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A STATUS REPORT REGARDING OIG FRAUD AND ABUSE ADVISORY OPINIONS

Introduction

Pursuant to Section 205 of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) ("HIPAA"), the Office of the Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") is now issuing advisory opinions as to whether or not specific activities or financial arrangements violate the Medicare/Medicaid Anti-Kickback statute, 42 U.S.C.A. § 1320a-7b (1997) (the "Anti-Kickback Statute"), or other fraud and abuse laws. HIPAA also mandates the OIG to issue Special Fraud Alerts to describe certain practices the OIG regards as unlawful. Notably, the Balanced Budget Act of 1997 also requires the OIG to issue advisory opinions concerning whether physician referrals for certain health services (other than clinical laboratory services) are prohibited under the Stark Amendment, 42 U.S.C.A. § 1395nn (1997). Requests for such opinions could be made as of November 3, 1997.

Specifically, the advisory opinions address: (1) what constitutes prohibited remuneration; (2) whether an arrangement or proposed arrangement satisfies one of the enumerated exceptions in 42 U.S.C.A. §1320a-7b(b)(3) (1997) or the "safe harbor" regulations at 42 C.F.R. § 1000.952 (1997); (3) what constitutes an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under 42 U.S.C.A. § 1320a-7b(b) (1997); and (4) whether an activity or proposed activity constitutes grounds for the imposition of civil or criminal sanctions under 42 U.S.C.A. §§ 1320a-7a and 1320a-7b (1997).

Health care industry officials lobbied heavily for the advisory opinion process, viewing it as a means of eliminating the legal ambiguity surrounding many health care business arrangements. Enforcement agencies,

including the OIG, opposed the process from the start because of concerns that criminal investigations might be hindered by prior advisory opinions holding a particular arrangement to be legitimate. While Section 205 of HIPAA does provide that advisory opinions are binding on the Secretary and the party or parties requesting the opinion, the regulations promulgated by the OIG state that no other individuals or entities may rely on an opinion.

Background: Anti-Kickback Statute, "Safe Harbor" Provisions and Fraud Alerts

Generally, the Anti-Kickback Statute imposes civil monetary or criminal penalties for entities or individuals who knowingly and willfully receive, pay, offer, or solicit any remuneration "directly or indirectly, overtly or covertly, in cash or in kind" in order to induce business reimbursed under the Medicare or Medicaid programs. 42 U.S.C.A. §1320a-7b (1997). Types of remuneration specifically prohibited by the statute include kickbacks, bribes, and rebates. In addition to the civil or criminal sanctions which may be imposed, violators may also be subject to exclusion from the Medicare and Medicaid programs. 42 U.S.C. §1320a-7 (1997).

Because the Anti-Kickback Statute is so broadly worded, the Medicare and Medicaid Patient and Program Protection Act of 1987 (Pub. L. No. 100-93) required the promulgation of regulations, or "safe harbor" provisions, specifying various payment and business practices which will not be treated as criminal offenses or serve as a basis for program exclusion. The thirteen safe harbor provisions, which specify certain practices which are considered to be legal, appear at 42 C.F.R. § 1001.952 (1997).

Advisory Opinions Provide Case-Specific "Safe Harbors"

The OIG's analysis of the advisory opinion process is similar to that of the safe harbor provisions with one major exception: whereas the safe harbor provisions describe generalized, hypothetical arrangements which are protected, an advisory opinion applies only to the particular facts of a specific arrangement. While an opinion may serve to shield the requestor from prosecution, as noted above, the OIG has emphasized that it may not be relied upon by a third party, even in the case

of factually similar arrangements. Moreover, the OIG's advisory opinions do not bind any agency other than HHS, and the OIG reserves the right to reconsider and modify or rescind an opinion "where public interest requires." For example, if it determines that material information regarding the proposed arrangement was withheld by the requestor, the OIG may declare the opinion void and without force or effect. In the event the opinion is modified or terminated, however, the OIG will not proceed against the requestors for any action taken in good faith reliance upon the opinion.

For several articulated reasons, the OIG will not issue advisory opinions for hypothetical or generalized arrangements. First, the Anti-Kickback Statute imposes liability on specific people with respect to particular factual circumstances. Second, with intent-based laws like the Anti-Kickback Statute, it may not be possible to determine whether a certain general practice is invariably good or bad. Differing intentions of parties may warrant different conclusions in the resulting opinions, even if those opinions address similar factual situations. Finally, OIG representatives have stated that particularized or case-specific treatment is appropriate where specific arrangements that might otherwise be problematic contain limitations, requirements or controls that give adequate assurance that federal health care programs will not be abused.

