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In This Issue

continues on page 2—

OIG 2007 Advisory Opinions

No. 07-01: OIG Declines to Impose Sanctions on Hospital's Proposed Free Acute Dialysis Services

On January 18, 2007, the OIG issued Advisory Opinion 07-01, addressing a hospital's proposal to provide free acute dialysis treatment services to chronic dialysis patients, some of whom may be Medicare or Medicaid beneficiaries, have applications with those programs pending, or who will become eligible for Medicare in a short period of time, and who are unable to obtain dialysis in their own community. The OIG analyzed the proposal under the antikickback statute, 42 U.S.C. § 1320a-7b(b), and CMP provision prohibiting inducements to beneficiaries, 42 U.S.C. § 1320a-7a(a)(5). The OIG concluded that although the proposal could potentially implicate both the antikickback statute and CMP provision, it would not impose sanctions under the facts presented.

The large, public health system requesting the opinion is required, pursuant to state law, to provide health care services to the residents of an underserved county with a high percentage of indigent patients. The requestor operates an acute-care hospital that has a dialysis unit which provides dialysis only to inpatients or those seen in the emergency department who are in acute need for dialysis. The hospital does not offer chronic dialysis services for outpatients. Its outpatient renal clinic provides care to patients in all stages of chronic kidney disease, but who do not need dialysis. Once a patient requires dialysis, the patient is no longer treated at the renal clinic.

The requestor certified that chronic dialysis patients lack access to dialysis services for a variety of reasons, including: (i) lack of health insurance or other payment sources, (ii) lack of open dialysis chairs in the County and surrounding areas, (iii) inability to transfer to a privately owned dialysis unit or inability to sit in a dialysis chair for the four-hour treatment, or (iv) other problems, such as behavioral and psychiatric issues, which make them poor candidates for treatment in such a clinic.

Since chronic dialysis patients are unable to obtain dialysis services in the community, many of them forego treatment until their condition becomes so acute that they present to the hospital emergency department and have to be admitted for emergency inpatient dialysis, or they present to the renal clinic. To prevent their condition developing into an emergency situation, these patients are admitted for inpatient dialysis.

The requestor estimates that, at any given time, the hospital has 10 to 15 chronic dialysis patients occupying inpatient beds, and who only receive thrice-weekly inpatient dialysis services. The hospital does not bill anyone for these inpatient admissions and services, and absorbs the costs itself. However, because the beds are occupied by chronic dialysis patients who could receive outpatient dialysis if they had access to it, accessibility to these beds by other patients is limited. Acute patients in the emergency department have to wait for inpatient beds. This results in the emergency department reaching capacity, which, in turn, requires the hospital to divert patients to other emergency rooms.

Under the proposed arrangement, the hospital would admit chronic dialysis patients for dialysis three times per week. After each treatment, consistent with standards for

In This Issue

—from page 1

NO. 07-14: OIG Approves Exclusive Contracts for Ambulance Transport Services *PAGE 15*

NO. 07-15: OIG Approves Medigap Policy's Use of Preferred Hospital Network *PAGE 17*

NO. 07-16: OIG Approves Educational Videos to Prospective Surgical Patients *PAGE 18*

NO. 07-17: OIG Approves Excluded Individual's Transfer of Intellectual Property Rights to Children's Company *PAGE 19*

NO. 07-18: OIG Approves Cost-sharing and Premium Aid to Medicare and Medicaid Patients *PAGE 19*

NO. 07-19: OIG Approves Free Test Reports for Hospital *PAGE 20*

NO. 07-20: OIG Approves Location of Physician-owned Medical Imaging Center *PAGE 22*

NOS. 07-21 & 07-22: OIG Approves Gainsharing arrangements Involving Cost Savings in Cardiac Surgeries *PAGE 22*

routine outpatient dialysis, the hospital would immediately discharge the patient, thus obviating the need for such patients to essentially live in the hospital. The hospital stipulated that it would neither bill the patient or any third-party payor, nor advertise the availability of this arrangement.

The requestor certified that the outpatient clinics in the area would not accept patients with pending Medicare or Medicaid applications. It stated that, pursuant to the proposed agreement, it would try to bridge the gap by having the hospital's renal case manager/social worker assist any chronic dialysis patient in finding an available outpatient dialysis chair in the community when the patient subsequently becomes eligible for Medicare or Medicaid. In light of the fact that the hospital does not offer outpatient dialysis, these patients would not return to the hospital for such services.

In analyzing this proposed arrangement, the OIG concluded that it could potentially implicate both the antikickback statute and the CMP prohibition against beneficiary inducement. However, the OIG noted that the proposed arrangement presents a minimal risk of fraud and abuse and also provides significant benefits to an under-served patient population. The OIG concluded that it would not impose sanctions.

The OIG began by analyzing the proposed arrangement under the CMP. The OIG said the threshold question is whether free chronic dialysis treatments constitute remuneration to the recipients. Because the dialysis treatments have more than a nominal value, they would constitute remuneration for purposes of the CMP.

Next, the OIG considered whether the free chronic dialysis treatments would be likely to influence patients to select the hospital as their provider of items and services payable by Medicare or Medicaid. The OIG concluded that this was unlikely for the following reasons:

- The free treatments would not precipitate an ongoing relationship because neither the hospital nor the clinic offers outpatient dialysis services. Additionally, the hospital will assist the patients in locating an available chair at an unaffiliated local outpatient dialysis facility.
- The hospital will not advertise the proposed arrangement.
- Although the free dialysis treatments could cause general goodwill in the sense that they could potentially influence patients to choose the hospital for non-dialysis services, the OIG found this possibility too speculative and attenuated by circumstances beyond the hospital's control.
- Having concluded that the proposed arrangement is unlikely to influence patients to select the hospital as their provider of items or services payable by Medicare or Medicaid, the OIG stated that it is unnecessary to analyze whether the requestor knows or should know that the proposed arrangement would have such an effect.
- The OIG next proceeded to analyze the proposed arrangement under the antikickback statute. For the reasons set forth above and below, the OIG concluded that the proposed arrangement poses a minimal risk of fraud and abuse, and, consequently, it would not impose administrative sanctions on the requestor in connection with the antikickback statute.
- The hospital will absorb all costs associated with providing the dialysis services to chronic dialysis patients. The hospital will not bill any federal health care programs for these services.
- The proposed arrangement will discourage chronic dialysis patients from self-referring back to the hospital for dialysis by providing the assistance of the renal case manager/social worker to help place patients in available local outpatient dialysis chairs as soon as possible.
- The hospital has a legitimate business purpose for participating in the proposed arrangement because it will free up inpatient beds for those patients requiring inpatient services for which the hospital can receive reimbursement.

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- The proposed arrangement is consistent with the hospital's statutory duty to provide health care to the residents of the county in which the hospital is located, and its mission to serve underserved populations (e.g., the insured and those suffering from behavioral and psychiatric issues that cause other providers to turn them away).

No. 07-02: OIG Rejects Proposal to Subsidize Ambulance Costs

In OIG Advisory Opinion 07-02, issued March 14, 2007, the OIG reviewed a proposed arrangement to subsidize the cost of ambulance transportation costs for patients transported to a hospital from outside the local area in which the hospital is located. The OIG concluded that the proposed arrangement could constitute grounds for the imposition of sanctions under the CMP provision prohibiting inducements to beneficiaries and the antikickback statute.

The requestor told the OIG that, historically, claims for transportation costs for patients transferred to the hospital from distant (i.e., non-local) hospitals by ambulance were generally paid by the local Medicare carrier. However, more recently, the carrier began denying claims for the reimbursement of such costs on the basis that the Medicare reimbursement rules permit reimbursement only of local ambulance transportation costs unless transportation to a more distant hospital is warranted due to the patient's condition, which may require a higher level of care or other specialized services available only at the more distant hospital. This prompted patient complaints about bills they had begun receiving from their ambulance suppliers for the uncovered portion of non-local ambulance trips. Additionally, physicians had become disinclined to order or recommend transfer of their patients to the hospital if they knew their patients might incur excess mileage charges.

Under the proposed arrangement, the hospital would contract with various air and ground ambulance suppliers to transport patients to the hospital from non-local hospitals. The hospital would pay the ambulance suppliers a negotiated fee for such services and submit the claims for reimbursement directly to third-party payors, including Medicare and Medicaid. The hospital would absorb any charges not covered by the insurers. While anticipating that most of the patients affected by this agreement would be cardiac patients, the arrangement would not be restricted to such patients; nor would it be based on individual determinations of financial need.

The OIG concluded that this proposed arrangement could constitute grounds for the imposition of sanctions under the CMP prohibiting inducements to beneficiaries and the antikickback statute for the following reasons:

- The payment or subsidy of transportation costs that would otherwise be borne by the patients could constitute prohibited remuneration to the patient. This is true whether the expense is the additional costs of non-local transportation (e.g., excess mileage charges) or the patients' cost-sharing obligations.

- The arrangement is likely to influence the patients' initial and subsequent choice of the hospital or ambulance provider.

- Although the requestor stated that the hospital would not advertise the transportation subsidy directly to patients, the OIG stated that such program safeguards were insufficient because physicians would know about this subsidy and that it would influence their referral decisions. Moreover, the proposed arrangement may operate in conjunction with advertising the hospital's inpatient and outpatient services to influence the choice of provider.

- The OIG noted that the requestor itself had acknowledged that the transportation subsidy is likely to generate business for the hospital, including federal health care program business.

> *"Some health care providers had interpreted the OIG's 2002 letter regarding complimentary local transportation programs as providing carte blanche to free and discounted transportation programs. In light of Advisory Opinion 07-02, however, some providers may need to reevaluate their transportation programs."*

Advisory Opinion 07-02 is helpful because it provides additional guidance regarding the OIG's position with regard to the provision of free or discounted transportation. Some health care providers had interpreted the OIG's December 9, 2002, letter regarding complimentary local transportation programs as providing carte blanche to free and discounted transportation programs. In light of Advisory Opinion 07-02, some health care providers may need to reconsider their transportation programs.

No. 07-03: OIG Approves Credit Card Rewards to Benefit Nursing Home, Employees

On April 3, 2007, the OIG issued Advisory Opinion 07-03, approving a residential health care facility's proposal to utilize rewards obtained from the use of a credit card to purchase additional goods and services for the facility and to give rewards to the facility's employees. In a relatively rare decision, the OIG concluded that the proposed arrangement would not generate prohibited remuneration under the antikickback statute.

The requestor, an entity that operates a nursing home, sought approval to utilize a credit card issued in its name to purchase goods and services for the facility. The credit card would offer rewards, such as airline miles, cash rebates and other items. Depending on the type of purchase, the nursing home anticipated seeking reimbursement from Medicare or Medicaid for the costs associated with some purchases. The OIG noted that neither the credit card issuers nor any of the sponsors were affiliated with the health care industry. Under the proposed arrangement, the nursing home hoped to utilize the points to either purchase additional goods and services for the facility or to provide performance-based rewards to its employees. The nursing home certified that rewards to employees would not be based directly or indirectly on referrals or the generation of business payable under any federal health care program.

