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OIG highlights accomplishments for fiscal year 2007

The HHS Office of Inspector General (OIG) reported a $5 billion dollar fiscal year (FY) 2007 increase in savings and expected recoveries from FY 2006 in its semi-annual report to Congress issued on December 14, 2007. The total savings and expected recoveries for FY 2007 is $43.08 billion, a more than 50 percent increase from five years ago, according to the OIG. The OIG also reported 3,308 exclusions of individuals and entities for fraud and abuse related activities during the six month reporting period from April 1, 2007, through September 30, 2007. Of the 3,308 exclusions, 447 involved criminal actions for crimes against HHS programs, and 262 involved civil actions including False Claims Act (FCA) cases, civil monetary penalties law (CMPL) settlements, and administrative recoveries related to provider self disclosure matters.

2007 OIG accomplishments. As part of its report to Congress, the OIG highlighted several major accomplishments from FY 2007, including:

- The Purdue Companies and three top executives agreed to pay $635 million to resolve federal, state, and private charges involving the marketing of the drug OxyContin®. Specifically, the settlement resolved allegations that the defendants deceptively marketed OxyContin® to doctors by telling them that the timed-release version was less prone to abuse and less likely to cause addiction than the immediate-release version of the drug.
- The OIG launched an aggressive effort to tackle Medicare fraud in South Florida, most notably against infusion therapy providers. The effort resulted in recoveries of $54.3 million and recommendations for (1) mandatory site visits, (2) adjusted contractor standards for processing new provider applications, (3) reviewing all reassignments in high-risk areas, and (4) strengthening revocations.
- The OIG identified data limitations and other factors affecting the Food and Drug Administration's (FDA's) ability to effectively manage the Bioresearch Monitoring program. The OIG also concluded that the FDA's guidance and regulations do not reflect current clinical trials practices and recommended steps to improve its information systems and processes.
- The OIG negotiated a $42.65 million FCA settlement with Maximus, Inc., a revenue maximization consulting business, to resolve allegations that the company filed false claims for Medicaid-funded targeted case management services, which assist foster children with their medical, social, and educational needs.
- Advanced Neuromodulation Systems, Inc., a medical device manufacturer, agreed to pay $2.95 million and enter into a three-year corporate integrity agreement to resolve allegations that its spinal cord simulator marketing program utilized illegal kickbacks to induce physician referrals.

OIG News Release, Dec. 14, 2007; OIG Semi-Annual Report to Congress, April 1, 2007-Sept. 30, 2007, Health Care Compliance Reporter ¶530,649.

Wolters Kluwer Law & Business

Final Form 990 provides some transition relief

The Internal Revenue Service (IRS) released the final version of Form 990, Return of Organization Exempt from Income Tax, for use by nonprofit organizations for the 2008 tax year (for returns filed in 2009). The release completes a major redesign of the Form 990 that the IRS Exempt Organizations Division (EO) began in June 2007. The form had not seen a major redesign in 25 years and was considered out of date by users and the IRS.

"We needed a Form 990 that reflects the way this growing sector operates in the 21st century," said Steven Miller, commissioner of the IRS's Tax Exempt and Government Entities Division. "The [700] public comments ... helped us develop a final form consistent with our guiding principles of transparency, compliance and burden minimization."

Ranking Senate Finance Committee member Sen. Charles Grassley (R-Iowa) commended the IRS for doing "a good job of bringing about more reporting across the board and recognizing that the tax-exempt sector is a growing part of the economy." He expressed disappointment, however, that "the IRS isn't doing more to make sure nonprofits are accurately reporting the amount of money going to their charitable purpose.... The IRS easily could have done more to help donors really understand where their money goes."

The IRS provided transition relief for hospitals and issuers of tax-exempt bonds. Instead of completing Schedules H (hospitals) and K (bonds), organizations merely have to provide minimal identifying information for 2008, such as the name of the hospital or a description of the bond issue. "We believe the transition relief we are providing is appropriate and meaningful," EO Director Lois Lerner said.

