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HCFAC program recovered billions in fiscal year 2005

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

During fiscal year (FY) 2005 the federal government won or negotiated approximately $1.47 billion in judgments and settlements and obtained additional penalties in health care fraud administrative proceedings, according to the annual report for the health care fraud and abuse control (HCFAC) program.

HCFAC was established by the Health Insurance Portability and Accountability Act of 1996 to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. According to the report, in FY 2005, U.S. Attorney's offices opened 935 new criminal health care fraud investigations involving 1,597 potential defendants. Federal prosecutors had 1,689 criminal health care fraud investigations pending. A total of 523 defendants were convicted of health care fraud related crimes. The Department of Justice (DoJ) opened 778 new civil health care fraud investigations and had 1,334 investigations pending at the end of the year. DoJ filed complaints or intervened in 266 civil health care cases.

Fraud and abuse. Significant HCFAC accomplishments for FY 2005 included a $149 million settlement with GlaxoSmithKline to settle allegations of fraudulent drug pricing and marketing; $138.5 million settlement with AdvancePCS to settle allegations of kickbacks disguised as administrative fees; several convictions for pharmaceutical distribution fraud; and settlements with three hospitals regarding fraudulent billing schemes.

Durable medical equipment (DME) fraud was another area of focus in FY 2005. Recoveries included a $35 million settlement with Polymedia Corporation regarding improper claims for various diabetic nebulizer products; and a $17 million settlement with Apria, the nations largest supplier of DME, regarding allegations that they falsified documents certifying medical necessity, failed to obtain written prescriptions from physicians, and failed to notify patients of their option to purchase DME.

Quality of care. In addition to fraud and abuse, HCFAC has been effective in enforcement and oversight of issues relating to quality of care. Most notably, Boston Scientific Corporation paid $74 million to address the company's illegal distribution of a coronary stent delivery system. The company continued to ship the device for weeks after an internal investigation determined that a substantial number of the devices were not functioning properly.

The report also details other administrative and enforcement actions taken in FY 2005, including provider exclusions. In total, the Medicare Trust Fund received transfers over $1.5 billion as a result of these efforts. ■

Health Care Fraud and Abuse Control Program Annual Report for FY 2005, Aug., 2005, Health Care Compliance Reporter ¶370,023.

Wolters Kluwer Law & Business

OIG issues opinions on Medicaid P4P, dental network marketing plan; DME advertising plan

A state's plan for Medicaid pay-for-performance disbursements, and a proposed plan to market a dental network to patients were found to pose minimal kickback risks, while a proposal by a durable medical equipment (DME) manufacturer to provide advertising and reimbursement consultation services to its suppliers and beneficiaries would likely be subject to administrative sanctions. The Office of Inspector General (OIG) explained its position for each of these proposals in three advisory opinions issued from October 6 -13, 2006.

Medicaid pay-for-performance. A proposed arrangement that would allow an administrator to disburse pay-for-performance financial incentives on behalf of a state's Medicaid program would not be subject to sanctions under the anti-kickback statute. A state Medicaid program proposed to enter into an agreement with an outside administrator under which the administrator would develop and implement a disease management program that would provide more comprehensive and systematic care to chronically ill beneficiaries suffering from asthma, diabetes, chronic pulmonary disease, coronary disease, and congestive heart failure on behalf of Medicaid. The program would include a physician pay-for-performance program, which would provide cash incentives to physicians for ordering or recommending certain specified services shown to reduce disease exacerbations or improve clinical outcomes. Because state law prohibits Medicaid from drawing checks directly to physicians participating in the program, the administrator would disburse the incentives to physicians on behalf of Medicaid. The administrator's proposed duties as a payment administrator for the pay-for-performance program did not implicate the anti-kickback statute because: (1) the payments would be state funded and would not be made with the administrator's own money, (2) the administrator would not have control or discretion over the payments, and (3) the parties would take meaningful steps to minimize any misimpression by physicians that the administrator was paying them for referrals of Medicaid business.

OIG Advisory Opinion, No. 06-15, Oct. 6, 2006, Health Care Compliance Reporter ¶500,149.