Interestingly, even though the Anti-Kickback Statute is intent-based, advisory opinions will not address whether the requestor or other party has the intent required to constitute a violation of the statute. The OIG reasons that it is not practical for the agency to make a reliable, independent determination of the parties' subjective intent based only upon written materials submitted by the requestor. The OIG also will not issue advisory opinions on what constitutes fair market value for goods, services, or property, or whether an individual constitutes a bona fide employee for purposes of the "bona fide employee" safe harbor provision at 42 C.F.R. § 1001.952(i) (1997).

Procedural Requirements for Advisory Opinion Requests

The procedures by which requests are made and advisory opinions issued are outlined in an interim final rule published at 62 Fed. Reg. 7350 (1997). The rules describe

the requirements for filing requests, applicable fees, the OIG's time frame and other responsibilities in responding to requests, and access to advisory opinions by third parties. A 60-day public comment period followed the announcement of the interim rule, during which time the OIG received approximately thirty comments and suggestions. Final procedural rules are expected to be in place by the end of the year and will reflect any revisions made in response to the public input.

Full Disclosure Required

All requests for advisory opinions must concern an existing arrangement to which the requester is a party or an arrangement the requester plans to pursue. The request also must be in writing, fully disclose the identity to all parties to the arrangement that is the subject of the opinion and include the participants' Medicare and Medicaid provider numbers. Submissions need to include copies of all operative documents, such as contracts, leases, employment agreements, and any court documents. A detailed, narrative description of the arrangement in question must be included, and either the arrangement must be in existence at the time of the request or there must be a good faith intention to enter into the described arrangement in the near future. In cases where a particular arrangement is already in existence, the OIG does not guarantee immunity from prosecution should it determine that the arrangement violates the Anti-Kickback Statute or other fraud and abuse laws. This raises concerns that fear of prosecution may deter some parties from submitting inquiries, thereby undermining the overall purpose and effectiveness of the advisory opinion process. According to OIG representatives, the likelihood of any prosecutorial action by the OIG would depend on the particular facts of the arrangement, as well as considerations such as the parties' good faith efforts to comply with the statute and cease the prohibited activity. The concern over potential prosecution of existing arrangements was raised during the public comment period and is being addressed by the OIG during development of final regulations.

Fees and Time Involved

A $250 application fee must accompany each request for an advisory opinion. Significantly, requestors also will be charged an hourly rate of $100 for the time spent by OIG staff attorneys, supervisors, and support staff in

developing, writing, and releasing the opinion.

The OIG is required to issue an opinion within 60 days of receiving from the requestor all information necessary to render the opinion. To help facilitate processing and response to requests, the OIG provides a list of preliminary questions and a checklist designed to elicit the necessary factual information and ensure compliance with the initial application process. While not mandatory, the questions are recommended by the OIG as a means of expediting the advisory opinion process. The preliminary questions and checklist are available on the HHS/OIG web site at http://www.sba.gov/ignet/internal/hhs/hhs.html.

Actual costs and time involved may vary widely due to the varying nature and complexity of the requests received. Simple requests may take as little as three hours to analyze and produce a report, while requests involving multiple parties, intricate business arrangements or complex transactions could take in excess of 40 hours. The OIG estimates the minimum cost for an opinion will be $250, as initial processing of a request takes approximately two hours.

In order to accommodate requestors who may want to limit the costs of receiving an advisory opinion, the regulations provide that a requestor may designate a "triggering dollar amount" in its request. The OIG will stop processing and notify the requestor if it calculates that the cost of processing the request has reached, or is likely to exceed, that triggering amount.

Once the OIG issues an advisory opinion, the opinion is made available to the public at OIG headquarters and on the HHS/OIG web site. The names of the parties involved and other identifying references, however, are redacted from the published advisory opinion.

Advisory Opinions Issued

Considering the industry's strong support for such a mechanism, initial use of the OIG advisory opinion process has been minimal. Only 14 requests had been received when the HHS issued its first advisory opinion on June 10, 1997, despite the agency having anticipated a volume of approximately 500 requests per year. At the date this article went to press, six advisory opinions had been issued.

Advisory Opinion No. 97-1. In its first advisory opinion, the OIG determined that it is permissible for a charitable organization partly funded by kidney dialysis providers to pay health insurance premiums and other care-related costs for financially needy end-stage renal disease ("ESRD") patients.