New Form 990-EZ also is being phased in over a two-year period for small organizations that meet gross receipts and assets thresholds. Lerner noted, "This phase-in process will allow organizations to become familiar with the new Form 990."

"We're not done yet," Lerner said at the press conference unveiling the form. EO still has to prepare instructions, which it hopes to release in the first quarter of 2009. EO also continues to work on e-postcard filing for the smallest organizations. This will be released in January 2008.

The revised Form 990 consists of an 11-page core form and 16 schedules for particular activities. The final form allows organizations to describe their mission and accomplishments up-front and throughout the form. A checklist of trigger questions and schedules was moved to the front of the form, so that organizations would know what schedules to fill out. Lerner said there were several comments on the governance section. EO decided to break this up into good practices and tax-related questions. The schedule on compensation was retained, including questions on the five highest compensated employees.

Checkboxes were added to Schedule H, and EO asked for more reporting on community benefit, Lerner said. This will inform any subsequent analysis and action by EO. Schedule H also will include information about bad debts, Medicare shortfalls, and reimbursements. The hospital can explain how much it considers to be community benefit. "It's good to see a clearer, more uniform definition of community benefit. Some hospitals use a very loose definition, and this will help them focus," Grassley commented.

Lerner said that EO's compliance initiatives — for example, on political activity, hospitals, compensation, and bonds — led EO to request more information on Form 990. This will help EO better assess the compliance risks.

On the other hand, less information was requested about noncash contributions. Information on foreign grants need only be identified by region, not by country. Numerous changes were made to the form to address privacy and security concerns on the reporting of compensation and persons working abroad. EO previously announced that it was eliminating the metrics included in the draft but was including a two-year summary of financial information comparing the current and prior years.

CCH Washington Bureau, Dec. 20, 2007.

HealthSouth, physicians pay $14.9 million to resolve fraud, kickback claims

HealthSouth Corporation and two physicians have agreed to pay the United States $14.9 million to settle allegations that the heath care service provider submitted false claims to the government and paid illegal kickbacks to physicians who referred patients for care in some of its hospitals, rehabilitation clinics, and ambulatory surgery centers.

HealthSouth currently is the nation's largest provider of inpatient rehabilitation services, and also was one of the largest providers of outpatient rehabilitation services, ambulatory surgery services, and diagnostic imaging services until it sold those lines of business in 2007.

Fraudulent claims, kickbacks. According to the U.S. Department of Justice (DOJ), the settlement resolves allegations that HealthSouth submitted claims to Medicare and Medicaid for services provided to patients referred by two orthopedic surgeons with whom HealthSouth had financial relationships. At the time, HealthSouth also had financial relationships with the physicians' former partnership, the Alabama Sports Medicine and Orthopaedic Clinic, and their research and training foundation, the American Sports Medicine Institute. The claims submitted by HealthSouth violated the anti-kickback statute and the Stark law, the DOJ said.

The settlement also resolves allegations that HealthSouth paid kickbacks to, and entered into improper financial relationships with, other physicians in an attempt to induce the referral of patients. The government's investigation of those other physicians is ongoing.

"Hidden financial agreements between health care providers and physicians may influence where patients receive treatment, and what treatment is received," said Jeffrey S. Bucholtz, Acting Assistant Attorney General for the DOJ's Civil Division. He added, "Medicare beneficiaries deserve their physicians' unbiased judgment regarding their treatment, free of improper financial influences."

Settlement. Pursuant to separate settlement agreements, HealthSouth will pay $14.2 million, and the physicians will pay $700,000 to resolve the government's claims against them. Alice Martin, U.S. Attorney for the Northern District of Alabama, said that her office entered into a $450,000 settlement with one of the physicians and a $250,000 settlement with the other.