Marketing of dental network. A proposed arrangement that would compensate a marketing company for connecting dentists with patients who are potentially federal health care program beneficiaries would not be subject to administrative sanctions under the anti-kickback statute. The proposed arrangement poses little risk to the federal health care programs because few of the patients being referred are likely to be Medicare or Medicaid beneficiaries. In addition, reimbursement rules for dental care are such that the amount of federal dollars that are potentially payable for dental services through this arrangement are substantially constrained. Finally, the proposed arrangement does not create an incentive for the marketing company to generate federal health care program for the dentists.

OIG Advisory Opinion, No.06-17, Oct. 13, 2006, Health Care Compliance Reporter ¶500,151.

DME advertising arrangement. A DME manufacturer's proposed arrangement to provide advertising assistance to its DME suppliers and reimbursement consulting services to DME supplier customers could generate prohibited remuneration under the anti-kickback statute making it subject to potential administrative sanctions imposed by the OIG. Under the proposal, the manufacturer would provide free advertising for suppliers or underwrite the suppliers' advertising expenses. The proposed arrangement also would have included reimbursement consulting services such as claims submission information and advice on coding. The arrangement posed a risk of increasing program costs and overutilization because it takes into account the value of the DME suppliers' purchases, and incentivizes suppliers to steer patients to the manufacturer's products. In addition, the manufacturer's plan to help beneficiaries secure federal reimbursement could cause beneficiaries to receive greater quantities or more expensive equipment than they require. ■

OIG Advisory Opinion, No.06-16, Oct. 10, 2006, Health Care Compliance Reporter ¶500,150.

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Montana AG takes on community benefits issue

by Manish Bhatia, J.D., Contributing Editor

Following in the footsteps of the Internal Revenue Service (IRS), Montana Attorney General Mike McGrath sent a letter to 12 Montana nonprofit hospitals in an attempt to more closely monitor the charitable benefits provided by hospitals to the community. The letter gives the hospitals 45 days to provide information on the charity care and community benefits they provide to state residents in exchange for the tax-exempt status and benefits they receive.

The IRS recently pursued similar information when it sent Form 13790, Compliance Check Questionnaire/Tax-Exempt Hospitals, to 550 such nonprofit hospitals in May. The letter also follows similar efforts by other state attorneys general to determine what benefits nonprofit healthcare entities provide in exchange for property, income, and other tax exemptions.

The letter from Montana's attorney general requested information on pricing, collection, and charitable activities that are being carried out by some of the largest nonprofit hospitals in the state, as well as forms and procedures that are regularly utilized in the facilities. According to the letter, the inquiry is part of an initiative to fulfill the attorney general's duties in consumer protection, antitrust, and nonprofit supervision (see Mont. Code Ann. §§ 30-14-103, 30-14-205 and 35-2-131).

The practical purpose of the initiative is to ensure that hospitals are properly carrying out their charitable missions. The letter asks for information similar to recent requests the hospitals may have received from the IRS. The questions, according to the letter, are modeled after Form 13790 to make it as easy as possible for the hospitals to respond. "Because the IRS is unable to share your responses with us, we have to request the information from you directly under our state authority," the letter added. The office also requested that the hospital provide the same information that was, or would be, provided to the IRS.

The materials requested by the Montana attorney general's office included:

- copies of policies, procedures, or handouts dealing with charity care, including how it is advertised, how one applies for it, and how the hospital decides who receives it;
- copies of any paperwork a patient would sign when they are admitted into the hospital, including those used by the emergency room;
- the amount of charitable care provided by the hospital for the years 2004 and 2005, including calculations and the number of patients to whom care was provided;
- whether the calculations under the previous request include uncollectible debt or debt that is discharged in a bankruptcy, and the percentage of charity care provided during the years 2004 and 2005 that was related to uncollectible or discharged debt;
- information regarding the hospital's debt collection procedures and samples of a bill and any debt collection letters issued by the hospital, names and contact information of debt collectors utilized by the hospital;
- a list of the ten most billed procedures in calendar years 2004 and 2005, including the amount billed, the rate reimbursed for patients covered by Medicare and Medicaid, the rate reimbursed for patients covered by Blue Cross/Blue Shield and New West, and the rate charged to patients without insurance coverage; and
- any additional information that helps demonstrate the hospital's charitable nonprofit purpose or mission, such as money donated to other charities or other community outreach programs.

