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OIG 2008 Advisory Opinions

No. 08-01: OIG Approves Bulk Replacement PAP

The OIG's first advisory opinion for 2008, issued January 28, 2008, addresses whether a proposed "bulk replacement" PAP violates either the antikickback statute or CMP prohibition against inducements to beneficiaries. Bulk replacement PAPs provide free drugs in bulk quantities – typically on a monthly or quarterly basis – to hospitals, clinics, and other safety net providers to replace drugs dispensed to patients who meet established PAP criteria. The OIG concluded that the proposal potentially implicates the antikickback statute and the CMP. Nevertheless, based on a combination of safeguards certified by the requestor, the OIG approved the program and determined that the imposition of sanctions would not be warranted.

The partnership requesting the opinion is a nonprofit corporation that serves as a liaison between the pharmaceutical industry and its affiliated free clinics and federally qualified health centers (FQHCs) (collectively, clinics), for the clinics' low-income patients, i.e., those whose incomes are less than 200 percent of the Federal Poverty Level (FPL) and who do not have any outpatient prescription drug insurance coverage. The partnership is funded by state appropriations, contributions from individuals and foundations, and fees paid by the participating clinics. The partnership aims to make it easier for participating drug manufacturers to offer their bulk replacement PAPs to the partnership's affiliated clinics by imposing a number of uniform PAP operating standards on the clinics, including the requirements that they:

- Maintain separate, auditable records of all donated drugs received as the partnership's affiliate
- Maintain systems for separating PAP inventory from other purchased drugs
- Implement a computerized dispensing system that has the capacity to generate reports necessary for auditing and monitoring for compliance
- Agree to submit to annual on-site compliance audits
- Check and document patient eligibility before dispensing the PAP drugs

These terms and conditions are specified in written contracts between participating drug companies and the partnership, pursuant to which the clinics receive free prescription drugs.

The OIG first considered the application of the safe harbor for certain FQHC arrangements, 42 C.F.R. § 1001.952(w), and determined that the arrangement meets many, but not all, of the safe harbor's requirements. Specifically, the FQHCs do not make the requisite determinations regarding benefit to underserviced populations, and the free drugs offered by PAP sponsors are not offered to all FQHC patients regardless of payer status.

The OIG next analyzed application of the antikickback statute and the CMP prohibition against inducement to beneficiaries. Although the partnership limits utilization of the PAP drugs to uninsured patients with incomes below 200 percent of FPL, the OIG expressed

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concern that the arrangement (1) potentially raises compliance risks because it might induce the affiliate clinics to purchase the sponsors' other pharmaceutical products, which are payable by federal health care programs, or (2) acts as an improper influence on the prescribing patterns of physicians who work at the clinics. The OIG nevertheless approved the proposed arrangement, citing the following safeguards:

1. The agreement prohibits the stockpiling of surplus drugs that might be diverted to other uses by requiring sponsors to ship drugs monthly based on consumption by eligible patients in the previous months.

2. The arrangement is transparent. Its terms are documented, signed by the partnership and each PAP sponsor, and require the clinics to maintain auditable records so that compliance can be monitored.

3. The arrangement prevents PAP sponsors from "cherry picking" clinics for participation based on their use of other program-reimbursable products. The partnership has the sole discretion to decide which clinics meet the criteria to become partnership affiliates, and PAP sponsors are required to provide PAP drugs uniformly to all affiliates. Additionally, the partnership certified that the availability of drugs under the PAPs is not conditioned on the volume or value of program business or the inclusion of sponsors' other non-PAP products on the clinics' formulary.

4. The agreement protects the independent professional judgment of the clinics' prescribing physicians by ensuring that they do not receive any compensation that takes into account their prescribing patterns for PAP drugs, and by not tracking any physician's prescribing patterns of PAP drugs.

5. In its liaison capacity, the partnership insulates the FQHCs from potentially inappropriate influence by the PAP sponsors on the FQHCs' formulary decision-making process.

6. Although providing remuneration on the basis of payer status or ability to pay can be problematic in the case of the I-, this arrangement does not involve the kind of "cherry picking" of such patients that raises concerns in other contexts. The PAP drugs are dispensed solely to the type of vulnerable, financially needy patients who have no outpatient prescription drug coverage that the FQHCs are commissioned to serve.

Finally, the OIG notes that the donation of drugs by pharmaceutical companies to clinics such as these, whether through PAPs or directly, plays an important role in ensuring that these clinics continue to provide a safety net for medically underserved patients.

Advisory Opinion 08-01 follows a number of other advisory opinions dealing with PAPs. In analyzing PAPs, the OIG has recognized that these programs provide significant community benefit with limited risk to federal health care programs. Nevertheless, the OIG has refused to approve these programs across the board. Health care entities wishing to participate in or sponsor PAPs need to examine them on a case-by-case basis in light of the various guidance from the OIG.

No. 08-02: OIG Allows Honorary Charitable Donations

Advisory Opinion 08-02, issued on January 29, 2008, is one of a short list of advisory opinions in which the OIG has concluded that the antikickback statute is not implicated. The proposed arrangement involves a marketing and research company's idea to encourage physicians to complete online surveys by making a donation to a public charity in their honor. The OIG concluded that the antikickback statute was not implicated because the proposed arrangement did not generate any remuneration for the physician.

The requestor is a company that works with pharmaceutical and medical products manufacturers and the entities that distribute and market their products. The requestor helps its clients develop clinical, marketing, and other data about how physicians diagnose and treat certain illnesses. The requestor is not a health care provider or supplier and does not participate in any federal health care programs.

Physicians who participate in the requestor's web-based surveys are permitted to designate a public charity to receive donations "in the name of" the physician. The entity receiving the donation must be organized as a 501(c)(3), qualify as a public charity under 509(a), and meet the public support test under section 509(a). Donations may not be made to private foundations. The amount of the donation might vary between surveys, but would be uniform for all participants in a given survey. The charity's use of the donated funds would have no earmarks or restrictions. The physician in whose name the donation is made is not entitled to a tax deduction or to otherwise receive any monetary benefit from the donation. In addition, neither the physician in whose name the donation is made nor any of the physician's family may hold a position on the board of the designated charity, be employed by the charity, or have any other financial relationship with the charity.

> *"Advisory Opinion 08-02 confirms a common belief that a charitable donation in the name of a physician generally does not implicate the antikickback law so long as the physician is not entitled to a tax deduction or other monetary benefit from the donation."*

The OIG began its analysis with a discussion of the important role of charitable donations from health care providers and suppliers in strengthening the health care system. The OIG also recognized its "need to exercise caution in undertaking any enforcement action in this area." In something of a departure from its normal pattern, the OIG went beyond the specific facts of the proposed arrangement to warn that some charitable donations are nothing more than disguised kickbacks intended to induce referrals. The OIG then described several examples of potentially abusive arrangements.

In the end, the OIG concluded that no funds would be transmitted to the physician and the physician would not be entitled to any tax deduction or other economic benefit from the donation. The benefit to the physician would be "wholly intangible in the form of potential personal satisfaction." There would be "no actual or expected economic or other actionable benefit" to the physician. Despite the fact that the antikickback statute was not implicated by the proposed arrangement, the OIG also noted that the requestor had included several additional safeguards against potential abuse.

Advisory Opinion 08-02 confirms a common belief that a charitable donation in the name of a physician generally does not implicate the antikickback law so long as the physician is not entitled to a tax deduction or other monetary benefit from the donation. However, the OIG warned that it is aware of situations in which charitable donations are nothing more than disguised kickbacks intended to induce referrals.

No. 08-03: OIG Approves Prompt-pay Discounts

The OIG issued Advisory Opinion 08-03 on January 30, 2008, analyzing whether a proposed arrangement pursuant to which a health care system would provide prompt-pay discounts to inpatients and outpatients, including those covered by Medicare, Medicaid and other federal health care programs, violates either the CMP prohibition against inducements to beneficiaries or the antikickback law. The OIG concluded that the proposed arrangement (1) would not constitute grounds for imposing CMPs; and (2) could implicate the antikickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, but would not result in administrative sanctions under the antikickback statute or the CMP against inducements to beneficiaries.

The three-hospital health care system requesting the opinion proposes providing discounts to inpatients and outpatients, including federal health care program beneficiaries and other insured patients, regardless of their ability to pay, for promptly paying their cost-sharing amounts and amounts owed for noncovered services for which they received an advance beneficiary notice. The rationale for this discount, as certified by the requestor, is to reduce the health care system's accounts receivables and cost of debt collection, and to boost its cash flow.

The requestor certified that it would not claim the waived amounts as bad debt or otherwise shift the burden to the Medicare or Medicaid programs or other third-party payers or individuals. The discount would not be part of a price reduction agreement with third-party payers. The discount would be offered for both inpatient and outpatient services without regard to the reason for the patient's admission, length of stay, diagnostic-related group, or ambulatory payment classification. The costs associated with administering the prompt-pay discount program would be borne solely by the health care system. The discount (5 to 15 percent of the amount of the bill, depending on the timing of the payment and size of the remaining balance owed by the patient) would bear a reasonable relationship to the avoided collection costs. The prompt-pay discount program would not be advertised. Instead, patients would be notified of its availability only when they register for outpatient services and pay their cost-saving amounts, when written statements are sent to the patients by mail, when financial arrangements are made between the health care system

and patients, or after their admission for inpatient services. All payers would be notified of the discount.

In analyzing the arrangement, the OIG first concluded that the prompt-pay discount, as it applies to inpatient services, satisfies all the requirements of the safe harbor for waivers of beneficiary coinsurance and deductible amounts owed by patients. 42 C.F.R. § 1001.952(k). The health care system certified that it would not claim waived amounts as bad debt or otherwise shift the burden to the Medicare and Medicaid programs or other third-party payers or individuals. The health care system would make the waiver without regard to the patient's reason for admission, length of stay, or diagnostic related group. The waiver would not be part of a price reduction agreement with any third-party payer.

"One interesting point about Advisory Opinion 08-03 is that it seems to suggest that prompt pay discounts may not be advertised. Whether this should be a requirement when a discount is designed to encourage prompt payment is not clear."