The advisory opinion was requested by the American Kidney Fund ("AKF") and six companies that provide kidney dialysis services. Under the proposed arrangement, the six companies would donate funds to AKF, which then offered financial assistance to ESRD patients who needed to purchase insurance and transportation to and from dialysis facilities, and who had other needs, such as for medicine and/or Medigap insurance.

Federal law generally prohibits payments to a beneficiary if it is likely to influence the beneficiary's choice of a health care provider. Specifically, Section 1320a-7a of the Anti-Kickback Statute provides for the imposition of civil monetary penalties against any person who provides remuneration to a Medicare or Medicaid beneficiary when that person knows or should know that such remuneration is likely to influence the beneficiary's choice of health care provider or supplier.

In Advisory Opinion 97-1, the OIG determined that the donations by the companies to AKF would not constitute remuneration to an eligible beneficiary and would not be likely to influence a beneficiary's choice of a particular provider. Even though AKF funds 100% of all eligible requests, patients must provide proof of medical and financial need to meet AKF's eligibility criteria. AKF has absolute discretion regarding the use of provider contributions, and the donating companies have represented that they will not track the amounts that AKF pays on behalf of patients using their facilities. Thus, the OIG found that there was no apparent direct connection between the funding from the six contributing companies to the AKF and the use of these companies' services by the recipients. To the contrary, the opinion reasoned, "the insurance coverage purchased by AKF will follow the patient regardless of which provider the patient selects, thereby enhancing patient freedom of choice in health care providers."

Advisory Opinion No. 97-2. The OIG's second advisory opinion also involved payment of insurance premiums for

financially needy ESRD patients. This opinion addresses the question of whether such an arrangement constitutes grounds for the imposition of civil monetary penalties under 42 U.S.C.A. §1320a-7a (1997).

The arrangement at issue was a state-funded program of last resort which pays the medical expenses of ESRD patients who have no other source of funding for treatment. The program distributes state funds to qualifying renal dialysis facilities pursuant to written contracts that specify the maximum amount of funds granted to each facility and the purposes for which the funds are allocated. The program contracts with all chronic dialysis providers in the state. Under these contracts, the program reimburses the facilities for payment of Medicare Part B, Medigap, and major medical insurance premiums paid on behalf of indigent ESRD patients. Because the amount of money budgeted to each facility is fixed by contract in advance, funding may not always be available for otherwise qualifying patients at specific facilities. Consequently, such patients must reapply for funds through another contracting facility.

To qualify for the program benefits, patients must meet residency, citizenship, medical condition, and financial needs eligibility criteria. When evaluating whether to provide benefits to individual patients, the contracting providers must consider the cost savings that will accrue to the program along with the benefit to the patient. The program may decline to reimburse a facility for premium payments in the event that no cost savings to the program and no net benefit to the patient will be realized.

OIG determined that because the program is entirely state-funded, and funds are made available to all chronic dialysis facilities and all eligible patients in the state, the state-financed payments were not likely to influence patients in their selection of particular providers. Moreover, the opinion noted, the contract facilities do not have any substantial discretion regarding patient eligibility, since it is the state, rather than the facility, providing the remuneration. Thus, the OIG concluded, the arrangement did not constitute grounds for imposition of civil monetary penalties under 42 U.S.C.A. § 1320a-7a (1997).

Advisory Opinion No. 97-3. This advisory opinion addresses the issue of whether a transfer of $7,785 from an

Oregon nursing home resident to her nephew three months prior to her application for Medicaid benefits constitutes grounds for sanctions under 42 U.S.C.A. § 1320a-7b(a)(6) (1997). This section of the Anti-Kickback Statute prohibits knowing and willful disposition of assets in order to become eligible for Medicaid, if disposing of such assets results in a period of ineligibility for Medicaid. The requestors of the opinion were the Medicaid applicant and her financial advisor who counseled her in transferring the assets.

In determining that the requestors' actions did not constitute a violation of the Anti-Kickback Statute, the OIG focused on the last phrase of the provision, "if disposing of the assets results in a period of ineligibility." The asset transfer at issue would have created a three-month ineligibility period for state Medicaid benefits had the Medicaid applicant submitted an application for benefits at the time of the transfer. Under Oregon law, however, no period of ineligibility would be imposed, since the applicant delayed her Medicaid application until after the expiration of the three-month period of ineligibility. Because no period of ineligibility resulted from the transfer, the OIG reasoned that there could be no liability under 42 U.S.C.A. § 1320a-7b(a)(6) (1997).