In analyzing first the use of rewards to benefit the facility, the OIG found that the antikickback statute could not be implicated because there would be no referral of federal health care business between the credit card issuers or their affiliates and the nursing home. The OIG noted that reporting issues may arise when the nursing home uses the rewards to obtain covered items and services, but the nursing home certified that it would appropriately reflect items and services obtained through rewards on its cost reports and claims.

Second, the OIG found that the use of the credit card rewards to provide performance-based compensation to the requestor's employees falls within the statutory exception and regulatory safe harbor for employee compensation. The OIG acknowledged that risk of fraud was reduced because only the requestor's *bona fide* employees would be eligible to receive rewards and such rewards would be characterized as employee compensation for tax purposes. Because the arrangement would fall within the statutory exception and regulatory safe harbor, the OIG concluded that there was no prohibited remuneration under the antikickback statute.

No. 07-04: OIG Approves Patient Assistance Programs Benefitting Financially Needy Part D Beneficiaries

OIG Advisory Opinion 07-04, issued March 30, 2007, addresses a pharmaceutical company's patient assistant programs (PAPs), which will provide free outpatient prescription drugs to financially needy Medicare Part D enrollees entirely outside of the Part D benefit. The OIG concluded that while the arrangement could potentially generate prohibited remuneration under the antikickback statute, it would not impose sanctions based on the facts provided.

> *"Effective coordination between and PAP and the participant's Part D plan will help ensure that no payment is made for the free drugs by Medicare or the Part D plan and that no part of the cost of the drug is being counted towards the participant's TrOOP, and may have the additional benefit of enhancing patient safety and quality of care."*

The PAPs are operated by a wholly owned subsidiary of a pharmaceutical company that manufactures and markets numerous prescription drug products. The subsidiary has operated various PAPs that provide some of the manufacturer's drugs for free to qualifying financially needy patients who lack insurance coverage for outpatient prescription drugs.

Under the proposed arrangement, the pharmaceutical company will expand eligibility under its PAPs to include financially needy beneficiaries who are enrolled in a Part D plan. To qualify for assistance from the PAPs, the individual must use one or more of the PAPs' covered drugs and demonstrate financial need – based on a household income level below set multiples of the federal poverty level. Additionally, the applicant must have incurred outpatient prescription drug costs equal to 4 percent of household income during the coverage year and must anticipate that he/she will incur costs equal to or exceeding 10 percent of household income on outpatient drug costs that coverage year.

The applicant will receive the drugs free of charge and without any information regarding their value or cost. Assistance will be awarded to an applicant without regard to any provider, practitioner, supplier or Part D plan used by the individual, and without regard to the individual's choice of Part D plan, the benefit design of the applicant's Part D Plan, or where a Part D enrollee is on his/her Part D plan's benefit spectrum. Further, once a participant

begins receiving a drug for free from the PAPs, they will continue to receive this drug for the remainder of that coverage year without cost to Medicare or the participant.

The PAPs will maintain records of all drugs provided to Part D enrollees and will coordinate the assistance they provide with coverage under Medicare Part D. The PAPs will work with CMS to use a data sharing agreement to enable the PAPs to notify Part D plans regarding beneficiaries' participation in the PAP, to ensure that neither Medicare nor the Part D plan will incur a cost for the drugs being provided. The pharmacy providing the prescription drugs will receive fair market value for providing the applicable PAP drug. The drugs provided to the participant by the PAP will not count toward that individual's true out of pocket spending (TrOOP) under the Part D program.

The OIG begins its analysis by reiterating its observation in its Special Advisory Bulletin on PAPs for Medicare Part D Enrollees that manufacturer PAPs that subsidize the cost-sharing amounts for manufacturer's drugs payable in whole or in part by the Part D program present all the usual risks of fraud and abuse associated with kickbacks, including steering participants to particular drugs; providing a financial advantage over competing drugs; and reducing participants' incentives to locate and use less expensive, equally effective drugs. 70 Fed. Reg. 70,623 (Nov. 22, 2005).

The OIG concludes that the proposed arrangement contains sufficient safeguards to ensure that the PAPs will operate entirely outside the Part D benefit, and, therefore, presents minimal risk of fraud and abuse to the Part D program. First, the PAPs will notify enrollees' Part D plans that the free drugs are being provided outside the Part D benefit through a data sharing agreement with CMS. Such coordination will help ensure that no payment is made for the free drugs by Medicare or the Part D plan and that no part of the cost of the drug is being counted towards the participant's TrOOP. Effective coordination between and PAP and the participant's Part D plan, the OIG states, may have the additional benefit of *enhancing patient safety and quality of care*. Second, because an applicant's eligibility will be determined based on the individual's financial need using a methodology that is entirely divorced from the participant's Part D plan, the benefit design of that plan, or where the applicant falls in the Part D plan's benefit spectrum, the OIG views these safeguards as substantially mitigating the fraud and abuse risk.

The OIG believes these safeguards will (1) mitigate the risk that the PAPs' drugs will be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable under the Medicare Part D program; and (2) mitigate the risk that the PAPs' drugs will be used to increase costs to the Medicare Part D program.

Advisory Opinion 07-04 is one of a series of advisory opinions discussing PAP programs in the context of Part D.

No. 07-05: OIG Rejects Proposed Hospital/Physician Joint Venture in an ASC

In Advisory Opinion No. 07-05, issued June 19, 2007, the OIG rejected the proposed sale of interests in an established ambulatory surgical center (ASC) from physician investors to a local hospital, finding that the proposed arrangement could potentially violate the antikickback statute.

A physician-owned limited liability company currently operates the multi-specialty ASC at issue. Three orthopedic surgeons, who were the founding members of the ASC, own shares representing 94 percent of the equity in the ASC. Two gastroenterologists and two anesthesiologists own the remaining shares totaling 6 percent of the equity. The physician investors are the exclusive providers of services at the ASC and they bill federal health care programs for such services, where appropriate.

The proposed investor in the ASC is a 501(c)(3) nonprofit corporation that owns and operates a local, general acute care hospital. Under the proposed arrangement, the orthopedic surgeons would sell shares representing 40 percent of the equity in the ASC to the hospital at fair market value. The OIG notes that the amount paid by the hospital would exceed the amount initially invested by the orthopedic surgeons, and thus, the rate of return on the initial investment would be higher for the orthopedic surgeons than the hospital.

In analyzing the proposed arrangement, the OIG expressed its long-standing concerns about problematic joint venture arrangements between those in a position to refer business, such as physicians, and those furnishing items or services for which a federal health care program pays. The OIG then determined that the proposed arrangement does not qualify for safe harbor protection available under the safe harbor for returns on investments in hospital and physician-owned ASCs, 42 C.F.R. § 1001.952(r)(4). Stating that the arrangement fails to qualify under the safe harbor "for a number of reasons," the OIG acknowledges, as its only example, that the amount paid to the physicians would not be directly proportional to their initial capital investment.

Because the OIG found there was no safe harbor protection, it went on to analyze whether the proposed arrangement would pose a minimal risk under the antikickback statute. Finding that the arrangement poses more than a minimal risk, the OIG lists the following factors as demonstrating that the proposed arrangement may, at least in part, be related to referrals for federal health care business:

- The hospital planned to make a cash investment that is unrelated to the operation of the ASC.

- Not all of the physician investors were offered the opportunity to sell a portion of their investment interests, which raises the possibility that the hospital targeted a specific group whose referrals to the hospital or ASC are more valuable.

- The amounts payable to the investors would be proportional to their ownership interests, but not proportional to their initial investment, which would lead to a higher rate of return on the orthopedic surgeons' investment.

The OIG went on to conclude that the proposed arrangement could violate the antikickback statute and that the OIG could potentially impose administrative sanctions, despite recognizing that none of the listed factors, alone or in combination, necessarily indicated any fraud or abuse. The OIG made its conclusion on the basis that it could not rule out that the difference in cost of capital acquisition between the hospital and the orthopedic surgeons was not, at least in part, related to the volume or value of referrals or other business generated between them.

No. 07-06: OIG Approves Charitable Organization's Cost-sharing Aid to Medicare Beneficiaries

In Advisory Opinion 07-06, issued July 23, 2007, the OIG determined that it would not impose sanctions in connection with a charitable organization's arrangement to subsidize cost sharing and premium obligations owed by financially needy Medicare and Medicare patients with certain chronic diseases. The arrangement was analyzed under the prohibition against inducements to beneficiaries and the antikickback statute. The OIG concluded that the arrangement does not constitute grounds for the imposition of sanctions because it was unlikely that donor contributions would influence any patient's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan.

The requestors are a nonprofit, tax-exempt charitable organization (the foundation) and a health care consulting company (the administrator) whose employees established the foundation. The administrator has commercial clients that include pharmaceutical manufacturers whose products are, or might be, used by patients participating in the arrangement. The administrator provides certain administrative services to the foundation which operates a series of individual charitable funds that provide financial support to financially needy patients with chronic diseases for specific, documented out-of-pocket expenses associated with outpatient prescription drug treatment. The support is focused primarily on high-cost medications that typically present the greatest financial burden for patients.

The foundation is governed by an independent Board of Directors which handles all policy-making functions for the foundation such as patient eligibility requirements, disease funds served and program requirements for each disease fund. No board member has any financial or employment relationship with any donor or affiliate. Compensation paid to foundation employees, officers and board members, including compensation the administrator pays to its employees or agents assigned to the foundation, is consistent with fair market value in an arm's-length transaction and does not reflect the volume or value of business generated for donors. The foundation processes grant applications in order of receipt, on a first-come, first-served basis to the extent permitted by the foundation's available funding. The foundation determines patient eligibility for financial assistance based on the applicant's medical condition and financial need, which is determined by certain objective criteria. Financial assistance is provided for a specific period of time (up to one year), after which the recipient may reapply. In most cases, premium assistance grants are made directly by the foundation to the patient's insurance company. Cost-sharing grants are paid directly by the foundation to physicians, providers, and suppliers of items and services (including drugs). In those cases where third-party payment is not accepted, grants are made payable to the patient upon proof that the patient incurred the costs.

The administrator provides many services for running the foundation's daily operations, such as processing applications for assistance, providing the assistance for documented cost-sharing needs, preparing research reports, as well as certain routine functions such as staffing phone lines and maintaining records. Only foundation employees and contractors who are neither employees nor agents of the administrator may solicit donations, and the administrator does not decide programs or eligibility criteria for the foundation.