HealthSouth also will be required to amend its existing corporate integrity agreement to address kickback issues. "This settlement reflects the Office of Inspector General's resolve to hold responsible those who seek to influence the judgment of physicians through improper financial arrangements," Daniel Levinson, HHS Inspector General, stated. "It should be a reminder that federal health care program beneficiaries' referrals should be based on quality of care for the patient, not the financial benefit for any individual or company."

The settlement results from disclosures made by HealthSouth in 2004 and 2005 to the U.S. Attorney for the Northern District of Alabama and the HHS Office of Inspector General, after a change in management and an internal investigation.

Bucholtz said that the settlement "sends a loud message to health care providers that [the government] will strongly enforce the anti-kickback statute and the Stark law." Martin added, "To preserve the independence of health care providers, it is critical that business relationships not violate the anti-kickback statute, the Stark law, and the False Claims Act."

Thomas P. O'Brien, U.S. Attorney for the Central District of Florida, who also was involved in the investigation, said, "We will not be fooled when health care providers attempt to disguise kickbacks as cleverly crafted business arrangements. Medicare providers seeking federal funds must play by the rules. Providing sweet deals to physician groups to ensure a steady stream of referrals runs afoul of those rules and will not be tolerated."

DOJ Press Release, Dec. 14, 2007.

On The Front Lines

Teaching under the influence? Manufacturer support of continuing medical education programs

by Jeffrey Miller, CCH Health Care Compliance Editorial Advisory Board Member

Manufacturers, physicians and hospitals around the world strive to provide the highest quality health care products and services to their patients. It is no secret, however, that while they share the common goal of quality patient care, they have disparate financial interests. Manufacturers desire to sell their products and to generate returns for their investors. Hospitals must keep the "bottom line" in mind as well. Physicians, who use the products for their patients, and who often act as gatekeepers for product purchasers, are caught in the middle. With such a large variety of products and manufacturers available, physicians who are unfamiliar with a manufacturer's products cannot (and will not) recommend those products to their patients or their affiliated hospitals.

This dynamic creates an incentive for manufacturers to support physician education, including continuing medical education, to ensure knowledgeable physicians and open doors to patients and hospitals. This support often comes in the form of financial grants for continuing medical education courses. While designed to benefit manufacturers, this financial support benefits all parties involved, as knowledgeable physicians provide the highest quality patient care. Many view this financial support suspiciously, however, warning that it can inappropriately influence physicians' relationships with individual manufacturers, or their views of products' uses. When physician education becomes advertising, many argue, patient care is compromised. The purpose of this article is to provide an introduction to the primary U.S. federal laws as they apply to manufacturer support of continuing medical education, and to provide an update on current federal initiatives designed to regulate these relationships.[1]

Federal law and enforcement

There are three primary federal government agencies that oversee manufacturer support of continuing medical education (CME) programs: the Department of Justice (DOJ), the HHS Office of Inspector General (OIG), and the Food and Drug Administration (FDA). The DOJ and OIG enforce the federal anti-kickback statute. The FDA enforces the Food, Drug and Cosmetic Act (FDCA). Together, these agencies and statutes seek to protect the interests of quality patient care, maintain the competitive marketplace for health care items and services, and protect the federal government's financial interests in federally-funded health care programs.

The federal anti-kickback statute

The primary federal law that governs physician-manufacturer financial arrangements is the federal anti-kickback statute ("statute"). This statute provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration with the intent to induce the referral of patients or business that is reimbursed under federal health care programs.[2] "Remuneration" is defined very broadly, and includes any benefit, in any form, with no minimum value required.[3] The benefit can be provided in any form, directly or indirectly, overtly or covertly, in cash or in kind. In the CME context, benefits could include paying tuition for courses, funding physician expenses such as travel or lodging, or providing entertainment, meals, or gifts. The basic test of whether enough remuneration is involved is whether the benefit offered has materially influenced the professional clinical judgment of the other party.[4] To secure a conviction, the government only needs show that one purpose of the transaction, and depending upon the jurisdiction, not necessarily its primary purpose, was to induce referrals.[5]