With respect to the application of the prompt-pay discount to outpatient services, the OIG noted that the safe harbor was inapplicable because it applies only to inpatient services. The OIG nevertheless cited to language in the preamble to the 1991 final safe harbor regulations which provides that, although outpatients are not covered by this safe harbor, discounts which are not used to induce patient referrals but are, instead, implemented for the purpose of more successful bill collection, would not likely violate the antikickback law. The OIG pointed to the specific features of the discount program which, in its opinion, indicate that the program is being implemented for successful bill collection rather than as a disguised payment for referrals. First, the discount would not be advertised and the patient would be informed of the discount only during the billing process. Second, third-party payers would be notified of the discount program. Third, the costs of the discount program would be borne solely by the health care system. Fourth, the amount of discounted fees would bear a reasonable relationship to the amount of avoided collection costs.

For these same reasons, the OIG also concluded that no grounds would exist for the imposition of CMPs against the health care system.

Advisory Opinion 08-03 confirms a widely held view that prompt-pay discounts do not violate the antikickback statute. This position was based on language from a 1991 preamble that stated that by definition prompt-pay discounts are designed to induce prompt payment. One interesting point about this advisory opinion is that it seems to suggest that prompt-pay discounts may not be advertised. Whether this should be a requirement when a discount is designed to encourage prompt payment is not clear.

No. 08-04: OIG Approves Free Trial Prescription Program

In Advisory Opinion 08-04, issued February 5, 2008, the OIG addressed a proposed agreement pursuant to which a pharmaceutical manufacturer proposed offering a free trial prescription program to hemophilia A patients, including federal health care program beneficiaries. The OIG was asked to opine on whether this proposed arrangement would violate the antikickback statute. Based on the facts certified by the requestor, the OIG concluded that while the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, it would not impose administrative sanctions based on the facts of the particular arrangement.

The pharmaceutical manufacturer requesting the opinion manufactures health care products and pharmaceuticals, including a recombinant antihemophilic factor VIII product indicated for the prevention and control of hemorrhagic episodes and surgical and short-term routine prophylaxis in patients with hemophilia A. The medication is reimbursed by Medicare Part B under the average sales price methodology, and the Medicare beneficiary is responsible for paying the 20 percent cost share of the allowable Medicare benefit.

Patients with hemophilia A have a choice of medications for the disease. They can choose between other recombinant factor VIII products that are also manufactured by competitors of the requestor, or they can choose plasma-derived products. While the costs of the latter are generally less expensive than the recombinant products, there is greater risk of transferring blood-borne pathogens. Patients can switch between the two kinds of products with no adverse effects.

Under the proposed agreement, the requestor would offer a limited number of program enrollment forms to hemophiliac treatment centers and hemophilia/oncology physician practices (collectively, physicians). The numbers of enrollment forms would be based on ten percent of the U.S. hemophiliac A patients served by that practice, with a further limitation that no physician could receive more than 20 enrollment forms per year, per location). Furthermore, patients already on the medication would be ineligible to

participate in the trial program, and patients would not be allowed to enroll in the program more than once.

Physicians who elect to participate in the trial would identify patients who could benefit from the medication. The physician and patient would complete an enrollment form and this, together with the physician's prescription for the Medication, would be forwarded to the program administrator.

> *"Advisory Opinion 08-04 is consistent with a number of prior advisory opinions in which the OIG has recognized that arrangements that are beneficial to certain at-risk patient populations may be approved through the advisory opinion process, even though they potentially implicate the antikickback statute."*

The program administrator, a licensed pharmacy under contract with the requestor, does not distribute hemophiliac products commercially. After filling the prescription, the program administrator would ship the medication directly to the patient as a safeguard to ensure that the physician would neither bill for, nor resell, the medication. At no time would physicians have possession of the medication. The requestor certified that the program would comply with the Prescription Drug Marketing Act of 1987 (PDMA).

The requestor would not compensate any physician, directly or indirectly, for participating in the program. Neither the requestor nor the program administrator would charge the patient or any other third party (including federal health care programs) for the medication provided under the program.

The amount of medication each patient would be eligible to receive is based upon 10 doses for the average patient size for three age ranges. These amounts approximate the minimum amount necessary to permit a fair trial of the medication's efficacy. Physicians could not prescribe more than the trial quantity established for each age tier. There would be sufficient medication for approximately one to ten weeks depending on several factors, such as the patient's weight, severity of the illness, and level of activity. The total value of free medication provided to any one patient would range from $5,000 to $20,000.

Under the program, the medication would be offered free of charge. No third-party payer would be billed for the medication. Physicians would be required to sign a statement on the program enrollment form acknowledging that the medication is complimentary and may not be billed to third-party payers or resold. Patients would sign a similar statement which includes the fact that there is no obligation to purchase the medication after the trial as a precondition to participating in the program. Similarly, the program administrator would contractually acknowledge that the medication is provided at no cost to patients or health care providers, and that it would not resell the medication or bill any third-party payer.

In analyzing the proposed arrangement, the OIG first directed attention to its Compliance Program Guidance for Pharmaceutical Manufacturers (CPG) which highlights the risks involved when manufacturers provide free samples to recipients (e.g., physicians) treating federal health care program beneficiaries. While noting that physicians would not take possession of the Medication under the program, and that the program appeared to address the risks raised by the CPG, the OIG stated that this was not dispositive with regard to the fraud and abuse concerns related to the proposed arrangement, citing two potential kickback concerns: (i) kickbacks to participating physicians; and (ii) remuneration in the form of cost-sharing relief on the free drugs to induce participating patients to self-refer the medication in the future.

As to the first concern, the OIG concluded that the proposed arrangement does not appear to create any benefit, direct or indirect, monetary or economic, or any other kind of benefit for the participating physicians that would warrant imposing administrative sanctions. There are safeguards to ensure that no physician could take possession of the medication and then bill for it or sell it by virtue of the fact that the program administrator ships the medication directly to the patients. This addresses the specific risk outlined in the OIG's CPG concerning improper resale or billing of samples. Additionally, physicians would be required to certify on their enrollment forms that the medication is to be provided free of charge to the patient and is not to be billed to any third-party payer.

As to the second concern, the OIG concluded that the risk of patients being induced to self-refer the medication at the end of the trial creates a low level of risk of fraud and abuse and is readily distinguishable from riskier consumer-based programs for the following reasons:

1. The program creates no cost to federal health care programs and has safeguards to prevent billing for the samples.

2. Any risk of steerage associated with the program is offset by (a) the cost-sharing obligations that would

apply to any future medication; (b) no substantial barriers to prevent patients switching between competing treatments; and (c) the inability of patients to self-enroll in the program.

3. Any risk of overutilization associated with the program is reduced by the cost-sharing obligations, the nature of the medication, and the limitations placed on enrollment, namely patients cannot enroll more than once, and cannot enroll if they are already on the medication.

4. The program includes additional safeguards, including (a) the physicians do not take possession of the medication; (b) hemophelia treatment centers and physician practices will receive only a limited number of enrollment forms; (c) patients would not be obligated to purchase the medication in the future; and (d) the program would be structured to comply with the PDMA.

In a footnote, the OIG noted that the CMP provisions that relate to inducements to a beneficiary to choose a particular provider would not apply because the requestor, as a manufacturer that does not bill Medicare or Medicaid, would not meet the definition of a *particular provider, practitioner, or supplier* under the act.

Finally, the OIG notes that the result may have been different had different facts been presented, or if the sampling program was non-PDMA compliant.

Advisory Opinion 08-04 is consistent with a number of prior advisory opinions in which the OIG has recognized that arrangements that are beneficial to certain at-risk patient populations may be approved through the advisory opinion process, even though they potentially implicate the antikickback statute. Here, the OIG has recognized a number of safeguards that limit the potential fraud and abuse risk posed by the program for offering free trial prescriptions to hemophilia patients.

No. 08-05: OIG Approves Pharmaceutical Kiosks in Physician Offices

In an Advisory Opinion issued February 15, 2008, the OIG responded to a pharmaceutical company's request to determine whether its proposal to place electronic kiosks in certain physicians' waiting rooms that offered free disease-state screening questionnaires implicates either the antikickback statute or the CMP prohibition against inducements to beneficiaries. The OIG concluded that the proposed arrangement would not implicate the antikickback statute because the kiosks had no independent value to either the physicians or their patients, and, as such, could not generate any prohibited remuneration. For these same reasons, the OIG concluded that the proposed arrangement would not subject the requestor to CMPs for inducements to beneficiaries.

The pharmaceutical and health care company requestor the opinion develops, manufactures and markets pharmaceuticals for a number of diseases and conditions reimbursable by federal health care programs. The company proposes placing freestanding electronic kiosks in physicians' waiting rooms at no charge to participating physicians. The kiosks would contain a touch screen, keyboard, printer and software, and display interactive questionnaires involving one of four specific disease states. Physicians that would be targeted for placement of the kiosks include those who treat a large number of patients with these disease states. These physicians would be identified based on whether they have prescribed drugs in therapeutic classes commonly used to treat these disease states in the past. The prescribed drugs do not necessarily have to be those manufactured by the requestor. Physicians would not be required to prescribe these drugs as a precondition to hosting the kiosks.

> *"The OIG determined that the kiosks amounted to "little more than high-tech interactive brochures" with no independent value to the physicians."*

Patients may, but are not required to, complete questionnaires that may point to their having one of these disease states, but which would not draw any conclusions about the patient's condition or recommended therapeutic regime, or contain any message directed to their physician. Patients are simply advised to talk to their physicians as appropriate. Patients may print out their responses and share the results with their physicians.

Neither the kiosks nor questionnaires would mention the requestor's drug products; nor would they contain advertisements or incentives for using the kiosks, such as coupons, or offers of free items. The kiosks would carry a small image of the requestor's logo, a "brought-to-you-by" statement. The requestor's logo and a copyright notice would be included in a footer at the bottom of the questionnaires and printouts.

Patients would not be required to enter their names when completing the questionnaires. Questionnaires would include a screen with a privacy statement notifying patients that the requestor, and companies working with the requestor, would capture only general information such as the number of patients who complete questionnaires, the number of incomplete ones and the number of results printed out. No individual identifying information would be

captured. The requestor certified that it would meet all applicable privacy laws and that the information captured would not be available to its sales representatives.

Participating physicians would not pay the requestor to provide the kiosks, nor would the physicians be paid for hosting them. Kiosks would be installed in the waiting rooms for up to a one-year term, after which the requestor could either remove them or renew the term for an additional period of time. Physicians could request to have the kiosks removed at any time. At all times, the kiosks would remain the property of the requestor.

Based on these facts, the OIG first concluded that the proposal did not present a potential kickback from the requestor to the patient users. Nothing would induce patients to self-refer to the requestor's drugs because the kiosks contained nothing of value for the patients. Significantly, patients would not be offered incentives, such as coupons or free items, for participating.