The OIG separately analyzed the two remunerative aspects of the arrangement: the donor contribution to the foundation; and the foundation's grant to patients. The OIG determined that here, as in other similar arrangements, there is an independent, *bona fide* charitable organization interposed between donors and patients in a way that effectively minimizes the risk that a particular donor's donation will be used to influence referrals by the foundation, and effectively insulates beneficiaries' decision-making from information attributing the funding of their benefit to any donor. The OIG thus concluded that it is unlikely that donor contributions influence any patient's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan.

In reaching its conclusion on donor contributions, the OIG noted:

- Donors have no control over the foundation or its programs.

- The foundation has absolute, independent and autonomous discretion over the use of donor contributions, and assistance is awarded in an independent manner, severing all lines between donors and patients.

> *"The OIG concluded that the charitable organization's subsidization program would not constitute grounds for the imposition of sanctions because it was unlikely that donor contributions would influence any patient's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan."*

- The arrangement is wholly independent from the administrator's commercial consulting work for any existing or potential donors.

- Neither an applicant's choice of product, provider, practitioner, supplier, or insurance plan nor any donor's interests influence the foundation's decision to award assistance.

- The foundation provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

- The foundation does not provide donors with any data that would allow a donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services.

- The administrator's commercial consulting relationship with its pharmaceutical clients potentially creates a significant risk that the arrangement could be misused as a conduit for providing remuneration to Medicare or Medicaid beneficiaries who use the client's products. The OIG noted, however, that the requestors have certified that the consulting company's role as administrator of the arrangement is, and will remain, entirely separate from its commercial operations.

- The requestors certified that they will implement and maintain certain safeguards against improper influence by any pharmaceutical or other health care clients, including that the foundation will take certain practical steps to ensure that the administrator implements these safeguards, including the use of a designated compliance auditor and an independent review organization to monitor the ethical wall and the independence of the arrangement.

- Donor's earmarking donations for condition-specific programs should not pose a risk of abuse because the donors will have no influence regarding designation of the condition categories.

Based on these facts, the OIG does not believe that contributions made by donors to the foundation can reasonably be construed as payments to eligible beneficiaries of the Medicare or Medicaid programs, or to the foundation, to arrange for referrals.

The OIG noted that its conclusion is consistent with its November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70,623 (Nov. 22, 2005)), in which the OIG indicated that cost-sharing subsidiaries provided by *bona fide* independent charities, unaffiliated with donors, should not raise antikickback concerns even if the charities receive charitable contributions from those donors.

The OIG's analysis of the relationship between the foundation and the recipients of its assistance have similar safeguards, including:

- The foundation assists all eligible, finically needy applicants on a first-come, first-served basis, to the extent funding is available.

- The foundation's determination of an applicant's financial qualification for service is based solely on financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, products or plans; the identity of any referring party; or the identity of any donor who may have contributed for the support of the applicant's medical condition. The foundation notifies all patients they may switch providers, practitioners, suppliers, products or insurance plans, without affecting their eligibility for assistance.

- The arrangement expands, rather than limits, patients' freedom of choice.

- As a charitable organization, the foundation has an inherent incentive to monitor utilization.

This advisory opinion, like Opinions 06-09, 06-10, and 06-13 (see *Health Law Alert*, Summer 2007) makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy Medicare and

Medicaid patients by contributing to independent *bona fide* charitable assistance programs. A properly structured program, where an independent charitable organization is interposed between donors and patients, has the practical effect of severing the ties between donors and Medicare- and Medicaid-eligible patients.

No. 07-07: OIG Approves Cash Donation to Senior Residence Program

In Advisory Opinion 07-07, issued July 23, 2007, the OIG stated it would not impose administrative sanctions on a single cash donation to a senior residence program from a charitable foundation affiliated with a health system, even though the arrangement potentially could generate prohibited remuneration under the antikickback statute.

The health system operates, among other things, the only hospital in a city located in a federally designated "medically underserved area" under 42 C.F.R. part 51c. The health system formed, and provided the initial capital for, a foundation to assist hospitals and other nonprofit providers of health services within the region, and to provide grants and scholarships to ensure the continuation and improvement of quality health care offered to the region's residents.

The senior services nonprofit organization operates a retirement community whose charitable mission mirrors that of the foundation and the hospital. One member of the board of trustees of the senior services nonprofit also serves as a director for the foundation. Another member of the senior services board also serves as a director for both the health system and the hospital.

The retirement community provides housing options for seniors in the region, including 41 independent living cottages, a personal care program for seniors who can no longer function in an independent living environment, a Medicare- and Medicaid-certified skilled nursing facility offering 24-hour care, and an Alzheimer's unit. In 2003, the retirement community developed a residential project to de-institutionalize nursing home residents in order to improve their quality of life. It serves an important function as the only senior housing program in the region that addresses the residents' particular needs. The residential project includes residents insured by Medicare and Medicaid, as well as those who are privately insured. Seniors may qualify to participate in the program without regard to their ability to pay.

The retirement community planned to house 112 seniors in 10 residential project homes on its city campus. To finance this development, the retirement community reached out to both individuals and institutions with wide-ranging, community-based fund raising efforts to raise $3.9 million for the project. Based on its own projected budget, the retirement community asked the foundation to provide a single, unrestricted contribution of $100,000, which is proportionate to contributions made by other businesses of comparable size to the foundation. The foundation certified that neither it, nor the health system, exerts or will exert any influence over the retirement community's use of the donated funds.

> *"In Advisory Opinion 07-07, the OIG concluded that the limited overlap of directors and officer of these nonprofit organizations and the health system and its affiliates did not indicate that the foundation was involved in anything other than a legitimate charity arrangement."*

The retirement community may, but is not required to, purchase various items and services from the health system. The foundation certified that the retirement community implemented and would maintain safeguards against improper influence by the health system. The safeguards included the fact that the donation was not based on any linkage to potential referrals from the retirement community or its employees or contracting physicians for items or services to a health-system affiliate or a health-system-employed or contracting physician. Additional safeguards included not requiring or encouraging any physicians to refer residents to the health system, and not tracking any patient referrals to the health system. All payments by the retirement community to the health system's entities for services would be consistent with fair market value in arms-length dealing, unrelated to the volume or value of referrals of the retirement community residents to the health system or its affiliates. Finally, the foundation certified that the retirement community would advise residents in writing of their freedom to choose heath care providers.

The OIG notes that charitable foundations play an essential role in sustaining and strengthening the health care safety net, and acknowledges that the majority of donors who make contributions to tax-exempt organizations and the majority of tax-exempt donees who solicit or accept donations, including donors and donees with ongoing business relationships with one another, are motivated by *bona fide* charitable purposes and a desire to benefit their communities. Many health care providers, like the retirement community, are nonprofit organizations which

are community-based service providers. They depend on tax-deductible charitable donations to fund all or part of their operations. The OIG points out that a business relationship between a donor and a donee does not make a tax-deductible donation automatically suspect under the antikickback statue.

In this case, the OIG determined that although the crux of the donation was an unrestricted donation from a charitable foundation to a nonprofit senior-care organization, the donation warrants closer scrutiny for the following reasons: (1) the donor foundation's affiliation with the health system through its origins, common officers, and director; (2) the overlap with the senior-service nonprofit's board on the one hand, and the boards of the foundation, health system, and hospital on the other hand; and (3) the possibility that the retirement community may generate federal health care program business for the health system. To assess the risk of fraud and abuse, the OIG considered whether there was any nexus between the donation and the generation of federal health care program business by the retirement community for the health system.

Based on its view that the particular facts involved here make it unlikely that any purpose of the proposed donation was to generate business for the health system, the OIG concluded that the donation was unlikely to result in fraud or abuse under the antikickback statute. Among other factors, the OIG notes that:

- The donation was unrestricted as to the use of funds.
- The donation was made as part of a broad solicitation of funding by the retirement community.
- The donation was in proportion to contributions from other region businesses of similar size to the foundation.
- The donation constituted only a small percentage of the retirement community's overall fundraising campaign.
- The donation represented a one-time only, fixed-in-advance payment.
- Certification by the foundation that the retirement community implemented and will maintain the safeguards against improper influence by the health system or any of its affiliates as discussed above.

In addition to these factors, the OIG notes that the reason for the donation – the development of an affordable and innovative nonprofit senior care facility in a medically underserved area clearly furthered the mission of the charitable foundation, which was formed to assist health care providers in the region and to improve the quality of health care services provided there.

The OIG indicated that it was not surprised that nor-health care institutions that share similar missions in a medically underserved area would also share common origins, directors, and officers, and that they would share patients and do business with one another. The hospital is the only one in the city in which the retirement community is based.

Advisory Opinion 07-07 is useful because, based on these facts, the OIG concluded that the limited overlap of directors and officer of these nonprofit organizations and the health system and its affiliates did not indicate that the foundation was involved in anything other than a legitimate charity arrangement.

No. 07-08: OIG Rejects Free Home Oxymetry Testing

In Advisory Opinion 07-08, issued July 23, 2007, the OIG analyzed a proposed arrangement by DME suppliers to provide free in-home congestive heart failure (CHF) assessments, including free overnight oximetry testing to Medicare and Medicaid beneficiaries. In issuing an unfavorable opinion, the OIG concluded that the proposed arrangement could be subject to sanctions under both the prohibition against inducements to beneficiaries and the antikickback statute.

As background, the OIG noted that the Medicare program only reimburses home oxygen for patients (1) if they have certain underlying disease states or diagnoses (one of which is recurring CHF); and (2) if prescribed by a physician. Additionally, Medicare only covers physician-prescribed home oxygen if supported by an oximetry test that measures blood-oxygen levels. Home-based oximetry tests are reimbursed by Medicare when performed under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF). The requestors estimate, based on the non-geographically adjusted 2006 Medicare Physician Fee Schedule rates for IDTFs, that the value of IDTF overnight oximetry test is approximately $22. A DME supplier cannot conduct a qualifying oximetry test.

The requestors report that the time lag between the time a physician writes the order for the oximetry test and the time when the test is actually performed normally ranges from a few days to several weeks. Medicare does not cover oxygen prior to the completion of the qualifying test.

Although many of their DME and home goods and services are federally reimbursable, the requestors stated that they would neither seek federal reimbursement for any aspect of the CHF assessment with oximetry testing, nor for any other evaluative or educational services performed in connection with the provision of these items and services. The proposed arrangement would be publicized exclusively to physicians whose orders are required for all assessments. However, the requestors certified that they would not be referenced in any patient communications or

marketing materials. Beneficiaries typically would learn about the proposed arrangement from their physicians. Finally, the requestors certified that they would provide patients with written freedom of choice disclosures.

The OIG began its analysis by noting that arrangements whereby prospective providers or suppliers offer federal health care program beneficiaries noncovered items or services free of charge implicate the fraud and abuse laws and must be closely scrutinized.