Violation of the statute is a serious crime. It is classified as a felony, and is punishable for individuals by restitution plus fines of up to $250,000, and imprisonment for up to five years.[6] Corporate penalties can include up to $500,000 in fines, restitution, and potentially the imposition of a corporate integrity agreement as a condition of probation.[7] Courtesy of the Medicare and Medicaid Patient and Program Protection Act of 1987, upon conviction, the OIG is required to exclude persons and entities from participation in government-related health care programs (*e.g.*, Medicare, Medicaid, and Tri-Care).[8] Under the

Balanced Budget Act of 1997, the OIG also is authorized to levy additional civil monetary penalties of up to $50,000 for each violation.[9] Should the submission of claims to government programs be involved, a government claim for treble damages plus up to $11,000 per claim also could be asserted.[10]

As a criminal statute, the anti-kickback statute requires a showing of knowing and willful behavior "beyond a reasonable doubt." This is a significant limiting factor for prosecution under the statute. Some federal courts have construed this standard to mean that the defendant must have entered into the transaction with the specific intent to violate the statute.[11] Others have applied lesser standards, such as knowledge that the conduct was "wrongful"[12] or a "specific criminal intent to induce referrals."[13] Whatever the mental state required, any behavior that evidences a willful blindness, reckless disregard, or deliberate ignorance of the facts at issue could be used as evidence to help to satisfy the mental state requirement.[14]

The Food, Drug and Cosmetic Act

The FDCA imposes limits on how manufacturers of regulated products may advertise. Under the FDCA, not only are manufacturers prohibited from marketing or promoting unapproved products, but they also are prohibited from marketing or promoting approved products for unapproved uses (off-label promotion).[15] Significantly, the FDA has no jurisdiction over individuals or organizations that do not manufacture or sell the regulated products. As a result, the FDA can not and does not regulate discussions or exchanges of information regarding off-label uses by other individuals and organizations, including physicians and physician organizations. It does, however, prohibit manufacturers from promoting their products, or uses of their products, that have not been prior-approved.

Rising concerns and attempts at solutions

For many years, institutional academic-industry relationships have been prevalent and have had the potential to result in physician-related conflicts of interest. In a recent attempt to analyze the nature, extent, and consequences of this matter, the Institute on Medicine as a Profession (IMAP) conducted a survey of a large sample of U.S. physicians.[16] Published in the *New England Journal of Medicine* in April, 2007, this survey reported that sixty percent of all physician department chairs had some form of personal financial relationships with industry.[17] Sixty-seven percent of academic-institutional departments, as administrative units, had financial relationships with industry, including 65 percent of all clinical departments benefiting from the support of continuing medical education.[18] As demonstrated in this survey, the influx of industry support for continuing medical education appears to be pervasive.

The considerable support that industry has provided for CME has not gone unnoticed by physicians. Not surprisingly, physicians were the first to react to allegations that industry support of physician education could create conflicts of interest that would compromise patient care. As early as 1992, the American Medical Association (AMA) began issuing guidelines for its member-physicians regarding the receipt of financial support for continuing medical education.[19] While approving of the acceptance of this support as "contributing to the improvement of patient care," the AMA nevertheless warned physicians that the acceptance of any financial support personally could influence, or appear to influence, the physicians' use of industry products.[20] As a result, physicians were advised not to personally accept financial support to attend CME events. Instead, all financial support from manufacturers should be provided to the organization providing the CME event, which may in turn use the funds to defray the costs of the event.[21] To further guard against inappropriate influence or appearance, the AMA also advised that financial subsidies should not be accepted, directly or indirectly, to pay for the costs of physicians' travel, lodging or other personal expenses, nor for physicians' time.[22] Subsidies for hospitality should only be accepted for modest meals or social events that are held as part of the conferences or meetings.[23]