The OIG cautioned, however, that the fact that this proposed arrangement does not implicate the antikickback statute does not necessarily mean that it does not implicate other laws, such as federal and state consumer protection laws or Food and Drug Administration or Federal Trade Commission regulations. The OIG noted that its conclusion would likely be different if the kiosks were used to communicate offers of remuneration to patients, such as coupons, gifts, or free services. The OIG pointed out, however, that it is apparent that the kiosks are designed to direct patient inquiries regarding these four disease states for which the requestor's drugs are indicated, and that they are therefore a type of "direct-to-consumer" advertising often used by pharmaceutical manufacturers, which results in overutilization and the steering of patients to brand-name drugs instead of their cheaper generic equivalents.

The OIG next concluded that the proposed arrangement did not present a potential kickback from the requestor to participating physicians. In the OIG's view, the kiosks would not generate prohibited remuneration for purposes of inducing physicians to prescribe the requestor's drugs for the following reasons: (i) the kiosks would remain the requestor's property; (ii) the participating physicians would not receive any space rental, utility fees, or other compensation for hosting the kiosks; (iii) the kiosks would not increase the attractiveness of the physicians to prospective patients; and (iv) the kiosks were not viewed as saving the physicians or their staff any appreciable time. The OIG determined that the kiosks amounted to "little more than high-tech interactive brochures" with no independent value to the physicians. The OIG distinguished them from other multi-functional computers or fax machines that have independent value to physicians and which may otherwise act as inducements.

The OIG also emphasized the importance of the fact the requestor had included sufficient safeguards to protect patient privacy and noted that the requestor had certified that it would comply with all applicable privacy laws. Based on the totality of the facts, the OIG concluded that the proposed arrangement would not subject the requestor to administrative sanctions under the antikickback law or the CMP against inducements to beneficiaries.

Advisory Opinion 08-05 is interesting in the correlation it draws that leads the OIG to permit a drug manufacturer to place a computer kiosk in a physician's office without implicating the antikickback statute. Essentially, the OIG took the position that the kiosks were no more than high-tech brochures, and that it is common practice for drug manufacturers to leave their brochures in physician waiting rooms. It seems unlikely that Advisory Opinion 08-05 will open the flood gates to additional marketing activities by drug companies. As normal, the Advisory Opinion is limited to the specific facts presented in the request.

No. 08-06: OIG Rejects Free Labeling of Test Tubes, Collection Containers for Dialysis Facilities

In Advisory Opinion 08-06, issued May 2, 2008, the OIG considered a laboratory's proposal to provide selected dialysis facilities with free labeling of test tubes and specimen collection containers to send specimens to that laboratory for testing. The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute. A careful reading of this opinion suggests that the laboratory requesting the opinion may have been seeking a negative opinion.

Under the proposed arrangement, the laboratory requesting the advisory opinion would offer the free labeling of test tubes and specimen collection containers to dialysis facility customers, but only as necessary to retain their business. Absent the proposed arrangement, the dialysis facilities would incur the costs of labeling the test tubes and containers that they use for both composite rate tests (which are included in the composite rate that Medicare pays the dialysis facilities and are not separately billable), and for noncomposite rate tests (which the laboratory bills directly to Medicare and other payors). If the dialysis facilities receive the labeling services for free, they would reduce their costs for the composite rate tests and realize a greater portion the composite rate reimbursed by Medicare.

First, the OIG considered whether the proposed labeling arrangement could satisfy the personal services and management contracts safe harbor. The OIG concluded that the safe harbor was unavailable because the dialysis facilities would not pay any compensation to the laboratory for the labeling services. Given the lack of safe harbor protection, the OIG considered the proposed arrangement on its facts.

The OIG determined that the proposed arrangement had all of the hallmarks of certain disfavored arrangements described in prior guidance on the provision of free or below-market goods or services to actual or potential referral sources. *See* Special Fraud Alert, "Arrangements for the Provision of Clinical Lab Services." 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). In its Clinical Laboratory Fraud Alert, the OIG indicated that the provision of free items or services from a laboratory to a referral source creates "an inference . . . that the item or service is offered to induce referrals." The OIG also cautioned against "swapping" arrangements between laboratories and dialysis facilities in which the laboratory offers discounts on the facility's composite rate tests in exchange for the facility's referrals for noncomposite rate tests billable by the lab directly to Medicare or other federal health care programs.

> *"The question is whether laboratories will modify their existing arrangements or simply rely on the advisory opinion as the justification for not providing the labeling service anymore."*

The OIG noted two key features of the proposed labeling arrangement that resembled the disfavored arrangements described in the Clinical Laboratory Fraud Alert. First, the offering of labeling services at no charge gave rise to an inference that such services are intended to influence the dialysis facilities' choice of laboratory. This was clear from the requestor's representation that the free services would be offered to dialysis facilities only when necessary to obtain or retain their business. Second, the free labeling services would operate in effect as a price reduction or nonmonetary discount on the amount the dialysis facilities would pay the laboratory for composite rate tests. The risk is that the discounts would be offered in exchange for the dialysis facilities' referral of noncomposite rate tests to the laboratory as in a swapping arrangement. The OIG found an improper nexus between the free labeling services and the referral of other federal health care program business (e.g., the noncomposite rate tests). Consequently, the OIG found that the proposed arrangement posed a significant risk of improper swapping that could potentially generate prohibited remuneration under the antikickback statute.

The facts of Advisory Opinion 08-06 leave one with the suspicion that the laboratory requesting it may have been seeking a negative opinion. It is difficult to imagine how the OIG could approve an arrangement in which the requestor acknowledges that its action is based on whether it "would be necessary to obtain or retain the business" from a particular Dialysis Facility." Although this opinion suggests that the provision of free labeling services is suspect, there may be ways in which the arrangement might be modified to be consistent with the antikickback statute.

No. 08-07: OIG Approves Gift Card Program

Advisory Opinion 08-07, issued June 27, 2008, analyzes a proposed arrangement by a health care system to provide $10 gift cards to patients who experience service shortfalls. The OIG analyzed the proposed arrangement under both the prohibition against inducements to beneficiaries and the antikickback statute. The OIG concluded that (i) the proposed arrangement did not constitute prohibited remuneration under the prohibition against inducements to beneficiaries and (ii) while the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute, if the requisite intent to induce or reward referrals was present, the OIG would not impose sanctions based on the facts of the particular arrangement.

The requestor is a health care system with three hospitals, twenty-two clinics, one skilled nursing facility, and one health plan. The $10 gift cards are part of a program to address services shortfalls, such as excessive wait times, cancelled appointments, delayed meals, excess noise, housekeeping or dietary concerns, television not working, or lost personal items. The gift cards would be valid for certain local vendors, none of which provide health care items or services. The gift cards are not redeemable for cash or for services provided by the health care system. The health care system will develop a system to track gift cards to ensure that no patient receives more than $50 in gift cards per year.

The OIG began by analyzing the proposed arrangement under the prohibition against inducements to beneficiaries. The OIG noted that items of nominal value are not intended to induce a beneficiary to use a particular provider, practitioner, or supplier. For enforcement purposes, the OIG has previously stated that items of nominal value are no more than $10 per item or $50 in the aggregate on an annual basis but cannot be "cash or cash equivalents." Given that the proposed gift card arrangement was designed to satisfy these requirements, the real issue in the advisory opinion was whether the gift card constituted "cash or cash equivalents." The OIG concluded that the gift cards were not cash equivalents and thus, because the program provides only nominal value, it does not violate the prohibition against inducements to beneficiaries.

The OIG noted that the antikickback statute is intent-based. The OIG then concluded that it would not impose sanctions under the antikickback statute against the proposed gift card program "[f]or the same reasons" expressed by the OIG in relation to the prohibition against inducements to beneficiaries.

The significance of Advisory Opinion 08-07 seems limited. It does not appear to cover any significant new ground other than to confirm that gift cards that cannot be converted to cash are not "cash equivalents" — a term that also appears in the discount safe harbor to the antikickback statute.

No. 08-08: OIG Okays ASC Joint Venture Between Hospital Corporation, Surgical Group

In Advisory Opinion 08-08, posted July 25, 2008, the OIG found a joint venture between a hospital corporation and a surgical group contained sufficient safeguards to mitigate the potential risk of fraud and abuse under the antikickback statute so that the OIG would not impose sanctions.

The hospital corporation is a nonprofit corporation that owns and operates health care entities, including three hospitals and a physician practice. The surgical group is a partnership of orthopedic surgeons (surgeon investors), each having equal partnership interests in the group. The purpose of the joint venture was to create a company that owns and operates an ASC. The hospital corporation holds 30 percent of the ownership interests in the company and the surgical group holds the remaining 70 percent. The OIG noted that the joint venture did not meet the requirements of the safe harbor for hospital- and physician/surgeon-owned ASCs, but concluded that these shortcomings did not create a significant risk of fraud or abuse that is targeted by the antikickback statute.

> *"Although the joint venture in Advisory Opinion 08-08 fell outside of the protective parameters of the ASC safe harbor, the OIG found that it presented a low risk of fraud or abuse and therefore concluded it would not impose administrative sanctions upon the arrangement."*

The surgeon investors do not have a direct investment interest in the ASC; rather, their investment is through the surgical group and the company. Specifically, the surgeon investors made capital contributions in exchange for ownership interests in the surgical group, which in turn holds an ownership interest in the company that owns and operates the ASC. The OIG's concern with intermediate investment entities is that they will be used to redirect revenues to reward referrals. However, despite the existence of these "pass through" entities, the surgeon investors' ownership in the surgical group is proportionate to each surgeon's capital investment; thus, the OIG found that surgeon investors' return on their ASC investment is exactly the same as if they had directly invested in the ASC.

Four of the eighteen surgeon investors do not meet the requirement of the ASC safe harbor that at least one-third of their income during the past year be derived from the performance of ASC-qualified procedures. This requirement reduces the risk that surgeons will treat their investment as a way to profit from referrals to other physicians using the ASC, rather than use the ASC as a regular part of their medical practice. Nonetheless, the OIG noted that this joint venture is different from riskier ones in which the investors are significant referral sources for other investors in the ASC. In this case, only a small percentage of the surgeon investors will not regularly practice at the ASC and, further, this small number will rarely make referrals for ASC?qualified procedures other than pain management procedures. In the event such referral is required for a patient, these surgeon investors are qualified to perform the procedures in the ASC themselves, rather than refer the procedure to another co-investor. Furthermore, should a surgeon investor make referrals for pain management procedures at the ASC, the referring surgeon investor will personally perform such procedure.