In analyzing the proposed arrangement under the inducements to beneficiaries provision, the OIG first determined that the free CHF assessment with oximetry testing constitutes "remuneration" under the statute. The economic value of overnight oximetry, just one component of the assessment, is more than nominal. The OIG cautioned that even if the tests had no value in the sense that they were not reimbursable by Medicare, the tests nevertheless inure some benefit to the requestors who propose delivering them in a way that would lead a reasonable beneficiary to believe that he or she is receiving a valuable service for free; that the service might expedite access to covered oxygen supplies; and that the service might also contribute to a successful clinical outcome.

Next, the OIG considered whether the remuneration provided under the proposed arrangement would be likely to influence beneficiaries to select the requestors as their supplier of oxygen or other Medicare-payable goods and services. For the following reasons, the OIG concluded it would:

- Because the beneficiary's own physician would have recommended the requestors for the CHF assessment with oximetry testing, it is reasonable that a beneficiary would assume his or her own physician would recommend the requestors' other goods and services.

- While providing the free at-home CHF assessment with oximetry services, the requestors would have the opportunity to initiate a relationship with the beneficiary. Consequently, the beneficiary would be more likely to select the supplier with whom he or she is already familiar.

- Thus, the OIG determined that even if there was no obligation on the part of beneficiaries receiving the free CHF assessment to order supplies from the requestor, the proposed arrangement was likely to influence the recipients to select the requestors over competitors. Finally, the OIG determined that although freedom of choice disclosures are made to beneficiaries, such disclosures are insufficient without more to safeguard against improper beneficiary inducements.

Based on the totality of the facts, the OIG concluded it was probable that the requestors knew, or should have known, that the provision of free CHF assessments with oximetry testing would likely influence the recipients to select the requestors as their suppliers of federally payable business potentially in violation of the prohibition against inducements to beneficiaries. The OIG also stated that for the same reasons the proposed arrangement would potentially violate the antikickback statute.

The analysis and results in Advisory Opinion 07-08 are essentially the same as those in Advisory Opinion 06-20 (dealing with DME suppliers' proposal to provide free interim oxygen and free overnight oximetry testing) and Opinion 06-01 (dealing with a home health agency's practice of providing patients with free preoperative home safety assessments). This series of advisory opinions highlights the potential risks of suppliers providing free (or discounted) services to federal health care program beneficiaries, even if the free services are not covered by federal health care programs.

No. 07-09: OIG Approves Retailer's Member Reward Program

On August 21, 2007, the OIG issued Advisory Opinion 07-09 regarding a large retailer's program of offering relatively minimal annual financial rewards to its member customers for purchasing its goods and services, including prescription drugs reimbursable by federal health care programs. The arrangement was analyzed under both the prohibition against inducements to beneficiaries and the antikickback statute. The OIG concluded that although the reward program potentially implicates both the prohibition against inducements to beneficiaries and the antikickback statute, based on the particular facts of the program, it would not seek to impose administrative sanctions under either law.

The requestor operates membership warehouse clubs (warehouses) that sell a wide range of branded and private-label products in a wide range of merchandise categories, including some products and services, such as prescription drugs, which are reimbursable under federal health care programs.

The requestor members are individuals and businesses that pay $50 each year in exchange for the ability to purchase goods and services from the warehouses. The requestor also offers a premium membership, offering additional benefits to members that pay an annual fee of $100. Premium members receive an annual reward of less than 5 percent of the amount the member spent at the warehouses during the prior year. Other than certain exclusions (e.g., tobacco and alcohol products), all premium members' purchases, including their cost-sharing amounts or other out-of-pocket expenses, qualify toward their reward. Rewards are calculated based only on

amounts actually paid by the premium member. Amounts received from third parties are not included in determining the amount of the reward. The maximum annual reward cannot exceed $500. Members may use their rewards to purchase additional products and services, including those reimbursed by federal health care programs such as prescription drugs.

"The reward program at issue in Advisory Opinion 07-09 presented a low risk of steering beneficiaries to the warehouse to purchase pharmaceuticals or other federally payable items or services, and the reward amounts were not likely to influence members to select the requestor as their provider of items or services payable by federal health care programs."

The OIG first analyzed the arrangement under the CMP law. Although the OIG determined that the reward earned by premium members constituted remuneration, it found the amounts at issue were not likely to influence the members to select the requestor as their provider of items or services payable by federal health care programs for the following reasons:

- There is no direct tie between the annual reward and the purchase of federally payable items and services. Premium members are not required to buy such items and services in order to earn their reward. In fact, premium members may receive an award even if they purchase these goods and services from other providers, and the reward formula does not vary based on the types of services or products purchased.
- The purpose of the reward program, which predated Medicare Part D, was merely to influence overall shopping at the warehouses rather than to influence members to buy federally reimbursable goods and services.
- The reward is only incidentally related to federally reimbursable good and services.
- The method of distributing the reward (i.e., once a year and two months after the end of the year upon which the reward is calculated) mitigates the influence the instant discount of the time of sale could have on premium members' decisions to choose the warehouse as their provider of federally payable items and services.

For these reasons, the OIG concluded it would not impose sanctions on the requestor under the prohibition against inducements to beneficiaries.

With respect to the antikickback statute, the OIG concluded that the reward program presented a low risk of steering beneficiaries to the warehouse to purchase pharmaceuticals or other federally payable items or services. Beneficiaries who decide to become premium members need not buy any items and services reimbursable by federal health care programs from the warehouses, and the availability of the reward is not jeopardized if members purchase these covered goods and services elsewhere. The reward may be used towards the purchase of nearly all merchandise sold by the requestor; it does not obligate members to redeem their rewards for federally reimbursable goods and services. In the OIG's view, the program was unlikely to encourage the overutilization of these goods and services because of the relatively low value of the discount, the delayed payment, and the fact that members have to pay 100 percent of their cost-sharing amount up-front. The OIG concluded that the arrangement more closely resembled an across-the-board price reduction than a kickback scheme. Consequently, the OIG concluded that it would not impose sanctions on the requestor under the antikickback law.

No. 07-10: OIG Approves Hospitals' Payments to Physicians for On-call Services

In Advisory Opinion 07-10, issued on September 20, 2007, the OIG indicated that it would not impose sanctions against the requestor, a hospital that has developed an arrangement to compensate physicians for on-call coverage. The hospital had historically faced difficulty in securing on-call coverage from physicians in various specialties. The hospital, a not-for-profit with a charitable mission to provide services to the indigent, operates an emergency department (ED) that, in accordance with state law, always remains open and accepts patients regardless of their ability to pay. Due to various factors, including the financial burden of providing uncompensated patient care and malpractice insurance costs, local physicians had grown reluctant to provide on-call coverage or follow-up care for patients who had presented in the ED. The hospital consequently developed a program to compensate physicians for providing on-call and indigent care services.

The OIG analyzed the details of the hospital's program and concluded that, despite its continuing concern that that "on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a

hospital," this particular arrangement "presented a low risk of fraud and abuse." The OIG noted that, as a result of the difficulty faced by hospitals that must comply with EMTALA and provide necessary emergency care services, it has become increasingly common for hospitals to compensate physicians for on-call coverage in EDs. The OIG indicated that the following factors raised its comfort level with the arrangement:

- The payments appeared to be fair market value for actual services needed and provided. Under the arrangement, physicians are paid a per diem rate that reflects the burden on the physician and the likelihood that a physician in a particular specialty will be required to respond while on-call. In return for the on-call compensation, the physician is required to (1) provide one and a half days of on-call coverage each month without compensation; (2) provide follow-up care to any patient seen by the physician while on call in the ED; regardless of the patient's ability to pay; (3) maintain medical record documentation, and (4) participate in the hospital's care and risk management and performance improvement efforts.

- The payments are tailored in a manner that does not take into account potential referrals. The per diem payments are uniform within specialties, with the only variance being extra compensation for on-call coverage provided on weekends. The difference in payments for different specialties is intended to account for the extent to which uncompensated responsibilities will likely fall on certain specialties.

- The hospital demonstrated that there was a "legitimate, unmet need for on-call coverage and uncompensated care physician services." The OIG found this fact made it less likely that the arrangement was developed for the purpose of funneling remuneration to physicians in exchange for referrals.

The arrangement included features that minimize the risk of fraud and abuse, including the following: (1) the arrangement is provided uniformly to all physicians in the various specialties; (2) the on-call obligations are divided among physicians as equally as possible; (3) physicians are required to provide follow-up care regardless of the patient's ability to pay (avoiding the potential to "cherry pick" only the more lucrative ED patients); and, (4) the requirement that physicians complete medical records "promotes transparency and accountability."

No. 07-11: OIG Approves Grants for Cancer Patients' Out-of-pocket Treatment Costs

The OIG issued Advisory Opinion 07-11 on September 20, 2007, the latest in a number of opinions in which the OIG has approved insurance premium and cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with donors. In this Advisory Opinion, OIG analyzed whether a nonprofit, tax-exempt charitable organization's proposed arrangement to establish a foundation to provide grants to financially needy cancer patients to defray their out-of-pocket treatment costs would implicate the CMP prohibition on inducements for beneficiaries or the antikickback law. The OIG concluded that the arrangement could potentially generate prohibited remuneration, but stated that under the specific facts of this proposal it would not impose administrative sanctions.

> *"OIG Advisory Opinion 07-11 is the latest in a number of opinions in which the OIG has approved insurance premium and cost-sharing subsidies provided by bona fide, independent charities unaffiliated with donors."*

The requestor charitable organization is dedicated to helping cancer patients, their families, and caregivers. While its primary purpose is to offer counseling and educational services to people affected by cancer, it also offers limited financial assistance to financially needy patients. The organization intends to establish a foundation to help financially needy cancer patients pay for their drugs to treat certain types of cancer as well as certain conditions incident to cancer therapy. The foundation will offer patients, including Medicare and Medicaid beneficiaries, help with their cost-sharing obligations for drugs, and might offer help with insurance premium payments. Much of the foundation's funding would likely be provided by manufacturers of drugs that may be used by patients assisted by the foundation, with the balance coming from individual donors, corporations, and foundations.

Consistent with its prior opinions on this issue, the OIG first noted that there are two remunerative aspects of the arrangement that require scrutiny under the antikickback law: (1) donor contributions to the foundation; and (2) the foundation's grant to patients.

