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Allocation of Medicare Integrity Program funds questioned

by Geraldine Szuberla, J.D., Contributing Editor

To better ensure that Medicare Integrity Program (MIP) funds are appropriately allocated, the Government Accountability Office (GAO) recommends that CMS develop a method of allocating funds based on the effectiveness of its program integrity activities, the contractors' workloads, and risk. In response, CMS expressed concern that GAO's report appeared to emphasize the use of a quantitative measure that tracks dollars saved in relation to dollars spent as a way to allocate MIP funds. GAO acknowledged that such a measure cannot serve as the sole basis for informing funding decisions.

Current allocations. Funds allocated to the five Medicare program integrity activities generally have increased since fiscal year (FY) 1997, but the amounts of the allocations and the percentage increases varied by year and activity. For FY's 1997 through 2005, provider education received the largest percentage increase in funds, while audit and medical review received the largest share of funds. Among the five activities, from FY 1997 to FY 2005, CMS increased its allocation by about 45 percent for audits to $207.6 million, 40 percent for medical review to $165.9 million, 49 percent for secondary payer to $151.5 million, and 89 percent for benefit integrity to $118.5 million. CMS increased its allocation by about 590 percent for provider education to $70 million.

Contractor support. CMS allocates MIP funds primarily to support its contractors' program integrity efforts for the traditional Medicare program, known as fee-for-service Medicare. Among these contractors are fiscal intermediaries (intermediaries), carriers, program safeguard contractors (PSCs), and Medicare administrative contractors (MAC's). CMS has contracted with intermediaries, carriers, and MACs to perform two types of activities—claims processing and program integrity. Their claims processing activities include receiving and paying claims. These activities are classified as program management and are funded through a program management budget. In addition, intermediaries and carriers have been charged with conducting some program integrity activities under MIP, including performing medical review of claims.

Medical review. The four MACs selected in January 2006 will not conduct medical review activities. CMS plans to assign responsibility for medical review of claims to the MAC selected in July 2006 (Noridian Administrative Services, LLC) and to the other MAC contracts to be awarded in the future. MIP provides funds to support these program safeguard efforts. In addition, CMS uses MIP funds to support the activities of PSCs, which perform medical review

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Administration (cont.)

of claims and identify and investigate potential fraud cases; a coordination of benefits (COB) contractor, which determines whether Medicare or other insurance has primary responsibility for paying a beneficiary's health care costs; the National Supplier Clearinghouse, which screens and enrolls suppliers in the Medicare program; and the data analysis and coding contractor, which maintains and analyzes Medicare claims data for durable medical equipment, prosthetics, orthotics, and supplies.

Questions. GAO found that CMS does not have a means to compare quantitative data or qualitative information on the relative effectiveness of MIP activities that it could use in allocating funds. It noted that other agencies that investigate or prosecute fraud, such as HHS and the Department of Justice (DOJ), keep track of their successful cases, recoveries, and fines to demonstrate their results. GAO recommended that CMS assess the degree to which each of its contractors has contributed to HHS and the DOJ's successful investigations and prosecutions.

In regard to educating providers on appropriate billing practices, CMS may be missing opportunities to evaluate its contractors' performance, GAO said. Provider education can help reduce billing errors, but CMS has not evaluated the strategies used to modify the behavior of providers through education to determine if these strategies are achieving desired results, according to the GAO. In response, CMS officials stated that they are developing two initiatives that will measure the results of the audit and provider education activities.

GAO commented that medical review, provider education, and benefit integrity are activities for which allocation of MIP funds may not be optimal because CMS has not allocated funds within these activities based on information concerning contractor vulnerabilities. In addition, the amount of medical review funds allocated to individual contractors is not directly tied to the amount of benefits that they pay, which is a key measure of potential risk. Similarly, CMS has not adjusted the amount of funding for individual contractors to educate providers based on their relative risks.