Though the joint venture does not meet the requirement of the ASC safe harbor that the hospital investor may not be in a position to make or influence referrals to the ASC, the OIG found that sufficient safeguards were in place to limit such referrals. The requestor certified that the hospital corporation would refrain from any action that required or encouraged any affiliated physician to refer to the ASC and would not track such referrals, and that the compensation payable to affiliated physicians would not relate to the volume or value of such referrals. The OIG found these safeguards significantly constrained the hospital corporation's ability to direct or influence referrals to the ASC.

Finally, the hospital entered into a written agreement with its physician practice for the exclusive provision of anesthesiology services at the ASC on a part-time basis. This agreement, however, does not meet the personal services safe harbor, as required by the ASC safe harbor, because the agreement does not specify the schedule of part-time anesthesiology services. Nevertheless, the OIG focused on the other elements of the agreement, such as the fixed, set-in-advance compensation that is not related to the volume or value of the physicians' services. In addition, the anesthesiology services are set out in detail within the agreement and are reasonable and necessary for the ASC.

For these reasons, despite the fact that the joint venture lay outside of the protective parameters of the ASC safe harbor, the OIG found that it presented a low risk of fraud or abuse and concluded it would not impose administrative

sanctions upon the arrangement. This opinion demonstrates the OIG's willingness to perform a case-by-case basis analysis of arrangements that do not fit squarely within a safe harbor in an effort to identify sufficient safeguards that would justify a favorable opinion.

No. 08-09: OIG Approves Orthopedic Surgery/Neurosurgery Gainsharing Agreements

Advisory Opinion 08-09, issued July 31, 2008, is another favorable opinion on gainsharing arrangements. The gainsharing arrangement at issue, however, is in the context of orthopedic surgery and neurosurgery, which have yet to be discussed in the OIG's gainsharing advisory opinions.

The gainsharing arrangement at issue is among an academic medical center, orthopedic surgery groups that employ only orthopedic surgeons, and a neurosurgery group that employs only neurosurgeons. The employed surgeons have active medical staff privileges at, and refer to, the medical center, with which each group had entered into a separate gainsharing agreement. The arrangement is administered by a program administrator, who will collect data and analyze and manage the arrangement in exchange for a fixed monthly fee.

Pursuant to the arrangement, the medical center will pay the groups a share of the cost savings directly attributable to certain changes made in the groups' operating room practices performed in the course of spine fusion surgery. The changes fall into two categories: (1) limitation of the use of a certain biological to an "as-needed basis" and (2) standardization of the use of certain spine fusion devices and supplies where medically appropriate. The medical center pays each group 50 percent of the cost savings the group achieves for a period of one year, which constitutes the entire compensation paid to the groups for services performed pursuant to the arrangement with the medical center.

The groups' gainsharing payments under the arrangement were calculated by subtracting the *actual costs* incurred during the contract year for items and services subject to the cost saving measures and the *historic costs* for the same items and services when used by the groups during comparable surgical procedures in the base year. The groups received 50 percent of this amount, less 50 percent of the medical center's costs incurred to administer the arrangement. The groups distributed the payments to their members on a per capita basis.

The arrangement established certain baselines or "floors," below which no savings would accrue to the groups. For example, the program administrator determined that, prior to the arrangement. a certain biological had been used in 15 percent of patients during spine fusion surgery. The administrator concluded it would be reasonable to limit such use to 11 percent of cases without adversely impacting patient care. However, the groups would not receive credit for cost savings related to limited use of the biological if such use was reduced below the 11 percent baseline.

In addition to the baselines established for the particular cost savings measures, the arrangement imposed certain limitations or "caps" on the groups' aggregate payments. If a group's volume of performed procedures payable by federal health care programs in the contract year exceed the volume performed in the base year, the group receives no cost savings attributable to the additional procedures. If there is any indication that a surgeon altered his or her referral patterns in a manner beneficial to the medical center as a result of the arrangement, such surgeon is terminated from participation in the arrangement. Lastly, projected cost savings pursuant to the arrangement have been identified. Each group's payment will not exceed 50 percent of the group's share of such projected cost savings. Furthermore, each group is compensated solely for its own cost savings, not those of another group.

> *"The OIG found the arrangement in Advisory Opinion 08-09 to be different than gainsharing arrangements that pay a percentage of generalized cost savings not tied to specific cost-lowering activities, which often mask the true effects, sometimes negative, on patient care."*

The OIG concluded that the arrangement implicated the CMP provision against inducements to physicians to limit or reduce services to federal health care program beneficiaries, as well as the antikickback statute. Nevertheless, the OIG found the arrangement to contain sufficient safeguards to protect against the fraud and abuse targeted by both statutes.

- The cost saving measures were clearly identified in the agreements, which provides transparency that allows public scrutiny and physician accountability.
- There was credible medical support for the position that the cost saving measures did not compromise patient care.
- The cost savings payments were calculated based on all surgeries not just those reimbursed by federal health care programs. Moreover, such surgeries were not disproportionately performed on federal health care program beneficiaries.

- The utilization of baselines protected against inappropriate reductions in services.
- Despite the product standardization measure, individual physicians still had available the same devices and supplies, if needed.
- The arrangement was disclosed to patients.
- The financial incentives were reasonably limited in duration and amount.
- The payments are distributed to group members on a per capita basis which mitigates individual incentives to generate disproportionate cost savings.

With respect to the antikickback statute, the OIG noted that, though the arrangement would not fit within the personal services safe harbor (due to the percentage compensation structure), strict compliance with a safe harbor is not necessary to receive protection under the antikickback statute. The OIG found the arrangement's safeguards protected against fraud and abuse under the antikickback statute as it did under the CMP provision.

First, participation in the arrangement was limited to existing medical staff members, was limited to one year in duration, and capped the potential savings related to federal program beneficiaries. This reduced the likelihood that the arrangement could attract new referring physicians. Second, the arrangement did not reward referrals to the groups because the only participants are group members who personally perform procedures (spine fusion surgery) subject to the cost savings measures. This reduces any incentive for the groups to increase referrals. In addition, because payments were distributed on a per capita basis, there was no motive for surgeons to generate disproportionate cost savings.

Overall, the OIG found the arrangement to be different than gainsharing arrangements that pay a percentage of *generalized* cost savings not tied to specific cost-lowering activities, which often mask the true effects, sometimes negative, on patient care. The arrangement was different in that the cost savings measures and likely effects were limited in amount (the aggregate cap), duration (one year), and scope (savings were limited by certain baselines). The OIG did caution that payments of 50 percent of cost savings in other arrangements, such as multi-year arrangements or arrangements with generalized cost savings formulas could lead to a different result.

No. 08-10: OIG Disapproves Block Leases Between Physicians and Urologists

In Advisory Opinion No. 08-10, issued August 19, 2008, the OIG analyzed a proposed arrangement under which a physician practice group would provide space, equipment and personnel to groups of urologists through block leases. The OIG determined that the lease arrangement would subject the participants to CMPs and exclusion under the antikickback statute.

The physician group operates a freestanding facility in which it provides radiation and chemotherapy treatment such as intensity-modulated radiation therapy (IMRT), a common treatment for prostate cancer. The urology groups who refer to the physician group neither provide IMRT nor own facilities that provide IMRT. Some of these groups primarily refer to the physician group while other groups refer to a competitor of the physician group.

> *"Overall, the OIG was not convinced that the arrangement in Advisory Opinion 08-10 was designed to permit the physician group to do indirectly what it could not do directly, as is the case with joint ventures that do not pose a significant risk of fraud or abuse."*

Pursuant to the arrangement, the physician group would lease to the urology groups, on a part-time basis, the space, equipment, and personnel services necessary to perform IMRT. The urology groups would lease the examination and treatment rooms for fixed period of time of at least eight hours per week. The physician group would provide the urology groups with radiation supplies and billing services. Individual radiologists who normally perform services billed by the physician group would enter into contracts with the urology groups to supervise the IMRT procedures as independent contractors.

The urology groups would pay the physician group rent for the space, equipment and personnel, as well as communication and administrative expenses. The compensation would be set in advance and not vary with the use of the space, equipment, personnel or services. The leases would be at fair market value as validated by a third-party valuator. The professional and technical component of the IMRT services provided under this arrangement would be billed using billing numbers assigned to the urology groups.

At the outset, the OIG asserted that this arrangement constituted a contractual joint venture between the physician group and the urology groups and emphasized its long-standing concerns with such arrangements. The OIG found the arrangement to contain many of the characteristics found in suspect joint ventures that the OIG considers to

present a high risk of fraud or abuse, as described in its 1989 and 2003 Special Advisory Bulletins on joint ventures. Specifically, the urology groups would be expanding into a related line of business that would be dependent on their referrals. In addition, the urology groups would not actually participate in performing the IMRT, but would contract out substantially all IMRT operations, including the necessary professional services. In addition, the urology groups would incur little financial risk and would be in the position to ensure the success of the business by referring to the IMRT facility and choosing IMRT over other therapies for their patients. Further, the physician group is an established provider of the same services that the urology groups would provide and is fully capable of providing, billing and collecting for these services on its own. The urology groups essentially would be using the space, equipment and staff to serve the same patients it would have otherwise referred to the physician group for IMRT. The urology groups' aggregate income would vary with their referrals to the facility, as would likely the physician group's income. Finally the urology groups and the physician group would share the economic benefit of IMRT.

Overall, the OIG was not convinced that the arrangement was designed to permit the physician group to do indirectly what it could not do directly, a feature of joint ventures that do not pose a significant risk of fraud or abuse. Therefore, the physician group is essentially providing a referral source, the urology group, the opportunity to generate fees and profit.

The OIG further concluded that even if the individual agreements that create the arrangement could satisfy an applicable safe harbor (space and equipment rental or personal services) the safe harbor would only protect the remuneration paid by the urology groups to the physician group or individual radiologists for actual services or space and equipment rented. The potential compensation received by the urology groups would not be protected. The OIG emphasized that the *opportunity* to generate such fees and profits is itself remuneration that may implicate the antikickback statute. For these reasons, the OIG concluded it could potentially impose sanctions in connection with the arrangement.

The fact that the arrangement in Advisory Opinion 08-10 so closely mirrors those joint ventures that the OIG scrutinizes in its Special Advisory Bulletins suggests that the requestor sought a negative opinion of the arrangement.