Regarding donor contributions to the foundation, the OIG noted that long-standing guidance on these issues makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy patients, even beneficiaries of federal health care programs, by contributing to independent, *bona fide* charitable assistance programs. Under a properly structured program, such

donations should raise few, if any, concerns about improper beneficiary inducements. Regarding the proposed arrangement, the OIG concluded that its particular design and administration will interpose an independent, *bona fide* charitable organization between the donors and patients in a way that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor. Additionally, there appears to be only minimal risk that donor contributions will improperly influence referrals by the organization or foundation. The OIG reached this conclusion based on the following facts:

- No donor will exert control over the foundation or its use of donor contributions.
- The foundation will award assistance in an independent way that severs any link between donors and patients. Eligibility determinations will be based on its own objective criteria and applications will be considered on a first-come, first-served basis to the extent of available funding. Prior to applying for assistance, patients will have selected their provider or supplier, and will have a treatment regimen in place. While receiving assistance, all patients will be free to change providers, suppliers, products, or health care plans. The foundation will not refer any patient to any donor, provider, supplier, product, or plan.
- The foundation will award assistance without regard to any donor's interests and without regard to any applicant's choice of products, services, or insurer.
- The foundation will award assistance based upon reasonable, verifiable, and uniform criteria to measure financial need, and will do so in a consistent way.
- The foundation will not provide donors with data that would allow donors to correlate donations with the use of its products or services. Patients will receive no information about donors and donors will receive no information about other donors other than the foundation's publicly available annual report.
- Although donors may earmark contributions for certain disease categories, they will not have any influence over the foundation's selection of disease categories. These categories will be identified by the foundation in accordance with widely recognized clinical standards, in a way that covers a broad spectrum of available products, and without narrowly defining the categories.

Finally, the OIG analyzed the foundation's grants to federal health care program beneficiaries and concluded, based on the facts presented, that the Foundation's subsidy of premiums and cost-sharing obligations for eligible beneficiaries is not likely to improperly influence a beneficiary's selection of a particular provider, practitioner, supplier, product for the following reasons:

- Assistance will be given to all financially eligible patients on a first-come, first-served basis to the extent funding is available. Patients will be under the care of a physician with a treatment regimen in place at the time of application. The foundation will not make referrals or recommendation regarding specific providers, practitioners, suppliers, products, or plans. Patients will not be informed of donors' identities.
- The foundation's determination of financial need will be based solely on reasonable, verifiable, and uniform data that is applied in a consistent manner, and which does not take into account the identity of the applicant's provider, practitioner, supplier, referring party, or donor who may have contributed towards the applicant's specific disease category. Patients will be notified that they are free to switch providers, practitioners, suppliers, or products without jeopardizing continued eligibility. The foundation will notify Medicare beneficiaries that they are free to switch insurance plans, when permitted to do so by Medicare, without jeopardizing continued eligibility or assistance.
- The foundation's program will expand, rather than limit, beneficiaries' freedom of choice.
- Given the foundation's own interest as a charitable, tax-exempt entity that must maximize its scarce resources to fulfill its charitable mission, the foundation will have an incentive to monitor utilization.

No. 07-12: OIG Approves Low- and No-cost Therapy Services for Veterans' Nursing Homes

Advisory Opinion 07-12, issued October 10, 2007, analyzes whether a state-operated veterans' nursing home can accept low and no-cost bids for the provision of therapy services without violating the antikickback statute. While finding that the proposed arrangement implicates the antikickback law, the OIG ultimately concludes that the arrangement proposed by the state-operated veterans' nursing home poses minimal risk of fraud and abuse. The OIG warns, however, that a similar arrangement involving private nursing homes would likely lead to a different result.

The requestor is the state agency responsible for the care and assistance of a state's veterans and their spouses. Under state law, the agency is solely responsible for operating, financing, management, and general direction of the state's six veterans' homes. Importantly, the veterans' homes are not joint ventures or otherwise partnered with private entities.

As part of the process for hiring a contractor to provide physical therapy, occupational therapy, and speech

pathology services at the homes, the agency is required to use the competitive bidding process established by state law. The competitive bidding process dictates that the contract be awarded to the lowest bidder who is both responsive (conform to the bid requirements) and responsible (capable of providing therapy services and possesses the integrity and reliability to assure good faith performance). Under the bidding process, the winning bidder will receive an exclusive contract to provide therapy services at two of the veterans' homes for the term of the contract. Neither the winning bidder nor its employees may order therapy services; only veterans' homes' physicians are able to order therapy services.

"OIG Advisory Opinion 07-11 is the latest in a number of opinions in which the OIG has approved insurance premium and cost-sharing subsidies provided by bona fide, independent charities unaffiliated with donors."

The winning bidder may not bill the veterans' homes more than the bid price for uninsured residents. For residents who are beneficiaries of Medicare, Medicaid, or other third-party insurers, the winning bidder bills the insurer. With respect to cost-sharing amounts, the winning bidder looks to the veterans' homes for payment and is prohibited from sending bills to the residents or their families. The veterans' homes agree to pay the winning bidder the full cost-sharing amount that is due. For purposes of the invitation to bid, the veterans' homes calculated that approximately 20 percent of the therapy services would be provided to uninsured residents.

After reviewing the bids, the veterans' homes determined that the low bidder who was both responsive and responsible proposed a no-cost bid ($0) for one home and a low-cost bid (under $25 per hour) for another home. If the low bidder is awarded the contract, the savings from the bid would inure to the benefit of the state. The veterans' homes' physicians who are in a position to order the therapy services have no outside financial relationships or other side deals with the low bidder.

The OIG began its analysis by stating that the proposed arrangement implicates the antikickback statute because of the risk of swapping. In other words, the agency could be giving the low bidder exclusive access to federal health care program business in exchange for the low bidder providing therapy services to uninsured residents, for which the agency is financially responsible, for free or deeply discounted rates. Despite these concerns, the OIG refused to impose sanctions and issued a favorable advisory opinion based on the existence of a number of factors that suggested the proposed arrangement poses a minimal risk of fraud and abuse.

- *State Responsibility to Care for Veterans.* The OIG cited the existence of a comprehensive regulatory scheme to care for the state's veterans and their spouses. The OIG said: "States should have sufficient flexibility to organize such veterans' services in an efficient and economical manner." The OIG also noted that the proposed arrangement flowed from an open, competitive bidding process that was required by, and conducted in accordance with, state law.

- *Low Risk of Inappropriate Utilization.* The OIG emphasized that the therapy services must be ordered by the veterans' homes' physicians, who do not have outside financial relationships with the low bidder. The OIG also noted that the veterans' homes have an incentive to monitor utilization because they are responsible for the full cost of any Medicare or third-party copayments or deductibles.

- *No Negative Effect on Patient Care.* The OIG noted that the low bidder had met the bid requirements and was likely to fully and reliably render therapy services.

- *No Adverse Impact on Competition.* The OIG again noted that the proposed arrangement was the product of an open, competitive bidding process required by, and conducted in accordance with, state law.

- *Full Benefit of Savings Inures to the Benefit of the State.* The OIG observed that one of the "core evils" addressed by the antikickback statute is the abuse of a position of trust for personal financial gain. In contrast, the financial benefits of the proposed arrangement will inure to the benefit of the state and its citizens. The OIG stressed that it might have reached a different conclusion if the low bidder had provided the agency with remuneration that was not directly related to the provision of therapy services. For example, if the winning bidder had provided free physical therapy services for the agency's employees or free durable medical equipment for the veterans' homes.

- *No Improper Inducements.* The OIG warned that typically if a provider agrees to give something of value to a Medicare or Medicaid beneficiary, there is a risk that the gift is intended to induce the beneficiary to select that provider for federally reimbursable services. The OIG differentiated the proposed arrangement, saying: "It is within the State's discretion to determine that the State's veterans' cost-sharing amounts should be paid from the

public fisc." Finally, the OIG warned that "a private entity, such as a nursing home, paying cost-sharing amounts on behalf of its residents would raise fraud and abuse concerns not present in the Proposed Arrangement."

Advisory Opinion 07-12 suggests that government entities, in certain circumstances, may have greater flexibility in developing innovative arrangements to save the government money without violating the antikickback statute. The reasoning behind Advisory Opinion 07-12 is similar to that behind a series of advisory opinions that permitted various government entities to require insurance-only billing as part of a competitive bidding process for ambulance services. See Advisory Opinions 99-1, 99-5, 01-12, 01-18, 04-10, 05-07, and 06-06. However, Advisory Opinion 07-12 demonstrates that the government is willing to move beyond the fairly limited ambulance scenario to another government arrangement in which there are sufficient protections to conclude that the risk of fraud and abuse is minimal.

No. 07-13: OIG Disapproves Sale of ASC Ownership Interests to Optometrists

Advisory Opinion 07-13, issued October 12, 2007, analyzes the proposed addition of optometrists as owners of three single-specialty ophthalmology ASCs that are currently owned by ophthalmologists and a subsidiary of a nonprofit hospital system. Finding "no discernable safeguards" in the proposed arrangement, the OIG determined that the addition of the optometrists to the ownership of the ASCs could potentially generate prohibited remuneration in violation of the antikickback law and, thus, issued an unfavorable advisory opinion.

The advisory opinion request relates to a group practice and a surgical center. The group practice is composed of eight employed ophthalmologists, nine employed optometrists, and a wholly owned subsidiary of a nonprofit hospital system, each of which own a percentage of the group practice. The surgical center operates three Medicare-certified, single-specialty ophthalmology ASCs. It is owned by the eight ophthalmologists and the hospital. The optometrists do not have an ownership interest in the surgical center.

The optometrists make referrals to the ophthalmologists for the treatment of actual or suspected eye disease or injury. The group practice employees, including the optometrists, agree to refer patients for non-inpatient services to the group practice facilities or to the surgical center ASCs. The ophthalmologists perform ASC procedures at the surgical center ASCs. While some of the optometrists assist the ophthalmologists in the pre- and post-operative work in the surgical center ASCs, they do not actually perform any ASC procedures there.

Under the proposed arrangement, the hospital would transfer some of its ownership interest in the surgical center to the optometrists over a three-year period. The terms would be the same for each investor without regard to the volume or value of referrals. The price of the ownership interest would be determined in accordance with an independent appraisal of fair market value. No investor would receive financial assistance from the group practice, the surgical center, the hospital, or any other investor.

The OIG began its analysis by stating that ASC joint ventures that include investors in a position to generate surgical business are "susceptible to fraud and abuse." Despite this long-standing concern, the OIG noted that it has promulgated a safe harbor to protect physician ownership of ASCs under certain circumstances. The OIG noted that a key requirement under the safe harbor is that physician-investors perform ASC procedures on a regular basis while other investors are not in a position to generate referrals to the ASC or its investors.

The OIG found that the proposed arrangement fails to meet the safe harbor requirements because the optometrists do not perform ASC procedures but are in a position to generate referrals for the ophthalmologists and, indirectly, for the surgical center ASCs. The OIG then considered whether the proposed arrangement posed a minimal risk under the antikickback law, so that protection might be granted through the advisory opinion process. The OIG refused to grant protection, finding "no discernible safeguards" to minimize the risk that the proposed arrangement could be a disguised effort to allow the optometrists to profits from their referrals to the ophthalmologists who use the surgical center ASCs.