With respect to audit activities, GAO also questioned whether funding allocations are being adjusted as the importance of audit activities has changed over recent years. In FY 2004, CMS began to separately track some audit costs, such as those for desk reviews audits, and wage index reviews. This provided some information on how audit funds were being spent. GAO recommends the tracking of more detailed information on audit costs—such as at the provider level—than CMS currently tracks. This tracking could provide CMS with a better understanding of the value of its current mix of tasks, GAO said, particularly if it could associate the costs with the savings from the audits. ■

GAO Report, No. 06-813, Sept. 6, 2006.

Anti-kickback

OIG reviews PAPs, volunteer services, free oxygen services, specialty therapy assistance

by Stacey Fahrner, J.D., M.P.H., Contributing Editor

In recent advisory opinions, the Office of Inspector General (OIG) determined that two proposed arrangements from pharmaceutical manufacturers to provide drugs for financially needy beneficiaries, an arrangement to reimburse volunteer travel costs to rural areas, and an arrangement to provide financial assistance to patients requiring specialty therapy services posed minimal risks to Medicare. A durable medical equipment company's plan to provide free oxygen supplies, however, would be subject to administrative sanctions. The OIG explained its position for each of these proposals in three advisory opinions issued from September 14, 2006 to November 2, 2006.

PAPs for financially-needy Medicare Part D enrollees. Two proposed arrangements for the provision of drugs to financially needy Part D beneficiaries contain sufficient safeguards such that the arrangements pose minimal risk to the Medicare program. Under the proposed patient assistance programs (PAPs), the beneficiary would apply directly to the manufacturers for assistance and would obtain the drugs from a retail pharmacy. One program would provide the drugs free of charge; the other would

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Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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require the beneficiary to pay a cost sharing amount based on income.

Because the arrangements would operate completely outside the Part D benefit and would not steer the beneficiary to any particular provider or pharmacy, there is minimal risk for violating the anti-kickback statute. No payments would be made for the drugs by Medicare. Participation decisions would be made entirely on financial considerations and would not take into account a beneficiary's choice of Part D provider. Finally, the manufacturer would keep accurate records that would facilitate accountability and transparency in the program.

OIG Advisory Opinions, No.06-19, Oct. 26, 2006, Health Care Compliance Reporter, ¶500,153; No. 06-21, Nov. 2, 2006, Health Care Compliance Reporter, ¶500,155.

Outreach volunteer services program. The facts and circumstances of an Outreach Volunteer Services Program (the program), a volunteer services program for the provision of specialty medical care and professional development in rural areas, through which a hospital system (the requester) covers volunteers' travel costs, adequately reduces the risk of improper payment for referrals or the generation of federal health care program business.

By paying volunteer travel costs and bringing specialty care and professional education and collaboration to rural communities under the program, the requester arguably confers benefits on two potential referral sources: (i) the volunteer health care professionals; and (ii) the health care professionals and patients in the recipient communities.

This is remuneration that implicates the anti-kickback statute, but is not likely to be an improper payment to generate federal health care program business for the requester because:

- the program's structure ensures that the volunteers will not unduly profit from the trip;
- the program's structure makes it unlikely that the volunteers will generate appreciable referrals as a result of the program;
- the primary beneficiaries of any education or collaboration are the patients and residents of the recipient rural community; and
- apart from the convenience of locally available services, beneficiaries are offered no particular incentive to use the services of the volunteers or the requestor's facilities.

OIG Advisory Opinion, No.06-18, Oct. 26, 2006, Health Care Compliance Reporter, ¶500,152.

Arrangement to provide oxygen services free of charge. An existing and a proposed arrangement regarding oxygen services and products for Medicare beneficiaries would potentially violate the anti-kickback statute and be subject to administrative sanctions and civil monetary penalties.

Under the existing arrangement, the durable medical equipment (DME) company does not charge beneficiaries for interim oxygen home delivery. Under the proposed arrangement, the DME company would provide beneficiaries with overnight oximetry testing free of charge.

The provision of free testing and oxygen supplies constitutes a gift of more than nominal value to beneficiaries and creates an opportunity for the DME company to initiate a relationship with the beneficiary and influence his or her selection of a DME provider. Consequently, the arrangement could generate prohibited remuneration.

OIG Advisory Opinion, No. 06-20, Nov. 1, 2006, Health Care Compliance Reporter, ¶500,154.