No. 08-11: OIG Approves Waiver of Cost-sharing Obligations in Clinical Trial

On September 17, 2008, the OIG issued Advisory Opinion 08-11, addressing the issue of whether cost-sharing obligations may be waived for Medicare beneficiaries who are participating in the Long-term Oxygen Treatment Trial (the LOTT) sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and CMS. The requestors asked whether such waiver would constitute grounds for the imposition of sanctions under the beneficiary inducement CMP or the antikickback statute.

LOTT is a clinical trial designed to determine whether patients with Chronic Obstructive Pulmonary Disease (COPD) and moderate hypopoxemia at rest benefit from using continuous oxygen therapy. The study will be monitored by the NHLBI and CMS. In a national coverage determination, CMS extended Medicare coverage to the home use of oxygen for beneficiaries enrolled in LOTT. CMS has agreed to pay health care providers delivering care and other items or services under LOTT for those costs that are allowable for Medicare beneficiaries who participate in the trial. The trial is expected to last at least three and one-half years and all enrolled patients will be followed for a *minimum* of one year. Under the proposed arrangement, Regional Clinical Centers involved in the trial as well as other providers, practitioners, and suppliers that provide the oxygen equipment and other services, will waive cost-sharing obligations for protocol-required clinical services and oxygen therapy provided to the Medicare beneficiaries who enroll in LOTT.

> *"The OIG approved the waiver of cost-sharing obligations for beneficiaries participating in LOTT based partially on the fact that it is neither a commercial study nor a product-oriented or product-specific study."*

The OIG concluded that, under these particular circumstances, the proposed arrangement would not be subject to sanctions under the antikickback statute or imposition of CMPs for beneficiary inducements. The OIG's analysis noted first that LOTT is a government study co-sponsored and closely monitored by NHLBI and CMS, as well as a number of independent agencies. The NHLBI competitively selected the Regional Clinical Centers and the Data Control Center. LOTT is led by a steering committee that consists of a representative from each of the 14 Regional Clinical Centers and a representative from the Data Coordinating Center. It also includes a study Chairman selected by NHLBI, a representative from NHLBI, and a representative from CMS. All study decisions will be governed by a steering committee with the approval of NHLBI.

Second, the OIG based its conclusion on the fact that the LOTT is neither a commercial study nor a product-oriented

or product-specific study. Privately sponsored clinical trials that are used to study a specific product would present a different situation. The OIG specifically noted that the utilization of oxygen therapy and clinical services will be controlled and closely monitored by the LOTT protocol, and as such, the protection from over-utilization usually provided by cost-sharing requirements would be unnecessary. Finally, the OIG acknowledged that the proposed arrangement is a reasonable means of enhancing the likelihood of success of the trial because patients may not be as compliant with the study if they were required to pay cost-sharing amounts.

No. 08-12: OIG Okays Insurance Preauthorization Services

On September 19, 2008, the OIG issued Advisory Opinion 08-12, which addressed whether an entity can provide purely administrative insurance preauthorization processing and submission services for various radiology and imaging centers. The OIG determined that, based on the protections included in the arrangement, the arrangement would not generate prohibited remuneration under the antikickback statute.

Under the proposed arrangement, a new company (Newco), wholly owned by the requestor, would be formed to contract with various radiology and imaging centers across the nation. Newco would provide these "Centers" purely administrative services consisting solely of the processing and submission of insurance preauthorization for certain radiology and imaging procedures when a Center's patient's insurer required preauthorization. The Center's would pay Newco an identical, fair market, "per-service" fee for each preauthorization processed and submitted, regardless of whether the insurer ultimately grants the preauthorization.

The OIG concluded that the proposed arrangement would not fit into the safe harbor for personal services and management contracts because payments would be made on a "per service" basis and therefore could not be set in advance. Nevertheless, the OIG determined that the proposed arrangement would not generate prohibited remuneration under the antikickback statute. In making this determination, the OIG noted that:

1. Neither the requestor nor Newco (nor any affiliates) is, was, or would be a health care provider, practitioner, or supplier. Further, the requestor certified that Newco will provide purely administrative services at an arm's-length fair market rate and that neither the requestor nor Newco (nor their affiliates) would have the power to receive or influence referrals.

2. The proposed arrangement is distinguishable from arrangements involving marketing services (which can be problematic) because the services being provided are purely administrative and do not involve promotion. Further, neither the requestor nor Newco (nor the affiliates) would have contact with patients or anyone other than the Centers, and would not develop patient information through contacts with Center referral sources (such as patients or physicians). Accordingly, the services do not rise to the level of arranging for or recommending purchasing, leasing, or ordering items or services payable under a federal health care program.

> *"Neither the requestor nor Newco would have contact with patients or anyone other than the radiology and imaging centers, and would not develop patient information through contacts with the centers' referral sources, and, therefore the services do not rise to the level of arranging for or recommending purchasing, leasing, or ordering items or services payable under a federal health care program."*

3. The proposed arrangement is distinguishable from potentially problematic arrangements under which administrative services are provided by or on behalf of a supplier (such as an imaging company or a manufacturer) to an existing or potential referral source. The requestor's certification that neither the requestor nor Newco (nor their affiliates) are in a position to influence referrals indicates that the proposed arrangement does not pose the same risk of fraud and abuse that can be posed in the case of services provided by suppliers. The OIG noted that if a Center or other third party (such as a manufacturer) paid Newco to provide services on behalf of a referral source (such as a physician), thus relieving the referral source of the cost of processing and submitting preauthorizations, then the Center or other third party could be providing prohibited remuneration.

Given the above protections, the OIG determined that the remuneration paid from the Centers to Newco would not be prohibited under the antikickback statute. This opinion confirms that properly structured administrative services arrangements can avoid creating prohibited remuneration so long as appropriate protections and separations are in place.

No. 08-13: OIG Approves Medigap Policy Discounts for Use of Preferred Hospital Network

In Advisory Opinion 08-13, issued September 23, 2008, the OIG addressed the use of a "preferred hospital" network as part of a Medicare Supplemental Health Insurance (Medigap) policy and whether the arrangement would constitute grounds for sanctions under the CMP prohibition against beneficiary inducements or the anti-kickback statute. Under the arrangement, the Medigap plan indirectly contracts with hospitals for discounts on the otherwise applicable Medicare inpatient deductibles for its policyholders and also, at the time of the next policy renewal, reduces the premium for policyholders utilizing a network hospital for an inpatient hospital stay. The OIG determined that it would not impose sanctions because the arrangement posed a low risk of fraud and abuse, notwithstanding its determination that the arrangement generates prohibited remuneration under the antikickback statute and implicates the beneficiary inducement prohibition.

"Under the contracts between the requestors and the MCO, the requestors' policyholders receive discounts of up to 100 percent on Medicare inpatient deductibles incurred at network hospitals – deductibles that would otherwise be covered by the requestors' Medigap plans."

Under the arrangement, the requestors participate in an arrangement with an MCO which contracts with hospitals throughout the country to form a hospital network. Under the contracts between the requestors and the MCO, the requestors' policyholders receive discounts of up to 100 percent on Medicare inpatient deductibles incurred at network hospitals. These deductibles would otherwise be covered by the requestors' Medigap plans. If a policyholder visits a non-network hospital, the same deductibles are covered by the requestors' Medigap plans. The MCO network is open to any accredited Medicare-certified hospital that meets state law requirements.

In addition, the arrangement involves a return of a portion of the requestors' savings directly to policyholders who stay at network hospitals. Policyholders who are admitted to network hospitals receive a $100 credit against their next renewal premium. This feature of the requestors' arrangement is announced to policyholders, as required, in relevant plan and marketing materials.

The OIG determined that the arrangement implicates both the antikickback statute (as remuneration for selecting network hospitals) and the CMP on beneficiary inducements. Accordingly, the OIG determined that "both prongs" of the arrangement must be examined. Examining first the discounts offered on inpatient deductibles for stays at network hospitals, the OIG noted several reasons why the arrangement posed a low risk of fraud and abuse:

1. The arrangement will not affect per-service Medicare payments. Payments to hospitals will remain unaffected by beneficiary cost sharing.

2. The discounts should not increase utilization. The OIG noted that the discounts offered under the arrangement will be "invisible" to patients, since the patients have already purchased supplemental insurance to cover their cost-sharing obligations.

3. The arrangement should not unfairly affect hospital competition, since network membership is available to all properly accredited hospitals.

4. The arrangement should not affect professional medical judgment, since the patient's physician will not receive remuneration and the patient remains free to go to any hospital without incurring additional out-of-pocket costs.

In analyzing the second prong of the arrangement, the $100 credit offered to policyholders, the OIG noted that many of the above factors also applied. In addition, the OIG noted that there is a statutory exception for differentials in cost-sharing amounts as part of a benefit plan design. This statutory exception permits plan designs where plan enrollees pay different cost-sharing amounts based on, for instance, whether they use network or non-network providers.

Finally, the OIG noted that the arrangement as a whole has the potential to lower Medigap costs for plan enrollees who select network hospitals without increasing costs for those who do not. This consideration appeared to weigh heavily in the OIG's analysis – in conclusion, the OIG noted that "[b]ased on the totality of the facts and circumstances, and given the low risk of fraud or abuse and the potential for significant savings for beneficiaries," the OIG would not impose sanctions even though the arrangement "could potentially generate prohibited remuneration. . . ." Advisory Opinion 08-13 reconfirms the OIG's willingness to permit arrangements, even where prohibited remuneration could be created, so long as there are significant cost savings to the Medicare program or its beneficiaries.

No. 08-14: OIG Approves Motivational Incentives Offered by Substance Abuse Treatment Center

On September 24, 2008, the OIG issued Advisory Opinion 08-14, analyzing the application of the CMP prohibition against beneficiary inducement or the antikickback statute to a substance abuse treatment center's use of motivational incentives. The requestor, a nonprofit treatment center which treats a high proportion of Medicare beneficiaries, intended to offer motivational incentives (MIs) to help patients overcome difficulties maintaining abstinence or attending and participating in activities integral to their treatment plans. MIs are never issued in the form of cash; rather, they are gift certificates redeemable at gas stations, grocery stores, and similar locations. Generally, MIs are issued in amounts between $5 and $10, and the total amount of MIs issued to any patient were not expected to exceed $200 per month (and in most cases, were expected to be far less). Although the MIs generally would not exceed the amounts that may be offered to beneficiaries under the exception (as interpreted by the OIG) for items of "nominal value," the aggregate amount offered to some beneficiaries may exceed the $50 annual limit imposed on programs offering incentives of nominal value. MIs would be introduced only when a patient's treating physician determines that MIs are clinically indicated for effective treatment and would be issued in conformance with the treatment guidelines developed by NIDA and SAMHSA for the use of MIs.