Advisory Opinion 07-13 appears to be a fairly straight-forward analysis under the ASC safe harbor. It emphasizes that the ASC safe harbor is intended only to protect situations in which the ASC is an extension of the physician-investors' practice. The ASC safe harbor generally will not protect physician-investors who do not perform ASC procedures on a regular basis.

No. 07-14: OIG Approves Exclusive Contracts for Ambulance Transport Services

On October 12, 2007, the OIG issued Advisory Opinion 07-14, in which it analyzed a county's proposal to enter into exclusive contracts with three private ambulance companies pursuant to which the companies would bear the cost of transporting uninsured arrestees, and reimburse the county for the costs of providing certain specified administrative and emergency dispatch services. Consistent with previous analyses of public emergency services delivery systems, the OIG concluded that, while the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute, it would pose only minimal risk of fraud and abuse

and thus did not warrant the imposition of administrative sanctions.

The county operates an emergency medical services (EMS) system that provides ambulance transportation and pre-hospital emergency medical care to county residents. All EMS dispatches are conducted through the county Fire Protection District (FPD), which is a political subdivision of the state in which the county is located, and which is separate from the county government. The county's Board of Supervisors serves as the governing board of the FPD. The county is the governmental entity legally empowered to regulate the provision of EMS in the county.

Since 1981, the county has continuously contracted with the same three ambulance companies to serve the EMS system. The county entered into three new, essentially identical contracts with the ambulance companies. The new contracts, as did the prior ones, required the ambulance companies to bill and collect for their services from the individuals transported or from third-party payers. The proposed arrangement involves new provisions that would only take effect upon the OIG issuing a favorable advisory opinion.

There are three main provisions to the proposed arrangement.

- The ambulance companies are required to bear the cost of transporting arrestees (i.e., persons taken into custody by police or government agencies), many of whom are uninsured. The ambulance companies would be able to bill, or seek collection from, either the individual arrestee or a third-party payer, other than the county. No federal health care program would be billed for these services. The ambulance companies would be expected to transport, or care for, fewer than 400 arrestees annually, in all thee regions of the county combined.

- The ambulance companies will be required to reimburse the county for the costs the county incurs in providing quality assurance oversight, medical oversight, and contract administrative services with respect to the EMS system.

- The ambulance companies will be required to pay FPD a share of the overall estimated costs of providing EMS dispatch services. Such payment will not exceed actual costs in any given year.

The OIG concluded that the proposed arrangement would implicate the antikickback statute because it requires the ambulance companies to bear the cost of transporting uninsured arrestees, and also requires them to pay the county for certain services as part of the exclusive contracts to provide emergency ambulance transportation services in the county, some of which will be reimbursable under federal health care programs. Nevertheless, the OIG stated that it would not impose administrative sanctions in this case because the following factors mitigate the risk of fraud and abuse:

- The proposed arrangement would be part of a comprehensive regulatory scheme by the county to manage its emergency services, a function within its traditional police powers, and the county represented that it maintains the contracts with the ambulance companies consistent with the relevant government contracting laws.

- The ambulance companies would only partially reimburse the county's costs in providing oversight and administrative-related services and only partially reimburse FPD's costs in delivering dispatch services. Consequently, the ambulance companies will not be overpaying the sources of the referrals which, according to the OIG, is a "typical kickback concern." Moreover, it is reasonable to expect the county and FPD to seek reimbursement for services they provide to the ambulance companies where those services relate directly to the EMS that are the subject of the proposed arrangement.

- Although the aggregate oversight and administration payment and the dispatch services payment to the county and FPD would vary with the volume of referrals from the county, the OIG determined that these payments would not pose an increased risk of overutilization or increased costs to the federal health care programs because neither the county, the FPD nor the ambulance companies have significant ability to affect the utilization of "911" services. Ambulance companies are paid by Medicare and Medicaid on a fee schedule, and the ambulance companies remain obligated to bill for such services in accordance with applicable federal health care program payment and coverage rules.

- Despite the fact that the contracts with the ambulance companies were exclusive, they have been in place since 1981, and the county had maintained the contracts consistent with government contracting laws.

- The putative prohibited remuneration (i.e., the privately borne costs of uninsured arrestee transports, the oversight and administration payment and the dispatch services payment) would inure to the benefit of the public rather than private parties.

- The proposed arrangement would not represent a fundamental change in the delivery of emergency response services in the county as evidenced by the fact that the county had long-standing contracts with the ambulance companies. Moreover, the proposed arrangement was

initiated by the county rather than the ambulance companies or another ambulance company.

- Payments from the ambulance companies relate directly to the provision of emergency services under the proposed agreement. There is no ancillary or unrelated payment offered or paid by the ambulance companies to the county or FPD. The OIG stated that it might have reached a different conclusion had the ambulance companies been required to offer the county or FPD some remuneration not directly related to the provision of the emergency medical transports (e.g., free or reduced-cost equipment).

Advisory Opinion 07-14 is another in a long line of opinions in which the OIG permitted government entities to negotiate contracts with private ambulance providers. In many cases, these agreements would not have been permitted between private parties. However, they contained sufficient safeguards to permit them to move forward.

No. 07-15: OIG Approves Medigap Policy's Use of Preferred Hospital Network

The OIG issued Advisory Opinion 07-15 on December 3, 2007, analyzing whether a proposed arrangement to use a "preferred hospital" network as part of a Medicare Supplemental Health Insurance (Medigap) policy violates either the civil money penalty (CMP) prohibition on inducements for beneficiaries or the antikickback law. Based on these facts, and due to the low risk of fraud or abuse, the OIG determined that it would not impose administrative sanctions on the Requestor under the antikickback statute or the prohibition on inducements to beneficiaries.

Under the proposed arrangement, the requestor, a mutual life insurance company that offered Medigap policies nationwide, proposed contracting with one or more preferred provider organizations (PPOs) to include its policyholders in the PPOs' hospital networks. PPO network membership would be open to any accredited, Medicare-certified hospital. The requestor, who would otherwise be liable for its policyholders' Medicare Part A inpatient hospital deductibles under the beneficiaries' Medigap policies, would receive a discount of up to 100 percent on such deductibles. The PPOs' network hospitals would provide no other benefit to the requestor or its policyholders, and the requestor would pay the PPOs' an administrative fee. The proposed arrangement would not affect payments for covered services. Pursuant to this arrangement, the requestor would return part of its savings, in the form of a premium credit, to policyholders that use the PPOs' network hospitals for an inpatient stay. Savings achieved by the requestor would be reported to the state insurance department regulating Medigap plan premium rates.

As discussed below, the OIG determined that the proposed arrangement would not constitute grounds for imposing CMPs. Additionally, although the Medigap plan could potentially generate prohibited payments under the anti-kickback statute, given the low risk of fraud or abuse and the potential savings for Medicare beneficiaries, the OIG would not seek to impose administrative sanctions in connection with this proposed arrangement.

The OIG noted that although both the safe harbor for waivers of beneficiary coinsurance and deductible amounts and the safe harbor for reduced premium amounts offered by health plans are relevant to the proposed arrangement, neither of these safe harbors afforded protection in this case. The OIG reasoned, however, that when combined with Medigap coverage, the discounted inpatient deductibles presented a low risk of fraud or abuse for the following reasons:

"The requestor would return part of its savings, in the form of a premium credit, to policyholders that use the PPOs' network hospitals for an inpatient stay."

- The waivers will not increase or affect per-service Medicare payments. Payments to hospitals under Part A for inpatient services are fixed and unaffected by beneficiary cost-sharing.

- The discounts should not increase utilization since patients will have already purchased supplemental insurance to cover such obligations.

- The proposed arrangement should not unfairly affect competition among hospitals since membership in the networks will be open to any accredited, Medicare-certified hospital that meets the requirements of applicable state laws.

- The proposed arrangement is unlikely to affect professional judgment since the patient's physician or surgeon will receive no remuneration, and the patient may choose to go to any hospital without incurring any additional out-of-pocket expense.

The OIG further found that, for these same reasons, the premium credit for patients using in-network hospitals presented a low risk of fraud and abuse. Nevertheless, the OIG opined that the premium credit implicated the prohibition on inducements to beneficiaries because, unlike inducements to enroll generally in an insurance plan (which do not implicate the prohibition), the premium

credit in this case was premised on a patient choosing a particular provider from a broader group of eligible providers and that such inducements come within the prohibition. The OIG found, however, that there is a statutory exception for differentials in coinsurance and deductible amounts as part of a benefit plan design if, among other requirements, the differential has been properly disclosed to affected parties. This exception permits benefit plan designs under which enrollees pay different cost-sharing amounts depending on whether, for example, they use network or non-network providers. The OIG determined that although the premium credit in this case was not technically a differential in coinsurance or deductible amounts, the premium credit would have substantially the same purpose and effect.

The OIG also noted that the proposed arrangement, as a whole, has the potential to lower Medigap costs for those policyholders who select network hospitals, without increasing costs for those who do not. Also, since savings realized from this proposed arrangement will be reported to state insurance rate-setting regulators, it has the potential to lower costs for all policyholders.

No. 07-16: OIG Approves Educational Videos to Prospective Surgical Patients

The OIG issued Advisory Opinion 07-16 on December 5, 2007, analyzing whether a home health agency's (HHA) practice of providing prospective patients with free educational videos related to post-operative home-based convalescence violates either the CMP prohibition on inducements to beneficiaries or the anti kickback law. As discussed below, the OIG concluded that the arrangement would not constitute grounds for imposing CMPs and could implicate the antikickback statute but would not result in CMPs or administrative sanctions under the antikickback statute.

The requestor HHA provided home health care for patients who had undergone surgical knee and hip joint replacement. Many of these patients participated in Medicare, Medicaid, and other federal health care programs.

Orthopedic surgeons referred patients to the HHA for post-surgical care at the time of scheduling their surgery by completing patient referral paperwork and sending it to the HHA. The HHA provided no remuneration of any kind to the surgeons for referring such patients, and the surgeons had no financial or employment interest in the HHA.

Pursuant to the arrangement, after the HHA received the patient referral paperwork it telephoned the patient to verify the referral and to confirm the patient's information. At the same time, the HHA reminded the patient of his/her right to choose a different home health provider. The patients were also told that they would receive a free educational video about the impending surgery a few days before the scheduled surgery. The educational videos educate patients about the restrictions and physical limitations they were likely to encounter during their home-based convalescence. The videos also advise patients about various issues that should be considered for their convalescent needs, such as furniture placement, sleeping and bathing arrangements, clothing, and durable medical equipment. The videos did not contain any medical advice or diagnoses. Instead, they advised patients to consult with their own physicians and therapists about the various issues addressed in the videos. At the conclusion of the videos, voiceover and video place cards identified the HHA as the videos' producer. Other than this, the HHA, its staff and services, were not mentioned. There were no substantive promotional claims made on behalf of the HHA. Similar information to that contained in the videos was available on the Internet and other public sources without charge. The HHA did not require prospective patients to review the video as a precondition to receiving services from the HHA. Patients were allowed to keep the videos, which, the HHA estimated, had essentially zero resale value.