Financial assistance and therapy management services to beneficiaries. A proposed arrangement to provide financial assistance and therapy management services for patients with certain diseases that require specialty therapy medications poses minimal risk to the Medicare program because the design and administration of the arrangement would not influence beneficiary decision making regarding selection of providers and there is minimal risk that donor contributions would improperly influence referrals. Under the proposed arrangement, donations would be accepted from manufacturers, pharmacies, and infusion companies. Donors would not be supplied with any patient information, and patients would not be informed of the identity of the donors. Finally, an independent charitable organization would accept the donations and manage the program providing a buffer between donors and patients to sufficiently safeguard the Medicare program. ■

OIG Advisory Opinion, No. 06-10, Sept. 14, 2006, Health Care Compliance Reporter, ¶500,156.

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Keeping your friends close and your business partners closer: Legal dynamics in the relationships among hospitals, physicians and manufacturers (Part III)

by Steve Miller, J.D., and Jeffrey Miller, J.D., Contributing Editors

Hospitals, physicians and manufacturers of health care-related products around the world strive to provide the highest quality health care products and services achievable. In a complex (and sometimes counterintuitive) regulatory environment defining the limits to appropriate business transactions can be a challenge. This four part article provides an introduction to the federal anti-kickback statute that addresses hospital and manufacturer rules in discounting prices without discarding compliance, and provides guidelines for physician consulting and professional services arrangements.

Part I provided the background on the anti-kickback statute and the details of how an arrangement may be protected from prosecution under the statute. Part II provided details of the discount exception and potential discount risks; consignment arrangements; implementing controls to prevent unidentified discounts; and the effect of failing to satisfy the requirements of the safe harbor. Part III focuses on manufacturer-physician consulting and professional services arrangements including compensation arrangements.

Manufacturer-physician consulting and professional services arrangements[45]

The legal requirements that govern physician consulting and professional services arrangements are based upon the type of relationship addressed.[46]

Employment relationships. Employing physicians is the easiest way to comply with most of the elements of the statute's safe harbor requirements. Moreover, employment relationships, over all other forms of physician relationships, have the fewest limitations. Under the federal anti-kickback statute, protection can be obtained easily under the bona fide employee exception or the employment arrangements safe harbor.[47] Most physicians, however, may be unable to qualify as true employees. Under these standards, the physicians must be bona fide employees as defined in the federal Internal Revenue Code.[48] If this cannot be achieved, other forms of relationships must be considered.

Independent contractor relationships. Physicians are most commonly engaged to provide consulting or other professional services through contractual agreement. For independent contractor relationships, the federal anti-kickback statute contains the personal services/management contracts safe harbor.[49] This safe harbor requires that:

1. the arrangement is set out in a written agreement that is signed by the parties;
2. the arrangement covers all of the services the physician provides for the term of the agreement, and specifies the services to be provided;
3. if the agreement is intended to provide for the services on a periodic, sporadic or part-time basis, rather than on a full-time basis, 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 to the physician over the term of the agreement be set in advance, be consistent with fair market value in arms-length transactions,[50] and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal health care programs;
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; and
7. the aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

The Office of Inspector General interprets the safe harbor's "set in advance" standard to require the compensation be in an aggregate amount. As a result, it excludes "per unit," hourly and similar compensation structures from safe harbor protection.[51] Additionally, the OIG describes "commercially reasonable" to mean that the services provided have intrinsic commercial value to the

purchaser of those services, without consideration of the volume or value of referrals.[52] In this regard, the OIG recognizes that compensating small numbers of physicians for bona fide consulting or advisory services is unlikely to raise any significant concerns. All physician services, however, must bring demonstrable value, independent of business generation, if any, for the manufacturer.[53] Compensating physicians as "consultants" to attend meetings or conferences in a primarily passive capacity, along with presenting ghost-written papers or speeches (even when there is full disclosure of the physician's conflict of interest) is suspect.[54]

Defining "fair market value"

