on-call arrangements to meet all of the requirements of the Personal Services Safe Harbor, hospitals frequently encounter difficulties when attempting to do so in practice.

As described above, the Personal Services Safe Harbor requires the aggregate compensation paid to a physician to be "set in advance." The OIG, however, has determined that when a physician's monthly compensation under an on-call arrangement potentially varies from month-to-month, the compensation is not set in advance. Generally, physicians paid on a *per diem* or per activation basis for providing on-call coverage are paid a different amount each month. Thus, because a significant number of hospitals pay

their physicians for providing on-call coverage on a *per diem* or per activation basis, such arrangements cannot meet the set-in-advance requirement of the Personal Services Safe Harbor.

Moreover, on-call coverage generally is furnished by physicians on a temporary, rather than full-time, basis. The Personal Services Safe Harbor requires agreements for temporary services to state with specificity when the services will be provided, the length of time for which they will be provided, and the precise compensation that will be provided at each interval of service.

Many hospitals, however, are unable to establish their call rotation schedules one or more years in advance. As such, these hospitals' on-call arrangements do not meet all of the requirements of the Personal Services Safe Harbor.

OIG Advisory Opinion 07-10

In AO 07-10, a nonprofit tax-exempt medical center requested that the OIG determine whether the medical center's on-call and uncompensated care arrangement subjected the hospital to sanctions under the Illegal Remuneration Statute. Prior to implementing the arrangement, the medical center had encountered substantial difficulty in obtaining sufficient physician on-call and follow-up inpatient coverage.

The inability to obtain such coverage forced the medical center to transfer a number of patients to other area hospitals, thereby preventing the medical center from fulfilling its charitable mission. In response to this dilemma, the medical center formed a committee comprised of board members and other medical center officials to study the problem and make remedial recommendations.

After investigating the matter, the committee recommended that the medical center start paying physicians within certain physician specialties to induce them to provide on-call and follow-up inpatient coverage. The medical center ultimately agreed with the committee's recommendations and implemented the arrangement.

In implementing the arrangement, the medical center entered into a series of two-year on-call agreements with physicians within certain physician specialties.[6] Under the agreements, the physicians are obligated to provide on-call coverage, furnish follow-up inpatient care and consultative services, timely respond to ED calls, cooperate in the medical center's quality assurance initiatives, and document in the patients' medical records the services they provide under the arrangement. Physicians providing on-call coverage are monitored by the medical center to ensure that they are complying with the terms of the on-call agreements.

In exchange for providing on-call coverage and other services, the physicians are compensated by the medical center on a *per diem* basis. The *per diem* rate received by the physicians varies only in accordance with the particular physician's specialty and the day (*i.e.*, weekday versus weekend) on which the coverage is provided. Thus, physicians within the same physician specialty receive identical *per diem* compensation under the arrangement. The *per diem* rate paid by the medical center to each physician specialty was reviewed by a fair market value consultant to ensure that the compensation was consistent with fair market value and not determined in a manner that took into account the volume or value of the referrals generated by the parties.

The OIG concluded that, although the arrangement did not qualify for Personal Services Safe Harbor protection, the agency would not "for a combination of reasons" impose sanctions on the medical center. Specifically:

- First, the OIG determined that the hospital had a legitimate unmet need for providing compensation to its physicians for providing on-call coverage. The medical center had been unable to staff its ED with qualified physicians and had been compelled to outsource its emergency care to other area hospitals.
- Second, the OIG found it persuasive that the medical center's fair market value consultant had determined that the compensation provided by the medical center to the physicians was consistent with fair market value for actual services and did not take into account the volume or value of referrals or other business generated by the physicians.
- Finally, the OIG noted that certain other features of the arrangement mitigated the risk that it would violate the Illegal Remuneration Statute. The arrangement was offered uniformly to all physicians within the same specialty, participating physicians were required to provide inpatient follow-up care to patients admitted to the medical center regardless of the patients' ability to pay, and the arrangement was structured such that any increased cost would be borne by the medical center, not the government health care programs.

In summary, the OIG found that, although the arrangement did not comply with all of the requirements of the Personal Services Safe Harbor, the arrangement contained "safeguards sufficient to reduce the risk that the remuneration is intended to generate referrals of Federal health care program business." The OIG, however, cautioned hospitals that each on-call arrangement should be independently evaluated under a totality of the circumstances approach.

Using AO 07-10 as guidance

The AO 07-10 guidance addresses several scenarios. What follows is an overview of how AO 07-10 relates to hospitals considering whether to pay for on-call coverage, hospitals in the process of implementing an on-call arrangement, and hospitals already paying for on-call coverage.