Advisory Opinion 97-4. In its fourth advisory opinion, the OIG determined that an ambulatory surgical center's practice of declining to pursue collection of copayments directly from Medicare beneficiaries may constitute grounds for the imposition of criminal and/or civil monetary penalties under the Anti-Kickback Statute.

Medicare payment for ambulatory surgical center ("ASC") services consists of a facility fee and a professional fee. Both fees are subject to Medicare Part B coinsurance and deductible amounts (collectively, "Medicare Copayments"). The requestor of this opinion is an ASC that provides services to certain Medicare beneficiaries whose former employers contract for complementary coverage to cover the cost of Medicare Copayments. The company administering the complementary coverage plan ("CCP") for patients who were treated at the requestor's facility would pay a copayment amount to the physician who rendered the endoscopy services, but refused to pay the copayment amount for the facility fee to the requestor. The CCP denied payment of the copayment for the facility fee because the requestor was not one of the CCP's

participating ACS facilities.

Despite the refusal of the CCP to pay the facility fee copayment amount, the requestor continued to treat beneficiaries who received complementary coverage from the CCP. Each time CCP denied the claim for payment of the facility fee copayment amount, the requestor would send a standardized appeal letter. However, if the CCP continued to deny payment, the requestor would not pursue payment from the covered beneficiaries.

The OIG determined that the arrangement described by the requestor, whereby the requestor would not pursue payment of the facility fee copayment directly from beneficiaries, may constitute a violation of Section 1320a-7b(b) of the Anti-Kickback Statute because prohibited "remuneration" under the statute specifically includes waivers of coinsurance and deductible amounts that are likely to influence a beneficiary's choice of a particular provider. Medicare beneficiaries are obligated to pay Medicare Copayments, and any waiver of that obligation constitutes remuneration to the beneficiary. The opinion notes that the requestor's proposal to refrain from pursuing collection of the copayments from the beneficiaries was intended, at least in part, to encourage beneficiaries to obtain services at the facility.

The opinion further found that the arrangement did not meet the criteria for an exception under Section 1320a-7b (b)(3) of the Anti-Kickback Statute because it did not provide for individualized determinations of financial hardship or reasonable collection. The opinion states, "[W] hen an insurer has taken a consistent position with the provider that a category of claims are not covered, the provider's continued submission of such claims, including subsequent appeals, is not a *bona fide* collection effort." Advisory Opinion 97-3. In such cases, the opinion indicates, the provider must pursue the beneficiary to collect Medicare Copayments.

Advisory Opinion No. 97-5. Advisory Opinion No. 97-5 involved a proposed joint venture between a group of radiologists and a hospital system to form an outpatient radiology imaging center (the "Center"). The opinion addresses two issues raised by the joint venture: (1) whether distributions from the joint venture would constitute remuneration for referrals; and (2) whether the joint venture would serve as a mechanism for the

radiology group to reward the hospital system for revenues received as a result of the radiology group's arrangement with one of the hospital system's facilities. Although the OIG determined that the proposed financial arrangement did not fall under any of the statutory or regulatory "safe harbor" protections, it concluded that the arrangement would not generate prohibited remuneration within the meaning of the Anti-Kickback Statute, and therefore would not constitute grounds for the imposition of civil or monetary sanctions.

Under the proposed joint venture, the radiology group would own 51 percent of the Center, with the other 49 percent being owned by the hospital system. In return for their capital contributions, each member would receive voting and distribution rights proportional to its investment. The radiologists would not be employees of the Center and would not receive any compensation from the Center. Rather, they would enter into a service provider agreement under which they would be the exclusive providers of professional services to the Center. The radiology group would bill patients and third-party payers, including Medicare and Medicaid, for the professional component of the radiological services, and the Center would bill separately for its technical components to patients and third-party payers.

The OIG's initial inquiry was whether the distributions from the joint venture would constitute "disguised" remuneration for referrals by the investors to the Center. In evaluating the hospital system's role in relation to the joint venture, the OIG noted that as part of the proposed arrangement, the hospital had agreed that its employed physicians would make no referrals to the Center, and the Center would not accept any referrals from those physicians. Additionally, the opinion notes that the hospital system had agreed that it would: (1) take no actions to induce its medical staff to use the imaging Center; (2) inform the medical staff of its agreement; (3) not track physician referrals to the Center; and (4) continue to operate its hospital radiology units. Under those circumstances, the OIG concluded, referrals from non-employee physicians (those with admitting or staff privileges within the hospital system) would not be attributable to the hospital system.