> *"The educational videos educated patients about the restrictions and physical limitations they were likely to encounter during their home-based convalescence."*

In analyzing the arrangement under the CMP prohibition against beneficiary inducement, the OIG noted that it had previously taken the position that the CMP statute does not prohibit incentives that are only nominal in value (no more than $10 per item, or $50 aggregate, on an annual basis). The OIG then turned to the value of a video to a patient. While acknowledging that the information on the videos was generally available on the Internet and from other public sources, the OIG determined that the absence of a paying market for such educational videos was not dispositive of the issue. Although the OIG found it unlikely that a patient would believe the video was worth more than $10, it could not conclude that the video was of nominal value.

The OIG next analyzed whether or not the free videos were likely to influence prospective patients to select the HHA. Based on the following factors the OIG concluded that they would not: (i) the patient only received the video after his/her surgeon referred the case to the HHA; (ii) the implicit endorsement of the HHA by the surgeon's referral likely played a substantial role in the patient's choice; (iii) the videos' content was readily available from

other sources; and (iv) no information personally or individually applicable to any patient was provided in or with the videos.

Having concluded that the videos were unlikely to influence any patient to select the HHA, the OIG found it unnecessary to proceed to the third step of the CMP analysis regarding the HHA's knowledge of any influence on the patient.

For the same reasons discussed above, the OIG also concluded that the arrangement was unlikely to serve as a means of providing unlawful kickbacks to patients and, consequently, administrative sanctions under the antikickback statute were unwarranted.

The OIG did draw a distinction between this arrangement and other offers from HHAs, such as providing free in-person or telephone preoperative home safety assessments, noting that these were more problematic than the free video because they are personalized, often initiate a personal relationship between the prospective patient and the Agency's personnel, and are likely to leave the impression with the patient that he/she has received a valuable service. Consequently, in the OIG's view, the in-person or telephone assessments are more likely to influence a patient's choice in home health providers.

No. 07-17: OIG Approves Excluded Individual's Transfer of Intellectual Property Rights to Children's Company

The OIG issued Advisory Opinion 07-17 on December 19, 2007, analyzing whether the requestor, an individual excluded from participating in Medicare and Medicaid for five years, could transfer his intellectual property rights associated with an invention to a new company (Newco) created by his children. The requestor was concerned that the proposed arrangement would constitute indirectly furnishing the invention or causing claims relating to the invention to be submitted to federal health care programs in violation of his exclusion, thereby implicating the antikickback statute. Based on the requestor's certifications, the OIG concluded that the arrangement would not constitute grounds for the imposition of sanctions under 42 U.S.C.A. § 1320a-7a(a)(6).

- The requestor certified that he would neither directly nor indirectly submit claims for the invention to any federal health care program nor directly furnish any items or services that would be reimbursable by any federal program.

- The requestor proposed giving Newco a royalty-free, nonexclusive license for the life of the patent for the invention for sale or lease in the United States. Alternatively, Newco could decide to use the intellectual property associated with the invention under a covenant with the requestor pursuant to which the requestor would not sue Newco for infringement of his intellectual property rights.

- Newco would manufacture the invention and lease or sell it to independent distributors who, in turn, would lease or sell the invention to health care providers or suppliers who would bill federal health care programs.

- Newco would not have any relationship, financial or otherwise, with the requestor. The adult children would invest their own money in Newco and hire their own independent executive team to run Newco. Neither the requestor nor any company owned or managed by him would be investors, lenders, employees, managers, directors, consultants or have any control or role in Newco. After giving the patent rights, with no present or future fees, royalties, balloon payments, or other payments to Newco, the requestor would have no involvement in Newco.

The OIG concluded, based on these facts, that the intervening and independent entities (i.e., Newco and its distributors) would sufficiently attenuate the requestor from any claims submitted to federal health care programs by downstream providers or suppliers such that he would not be directly or indirectly furnishing the invention or causing claims to be submitted to federal health care programs in violation of his exclusion. Additionally, based on the requestor's certification that he would have no rights to current or future payments from Newco, the OIG determined that there was little risk that federal funds would make their way back to the requestor through Newco.

Finally, although the OIG recognized there was a risk that Newco could act as a conduit for payments to the requestor in light of the filial relationship between the owners of Newco and the requestor, the OIG concluded, based on the requestor's certification, that neither he nor his children had, or would make, any oral or written agreements during the term of the exclusion which would provide the requestor with any financial benefit or right to future financial benefit from Newco during the term of his exclusion.

No. 07-18: OIG Approves Cost-sharing and Premium Aid to Medicare and Medicaid Patients

Advisory Opinion 07-18, issued December 19, 2007, is another in a series of advisory opinions analyzing a charitable organization's program subsidizing cost-sharing amounts and premium obligations associated with outpatient drug treatment received by financially needy Medicare and Medicaid beneficiaries with certain chronic diseases. Consistent with its prior guidance in this area, the OIG concluded that it would not seek to impose administrative penalties under the CMP provision prohibiting inducements to beneficiaries or the antikickback statute.

The programs at issue in Advisory Opinion 07-18 are similar to those seen in a number of prior advisory opinions on this topic. See, e.g., Advisory Opinions 07-06, 06-13, 06-10, and 06-09. A nonprofit, tax-exempt, charitable foundation had been established to provide financial assistance to patients suffering from certain chronic diseases. It received financial support from pharmaceutical companies as well as other sources. The programs focused on high-cost medications, which typically present the greatest financial burden for patients. The foundation made decisions with regard to specific patients on a first-come, first-served basis in light of each patient's medical condition and financial need. Financial need decisions were based on national standards of indigence. The foundation paid grants directly to providers, if possible, or to patients based on proof that the patient had incurred the costs. Donors and grant recipients received only limited information.

Two features distinguished the programs at issue in Advisory Opinion 07-18 from the typical program. The first, and less significant, distinction was that the foundation operated a number of specific disease funds and permitted donors to earmark their contributions to support patients covered by specific disease funds. Within the disease fund, however, the donations must be unrestricted. Moreover, except in rare instances, at least two drug treatments, manufactured by different companies, were available to treat or prevent the disease covered by each disease fund.

The second, and presumably more significant, distinction was the identity of the foundation's administrator. The administrator, a health care consulting company, was a subsidiary of a leading pharmaceutical distributor, with commercial clients that included pharmaceutical manufacturers whose products may be used by patients receiving grants from the foundation.

The OIG analyzed the two remunerative aspects of the programs separately. First, the OIG considered the contributions of the donors (primarily the pharmaceutical manufacturers) to the foundation. Second, the OIG considered the grants from the foundation to Medicare and Medicaid beneficiaries.

With respect to the donor contributions to the foundation, the OIG made a detailed assessment of the foundation's design and administration to confirm that the foundation represented the interposition of an independent, *bona fide* charitable organization between donors and patients to "effectively insulate" beneficiary decision-making from donations. The OIG dedicated a significant portion of its analysis describing the safeguards implemented to avoid any inappropriate influence between the administrator's commercial consulting relationships with pharmaceutical manufacturers and its role as administrator for the foundation's programs. The OIG cited the following safeguards as "sufficiently mitigate[ing] the risk that the Foundation's subsidy decisions might be improperly influenced" by the administrator's commercial consulting clients:

- The administrator is contractually obligated by a confidentiality agreement to hold information developed for and through the foundation's operations in strict confidence.
- The foundation utilizes a separate project team, including both management and personnel, who are dedicated solely to the foundation and do not work for any of the administrator's other clients.
- Personnel assigned to the foundation have separate physical space.
- Data for the foundation is collected and maintained in separate electronic directories.
- The administrator's and foundation's staffs receive regular and comprehensive training on the implementation and maintenance of the ethical wall created by the safeguards.
- The administrator's employees and agents are banned from being involved in any of the foundation's fundraising operations or from soliciting suggestions from donors regarding the use of funds or delineation of drug categories.
- Tying, conditioning, or connecting donations to the foundation with the administrator's work for any commercial client or vice-versa is prohibited.
- Compensation paid to the foundation's employees, officers and Board members, officers, including compensation that the administrator pays to its employees and agents assigned to the foundation, is consistent with fair market value in arm's-length transactions and does not reflect in any manner the volume or value of business generated for any donor or donor affiliate.

The OIG also cited the foundation's use of a compliance auditor and an independent review organization to monitor the "ethical wall" and the independence of the foundation's programs.

With respect to grants from the foundation to Medicare and Medicaid beneficiaries, the OIG considered the typical factors in concluding that the foundation's programs had been structured so that they are not likely to improperly influence any beneficiary's selection of a particular provider, practitioner, supplier, or product.

No. 07-19: OIG Approves Free Test Reports for Hospital

On December 21, 2007, the OIG issued Advisory Opinion No. 07-19, analyzing whether an arrangement between a

critical care hospital and a physician radiology group practice pursuant to which the group practice furnished free written radiology test reports for the hospital's patients violated either the CMP prohibition on inducements for beneficiaries or the antikickback statute. The OIG concluded that these free written reports for patients eligible for Medicare, Medicaid, and other federal health care programs did not constitute remuneration and, as such, could implicate the antikickback statute. With respect to free radiological test interpretations for private pay patients, the OIG could not reach the same definitive conclusion. Nevertheless, the OIG concluded that because the arrangement posed only a low risk under the antikickback law, it would not impose administrative sanctions on the hospital in connection with the arrangement.

"The OIG stated that arrangements between traditional hospital-based physicians may implicate the antikickback statute if the hospital solicits or receives something of value—or the physicians offer to pay something of value—for access to the hospitals' federal health care program business."

The hospital was a small, rural hospital offering inpatient and outpatient services, including radiology services. The group performed radiology services on an exclusive basis for the hospital. The hospital, via teleradiology, transmitted digitalized images of the hospital's patients to the group for interpretation. After interpreting the images, the group prepared a written report to document the physician's interpretation for inclusion in the patient's hospital medical record, without charging the hospital for the services. The group billed third-party payers, including Medicare, Medicaid, and other federal health care programs for the physician interpretations.

The hospital certified that its exclusive relationship with the group practice was, and would continue to be, at fair market value in an arm's length transaction, including the value of the exclusivity (but not including the value attributable to referrals to the group).