What does AO 07-10 mean to hospitals considering whether to pay for on-call coverage?

AO 07-10 instructs hospitals contemplating entry into a compensated on-call coverage arrangement that they should not do so unless their decision is premised upon a "legitimate unmet need." The OIG indicated that a legitimate unmet need may include one or more of the following:

(i) compliance with the hospital's Emergency Medical Treatment and Active Labor Act (EMTALA) obligations;

(ii) lack of availability of certain physician specialties; and
(iii) lack of accessibility to trauma services.[7]

In AO 07-10, the medical center certified that, prior to implementing the arrangement, its ED was understaffed, requiring it to outsource emergency care to other hospitals. The OIG also found that these circumstances suggested that the medical center had a legitimate, unmet need for on-call coverage. Thus, hospitals that are thinking about paying for on-call coverage should document that they have a legitimate, unmet need for providing compensation.

Hospitals should be cautioned, however, that AO 07-10 is not a license to pay for on-call coverage. Indeed, the OIG cautioned that there are situations in which hospitals would not be justified in compensating physicians for on-call coverage. For example, the OIG indicated that the following compensation structures would not be legitimate:

- "lost opportunity" or similarly designed payments that do not reflect *bona fide* lost income;
- payment structures that compensate physicians when no identifiable services are provided;
- aggregate on-call payments that are disproportionately high compared to the physician's regular practice income; and
- payment structures that compensate the on-call physician for professional services for which he or she receives separate reimbursement from insurers or patients, resulting in the physician essentially being paid twice for the same service.[8]

Similarly, if a hospital has not encountered any problems obtaining qualified physicians to provide on-call coverage, the hospital presumably does not have a legitimate unmet need to start paying for on-call coverage.

What does AO 07-10 mean to hospitals in the process of implementing on-call arrangements?

AO 07-10 also provides guidance to hospitals that are in the process of implementing on-call arrangements. AO 07-10 instructs that the "key inquiry" in determining the appropriateness of an on-call arrangement is whether the compensation is:

(i) fair market value in an arm's length transaction for actual and necessary items or services; and
(ii) not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.[9]

To ensure that the arrangement complied with these requirements, the medical center engaged a fair market value consultant to verify that the compensation provided to each physician specialty was consistent with fair market value and not determined in a manner that took into account the volume or value of referrals generated by the particular physician. Hospitals implementing new on-call arrangements also should consider the appropriateness of engaging a fair market value consultant to evaluate the compensation provided under the arrangement. Hospitals that elect not to use a fair market value consultant nevertheless should use some other reliable method to confirm that their arrangements meet the compensation requirements interpreted in AO 07-10.

Hospitals also should consider incorporating provisions in their on-call agreements that place demands on their physicians beyond the time they spend taking call. As part of the arrangement addressed in the advisory opinion, the physicians were obligated to enter into two-year on-call agreements with the medical center. The agreements obligate the physicians to participate in the medical center's on-call rotation, as well as perform certain "additional services," including:

(1) providing follow-up inpatient care or consultative services;
(2) responding timely to ED calls;
(3) cooperating with the medical center's care management or risk management and quality initiatives; and
(4) completing patient medical records.

The agreements also require each physician to provide 18 days of on-call coverage per year without pay. On the basis of these additional services, the OIG concluded that the "*per diem* payments under the Arrangement [were] tailored to cover substantial, quantifiable services, a large portion of which are furnished to uninsured patients in the ED and afterwards." Accordingly, hospitals implementing on-call arrangements also should consider requiring their physicians to provide services in addition to on-call coverage.

Hospitals also should think about incorporating certain other safeguards that the OIG stated would further minimize an on-call arrangement's risk of fraud and abuse. Ordinarily, physicians within the same physician specialty should be treated uniformly under their arrangements. Paying or treating physicians within the same specialty disparately under an on-call arrangement gives the impression that the hospital is providing favorable treatment to its high referrers. As such, physicians within the same specialty should be offered the same compensation.

Hospitals should consider requiring physicians participating in their on-call arrangements to provide follow-up inpatient care to the patients they admit, regardless of the patients' ability to pay. Again, requiring physicians to provide services beyond on-call coverage demonstrates that the physicians are performing *bona fide* and quantifiable services.

What does AO 07-10 mean to hospitals already paying for on-call coverage?

Hospitals already paying for on-call coverage should use AO 07-10 as a tool to assess the integrity of their current arrangements. In particular, if the hospitals have not documented their patient care-related reasons for paying for on-call coverage, they should do so. Hospitals may look to the legitimate, unmet needs identified in AO 07-10, as well as other patient-related matters that may be relevant.