Although the letter specifically calls for the recipients to turn over the information they provided, or would have provided, to the IRS in completing Form 13790, an official with the Association of Montana Health Care Providers said the attorney general, in a meeting with the association, agreed to drop the requirement that the hospitals submit a completed Form 13790 to the state. ■

CCH Chicago Bureau, Oct. 16, 2006.

On The Front Lines

Keeping your friends close and your business partners closer: Legal dynamics in the relationships among hospitals, physicians and manufacturers (Part 1)

By Steve Miller and Jeffrey Miller, 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. The purpose of this article is to provide 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.[1]

The federal anti-kickback statute ("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 presented as payments, free product or services, rebates, prebates or benefits of any other kind, made directly or indirectly, overtly or covertly, or in cash or in kind. 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] The government need only show that one (1) 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 corporate integrity agreements as conditions of probation.[7] Courtesy of the Medicare and Medicaid Patient and Program Protection Act of 1987, upon conviction the Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") is required to exclude persons and entities from participation in government-related health care programs (e.g., Medicare, Medicaid and TRICARE).[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 could also be asserted.[10]

To temper the statute's prohibition, Congress created two categories of exemptions: (1) specific exceptions set forth in the statute itself; and (2) regulatory safe harbors. The exceptions are specifically defined circumstances that Congress carved out of the statute as legal, while the safe harbors are specifically defined circumstances in which the OIG has determined it will not pursue liability. Both categories of exemptions are founded upon the underlying purposes of the statute. According to the OIG, these purposes are five-fold:

(1) to ensure that medical decisions are made solely on the bases of appropriate clinical factors, and not on providers' personal financial concerns;
(2) to curb overutilization of federal health care program reimbursed services;
(3) to hold down cost increases to federal health care programs;
(4) to avoid interference with patients' freedom of choice; and
(5) to prevent anti-competitive referral practices.[11]

In effect, Congress provided two clear options when addressing arrangements that fall within the statute's purview: (1) demonstrating that one of the basic elements of the statute are not satisfied, potentially including that there was and is no intent to induce the referral of patients or business through the arrangement; or (2) satisfying the requirements of one of the statute's exceptions or safe harbors. When one of these two options is satisfied, the arrangement is protected from prosecution.

Should neither an exception nor a safe harbor cleanly apply, Congress provided one additional option: obtaining formal OIG acquiescence to the arrangement through the statute's advisory

opinion process.[12] Through this process providers can present the OIG with detailed facts on specific circumstances, obtaining the OIG's formal opinion as to the application of the statute and the federal civil monetary penalty law.[13] It is important to note that the advisory opinion process can take nine months or more to complete. If a favorable advisory opinion is obtained, however, the proposal will be insulated from OIG prosecution. On the other hand, if an unfavorable opinion is obtained, the risk of prosecution in pursing any similar arrangement may be increased.[14] In reviewing advisory opinion submissions the OIG considers the extent to which an exception or safe harbor can be applied, the purposes underlying the statute, any additional safeguards that providers implement to protect against fraud or abuse and any charitable or public policy concerns. As a result, providers may discover some additional flexibility in the application of the law through this process.[15]

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.[16] Others have applied lessor standards, such as knowledge that the conduct was "wrongful"[17] or a "specific criminal intent to induce referrals."[18] 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 satisfy the mens rea requirement.[19]

Hospital and manufacturer roles in discounting prices without discarding compliance

The discount exception and safe harbor The statute contains a statutory exception for discounts.[20] Under this exception, discounts that are properly disclosed and appropriately reflected in costs claimed or charges made to federally funded health care programs do not violate the statute.[21] The legislative history of this exception indicates that Congress provided this exception to encourage health care providers to seek discounts as part of their good business practices and pass the government's proportionate share of those discounts on to government funded programs.[22] When providers comply with this exception the statute is not violated.