The OIG stated that arrangements between traditional hospital-based physicians (such as radiologists) may implicate the antikickback statute if the hospital solicits or receives something of value—or the physicians offer to pay something of value—for access to the hospitals' federal health care program business. However, in this case, based on the Medicare payment rules, the OIG concluded that the provision of written radiology reports to the hospital by the group, free of charge, did not constitute remuneration under the antikickback statute for the following reasons:

- Preparation of a written radiology report that is included in a patient's hospital medical record is part of the covered professional service that is reimbursed to the radiologist by CMS under Medicare Part B. A radiologist is required to furnish this written report to a hospital in order to receive Medicare reimbursement.

- If the hospital reimbursed the physician group for costs incurred in preparing the written report, the group would receive double payment (i.e., from Medicare and the hospital) for the same service.

- By preparing a written report for inclusion in the patient's medical record, the physician group was not relieving the hospital of any financial costs the hospital was otherwise obligated to incur for Medicare patients.

- Pursuant to the conditions of participation and proper cost reporting for critical access hospitals, the hospital was required to maintain such written reports and was not obligated to incur the costs of preparing the written report.

However, with respect to non-Medicare patients, the OIG stated it was unable to conclude definitively that these written radiology reports did not constitute remuneration under the antikickback statute. Nevertheless, the OIG determined that the arrangement between the hospital and the physician group posed only a low risk under the antikickback statute because: (1) preparation of these written reports, like certain other services provided by hospital-based physicians under exclusive arrangements, appeared to be a reasonable and limited service that directly related to the professional radiology services provided by the physician group to the hospital; and (2) the arrangement was unlikely to result in overutilization of federally payable services or increased costs to the federal programs because the group's ability to generate additional Medicare Part B billings to recoup the costs it incurred for the written reports for non-Medicare beneficiaries provided to the hospital was limited by the nature of its hospital-based specialty.

Accordingly, the OIG concluded that although the arrangement could potentially generate prohibited remuneration and implicate the antikickback statute, it would not impose administrative sanctions on the hospital.

No. 07-20: OIG Approves Location of Physician-owned Medical Imaging Center

OIG Advisory Opinion 07-20, issued December 27, 2007, analyzes a proposed arrangement pursuant to which a physician proposes establishing a medical imagining center, to be jointly owned by him and his non-physician brother, in the same building in which the physician owns a medical practice.

The OIG analyzed this arrangement under the antikickback statute and the CMP provision for illegal remuneration. The OIG concluded that because the physician-owned imaging center poses only a little risk of fraud and abuse, administrative sanctions on the physician were not warranted.

The physician certified that the imaging center would be established in an area hardest hit by Hurricane Katrina. The sole hospital in this area was destroyed by the hurricane and has not reopened. Presently, there are no medical imagining centers in this area, and, because the health care infrastructure of the entire region has been significantly reduced, it is also more difficult for patients to obtain services outside the area in which the imaging center will be located. The population of this area remains well below 50-percent of its pre-Katrina level, and the population recovery rate lags well below that of other nearby jurisdictions.

The medical practice is co-owned by the physician and his nonphysician wife. The imaging center will be located in the same building as the practice. The physician certified that he and his brother will each contribute 50-percent of the capital necessary to fund the imaging center and will each own 50 percent of it. The brother will be employed by the imaging center as its business manager. He will be a *bona fide* employee and will be paid a salary that will be fair market value for actual and necessary services rendered, and will not take into account the volume or value of referrals.

The OIG first noted that the proposed arrangement did not meet the antikickback safe harbor for investment in small entities in underserved areas because 100 percent of the investment interests are to be held by investors who are in a position to make or influence referrals to the imaging center.

The OIG next considered the totality of facts and circumstances to determine the extent of the risk posed by the proposed arrangement. The OIG concluded that even though 50 percent of the venture will be owned by the physician's brother who will be employed as the business manager (as opposed to a wholly disinterested investor), this does not materially increase the risk of fraud and abuse, particularly when viewed in light of the proposed arrangement's substantial potential community benefits.

The OIG noted that the brother is not currently involved in health care business and that he will not be compensated in any way that depends on his generating business for the imaging center as its business manager. He will receive a fair market value salary for actual and necessary service rendered to the imaging center. He will put up real capital and will receive returns that are proportional to his capital contributions. The terms of the investment will not be related to the previous or expected volume of referrals. The OIG noted that, although the brother, as a relative of a physician, may be in a position to influence referrals, he can only do so through his relationship with his brother, already an investor in the imaging center. The OIG indicated that the fact that the physician already has substantial independent reasons to refer patients to the imaging center, on the facts presented, his family relationship should not increase the capacity of investors, as a whole, to influence referrals.

Finally, the OIG noted that any residual risk posed by the proposed arrangement is offset by the special conditions in which the proposed arrangement is to be implemented, pointing out that the preamble to the safe harbor for investment in entities in underserved areas states: "Paramount among the OIG's concerns is that beneficiaries have adequate access to quality health care." In this case, the imaging center is to be created in an area devastated by Hurricane Katrina. The only hospital that existed at the time of Katrina has not been reopened. In the OIG's view, it is possible, even likely, that the limited availability of health care services discourages the return of some former residents, and the rebuilding of the community as a whole. Consequently the OIG stated that, in this case, it would not impose administrative sanctions under the antikickback statute.

Nos. 07-21 and 07-22: OIG Approves Gainsharing arrangements Involving Cost Savings in Cardiac Surgeries

The OIG issued two advisory opinions on December 27, 2007, concerning gainsharing arrangements involving cost-savings between the requestor hospitals and (1) a group of cardiac surgeons (Advisory Opinion 07-21) and (2) a group of anesthesiologists (Advisory Opinion 07-22). The hospital in each arrangement agreed to share with the respective physician groups a percentage of the hospital's cost savings arising from the physicians' implementation of a number of cost-reduction measures in certain cardiac surgical procedures, as measured based on the physicians' reduction of waste and use of specific devices, items, and supplies during designated cardiac procedures. The OIG considered the arrangements under the CMP prohibition on reducing or limiting direct patient care services provided to federal health care beneficiaries and the antikickback statute. Although the OIG concluded that the arrangements implicated both the CMP and antikickback statutes, the OIG nevertheless determined,

based on the particular facts presented, that it would not impose CMPs or administrative sanctions.

Pursuant to both arrangements, the hospitals hired third-party program administrators to identify cost-savings that the anesthesiologists and cardiac surgeons could achieve by changing certain standard practices during cardiology procedures. The hospitals agreed to share 50 percent of the cost savings directly attributable to specific changes made by the surgeons and anesthesiologists in their operating room practices based on the administrator's cost-saving recommendations.

Each arrangement contained several safeguards to protect against inappropriate reductions in services and to ensure that the recommendations made for cost savings did not adversely affect the quality of care provided to the hospitals' patients:

- Objective historical data and clinical measures were reasonably related to the practices and the patient population at the hospital.
- In some cases, national data was used to establish "floors" below which no savings would accrue to the physicians.
- No cost-sharing amounts were allocated to physician groups for procedures involving reductions in historical quality indicators established by the Society of Thoracic Surgeons.
- Individual physicians made case-by-case determinations as to the most appropriate devices, items, or supplies that they used and still had available the same selection of devices, items, or supplies under the arrangements as before.

The OIG's analysis of the gainsharing arrangements in Advisory Opinions 07-21 and 07-22 follows that in its prior eight gainsharing advisory opinions. The OIG first stated that properly structured arrangements to share cost savings may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. The OIG noted its concern, however, that gainsharing arrangements can potentially influence physician judgment to the detriment of patient care.

In its CMP analysis of the arrangements, the OIG found that the arrangements implicated the CMP because the bulk of the cost-saving measures might have induced the physicians to reduce or limit the then-current medical practice at the hospitals. Notwithstanding this determination, the OIG concluded that several features of the arrangements, in combination, provided sufficient safeguards that would preclude the OIG from seeking sanctions:

- The arrangements clearly and separately identified cost-saving actions and resulting savings. Additionally, the arrangements allowed for transparency and public scrutiny as well as physician accountability.
- Credible medical evidence supported a determination that the implementation of the cost-saving measures would not adversely affect patient care. The arrangements would be periodically reviewed for any adverse effects on clinical care.
- Payments to the physician groups would be calculated on the basis of all related services regardless of the patients' insurance coverage, except that payments related to procedures covered by federal health care programs would be subject to a cap.
- The arrangements protected against inappropriate reductions in services by setting baseline thresholds beyond which no savings accrued to the physician groups.
- Product standardization further protected against inappropriate reductions in services, supplies, and devices by ensuring that individual physicians continued to have access to the same selection of services, devices, and supplies.
- Written disclosures to patients whose care might be affected by the arrangements offer some protection against possible abuses of patient trust.
- The financial incentives under the arrangements were reasonably limited in duration and amount.
- The physician groups distribute their profits to members on a per capita basis, which mitigates any incentive for an individual physician to generate disproportionate cost savings.

Turning its analysis to the antikickback law, the OIG first determined that the personal services safe harbor (42 C.F.R. § 1001.952(d)) would not afford protection to the arrangements because the aggregate compensation was not set in advance. The OIG found that the arrangements could result in illegal remuneration under the antikickback law if the requisite intent was present, but determined that it would not impose sanctions under the antikickback statute because:

The arrangements were unlikely to increase referrals because: (i) they were limited to physicians already on staff, thus reducing the likelihood that the arrangements would attract other physicians to the hospital; (ii) the savings attributable to federal program beneficiaries was capped; and (iii) the term of the arrangements was limited to one year.

- Each group was the sole participant of its respective arrangement, and each group was composed entirely of its respective specialty. In addition, the groups agreed to distribute their payment on a *per capita* basis.

- The arrangements set out with specificity the particular actions that generated the cost savings on which the payments were based.

- Many of the recommendations did not represent a change in operating group practice.

- While most of the recommendations presented minimal risk, some did increase the risk of physician liability. The OIG said it was not unreasonable for the physicians to receive compensation for the increased risk associated with the change of practice.

- Payments to the physician groups were limited both in duration and scope. Payments were limited to the contract year, and the total savings that could be achieved from implementing any one recommendation were limited by appropriate utilization levels.

- Payments under the arrangements do not appear unreasonable given, among other things, the nature of the actions required to implement the recommendations, the specificity of the payment formula and the cap on remuneration.

Although the OIG applied the same analysis to both physician groups, the OIG noted that it is less likely that the anesthesiology group in this case would make referrals to the hospital in violation of the antikickback law. The discussion of the anesthesiologists' gainsharing arrangement provides helpful insight into the OIG's perspective of anesthesiologists as referral sources. The OIG makes a clear distinction between anesthesiologists who perform pain management services (and thus are potential hospital referral sources) and anesthesiologists who administer anesthesia strictly as ancillary to procedures performed by other physicians (and thus are generally not hospital referral sources).

Finally, the OIG cautioned that payments of 50 percent of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could lead to a different result. In a footnote, the OIG indicates that in a multi-year arrangement the percentage payment would have to be re-based and that no advisory opinion protection would be afforded for any additional years.

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