Under the anti-kickback statute "fair market value" is defined as the value of the services for general commercial purposes, not adjusted for any additional value that one party might bring that could be attributed to that party's ability to generate business or patient referrals.[55] While in general, this definition provides some insight into how the OIG views the value of physician compensation. Additional insight can be found by reviewing a sister law to the statute: the Ethics in Patient Referral Act, referred to as the Stark law ("Stark").[56] In Stark, CMS defines "fair market value" as:

> the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement.[57]

The Preamble to the regulations states that any method that provides sufficient evidence that the compensation is "comparable to what ordinarily is paid for an item for service in the location at issue, by parties in arms-length transactions who are not in a position to refer to one another" is acceptable.[58] No independent valuation is required and the amount of analysis that is sufficient to determine "fair market value" will vary from case to case. The government, however, will give independent valuations more weight than internally generated valuations, as it believes that internally generated valuations are frequently biased and susceptible to manipulation.[59]

Valuing arrangements for compensation

The determination of fair market value compensation is not a "cookie-cutter" process. There are a variety of legitimate techniques that can be used, and the government subscribes to no particular technique other than that the value should be based upon the worth of the services provided in the marketplace.[60] Manufacturers do need to recognize, however, that a consistent approach to valuing physician compensation, supported by a written company policy, should be the foundation for addressing compensation valuation. It is not advisable for a manufacturer to have various approaches to each individual physician compensation arrangement. Variable approaches undermine the compensation valuation process by leading to questions regarding which approach is most accurate, and why one approach was chosen over another. These questions can result in valuation legitimacy issues for government agents and physicians alike. In some physicians' minds inconsistency also means inequality, which can result in physician dissatisfaction as well.

Generally, compensation is valued by comparison to marketplace compensation based on benchmark comparisons and assumptions.[61] This technique uses marketplace salary surveys as the baseline, incorporates market conditions, and physician and position uniqueness, and then determines a rate that is consistent with the market compensation at the xth percentile for similar services.[62] For consulting and professional services arrangements, the determination of the fair market value can be benchmarked utilizing a 40-hour work-week. The comparative data sources tend to be from academic physician compensation surveys or surveys highlighting administrative leadership positions. In some cases, however, the determination of fair market value is more appropriate utilizing comparative compensation surveys highlighting similar practicing physicians. It is advisable to select several surveys and develop a composite index by specialty as the survey compensation amounts can vary by as much as 15 percent-20 percent or more. When developing the benchmark for fair market value, key qualitative characteristics of the position such as experience, clinical specialty, and geographic location are factored into the compensation determination. In addition, the valuator needs to use judgment in testing the survey rates with the position description and other factors influencing the current marketplace.

The marketplace comparable compensation is by far the most common and useful. At times, however, it can be outdated regarding specific specialties given the retrospective nature of the marketplace surveys. There are several secondary sources for validating the marketplace compensation for specific clinical specialties, including, but not limited to:

1. verification with physician recruiting agencies to confirm "going rates" for specific specialties;
2. Internet physician recruitment sites; and
3. Internet sites for clinical trade organizations for the specific specialties, many of them publish articles and surveys on current compensation trends.

By using these additional resources, manufacturers can better hone their physician compensation valuation techniques.

Obtaining outside assistance in performing physician compensation valuations can be time consuming and expensive. Because of those issues, most manufacturers will desire to perform their own physician compensation valuations internally. Most arrangements can be valued effectively through well-developed internal valuation techniques. When using internal valuations, however, objective techniques that are the least susceptible to allegations of bias and manipulation as possible should be used, and careful, detailed documentation should be retained with each contract. Independent valuations

should be considered for difficult or sensitive circumstances; the burden of establishing the fair market value of any given arrangement rests with the parties involved in the agreement and the OIG considers internal valuations to lack strong evidentiary value, making them subject to increased scrutiny.[63]

Hourly rates and other forms of variable compensation

As discussed above, the requirements of the anti-kickback statute's personal services or management contacts safe harbor can only be satisfied where compensation is structured as an annual aggregate amount; it cannot be satisfied for compensation arrangements structured as hourly rates, per-unit compensation or similar variable compensation schemes. Many manufacturers and physicians will find this requirement cumbersome as specific annual need for consulting and professional services is difficult to define a year in advance. When manufacturers and physicians decide to structure compensation through a variable method, the failure to fully comply with the safe harbor does not mean that the arrangements violate the statute. It simply means that the arrangements are not protected from prosecution. Arrangements that do not qualify for safe harbor protection are evaluated on a case-by-case basis to determine whether one purpose of the arrangement is to induce the referral or generation of business.