This statutory exception, on its face, appears fairly simple to understand and straightforward to apply. This apparent simplicity, however, is misleading. Following the creation of this exception the OIG created the discount safe harbor. This safe harbor provided additional detail on the requirements for discounts.[23] The discount safe harbor was intended to ensure that discounts are fully and properly reported to government funded programs and better define the roles of providers and their suppliers in this process, essentially serving the same purpose as the exception.[24] Its requirements, however, are significantly more complex and, by its terms, limited eligible transactions to certain categories of price reductions that fall within the safe harbor's definition of "discount."[25] The simpler terms of the statutory exception may be easier (and more flexible) to apply, however, the OIG has taken the position that discounts that do not satisfy the requirements of the safe harbor do not qualify for protection under the exception.[26] As a result, manufacturers and hospitals seeking to obtain assurance that their arrangements are legal are wise to use their best efforts to satisfy the safe harbor's requirements.

The discount safe harbor defines a "discount" to be "a reduction in the amount a buyer ... is charged for an item or service based upon an arms-length transaction."[27] This definition clarifies that the safe harbor only protects discounts in an item's price.[28] This definition specifically excludes:

1. cash payments or cash equivalents;
2. supplying one good or service without charge, or at a reduced charge, to induce the purchase of a different good or service (unless the goods or services are reimbursed by the same federal health care program under the same payment methodology, and the reduced charge is fully disclosed and accurately reflected to the federal health care program);
3. any reduction in price applicable to one payer but not to a federal health care program;
4. the routine reduction or waiver of any coinsurance or deductible amounts owed by government funded health care program beneficiaries;
5. warranties;[29]
6. services provided in accordance with a personal or management services contract;[30] or
7. other remuneration not explicitly described in the safe harbor.[31]

The OIG notes that arrangements that supply one good or service without charge or at a reduced charge to induce the purchase of a different good or service are problematic because they can shift costs among reimbursement systems or distort the true costs of all items.[32] These arrangements, however, are protected by the safe harbor when the net value can be properly reported to government funded programs.[33] For example, the term "discount" would not include a price reduction on an item covered by a hospital's Diagnostic Related Group ("DRG") payment system in exchange for the purchase at full price of capital equipment separately reimbursed on a reasonable cost basis. The term "discount," however, would include a price reduction for sterile gauze pads in exchange for the purchase of surgical tape, both of which are included in the hospital's DRG payment.

The OIG also specifies that the safe harbor does protect rebate checks, redeemable coupons and credits so long as these forms of discounts:

(1) are not negotiable to third parties;

(2) can only be applied to the same good or service that was purchase or provided;

(3) are fully and accurately reported to government funded programs; and

(4), except in the case of rebates, are provided at the time that the goods or services are purchased or provided.[34]

For rebates, the terms of the rebates must be fixed in writing at the time of the sale.[35]

Satisfying the requirements of the safe harbor

Hospital and manufacturer requirements for complying with the safe harbor are broken down into several differing categories, depending upon the nature of the buyer. Buyers must satisfy one of three sets of requirements, depending upon whether the buyers are health maintenance organizations (HMOs), cost-reimbursed, or paid on the basis of charges. For cost-reimbursed buyers, like hospitals, the essential requirement is that the actual acquisition cost, net of any discounts, must be reported accurately to government funded programs.[36] Specifically, for transactions involving hospitals and medical device manufacturers, hospitals are required to ensure that:

1. the discount is earned based on purchases of the same goods or services bought within the hospital's single fiscal year;

2. the hospital claims the benefit of the discount in the fiscal year in which the discount is earned, or the following year;

3. the hospital fully and accurately reports the discount in the applicable cost report; and

4. the hospital provides, upon request by the HHS Secretary or any state agency (together as "HHS"), the discount information provided to it by the manufacturer.

In this context, seller-manufacturers must satisfy their own requirements. In essence, manufacturers are responsible for providing their customer-hospitals with notice of the hospitals' responsibilities to report cost information accurately to government funded programs, while providing them with the information that they need to satisfy these obligations.[37] Specific obligations vary depending upon whether the amount of the discount is known at the time of sale, or whether it is determined at a later time. In summary, manufacturers' responsibilities as follows:

1. When the amount of the discount is known at the time of sale, the manufacturer must:

a. fully and accurately report the discount on an invoice, coupon or statement submitted to the hospital;

b. inform the hospital in a manner that is reasonably calculated to give it notice of its obligations to report the discount to government funded programs, and to provide the discount information to HHS upon request; and

c. refrain from doing anything that would impede the hospital from satisfying its obligations under the safe harbor.[38]

Manufacturers are required only to report a single final price, net of all discounts.[39] This price, however, must reflect the actual purchase price.[40]

2. When the value of the discount is not known at the time of sale, the manufacturer must:

a. fully and accurately report the existence of the discount program on an invoice, coupon or statement submitted to the hospital;

b. inform the hospital in a manner reasonably calculated to give notice of its obligations to report the discount to government funded programs, and to provide the discount information to HHS upon request;

c. when the value of the discount becomes known, provide the hospital with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and

d. refrain from doing anything that would impede the hospital from satisfying its obligations under the safe harbor.