Also prompted by rising concerns regarding academic-institutional industry relationships, industry associations worked to develop guidelines for their own members. Following the AMA's lead, the Pharmaceutical Research and Manufacturers Association of America (PhRMA) developed and published a code of conduct governing academic-institution industry relationships for its members in 2002.[24] Entitled the "Code of Interactions with Healthcare Professionals" ("PhRMA Code"), this code supports pharmaceutical companies in their efforts to provide financial support for CME events, proffering that such support "contributes to the improvement of patient care."[25] The PhRMA Code, however, asserts that pharmaceutical companies should satisfy certain limiting conditions designed to ensure that relationships remain ethical and protect against undue influences at CME events. As an initial limitation on pharmaceutical company support for CME events, the PhRMA Code provides that financial support should only be provided when the CME events are held at "appropriate locations" where the gatherings primarily are dedicated, both in time and in effort, to promoting objective scientific and educational activities, and when the main incentives for bringing attendees together are to further their medical educations.[26] Similar to the AMA guidelines, the PhRMA Code further states that pharmaceutical manufacturers should provide any financial support directly to the CME sponsors, and not to individual physicians or academic departments.[27] The CME sponsors should then use the support to defray the overall costs of the CME events.[28] Also similar to the AMA guidelines, the PhRMA Code further provides that pharmaceutical companies should not pay for the costs of physi-

cian travel, lodging or other personal expenses, nor for physicians' time.[29] Meals and receptions are permissible when they are modest and conducive for discussion among CME faculty and attendees, and are subordinate in the amount of time spent at the CME event on educational activities.[30] Finally, the PhRMA Code instructs that the CME sponsors should have exclusive control over the CME course content, the CME faculty, the educational methods used, the educational materials provided, and the CME venue.[31]

Asserting a need for increased industry efforts to limit inappropriate influences upon physician education, the OIG offered its own recommendations for limiting industry influence shortly after publication of the PhRMA Code. These recommendations were provided in the form of its Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance").[32] In its Guidance, the OIG acknowledged that industry educational funding "can provide valuable information to the medical and health care industry."[33] The OIG also noted the possibility, however, that industry could use financial support of CME events to provide financial benefits to individual physicians in violation of the federal anti-kickback statute, or to inappropriately influence the substance of educational programs in violation of the FDCA.[34] While the OIG did not recommend specific actions, the OIG advised pharmaceutical manufacturers to take steps to eliminate these possibilities.

Recognizing that "adherence to ethical standards and compliance with applicable laws are critical to the medical device industry's ability to continue its collaboration with health care professionals,"[35] the medical device industry entered the fray as well. On January 1, 2004, the Advanced Medical Technology Association (AdvaMed) created its own set of guidelines specifically designed for medical device manufacturers.[36] These guidelines, known as the Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"), were generated to help to ensure that medical device company financial support for physician education serves the goals of quality patient care and patient safety. Among other points, the AdvaMed Code requires that financial support only be provided when the CME events are primarily dedicated to promoting objective scientific and educational activities.[37] Similar to the AMA guidelines and the PhRMA Code, the AdvaMed Code further states that medical device manufacturers should provide any financial support directly to the CME sponsors, and not to individual physicians or academic departments.[38] The CME sponsors should then use the support to defray the CME event costs.[39] Also similar to the AMA guidelines and to the PhRMA Code, the AdvaMed Code instructs that medical device company financial support should only defray the costs of bona fide educational activities.[40] Meals, receptions and hospitality are permissible, whether provided through financial support to the CME sponsor by medical device companies, or directly by the medical device companies themselves. However, they must be modest in value and subordinate in the amount of time spent at the CME event on educational activities.[41] Finally, the CME sponsors should be responsible for control over the CME course content, the CME faculty, and the educational methods and materials used.[42]