At the outset of its analysis, the OIG noted that it is particularly concerned that addiction treatment centers might induce beneficiaries to obtain federally payable items and services by offering them incentives for the accomplishment of treatment goals that are not in fact part of a clinically appropriate treatment program. The OIG went on to note, however, that several features of the incentive program at issue lowered the risk of fraud and abuse:

1. The arrangement follows the guidelines for the use of MIs in addiction treatment developed and published by NIDA and SAMHSA. Under these circumstances, the OIG noted, the MIs are "integral" to a patient's clinical care.

2. The MIs are never issued in cash, are generally of small value, and are not expected to exceed $200 per month or last more than three months. The OIG noted that the advisory opinion would be without force and effect if the MIs awarded "routinely" approached $200 a month or were offered for more than three months.

3. The MIs are introduced only when the patient's treating physician determines they are clinically necessary and patients must "earn" MIs by accomplishing goals related to their treatment plan.

4. The MI program is not advertised and is not discussed with new patients – a fact which led the OIG to conclude that the program is a "... treatment option, not a marketing or promotional effort."

5. The MI program is part of a larger treatment plan that is medically necessary and appropriate.

> *"The OIG is particularly concerned that addiction treatment centers might induce beneficiaries to obtain federally payable items and services by offering them incentives for the accomplishment of treatment goals that are not in fact part of a clinically appropriate treatment program."*

Taken together, the OIG determined that these features distinguished the incentive program from problematic programs that offer free goods or services or other remuneration to beneficiaries as incentives to obtain Medicare and Medicaid reimbursable items and services. Even though the program could generate prohibited remuneration, the OIG would not impose sanctions. Advisory Opinion 08-14 further demonstrates the OIG's willingness to allow programs, even those in which there is a potential for fraud or abuse, whose purpose is related to increasing the quality of beneficiary care.

No. 08-15: OIG Approves Cardiology Gainsharing Agreement

In Advisory Opinion 08-15, issued October 6, 2008, the OIG analyzed an existing gainsharing agreement between a hospital and several cardiology groups, under which the cardiology groups would be paid based on the hospital's savings across 30 specific recommended savings areas in relation to cardiac catheterizations performed in the hospital's laboratory. These areas of potential savings, which were identified by a program administrator tasked with analyzing and administering the program, can be grouped into three broad categories – Product Standardization (25 items), "Use as Needed" Devices (4 items), and Product Substitution (1 item).

Payments under the arrangement would be made on a yearly basis, based on 50 percent of the savings realized by each group with respect to each of the 30 cost-saving areas. In certain areas, protections had been developed (for instance, creating "floors" in terms of usage reduction under which the cardiology groups would not receive

credit for any additional savings) to ensure that the payments do not improperly encourage physicians to refuse to provide medically appropriate care. Protections were also created to ensure that physicians do not alter their referral patterns and to ensure that the cost-saving measures are clearly disclosed, described, and consented to by patients in advance of their procedures.

> *"The OIG once again has made clear that it is amenable to gainsharing arrangements so long as they include appropriate protections against fraud and abuse and inappropriate patient care."*

In analyzing the arrangement, the OIG reiterated its prior position and long-standing concerns about gainsharing. Specifically, the OIG noted that it remains concerned that gainsharing programs can lead to (i) stinting on patient care, (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer gainsharing opportunities, (iii) payments in return for patient referrals, and (iv) unfair competition (as hospitals race to offer more and better gainsharing programs to foster physician loyalty and attract referrals). The OIG noted specifically that gainsharing programs could be an improper payment to induce the reduction or limitation of services under the CMP provisions of the Social Security Act and could potentially generate improper remuneration under the federal antikickback statute. But consistent with earlier gainsharing Advisory Opinions, based on specific safeguards included in the arrangement, the OIG concluded that it would not impose civil monetary penalties or administrative sanctions. *See*, e.g., OIG Advisory Opinions 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21 and 07-22.

In Advisory Opinion 08-15, as in its previous gainsharing opinions, the OIG made clear that it is amenable to gainsharing arrangements so long as they include appropriate protections against fraud and abuse and inappropriate patient care.

No. 08-16: OIG Okays Gainsharing Agreement with Medical Staff

On October 5, 2008, the OIG issued Advisory Opinion 08-16, in which it analyzed a proposed gainsharing arrangement between a hospital and a to-be-formed physician group. Under the arrangement, the hospital would share with the physician group up to 50 percent of certain performance-based compensation the hospital receives from a private insurer.

The hospital is eligible to receive the performance-based compensation from the insurer as a yearly bonus (up to 4 percent of its annual base compensation) for meeting certain quality and efficiency benchmarks. The hospital cannot meet these benchmarks, however, without the assistance and cooperation of its staff. Therefore, the hospital proposed that physicians with privileges at the hospital form a limited liability company specifically for the purpose of entering into an agreement with the hospital to share in the bonus compensation (up to 50 percent) the hospital receives from the insurer.

The arrangement between the hospital and the physician group would contain several important safeguards to prevent negative effects on patient care. Quality targets which are determined to have a detrimental effect on patient care would be terminated. The hospital will also monitor for changes in physician referral patterns, including changes in patient mix. Should a physician change his or her referral patterns in response to the arrangement, he or she will be terminated from the program. The Hospital will also maintain all records of performance in relation to the gainsharing program and make them available for the Secretary's inspection.

The OIG analyzed the program in relation to both the antikickback statute and the CMP prohibition against inducements to physicians to limit or reduce services to federal health care program beneficiaries. The OIG noted that the arrangement might implicate the CMP by inducing physicians to refer or to limit the care they provide beneficiaries. Nevertheless, the OIG noted several features of the arrangement that reduce these risks:

1. Credible medical evidence showed that the arrangement could improve patient care and was unlikely to adversely affect it. The OIG noted that each of the quality measures corresponds to a standard published in the Quality Measures Manual, a collaborative effort by CMS and the Joint Commission.

2. There would be no incentive for a physician to apply a specific standard in medically inappropriate circumstances.

3. The quality measures were reasonably related to the hospital's practice and patient population.

4. The measures which could result in additional physician compensation would be clearly communicated to both physicians and their patients. The OIG believed this transparency would allow for public scrutiny and, where appropriate, accountability.

5. The hospital certified that it would monitor the quality targets to protect against inappropriate reductions in patient care.

Accordingly, the OIG determined that it would not impose sanctions in relation to the CMP.

In terms of the antikickback statute, the OIG reiterated its concerns that gainsharing arrangements pose a threat of payment for referrals. It noted, however, that specific features of the Arrangement limited this risk, including:

1. Membership in the physician group would be limited to physicians who had been on the active medical staff of the hospital for a year, thus discouraging physicians from joining the staff purely to join the group. In addition, compensation paid to the group would be subject to a cap based on the previous year's compensation paid by the insurer, such that an increase in referrals would not mean an increase in physician compensation. Finally, the hospital would monitor and respond appropriately to any changes in physician referral patterns.

"The hospital proposed that physicians with privileges at the hospital form a limited liability company specifically for the purpose of entering into an agreement with the hospital to share in up to 50 percent of the performance-based bonus compensation the hospital receives from a private insurer."

2. Physician compensation would be distributed on a per capita basis, rather than on a volume or value basis. Accordingly, there was minimal threat of individual physicians being rewarded for the volume or value of their referrals.

3. The arrangement's transparency should help ensure its use to improve quality, not reward referrals.

4. The oversight of the insurer would help ensure that payments would be based on achieving quality and efficiency goals, rather than on referral value.

5. The arrangement was based on a three-year agreement and therefore would be limited in time.

6. The hospital certified that meeting quality targets was an important part of its overall program and that it could not meet these targets without staff cooperation.

Accordingly, the OIG determined that the arrangement posed a low risk of fraud and abuse and that it would not pursue sanctions under the antikickback statute. This advisory opinion reconfirms the OIG's position that gainsharing arrangements are suspect, but can be permissible if they both serve a valid purpose and include appropriate safeguards.

No. 08-17: OIG Gives Okay to PAP Administered by Internet-based Pharmacy

OIG Advisory Opinion No. 08-17, issued October 14, 2008, addresses a nonprofit foundation providing financial assistance to cover cost-sharing amounts owed by financially needy patients (uninsured and insured, including Medicare and Medicaid beneficiaries) receiving outpatient drug therapy for a particular disease state. The OIG analyzed the program under both the CMP prohibition against inducements to beneficiaries and the antikickback statute. Similar to Advisory Opinions 06-09 and 06-13, and consistent with the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, the OIG concluded that (i) the proposed arrangement did not constitute prohibited remuneration under the prohibition against inducements to beneficiaries and (ii) while the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute, the OIG would not impose sanctions based on the facts of the particular arrangement.

The foundation would enter into an agreement with an affiliate of its parent corporation for management of a patient assistance program (PAP). The affiliate is a national, Internet-based specialty pharmacy that serves patients with the particular disease state. The pharmacy's tasks would be non-discretionary (administering the funds, processing applications for assistance, determining eligibility based upon the foundation's established criteria, and disbursing the financial assistance for documented cost-sharing needs). The pharmacy would use separate staff for the PAP and keep separate books and records. The pharmacy's compliance officer would incorporate the PAP administrative functions into the pharmacy's compliance monitoring program, conduct an annual compliance review of the PAP, and report directly to the foundation Board for these functions. The pharmacy would be paid a fair market value amount for the services it provides to the foundation. The OIG was not asked—nor did it opine—on the arrangement between the foundation and the pharmacy.

The foundation would be run by an independent board of directors that would make all policy determinations, including the requirements for eligibility. The Board would have seven members, four of whom would also be members of the foundation's parent organization's board. The other members would be unaffiliated with the entities, but might be patients, parents of patients, researchers, and providers. No foundation donors would

serve on the board. Foundation donations would be cash and would come from donors, including manufacturers of the disease state drugs or drug delivery devices. The donations would be unrestricted and could be discontinued at any time. Although the foundation would provide donors with aggregate information regarding the use of the foundation PAP, there would be no information that could be used to correlate PAP recipients with the donors' products. PAP recipients would not know the identity of foundation donors.