The Stark II Phase II final interim final rule provides some insight into how the government might approach valuing an hourly payment arrangement for personally performed services. Under these rules, compensation is considered to be fair market value (under Stark) if:

(1) the hourly rate is less than or equal to the hourly rate for emergency room physician services in the relevant physician market (provided there are at least three (3) manufacturers providing emergency room services in that market); or

(2) the rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty in at least four (4) of six (6) specifically identified compensation surveys, and dividing by 2,000 hours.[64] Compliance with these two Stark "safe harbors" is completely voluntary. Providers may establish fair market value through other methods of their choosing.

Independent review and approval

When approaching physician compensation, manufacturers should consider instituting a process that requires prior review and approval by officially authorized independent body before implementing an arrangement where physician compensation that is unusually high or involves a compensation arrangement that is significantly outside the norm for the organization. This review should be performed by a body officially authorized by the organization's Board of Directors, and the results of these reviews should be reported to the Board. Such reviews serve many good purposes, such as providing unbiased opinions of the intrinsic reasonableness of the proposed arrangements, and demonstrating the parties' intent to ensure that the arrangements are legal. They also support organizations' Boards of Directors in their fiduciary duties to care to assure that they adequately oversee manufacturer operations by demonstrating their good faith efforts to be fully informed and to exercise their best judgment regarding the significant organizational activities.[65] With the implementation of the Sarbanes-Oxley Act of 2002 organizations are wise to ensure that their Boards are knowledgeable and sufficiently involved in key decisions and significant, out of the ordinary transactions; particularly when serious issues or fraud and abuse may be involved.

Part IV, the conclusion of this four part article, discusses charitable donations to hospitals including anti-kickback concerns. Industry guidance and codes of ethics regarding hospital/manufacturer relationships also will be discussed.

Jeffrey B. Miller, Esquire *is Chief Compliance Officer and Counsel with Synthes, Inc., a global medical device company. He leads Synthes' world-wide efforts on legal and regulatory compliance, providing direction and advice to business units spanning more than 91 countries. Prior to joining Synthes Mr. Miller worked as Associate Corporate Counsel for Mercy Health System of Southeast Pennsylvania, focusing on health care regulation and reimbursement, physician relationships, complex corporate transactions, corporate compliance and the identification, investigation and resolution of fraud and abuse-related issues.*

Stephen Miller, J.D. *Corporate Compliance Officer, oversees the administration of Capital Health System's Corporate Compliance Program. His responsibilities include developing policies and procedures designed to ensure CHS' compliance with all federal, state and local laws. He also oversees compliance audits and annual and risk specific compliance training for CHS employees. He earned his Bachelor of Arts degree from West Virginia Wesleyan College and his Juris Doctor degree from Widener University School of Law, Harrisburg PA.*

45 This discussion is limited to those manufacturers who do not have subsidiaries that supply and bill government-funded programs directly for designated health services as defined in the Ethics is Patient Referral Act ("Stark"), 42 U.S.C. §1395nn; 42 C.F.R. §411.350 *et. seq.* Stark's designated health services include clinical laboratory services, physical therapy services, occupational therapy services, speech-language pathology services, radiology, including magnetic resonance imaging, computerized axial tomography scans and ultrasound services, radiation therapy services and supplies, durable medical equipment and supplies, parenteral and enteral nutrients, equipment and supplies, prosthetics, orthotics and prosthetic devices, home health services and supplies, outpatient prescription drugs, preventative screening tests, immunizations and vaccines, and inpatient and outpatient hospital services. Manufacturers that do supply these items or services, and submit claims directly to government-funded programs, should seek legal advice on Stark's application. *Final rule,* 66 FR 856, 857, 934, Jan. 4, 2001. (see Health Care Compliance Reporter ¶177,002).