The OIG further found that the radiology group radiologists would also be unlikely to generate an

appreciable number of referrals to the Center, because radiologists generally do not order the radiological tests they perform. Such tests typically are ordered by a patient's attending physician. Thus, since neither the radiology group nor the hospital system would be in a position to generate or influence an appreciable number of referrals to the Center, the OIG concluded that the distribution of any profits would not constitute illegal remuneration in exchange for referrals.

The second issue addressed in the opinion was whether the proposed joint venture would serve as a mechanism for the radiology group to indirectly reward the hospital system for revenues received as a result of the radiology group's arrangement with one of the hospital system's facilities. Notwithstanding the joint venture arrangement, the radiology group is the exclusive provider of professional radiology services for one of the hospitals in the hospital system. In addition, the hospital also provides the radiologists with office space, and one of the doctors in the radiology group serves as director of the hospital's radiology department.

The OIG found that because both the radiology group and the hospital system had made substantial financial investments in the joint venture, and that control of the venture and the distribution of profits would be in direct proportion to such investments, each party's return on investment would be commensurate with its undertakings and would not appear to represent illegal remuneration or compensation to the hospital or hospital system for their referrals to the Center. Moreover, the OIG noted that because the value of the premises and equipment provided to the radiology group are substantially equal to the value of the radiologist's services to the hospital as director of radiology, any profit distribution from the Center would not represent illegal remuneration for the use of the hospital's space and equipment.

The OIG cautioned, however, that even in situations where each party's return is proportionate with its investment, the "mere opportunity to invest" and receive profit distributions may constitute illegal remuneration if offered in exchange for past or future referrals.

Advisory Opinion No. 97-6. In its sixth advisory opinion, the OIG found that hospitals that, without charge, restock ambulances with supplies or medications used while

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transporting patients to the same hospitals would likely be violating the Anti-Kickback Statute.

This advisory opinion request was submitted by a company which owns and operates two acute care hospitals in a particular city. Under the evaluated arrangement, the hospitals would restock, without charge, ambulances with any supplies or medications used while transporting patients to the hospitals. Neither the company nor the hospitals would bill any federal health care program, and the ambulances would receive no other reimbursement for the items supplied.

State regulations require that municipal ambulance services transfer patients to a hospital emergency room selected by the patient or the patient's physician unless the ambulance attendant determines that transport to another facility is necessary to save the patient's life or limb or the ambulance service is operating under a government-approved local or regional diversion plan or medical triage protocol.

The OIG determined that the hospital's provision of free supplies and medication to the local ambulance services "fits squarely within the meaning of remuneration for purposes of the Anti-Kickback Statute," which prohibits remuneration in exchange for patient referrals, since at least one purpose of the proposed arrangement could be to induce the ambulance services to bring patients to the hospitals. Additionally, the OIG found that such an arrangement poses a risk of improper steering of patients and unfair competition.

In reaching its conclusion, the OIG rejected the requesting company's contention that compliance with the state regulation would be sufficient to deter abuses addressed by the Anti-Kickback Statute. The opinion noted that "patients in need of ambulance services are often in a vulnerable state, and their choice of emergency room may be influenced by ambulance personnel." Under the proposed arrangement, where the provision of free supplies and medication would relate directly to the delivery of patients, such remuneration would be "highly suspect." The OIG also rejected the company's position that the restocking arrangement would not be abusive because it would not lead to increased costs for the federal health care programs. The opinion points out that "increased costs to the programs is not the only criteria

used in determining whether a particular business arrangement is abusive."

Practical Application

Many health care representatives have generally been aware of the OIG advisory opinion process. In practice that process has been utilized on a limited basis, presumably because of the extensive disclosure required and the significant costs involved. While the several opinions issued to date may be of interest to particular providers, the practical utility of these determinations is at best limited. Since the opinions cannot be relied on by third parties, they hold no precedential value.

If you desire more information about the advisory opinion process, or have a question concerning its application to a particular arrangement, please do not hesitate to call Michael E. Reed (312) 609-7428 or any other member of the Health Care Practice Group.

- Return to the Health Care index.
- Return to the Vedder Price Publications Page.
- Return to: Top of Page.

Home | Legal Services | Attorneys | **Publications** | Recruiting | Seminars | Speakers | Alumni | Contact Us | Search
Top of Page