> *"The OIG relied on a number of PAP features to conclude that the donations would be unlikely to influence any patient's selection of a particular provider, practitioner, supplier, product, or insurance plan."*

Patients requesting financial assistance from the foundation would be required to complete an application. Applicants would be judged according to objective criteria on a first-come, first-served basis. Eligible patients would receive a card to be presented to the patient's pharmacy. The pharmacy would receive the cost-sharing amounts directly from the foundation. Patients without a pharmacy provider would receive a list of pharmacies, but the list would not highlight the pharmacy administering the PAP (although it could be included).

The OIG's opinion focused on two relationships: donations to the foundation and the foundation grants to Medicare and Medicaid beneficiaries.

The OIG concluded that the PAP "interposes an independent, bona fide charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor." The OIG relied on a number of PAP features to conclude that the donations would be unlikely to influence any patient's selection of a particular provider, practitioner, supplier, product, or insurance plan:

- No donor has control over the foundation or the PAP.
- The foundation would use its own, independent, objective criteria and would be independent of the pharmacy.
- PAP assistance would be independent of donors' interests and the patients' choice of products, providers, suppliers, or insurance plans.
- Financial need would be uniformly measured and consistently applied.
- Donors would not receive patient-specific information. Patients would not receive donor information.
- The pharmacy's role as the administrator of the PAP would be completely separate from its business operations.

The OIG found minimal risk that the PAP assistance to Medicare and Medicaid beneficiaries would influence the patients' choice of providers or that donors' contributions would influence referrals by the foundation because:

- Applications for assistance would be handled on a first-come, first-served basis to the extent funding is available. Patients would already be under the care and treatment of a physician, and no patient steering would take place.
- Financial need would be uniformly and objectively determined.
- Patient choice would be enhanced with the PAP because the patient would be free to change providers and suppliers while receiving PAP assistance.

In conclusion, the OIG determined that the proposed arrangement would not constitute grounds for civil monetary penalties under the beneficiary inducement provisions — and, although the arrangement could implicate the antikickback statute, the OIG would not subject it to administrative sanctions.

No. 08-18: OIG Approves County Fund for Payment of Cost-sharing Amounts

On October 21, 2008, the OIG issued Advisory Opinion 08-18, addressing a proposal whereby a medical center that provides ambulance services would not bill bona fide county residents for Medicare cost-sharing amounts for ambulance services, but would rather accept payment from a county fund created through a special tax. The OIG considered the proposed arrangement under both the CMP prohibition of inducements to beneficiaries and the antikickback statute, and concluded no sanctions would be imposed because there was not a routine waiver of cost-sharing amounts.

The requestor is a hospital that provides EMS transportation services to residents of the county in which it is located. Under the arrangement, the hospital, after providing transport services to a county resident, will not bill the resident for otherwise applicable cost-sharing amounts. Instead, these cost-sharing amounts would be paid directly by the county out of a fund created from a special tax assessment on all county residents. The tax revenue designated for this fund each year would approximate the

annual total cost of cost-sharing amounts for county residents for that year.

In analyzing the arrangement, the OIG noted its long-standing concerns with regard to the routine waiver of cost-sharing amounts. The OIG noted, however, that because the amount of tax revenue designated for the fund each year would approximate the cost-sharing amounts due from county residents that year, and because the cost-sharing amounts would be collected and paid by the county, the arrangement would not actually involve the routine waiver of cost-sharing amounts. Accordingly, the OIG determined that it would not impose administrative sanctions with regard to the arrangement.

"Cost-sharing amounts for EMS transportation services would be paid directly by the county out of a fund created from a special tax assessment on all county residents."

Advisory Opinion 08-18 continues an OIG willingness to permit county and municipal ambulance arrangements that may not precisely confirm to a safe harbor, so long as they do not pose a significant risk of federal health care program abuse.

No. 08-19: OIG Okays Pay-per-call Advertising

On November 5, 2008, the OIG released Advisory Opinion 08-19, which considers the application of the antikickback statute to Internet advertising paid for by chiropractors on a "pay-per-call" or "pay-per-lead" basis. The OIG determined that the arrangement would not be subject to sanctions, given certain important conditions and safeguards built into the arrangement. The conditions and safeguards described by the OIG, however, significantly narrow the universe of acceptable arrangements.

In the arrangement at issue, a provider of internet advertising leads was paid by chiropractic providers on a "per call" or "per lead" basis. The service, which functions through a web site, asks prospective patients for their zip codes. In response, it provides a list of chiropractic providers in their geographic area, along with a contact email and telephone number. If a prospective patient contacts a particular provider through the supplied email or telephone number, the contacted provider pays the advertising service a fair market fee for their referral service.

In analyzing the arrangement, the OIG noted that it would not completely meet the requirements of any safe harbors and therefore could be subject to sanctions. The OIG explained that advertising arrangements which involve "per patient," "per unit of service" or other variable compensation structures are "particularly problematic." Importantly however, the OIG specifically singled out certain features of the arrangement that it believed limited the threat of fraud or abuse posed by the arrangement:

- The advertising company is in no way involved in the health care industry other than as a referring advertiser. Its referrals will not take advantage of a patient trust relationship, as in the case of so-called "white-coat" referrals from physicians.

- The advertising service web site does not collect patient information, including information regarding a patient's insurance or eligibility for government benefits. It will not target or even distinguish federal program beneficiaries.

- The web site posts a clear disclaimer to patients that listed providers have paid to be listed on the service's web site (a further bulwark against a patient's potential belief that the service acts with any medical expertise.

- The price paid by the provider will be fair market value for the service provided and is not dependent on the services, including federal health care services, eventually purchased by patients. The payments will not be based on the "value" of the referral – a practice the OIG noted was specifically problematic.

- The service does not provide discounts, rebates, or other items of value to prospective patients or steer patients to any particular provider within their zip code. Patients are not being induced to use a particular provider.

- The service does not require providers to advertise for any set amount of time, nor will it require that providers pay any set amount of total payments – they are free to end the relationship at any time.

Given these facts, the OIG determined that it would not pursue sanctions against the parties, even though the arrangement may implicate the antikickback prohibitions.

This list, while not definitive, provides important guidance to providers of any health care service who wish to engage a similar referral service. While the opinion makes clear that such a referral relationship is possible, it also makes clear that relationships without sufficient safeguards run significant risk of government sanctions. Providers wishing to engage a referral service on a per-referral basis should, at a minimum, ensure:

- They are paying fair market value for the leads they receive.

- They are paying based on the number of leads, not based on whether a prospective patient becomes a patient, or based on the value of services provided to a patient.

- The referral service does not in any way target, identify, or induce federal or state beneficiaries.

- The referral service does not offer to steer patients to a particular provider.

"The list of features the OIG viewed as measures protecting against fraud and abuse, while not definitive, provides important guidance to providers of any health care service who wish to engage a similar referral service."

- The referral service

  - is not involved in the provision of health care ("white-coat" marketing), and

  - does not in any way state or imply that it warrants a patient's special trust, or that it has a unique knowledge of what constitutes a quality provider. It is worth noting that statements such as these may also invite the scrutiny of state professional boards.

No. 08-20: OIG Approves DMEPOS Consignment Closets

On November 19, 2008 the OIG issued Advisory Opinion 08-20, addressing a proposal whereby two DME suppliers would (i) place an inventory of DMEPOS in consignment closets on-site at certain hospitals, and (ii) have licensed personnel on-call or on site at the hospital to train and educate patients who have selected one of the suppliers to supply their DMEPOS needs. The OIG determined that the arrangement would not generate prohibited remuneration under the antikickback statute.

Under the arrangement, suppliers would enter into agreements with various hospitals that would permit them to maintain an inventory of DMEPOS in consignment closets in the hospitals. DMEPOS from these closets would be distributed as needed to hospital patients who selected one of the suppliers as their DMEPOS supplier. The suppliers would not pay anything to the hospital for the use of the closets, nor would patients' choice in DMEPOS suppliers be limited. When selected, suppliers would continue to bill patient's private insurer or government payor program as appropriate. Suppliers would also station licensed personnel (use registered nurses or respiratory therapists) on-call or on-site at the hospital. When one of the suppliers is selected by a patient, the on-site personnel would perform all training, education and coordination of care services necessary for compliance under CMS's final 2008 DMEPOS Quality Standards. The hospital will provide on-site personnel with a desk and a phone (at no charge to the suppliers) so the site personnel might perform the necessary Quality Standards activity. Prior to a patient's selection of suppliers for his or her DMEPOS needs, the site personnel will not have any contact with patients. Site personnel will not have an opportunity to influence hospital referrals, nor will they perform any work for the hospital – they will only perform necessary Quality Standards activities.

In analyzing the arrangement, the OIG noted that it has had a long-standing concern regarding aggressive DME marketing, which it believes can lead to overutilization, increased costs, inappropriate medical choices and poorer quality patient care. The OIG determined, however, that the arrangement did not implicate the antikickback statute. In making this determination, the OIG noted that no remuneration will flow from the suppliers to their potential referral sources (the hospital and its staff). Under the arrangement, the referrals and all remuneration (use of the closet, desk and telephone) will all flow "the same way" – from the hospitals to the suppliers. In addition, the OIG noted that while it maintains its concern in regard to the provision of free services (where, for instance, a phlebotomist stationed in a physician's office provides the office with no-cost telephone or receptionist services) personnel under the arrangement will only perform work in relation to the necessary Quality Standards. Accordingly, the OIG determined that now financial benefit accrued to the hospitals' benefit and the Arrangement did not produce prohibited remuneration.

No. 08-21: OIG Approves Cardiology Gainsharing Agreement

On November 25, 2008, the OIG issued Advisory Opinion 08-21, concerning an existing gainsharing agreement between a hospital and four cardiology groups based on certain cost-saving measures implemented in certain cardiac catheterization procedures.

As in past advisory opinions, this gainsharing arrangement concerned the use of specific medical devices and supplies during the designated procedures. Like Advisory Opinion 08-15, the arrangement at issue involved the cardiology group's year-over-year reduction in costs in three general areas: Product Standardization; "Use as Needed" Devices; and Product Substitutions. As in 08-15, the program was developed and overseen by an independent Program Administrator, and safeguards were put in place to ensure that participating physicians continued to make appropriate medical decisions, did not alter their referral patterns, appropriately disclosed the gainsharing

arrangement to patients, and kept all appropriate records and documentation.