All educational courses in the United States must be accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide physicians with CME credits, and in 2004 the ACCME took action and adopted its "Standards for Commercial Support."[43] These standards were designed specifically to ensure that CME providers maintain their independence from industry financiers.[44] Set out in six main parts, the ACCME Standards for Commercial Support provide that CME providers must ensure that they maintain their independence from their industry financial supporters.[45] This independence must be maintained through, among other requirements, the CME providers controlling the identification of CME needs, the determination of educational objectives, the selection and presentation of educational content, the selection of faculty, the selection of educational materials, and the evaluation of program effectiveness.[46] All relevant financial relationships between all individuals involved in the control of the content of CME activities and industry must be clearly disclosed, along with the industry support of the CME events themselves.[47] Numerous other requirements that are similar to the AMA guidelines, the PhRMa Code and the AdvaMed Code apply as well, including that: (1) all payments made to the individuals involved in the CME events must come only from the CME providers; (2) social events and meals cannot take precedence over the educational events; and (3) industry financial support cannot be used to pay for the travel, lodging or other personal expenses of physician attendees, nor for physician attendees' time.[48] All educational presentations must be without commercial bias, and must provide balanced views of available therapeutic options.[49]

Despite the voluntary promulgation of guidelines and limitations by these organizations, including the release of recommendations by the OIG, this issue appears to be headed towards a boiling point in the halls of the United States Congress. In June, 2005 Senators Max Baucus (D-Mont.) and Charles Grassley (R-Iowa), Chairman and Ranking Member of the Senate Committee on Finance, began formal inquiries of the twenty-three largest drug manufacturers in the United States following allegations that they were utilizing educational grants to promote off-label uses for their medications. This past April, the Senate Committee on Finance released a committee staff report to the Chairman and Ranking Member on the use of educational grants by pharmaceutical manufacturers.[50] In the report, the committee staff concluded that while the pharmaceutical industry is paying increased attention to its compliance with federal law, some CME events, and their associated physicians, are improperly influenced by industry sponsors.[51] Supporting its conclusions, the report cited several specific instances of improper influence, including a 2004 instance in which Warner-Lambert paid $430 million to settle allegations that it funded purportedly independent educational events to promote its anti-epilepsy drug, Neurotin®, for off-label uses, and a 2005 instance in which Serono Laboratories paid $704 million to settle allegations that it engaged in the same improprieties related to its drug, Serostim.®

Conclusion

Manufacturers, physicians and hospitals around the world strive to provide the highest quality health care products and services to their

patients. It is no secret, however, that while they share a common goal for quality patient care, they have disparate financial interests. This dynamic creates an incentive for manufacturers to support physician education, including continuing medical education, to ensure knowledgeable physicians and open doors to patients and hospitals. This support often comes in the form of financial grants for continuing medical education courses. Many view this financial support suspiciously, however, warning that it can inappropriately influence physicians' relationships with individual manufacturers, or their views of products' uses. While physicians, industry and the OIG have worked to protect the interests of patients, in light of the current activity in Congress it is likely that the development of additional law and regulation will be an important issue for some time.

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1 This article is not intended to provide legal advice, and should not be used for that purpose. Manufacturers and providers involved in specific transactions should review them with legal counsel. In addition to the federal anti-kickback statute, other federal and state laws and regulations may also apply.

2 42 U.S.C. §1320a-7b(b).

3 *See Final rule*, 56 FR 35952, July 29, 1991 (describing the applicable standard as "to lead or move by influence or persuasion").

4 *See* letter dated May 20, 1991, from Richard P. Kusserow, Inspector General, to Paul C. Rettig, Executive Vice President of the American Hospital Association (asserting that case law "makes it clear that the Statute's prescriptions apply to those who can materially influence the flow of Medicare and Medicaid business.").

5 *See United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988, 106 S.Ct. 396 (1985) (holding that the intent standard is satisfied if the payment made is at least in part for the purpose of inducing referrals); *compare Greber*, 760 F.2d 68, *with United States v. Bay State Ambulance*, 874 F.2d 20(1st Cir. 1989) (holding that the intent standard is satisfied only if the primary purpose of the payment is to induce referrals).