46 While without the force and effect of law, industry and professional associations also provide guidance on structuring manufacturer-physician relationships. Guidance can be obtained from the Pharmaceutical Research and Manufacturers of America ("PhRMA") in its Code of Interactions with Healthcare Professionals. PhRMA can be located on the internet at *http://www.phrma.org/*. Guidance also can be obtained from the Advanced Medical Technology Association ("AdvaMed") in its Code of Ethics on Interactions with Health Care Professionals. AdvaMed can be located on the internet at *http://www.advamed.org/*. The OIG specifically recognized the PhRMA Code as providing "useful and practical advice for structuring these relationships." *Notice,* 68 FR 23731, 23737, May 5, 2003. (see Health Care Compliance Reporter ¶156,014).

47 42 U.S.C. §1320a-7b(b)(3)(C); 42 C.F.R. § 1001.952(i).

48 42 C.F.R. §1001.952(i), *citing* 26 U.S.C. § 3121(d)(2). *See also* 20 C.F.R. §404.1007 (providing the indicia of "employment").

49 42 C.F.R. §1001.952(d).

[50] The PhRMA Code and AdvaMed Code both assert that physicians should be paid reasonable compensation, and may be reimbursed for reasonable (modest) travel, lodging and meal expenses incurred while providing their services. Additionally, they assert that physicians selected to perform consulting and professional services should be selected based upon criteria directly related to the purpose of the agreement, and by individuals who have the expertise required to evaluate the consultants on those criteria.

[51] *Final rule,* 64 FR 63517, 63518, 63526, Nov. 19, 1999. *See also OIG Advisory Opinion*, No. 03-8, April 3, 2003.

[52] *Id.* at 63525.

[53] The PhRMA Code states that there must be a "legitimate need" for the services, which must be clearly defined in advance of initiating the arrangement with a potential consultant.

[54] Other suspect compensation arrangements include questionable research or preceptor ("shadowing") arrangements, compensation for time spent listening to sales representatives, and compensation for reviewing web sites or other marketing materials ("detailing"). OIG Compliance Program Guidance for Pharmaceutical Manufacturers, *Notice,* 68 FR 23731, 23738, May 5, 2003.

[55] 42 C.F.R. §952(b)(5); *Final rule*, 56 FR 35952, July 29, 1991 (equating the definition of "fair market value" for the equipment rental safe harbor to the standard of fair market value for the personal services/management contracts safe harbor).

[56] 42 U.S.C. §1395nn; 42 C.F.R. §411.350 *et. seq.* The Stark law does not apply to medical device manufacturers' independent contractor relationships with physicians. However, its guidance for determining fair market value compensation is frequently applied to physician relationships in other contexts, including hospital-physician and physician practice relationships. As a result, government sources are likely influenced by Stark, and manufacturers should consider its guidance on fair market value when creating their relationships.

[57] *Final rule,* 66 FR 856, 857, 944, Jan. 4, 2001.

[58] 66 FR at 945.

[59] *Id*.

[60] *Final rule,* 56 FR 35952, July 29, 1991; *Final rule,* 66 FR 856, 857, 945, Jan. 4, 2001.