Buyer-hospital and seller-manufacturer requirements, while inter-related, are independent of each other. When the manufacturer-seller has done "everything it reasonably could under the circumstances to ensure that the buyer understands its obligation to report the discount accurately" the manufacturer is protected irrespective of the hospital's omissions.[41] To receive this protection, however, the manufacturer must report the discount to the hospital accurately and inform the hospital of its obligation to report the discount.[42] As a result, when a buyer or seller satisfies its obligations it obtains safe harbor protection.

Conclusion

Part I of this article 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 will discuss the discount safe harbor and how the type of relationship addressed can impact the legal requirements that govern physician consulting and professional services arrangements, including employment and independent contractor relationships.

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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 (3rd Cir. 1988) (see Health Care Compliance Reporter ¶241,016), *cert. denied*, 474 U.S. 988, 106 S.Ct. 396 (1985) (the intent standard is satisfied if the payment made is at least in part for the purpose of inducing referrals); *Compare United States v. Bay State Ambulance*, 874 F.2d 20 (1st Cir. 1989) (see Health Care Compliance Reporter ¶201,038) (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) (see Health Care Compliance Reporter ¶16,457B-2).

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-7(a).

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 the 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) (see Health Care Compliance Reporter ¶243,029).

11 *See* "Briefing: Safe Harbor Regulations," Office of Inspector General, Department of Health and Human Services, Aug. 6, 1991.

12 42 C.F.R. § 1008.47. Requestors are required to pay a $250.00 filing fee, and to reimburse the OIG for all of its costs incurred in issuing an opinion.

13 42 U.S.C. § 1320a-7a.

14 The failure to seek an advisory opinion cannot, by regulation, be used by the government as evidence to prove wrongful intent. 42 C.F.R. § 1008.55(a).

15 An analysis of OIG Advisory Opinions appears to reveal that the OIG exempts some arrangements based primarily upon certain charitable, public policy factors, often centered on supporting the continued provision of historically provided charitable care. *See* OIG Advisory Opinion No. 02-11, Aug. 19, 2002 (see Health Care Compliance Reporter ¶500,085); OIG Advisory Opinion No. 02-1, April 11, 2002 (see Health Care Compliance Reporter ¶500,075). Additionally, while the OIG may not specifically address these same concerns in its analyses of each anti-kickback statute exception and safe harbor, it also appears that it does weigh these factors when determining whether or not an exception or a safe harbor is satisfied. *See* "Briefing: Safe Harbor Regulations," Office of Inspector General, Department of Health and Human Services, Aug. 6, 1991.

16 *Hanlester v. Shalala*, 51 F.3d 1390 (9th Cir. 1995) (see Health Care Compliance Reporter ¶247,026).

17 *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996) (see Health Care Compliance Reporter ¶246,012).

18 *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) (see Health Care Compliance Reporter ¶248,015) ("purposely intending to violate the law").

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

20 42 U.S.C. §1320a-7b(b)(d)(A).

21 *Id.*

22 *See* H.R. Rep. No. 95-393, 92 Cong., 2d Sess. (1977).

23 42 C.F.R. §1001.952(h).

24 *Final rule,* 64 FR63517, 63518, 63526, Nov. 19, 1999 ([D]iscounts for health care items and services are encouraged … so long as federal health care programs share in the discount where appropriate … . Arrangements in accordance with which federal programs get less than their proportional share of the savings … are seriously abusive.").

25 42 C.F.R. §1001.952(h)(5).

26 *See Final rule,* 56 FR 35952, 35956-67, July 29, 1991 (stating that the OIG has the authority to interpret terms used by Congress in the exceptions); Final rule, 59 FR 37202, 37205-206, July 21, 1994 (stating that all discounts protected under the exception also are protected under the safe harbor).