6 42 U.S.C. §1320a-7b(b); 18 U.S.C. §3571. Actual sentences are set in accordance with the Federal Sentencing Guidelines. United States Sentencing Commission, Guidelines Manual, §3E1.1 (Nov. 2003).

7 42 U.S.C. §1320a-7b(b)(2)(A); 18 U.S.C. §3571.

8 42 U.S.C. §1320a-7(a).

9 42 U.S.C. §1320a-7a.

10 Citing providers' general certifications that all claims are "in compliance with the law," the government has alleged (and some jurisdictions have agreed) that violations of the statute could result in liability under the Federal False Claims Act on the theory that satisfaction of the statute's requirements is material for program reimbursement. 31 U.S.C. §3729(a). *See Thompson v. Columbia/HCA*, 125 F.3d 899(5th Cir. 1997).

11 *Hanlester v. Shalala*, 51 F.3d 1390(9th Cir. 1995).

12 *United States v. Jain*, 93 F.3d 436(8th Cir. 1996).

13 *United States v. LaHue and Anderson*, 261 F.3d 993(10th Cir. 2001); see *also United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (holding that the appropriate standard is "purposely intending to violate the law").

14 *United States v. Wert-Ruiz*, 228 F.3d 250 (3d Cir. 2000).

15 21 U.S.C. §360aaa; 21 C.F.R. §99.405.

16 More information on IMAP can be found on its website at www.imapny.org.

17 E.G. Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 New Eng. J. Med., 1742-50 (April 26, 2007).

18 *Id.*

19 AMA Ethical Opinions/Guidelines, at E-8.061, Gifts to Physicians from Industry, *available at* http://www.ama-assn.org/ama/pub/category/4001.html.

20 *Id.* at paragraph 4.

21 *Id.*

22 *Id.* at paragraph 5.

23 *Id.*

24 More information on PhRMA can be obtained from its website at www.phrma.org.

25 PhRMA Code of Interactions with Health Care Professionals, Introduction (July 1, 2002), *available at* http://www.phrma.org/files/PhRMA%20Code.pdf.

26 *Id.* at §3(d).

27 *Id.* at §3(a).

28 *Id.*

29 *Id.* at §3(b).

30 *Id.* at §3(c).

31 *Id.* at §3(a).

32 *Notice*, 68 FR 23731, May 5, 2003.

33 *Id.* at 23735.

34 *Id.* at 23735, 23738.

35 Code of Ethics on Interactions with Health Care Professionals, at §1 (Jan. 1, 2004), *available at* http://www.advamed.org/NR/rdonlyres/FA437A5F-4-C75-43B2-A900-C9470BA8DFA7/0/coe_with_faqs_41505.pdf.

36 More information on AdvaMed can be obtained from its website at www.advamed.org.

37 Code of Ethics on Interactions with Health Care Professionals at Section 3.

38 *Id.*

39 *Id.*

40 *Id.*

41 *Id.*

42 *Id.*

43 Accreditation Council for Continuing Medical Education, Standards for Commercial Support (Sept. 2004) *available at* http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

44 *Id.*

45 *Id.* at Standards 1, 3.

46 *Id.*

47 *Id.* at Standard 2.

48 *Id.* at Standard 3.

49 *Id.* at Standard 5.

50 Committee Staff Report to the Chairman and Ranking Member on the Use of Educational Grants by Pharmaceutical Manufacturers, United States Senate, April, 2007.

51 *Id.* at Section VI.

OIG approves Medigap, PPO arrangement

An arrangement between an insurer that offers a Medigap policy and one or more preferred provider organizations (PPOs) would not constitute grounds for the imposition of civil monetary penalties or administrative sanctions under the anti-kickback statute, according to the Office of Inspector General.