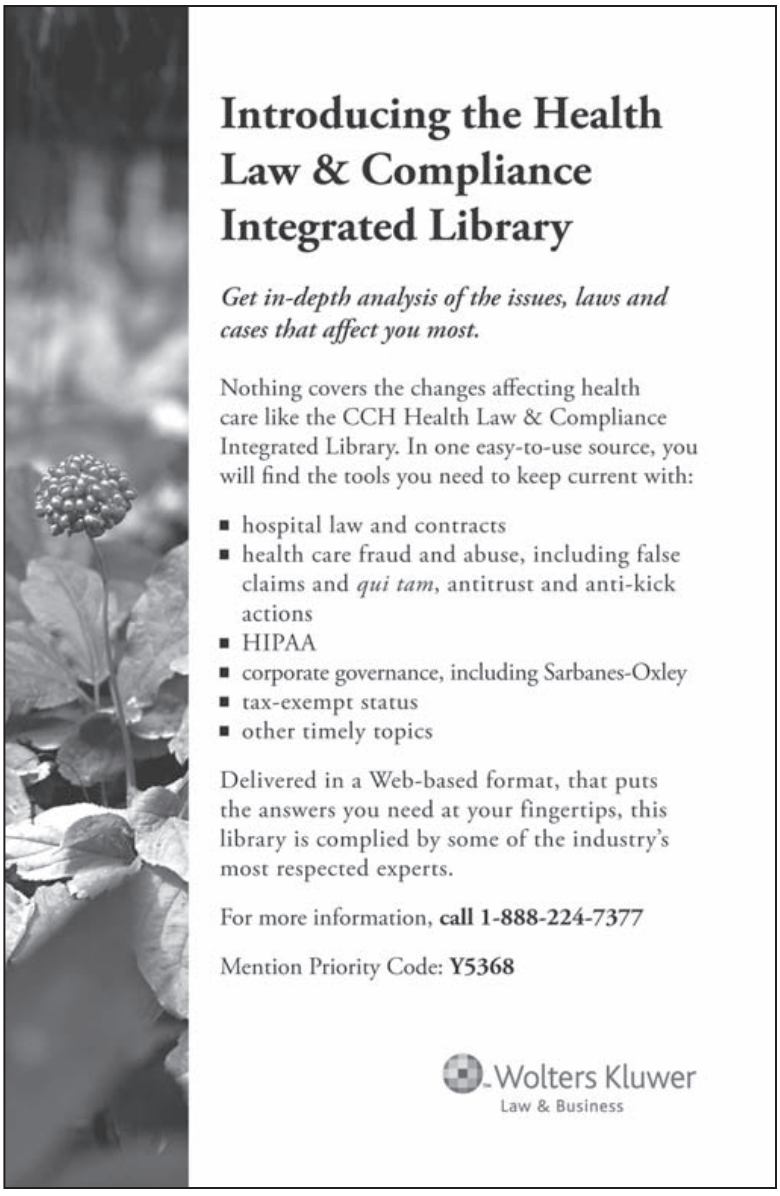
[61] Legitimate alternative compensation valuation methodologies may also be available. These alternatives may include bid-type processes, single-source processes and income replacement models. Manufacturers with questions regarding compensation valuation models should seek advice from legal counsel and professional financial advisors experienced in physician compensation valuation.

[62] CMS recognizes the following compensation valuation surveys as legitimate for use in compensation valuation under Stark: Sullivan, Cotter & Associates - Physician Compensation and Productivity Survey; Hay Group - Physicians Compensation Survey; Hospital and Healthcare Compensation Services - Physician Salary Survey Report; Medical Group Management Association - Physician Compensation and Productivity Survey; ECS Watson Wyatt - Hospital and Health Care Management Compensation Report; and William M, Mercer - Integrated Health Networks Compensation Survey. 42 C.F.R. §411.351; *Interim final rule*, 69 FR 16053, 16092, March 26, 2004. While not strictly binding, CMS' indications may have an influence on the OIG. Other sources of physician compensation information may be valid as well.

[63] *Final rule*, 66 FR 856-57, 944-45, Jan. 4, 2001.

[64] *See* footnote 57, *supra*.

[65] *See In re Caremark International, Inc.*, 698 A.2d 959 (De. Ch. 1996) (see Health Care Compliance Reporter ¶216,026) (providing for the board's duty to assure that adequate information gathering and reporting systems exist). *See also OIG Compliance Program Guidance for Hospitals*, *Notice,* 63 FR 8987, 8988, Feb. 23, 1998; *OIG Compliance Program for Individual and Small Group Physician Practices*, *Notice,* 65 FR 59434, 59440, 59446-47, Oct. 5, 2000 (see Health Care Compliance Reporter ¶183,001); *Federal Sentencing Guidelines*, § 8A1.2 Commentary ¶3(k) (relating to effective programs to prevent and detect criminal violations). This independent review process could be managed as part of the organization's corporate compliance program. Most for-profit, publicly-traded organizations must also comply with, the requirements of the Sarbanes-Oxley Act of 2002 (PubLNo 107-204) (July 30, 2002).