27 42 C.F.R. §1001.952(h)(5).

28 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, *Notice*, 68 FR 23731, 23735, May 5, 2003 (see Health Care Compliance Reporter ¶510,018).

29 Warranties are subject to their own safe harbor. *See* 42 C.F.R. §1001.952(g).

30 Personal services and management contracts are subject to their own safe harbor. *See* 42 C.F.R. §1001.952(d).

31 The OIG notes that discounts resulting in below-cost arrangements, or arrangements that in the aggregate provide lower prices to customers with higher levels of government-funded program business are particularly suspect. OIG Supplemental Compliance Program Guidance for Hospitals, *Notice*, 70 FR 4858, 4869, Jan. 31, 2005 (see Health Care Compliance Reporter ¶510,017).

32 *Final rule,* 64 FR 63517, 63518, 63530, Nov. 19, 1999.

33 *Id.*

34 *Final rule*, 56 FR 35952, July 29, 1991. *See also Final rule*, 64 FR 63517, 63518, 63529, Nov. 19, 1999 ("a coupon for a certain dollar amount off any goods sold by the seller is not included in the definition.") "Up front rebates" and "pre-bates" also are not protected. *Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Notice,* 67 FR 62057, 62061, Oct. 3, 2002 (see Health Care Compliance Reporter ¶510,018).

35 42 C.F.R. §1001.952(h)(4).

36 42 C.F.R. §1001.952(h)(1).

37 42 C.F.R. §1001.952(h)(2).

38 Manufacturers are protected where they are not complicit in their customers' noncompliance with customer responsibilities. *Final rule*, 64 FR 63517, 63518, 63529, Nov. 19, 1999.

39 *Final rule,* 56 FR 35952, 35981, July 29, 1991; While no specific form of invoice, coupon or statement is required in the regulations, the OIG has required in corporate integrity agreements that discounts be documented in such a manner that the line item prices of each item (including, if applicable, when the items are delivered free of charge) be able to be separately and readily identified by each party to the transaction.

40 *Final rule,* 59 FR37202, 37206, July 21, 1994; *Final rule,* 64 FR 63517, 63518, 63527, Nov. 19, 1999.

41 *Final rule*, 64 FR 63517, 63526-27, Nov. 19, 1999.

42 *Id.*

Tax-Exempt

AHA faults IRS questionnaire for tax exempt hospitals

by Jeffrey Carlson, Contributing Editor

The American Hospital Association (AHA) has taken the Internal Revenue Service (IRS) to task on its Tax Exempt Hospitals Compliance Questionnaire (Form 13790) following the IRS's request for ways to enhance the quality, utility, and clarity of the information to be collected and ways to minimize the burden of the collection of information on the respondents. The AHA hand delivered its comments on October 6, 2006, to IRS Reports Clearance Officer Glenn P. Kirkland.

Form 13790 shortcomings. Specifically, the AHA challenged the limiting of questions solely to individual hospitals, and not applicable hospital systems, which they argued could lead to misleading responses. As an example, the AHA said responses to one question on program costs could result in an understatement of actual expenditures because the hospital would report only what it spends on certain programs, not the total provided by the system.

In addition, the AHA noted that by requesting text responses, many questions would not be answered uniformly. Similarly, the Association stated that yes/no questions result in inconsistent answers, multiple choice answers to certain questions do not provide information on how often or how prevalent the event is, and uncompensated care questions do not specify whether the response is to be based on costs or charges.

The AHA also challenged questions that do not indicate when hospitals should include employee time spent as part of any community benefit program and queries on other programs and activities do not inform respondents how to describe the programs and activities or how to report costs. ■

CCH Washington Bureau, Oct. 11, 2006.

In The News

A new report on hospitals, entitled "My Brother's Keeper," reflects growing criticism of community benefit practices. Released on October 11, 2006, by PricewaterhouseCoopers Health Research Institute, the report comes as state and federal officials and consumer advocates press hospitals to defend the amount of community benefit they provide, and explain pricing practices that call into question hospitals' commitment to their tax-exempt purpose. ■

CCH Washington Bureau, Oct. 18, 2007.