Hospitals also should ensure that their payments to physicians for on-call coverage are consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals or other business generated by the physicians. As noted earlier in this article, it often is advisable that hospitals engage independent valuation consultants in this process.

Hospitals with on-call arrangements also should compare their on-call agreements with the AO 07-10 agreements. Many hospitals will discover that, even though their on-call physicians perform the additional services contained in the AO 07-10 agreements, their on-call agreements do not

expressly obligate them to perform such additional services. As indicated, the OIG concluded that the medical center's inclusion of such additional services in its on-call agreements made the arrangement appear "tailored to cover substantial, quantifiable services...." Accordingly, hospitals that determine that their existing agreements do not obligate their physicians to provide any services beyond taking call should consider amending them to include such a requirement. ■

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[1] See 42 C.F.R. § 411.357(d).

[2] *OIG Advisory Opinion*, No. 07-10, Sept. 20, 2007.

[3] 42 C.F.R. § 1001.952(d).

[4] In the preamble to the proposed safe harbor regulations, the OIG warned that "where individuals and entities have entered into arrangements that are covered by the statute, where they have chosen not to comply fully with one of the exemptions in these regulations, they would risk scrutiny by the OIG and may be subject to civil or criminal enforcement action." *Proposed rule*, 54 FR 3088–89, Jan. 23, 1989.

[5] *OIG Advisory Opinion*, *supra* note 2.

[6] *Id.* The physician specialties to which the arrangement was offered included: pulmonology, cardiology, hospitalists, gastroenterology, infectious disease, renal/nephrology, neurology, endocrinology, hematology/oncology, general surgery, obstetrics/gynecology (OB/GYN), neurosurgery, orthopedics, urology, anesthesiology, ophthalmology, oral/maxillofacial surgery, and otolaryngology.

[7] *Id.*

[8] *Id.*

[9] *Id.*

Quality of Care

OIG, HCCA address board oversight of long-term care quality

A joint report by the HHS Office of Inspector General (OIG) and the Health Care Compliance Association (HCCA) focuses on the challenges and opportunities for boards of directors in the long-term care setting. The January 31, 2008, report recommends addressing these challenges and opportunities using a "Quality of Care Dashboard," a management tool that may provide a way to assess and oversee performance on quality of care issues. The report is the product of a roundtable partnership which invited representatives from the long-term care industry to inform the OIG and HCCA of issues surrounding the oversight of quality of care by boards of directors. The roundtable focused its discussions with four breakout sessions covering the following topics: (1) commitment to quality; (2) processes related to monitoring and improving quality of care; (3) outcome measures for quality of care; and (4) challenges and opportunities in using a Quality of Care Dashboard.

Commitment to quality. A main theme of the commitment to quality session was communication, specifically how a board receives quality of care information and communicates its commitment to quality throughout an organization. An organization first must have a structure and forum in which a compliance officer has the opportunity to communicate quality issues directly to the board. A board needs to be actively engaged with the compliance officer to make sure that the issues raised are being addressed. A board also should assess the organization's culture, specifically whether employees feel comfortable discussing quality issues openly. Proper structures and processes that are routinely evaluated is another indicator of a board's commitment to quality, as is the proper allocation of resources. A failure to address issues like staffing, equipment, and infrastructure can adversely impact quality of care.

Process. Structural tools are key to an effective process for quality of care. The board must receive regular reports with indicators such as patient and customer satisfaction, financial measures, staffing, and nursing hours. The validation of the information received in such reports through internal or external experts is also crucial. Educating boards about quality and the data received in quality reports is necessary through presentations or by bringing in experts. Boards must coordinate a system wide response to quality issues, rather than putting "band-aids" over symptoms while ignoring the underlying problem.

Outcomes. Participants in the roundtable identified key outcome categories that have proven to be valuable measures in assisting boards with meeting their oversight responsibilities, such as: (1) surveys performed by the state survey agencies; (2) resident outcomes and care delivery; (3) events reporting; (4) complaints from patients, family members, and staff; and (5) financial indicators. Just as important as receiving the proper information is making sure the board is sufficiently educated and trained on how to understand the outcome information and data reported to them, according to the report.