Anti-kickback (cont.)

Physician compensation raises red flag

by Stacey Fahrner, J.D., M.P.H., Contributing Editor

A New Jersey academic medical center, already under a deferred prosecution agreement (DPA) with the federal government for Medicaid fraud, has allegedly paid physicians for referrals to its struggling cardiac surgery department in violation of the anti-kickback statute, according to an interim report by a federal monitor.

Referral scheme. The medical center had failed to meet state licensing requirements due to the low patient volume. In an attempt to increase patient volume, officials developed a plan to pay physicians in the community to refer their patients to the medical center. Officials concealed the illegal payments as salaries by creating part time professorship positions for the referring physicians. According to the report, the referring physicians did little to warrant the "salaries," and were often paid more than full-time faculty. In his report, the federal monitor called the program "nothing more than a poorly disguised cover-up of knowing and willful violations of federal law."

Violations of the deferred prosecution agreement. Under the terms of the DPA, the medical center was obligated to disclose to the federal monitor any allegations of unlawful conduct. The violations associated with referring physician salaries were first brought to light in a consultant's report, however, instead of disclosing the findings of the report, an e-mail message trail showed that medical center officials encouraged the consultant to change the conclusions by revising the methodology and redoing the analysis. In addition, medical center officials failed to disclose a $2 million settlement with a whistle-blower.

The federal monitor's investigation is on going; however, he has recommended that certain key employees, consultants, and outside counsel be provided with a copy of the DPA and agree to abide by its provisions. The federal monitor also stated that the U.S. Attorney's office will be updated to the extent of the medical center's violations of federal law and the DPA. ■

Federal Monitor's Interim Report, Nov. 13, 2006.

In the News

CMS revises hospital conditions of participation

In response to concerns of the health care community that the old regulations were outdated and unduly burdensome, CMS published a final rule revising requirements in the hospital conditions of participation (CoPs) for completion of history and physical examinations, authentication of verbal orders, securing medications, and completion of post anesthesia evaluations. "We always want to make sure that Medicare beneficiaries receive the best possible health care, and one important way to do that is to provide rules and guidelines that enable providers to operate smoothly and efficiently," said CMS Acting Administrator Leslie V. Norwalk. "We think these changes will better serve the health care industry as a whole." The final rule was published in the *Federal Register* on November 27, 2006, and become effective January 26, 2007.

Final rule, 71 FR 68671, Health Care Compliance Reporter, ¶700,019.

CMS names organizations to accredit DMEPOS suppliers

Eleven national accreditation organizations were selected by CMS to accredit suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) as meeting new quality standards under Medicare Part B. As part of the Medicare Modernization Act of 2003 (PubL No. 108-173), DMEPOS suppliers are required to meet new quality standards to bill the Medicare Part B program for DMEPOS furnished to Medicare beneficiaries, including walkers, wheelchairs, and hospital beds. Most of the accreditation organizations named are authorized to accredit both national and local suppliers, as well as mail order companies.

CMS News Release, Nov. 22, 2006.

AHA criticized for including bad debt as community benefit

A senior lawmaker with oversight responsibility on tax exempt hospitals sharply criticized a new guidance by the American Hospital Association (AHA), which calls for the inclusion of bad debt and Medicare underpayment at cost as part of community benefit reporting. The AHA called for the change in a November 13, 2006, letter to association members that provided guidance on how to determine and report the financial value of a nonprofit hospital's community benefit. In the letter, the AHA advocated the use of the Catholic Hospital Association's (CHA's) "hospital community benefit report," which is submitted with tax forms to the Internal Revenue Service. Unlike the CHA, however, the AHA also recommended that hospitals include bad debts as part of the report. "Right now, reporting standards are all over the map, and it's nearly impossible to know what's real and what's accounting gimmickry," said Senate Finance Committee Chairman Charles E. Grassley (R-Iowa) in a written statement. "That's why I'm disappointed that the American Hospital Association isn't echoing the good work of the CHA and instead is calling on tax-exempt hospitals to report to the federal government and the public on bad debt as part of community benefits."

CCH Washington Bureau, Nov. 20, 2006.