Under the agreement, in exchange for an adminitrative service fee: (1) the Medigap policy holders receive access to the PPO hospital network; (2) the insurer receives a 100 percent discount on Part A hospital inpatient deductibles when its policy holders use PPO network hospitals; and (3) the insurer offers its Medigap enrollees a $100 credit towards the next year's renewal fees if they use PPO network hospitals. The agreement allows the PPO networks to discount the Medicare inpatient deductible for the insurer's Medigap policy holders by an amount for which the company would otherwise be liable.

The arrangement, however, presents a low risk of fraud or abuse because: (1) the waivers will not affect per-service Medicare payments because Part A hospital payments are fixed and unaffected by beneficiary cost-sharing; (2) the discounts should not increase utilization because the discounts are effectively invisible to patients who have purchased the Medigap insurance to cover deductible obligations; (3) competition between hospitals will not be affected because any Medicare certified hospital may participate in the PPO networks; and (4) the medical judgment of physicians will be unaffected because they will receive no remuneration and patients remain free to go to any hospital they like.

The premium credit for policy holders likewise presents a low risk of fraud or abuse because of its similarity in purpose and effect to the statutory exception for differentials in coinsurance and deductible amounts as part of a benefit plan design.

OIG Advisory Opinion, No. 07-15, Dec. 5, 2007, Health Care Compliance Reporter ¶500,172.

In the News

Applicability of anti-markup provisions delayed

CMS has issued a final rule delaying until January 1, 2009, the applicability of the anti-markup provisions of the physician self-referral regulations, as revised in the calendar year 2008 Medicare Physician Fee Schedule *Final rule* (72 FR 66221, Nov. 27, 2007), except with respect to: (1) the technical component of a purchased diagnostic test; and (2) any anatomic pathology diagnostic testing services furnished in space that (a) is utilized by a phyisician group practice as a "centralized building" (as defined at 42 C.F.R. §411.351) for purposes of complying with the physician self-referral rules and (b) does not quality as a "same building" under 42 C.F.R. §411.355(b). This final rule, which is effective January 1, 2008, was published in the *Federal Register* on January 3, 2008.

CMS Release, Dec. 28, 2007.

Hospital to pay $26 million to settle FCA claims

St. Joseph's Hospital of Atlanta, Inc., and St. Joseph's Health System, Inc., have agreed to pay the United States $26 million to resolve allegations that the hospital violated the Federal False Claims Act (FCA) with regard to improperly billing for inpatient admissions and other services, the Department of Justice announced. The settlement resolves an investigation of St. Joseph's Hospital's submission of Medicare claims from 2000 through 2005, where services that should have been billed as outpatient visits were charged at the higher rate as inpatient admissions. A whistleblower suit was filed by a former hospital employee, who will receive $4.94 million as her share of the settlement proceeds. As a condition of continued participation in the federal health care programs, the HHS Office of Inspector General has required St. Joseph's Hospital and Health System to enter into a corporate integrity agreement.

DOJ Press Release, Dec. 21, 2007.

Quality measures proposed for special needs plans

CMS and the National Committee for Quality Assurance (NCQA) have released for public comment a proposed set of structure and process measures for Medicare Special Needs Plans (SNPs). The proposed measures are part of the initial implementation of a strategy to evaluate the structure, processes, and performance of SNPs. The SNPs are available as part of Medicare Advantage and were created as part of the Medicare Modernization Act of 2003. They serve vulnerable groups of Medicare beneficiaries, including nursing home residents, beneficiaries with severe or disabling chronic conditions, and beneficiaries eligible for both Medicare and Medicaid. "Because they care for some of our most vulnerable citizens, [SNPs] must demonstrate that they are providing quality care and protecting the rights of Medicare and Medicaid beneficiaries," NCQA President Margaret E. O'Kane said. The measures released for comment examine how SNPs set up case management programs for members with complex needs and how they act to improve clinical care and patient experience. CMS also will require SNPs to begin reporting on 13 Healthcare Effectiveness Data and Information Set (HEDIS®) measures that will assess clinical performance.

CMS Press Release, Dec. 14, 2007.