Implementing a Quality of Care Dashboard. Developing an effective Quality of Care Dashboard involves many challenges, and opportunities must be examined with these challenges in mind. The specific challenges identified by participants include the following: (1) quality indicators are not a one size fits all proposition, and the diversity of board members in terms of sophistication level and competence must be taken into account; (2) boards' limited time and resources means information presented to the board must be prioritized; (3) an appropriate balance must be achieved between the need for information and potential legal liability concerns of board members; and (4) quality indicators lag behind other indicators in health care, necessitating scrutiny of indicators on a continuing basis. ■

Driving for Quality in Long-Term Care: A Board of Directors Dashboard, Jan. 31, 2008, Health Care Compliance Reporter ¶530,652.

Quality of Care

Stark regulations, quality of care top list of issues for 2008

Physician self-referral regulations and quality of care topped the list of health law issues for 2008 identified and ranked by the American Health Law Association (AHLA) membership and published in the January 2008 issue of the Health Lawyers News (HLN). The 2008 top ten health issues include:

- **Stark regulations and physician hospital relations.** New and proposed rules may have significant impact on relationships between health care systems and physicians as they relate to physician referrals, HLN noted.
- **Quality of care.** The provision of quality of care has become a major focus of federal agencies, hospitals, physicians, health plans, and Congress. The Medicare program has provided reimbursement incentives tied to providing quality care and reporting data on quality measures, and the Office of Inspector General has made it a top enforcement priority.
- **Medicaid and state law enforcement.** Based on the mandates and incentives provided by the Deficit Reduction Act of 2005 for states to increase Medicaid enforcement programs, providers that participate in state Medicaid programs may be audited by multiple agencies within the federal and state government. According to HLN, health lawyers will be essential in helping providers with the audit response process.
- **Physician/vendor relationships.** In addition to the increased focus of enforcement agencies and Congress on relationships between physicians and vendors to avoid conflicts of interest and uncover illegal kickbacks, 30 states have passed or proposed legislation regarding vendor gifts, HLN said.

Other health law issues that made it to the top ten include: fraud and abuse, false claims, and anti-kickback investigations; electronic health records; plan/provider competition for increasingly scarce resources; health reform and the State Children's Health Insurance Program; the redesigned IRS Form 990; and antitrust enforcement.■

Health Lawyers News, January 2008.

In the News

Merck settles FCA allegations for $650 million

Merck and Co., Inc. has agreed to pay the federal government more than $360 million and 49 states and the District of Columbia over $290 million to resolve two lawsuits filed by whistleblowers under the *qui tam* provisions of the False Claims Act. The settlement is one of the largest health care fraud settlements ever achieved by the Department of Justice, according to Attorney General Michael Mukasey. The first suit involved allegations that Merck failed to pay proper rebates to Medicaid and other government health care programs by improperly terming as "nominal" the prices it offered to hospitals to boost their sales and excluding those discounts from the prices it reported to the government. The second suit involved allegations that Merck established a marketing scheme in which it provided substantially reduced prices for its Pepcid® products once the hospitals agreed to use those products instead of a competitor's. As part of the resolution of these two cases, the HHS Office of Inspector General and Merck entered into a five-year Corporate Integrity Agreement to ensure that such improper conduct does not occur in the future.

DOJ Press Release, Feb. 7, 2008.

Hospital purchaser pays $2.5 million to resolve fraud allegations

IJKG, LLC, the buyer of Bayonne Medical Center, which is currently in bankruptcy, has agreed to pay $2.5 million to settle allegations of Medicare fraud. When it bought Bayonne, IJKG agreed to purchase the hospital's assets and settle the United States' claims against the hospital. The settlement resolves allegations that Bayonne purposefully inflated charges for inpatient and outpatient care to make these cases appear more costly than they actually were, and thereby obtained outlier payments from Medicare that it was not entitled to receive. The allegations were initially brought by a whistleblower under the *qui tam* provisions of the False Claims Act.

DOJ Press Release, Feb. 4, 2008.

OIG approves charitable contribution arrangement

A marketing and research company's proposal to encourage health care professionals to complete online surveys by offering them the opportunity to designate a public charity to which the company or one of its clients would make a monetary charitable contribution would not generate prohibited remuneration under the anti-kickback statute. Under the proposed arrangement, the company would encourage health care professionals to participate in program consultations by offering them the opportunity to designate a public charity to which the company or one of its clients would make a monetary charitable contribution in the name of the health care professional. All donations would be made directly to the charities, which would be 501(c)(3) organizations and public charities and would meet the public support test under §509(a) of the Internal Revenue Code. In the absence of any prohibited remuneration to the health care professionals, the Office of Inspector General would not impose administrative sanctions in connection with the proposed arrangement.

OIG Advisory Opinion, No. 08-02, Jan. 29, 2008, Health Care Compliance Reporter ¶500,181.