The OIG's analysis of this arrangement reiterated the OIG's concerns that gainsharing arrangements pose a significant threat of both abuse and poor patient care. As in 08-15, however, the OIG determined that this arrangement contained sufficient safeguards to minimize those risks and, under the totality of the circumstances, posed very little risk. Accordingly, the OIG determined that it would not pursue sanctions in respect to the gainsharing arrangement.

As in 08-15 and 08-16, Advisory Opinion 08-21 demonstrates the OIG's continued willingness to permit gainsharing arrangements so long as sufficient safeguards against fraud and abuse and ensuring quality patient care have been created.

No. 08-22: OIG Okays Part-time Physician Employment Arrangements

In OIG Advisory Opinion 08-22, the OIG concluded that the part-time employment of two physicians would not generate prohibited remuneration under the antikickback statute, and thus would not result in sanctions. The requestor of the opinion is a nonprofit tax-exempt corporation established for the purpose of employing physicians. It is wholly owned by another corporation, which is not identified, and the relationship between the physicians and the parent entity is not part of the OIG's analysis. Each of the physicians maintains medical practices separate and apart from the requestor. The requestor would employ the two physicians on a part-time basis to perform endoscopies on the requestor's premises. The amount paid to the physicians would be consistent with fair market value.

> *"The OIG found that the part-time employment arrangements would meet the statutory exception for employment arrangements and that the compensation paid to the physicians would not constitute prohibited remuneration under the antikickback statute."*

The OIG analyzed the part-time employment arrangement under the statutory employment exception and the regulatory definition of *remuneration*. In doing so, the OIG noted that the requestor certified that the physicians would be bona fide employees and they would be paid for professional services they personally perform. Further, endoscopy services are paid for in whole or in part by Medicare, Medicaid or other federal health care programs. Accordingly, the OIG found that the part-time employment arrangements would meet the statutory exception for employment arrangements and that the compensation paid to the physicians would not constitute prohibited remuneration under the antikickback statute.

Of particular interest, although the requestor certified that the amounts paid to the physicians would be fair market value, the OIG specifically states that it did not rely on the certification in rendering its opinion. Further, the OIG explicitly limits its opinion to the antikickback statute and contrasts the antikickback statute with the Stark self-referral statute, for which fair market value is a criterion.

No. 08-23: OIG Approves County's Insurance-only Billing for EMS Transportation Services

On December 12, 2008, the OIG issued Advisory Opinion 08-23, regarding a proposal whereby a county that provides EMS transportation services through its fire department would treat received tax revenue as payment of applicable cost-sharing amounts for bona fide county residents. Notwithstanding its many similarities to the circumstances of Advisory Opinion 08-18, the OIG found that the arrangement at issue, because the relevant provider is owned and operated by a state or municipality, would not generate prohibited remuneration under the antikickback statute.

Under the arrangement, the county would not bill bona fide county residents who receive EMS transportation services through its fire department. For residents, the county would treat any amount received from a resident's insurer (government or private) as payment in full. The county would treat received tax revenue as its "payment" for the purposes of residents' applicable cost-sharing responsibilities.

In analyzing the arrangement, the OIG noted that "insurance-only" billing may implicate the antikickback statute to the extent that it constitutes a limited waiver of federal health care program cost-sharing amounts. The OIG also noted, however, that a specific CMS manual provision (Medicare Benefit Policy Manual, Chapter 16, § 50.3.1) provides that:

> A [state or local government] facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment.

The OIG also noted that CMS has confirmed that, in this instance, facilit[ies] include a state or municipal ambulance

company that is a Medicare Part B supplier. Accordingly, since the county can not be required to collect cost-sharing amounts, the OIG determined that the arrangement would not generate prohibited remuneration under the antikickback statute. The OIG specifically noted that this provision does not apply in the case of a state or municipality that contracts with another entity for the provision of ambulance services. States and municipalities may not, in other words, require contracting private companies to waive cost-sharing obligations of their residents.

"The county would treat any amount received from a resident's insurer (government or private) as payment in full for EMS transportation services, while treating received tax revenue as its "payment" for the purposes of residents' applicable cost-sharing responsibilities."

As in Advisory Opinion 08-18, this opinion continues an OIG willingness to permit county and municipal ambulance arrangements that may not precisely conform to a safe harbor, so long as they do not pose a significant risk of federal health care program abuse.

No. 08-24: OIG Okays LLC Medical Practice Comprised of Physicians and Podiatrists

On December 29, 2009, the OIG issued Advisory Opinion 08-24 analyzing the investment by 23 physicians and podiatrists in a shared medical practice under the antikickback statute. While finding that the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute, the OIG concluded that it would not impose administrative sanctions because the proposed arrangement posed minimal risk of abuse.

The physicians and podiatrists formed a limited liability company to operate a medical practice located in a rural Health Professional Shortage Area. The practice offers various primary and urgent medical care as well as clinical laboratory and diagnostic laboratory services. With the exception of one investor physician, who holds a 1 percent interest in the entire practice and whose duties are solely administrative, all of the investors work at the practice on a part-time basis and see patients separately at different office locations not affiliated with the practice. Each investor owns a fixed percentage in the entire practice and shares in the practice's profits or losses in direct proportion to his or her ownership interest.

A central governing Board of Managers comprised of members of the practice has sole authority to make decisions for the practice, such as developing, drafting, and approving budgets, compensation rates, and staff salaries. The Board also has control over practice assets and liabilities, and formulates and approves practice policies and procedures that govern both clinical and business matters.

The practice has a single consolidated accounting system that manages billing and finances. All expenses and revenues are pooled across the practice and are not separated in relation to individual practice members.

The investors had already obtained a favorable advisory opinion from CMS regarding compliance with the rural provider exception under the Stark law. See CMS Advisory Opinion 2008-02 (June 2008). The requestors certified that the revenues generated by the practice from ancillary services are derived from "in-office ancillary services" as that term is defined under the Stark law.

The requestors also certified that the practice has, or will shortly achieve, compliance with the definition of *group practice* under the Stark law by restructuring the practice to bring in a number of urgent care physicians as members to meet the minimum percentages of physician-patient encounters conducted by practice members.

The OIG first determined that the antikickback safe harbor for investments in group practices was potentially applicable. However, the OIG concluded that the proposed arrangement did not satisfy all of the safe harbor requirements because a one percent ownership interest in the practice would be held by a physician who would not provide clinical services at the practice.

The OIG next evaluated the proposed arrangement based on the totality of the facts, and concluded that it posed little risk because, with the exception of the 1 percent interest held by the physician who would perform only administrative duties for the practice, the proposed arrangement otherwise appeared to comply in almost all other respects with the requirements of the safe harbor for investments in group practices. This physician's returns are directly proportional to his investment interest, and he provides substantial services integral to the practice's operation and administration, which minimize the risk that his small equity interests reflect referrals.

Based on the foregoing, the OIG concluded that the proposed arrangement presents a minimal risk of abuse and that it therefore would not seek to impose administrative sanctions in connection with the antikickback statute.■

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No. 08-01: CMS Okays Hospital System's Proposal to Develop Physicians' EHR Interface

In its first advisory opinion of 2008, CMS responded to a nonprofit hospital system's request for an opinion regarding its proposal to contract with a software vendor to develop and license customized software that would allow the requestor's own EHR system to communicate with those owned by its staff physicians' practices to enable such physician practices to order, or communicate the results of, tests and procedures furnished by the hospital. Specifically, the hospital system sought an opinion from CMS as to whether or not its proposal fell within the definition of a compensation arrangement as defined by the Stark law and, if so, whether the proposal satisfied the requirements of an exception to the Stark law.

Based on the specific facts and law as discussed more fully below, CMS concluded that the proposed arrangement was excluded from the statutory definition of a compensation arrangement. Having so concluded, it was not necessary for CMS to determine whether the proposed arrangement satisfied any of the Stark exceptions.

The physicians on the hospital system's staff were able to view laboratory reports for the system's patients over a protected Internet connection. Noting that many of its staff physicians' practices had begun purchasing and using their own EHR systems, the hospital system proposed expanding access to patient data by permitting these physician practices to order and review laboratory tests and procedures. To this end, the hospital system proposed contracting with a software vendor to develop several versions of an interface (to accommodate the various types of EHR systems owned by the individual physician practices) to integrate the physicians' EHR systems with the hospital system's own customized health care software information system in a way that would facilitate the secure transfer of patient data between them. The hospital system would pay the vendor for the development of the interfaces as well as for the licenses that would authorize their use by the physician practices. The hospital system certified that interfaces would be used only by physicians on its staff, and for the sole purpose of ordering and communicating laboratory tests and procedures for its patients. The hospital system further certified that no other items or services would be provided to the physician practices in connection with this proposal. Finally, the hospital system certified that interfaces could not be modified to perform any alternate function; nor could the physician practices sell, transfer, or otherwise assign their licenses to access the hospital system's information system.

CMS began its analysis with the Stark Law definition of a compensation arrangement:

> Any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C). [Subparagraph (C) excludes from this definition] "items, devices, or supplies that are used solely . . . to order or communicate the results of tests or procedures for such entity.

CMS pointed out that the hospital system had certified that the physician practice interfaces (1) would be used solely to order or communicate the results of tests and procedures furnished by the hospital system; (2) could not be modified to perform an alternate function; and (3) could not be resold, transferred or assigned by a physician practice. Applying the law to these facts, CMS concluded that the provision of such interfaces did not meet the Stark Law's statutory definition of *compensation arrangement*.

In reaching this conclusion, CMS cautioned that its analysis was restricted to use of the interfaces for purposes of ordering or communicating the results of tests or procedures furnished by the hospital system; that its analysis did not extend to the use of these interfaces for any other purpose.

Two additional rules could have been applied in CMS's analysis of the proposed EHR system interfaces. In 2006, CMS finalized a rule creating a Stark exception permitting donations from hospitals and certain other health care groups to physicians for establishing electronic prescribing and EHR capabilities. 71 Fed. Reg. 45,140 (Aug. 8, 2006). At the same time, the OIG finalized an antikickback safe harbor for certain financial relationships between physicians and other health care providers for establishing health information technology systems. 71 Fed. Reg. 45,110 (Aug. 8, 2006). Interestingly, CMS made no reference to either of these rules even though the advisory opinion dealt specifically with EHR systems.

No. 08-02: CMS Approves Physicians' Ownership/ Investment Interest in Diagnostic Center

In advisory opinion CMS-AO-2008-02, issued June 2008, CMS analyzed the financial arrangement between physicians and a diagnostic center pursuant to which the owner physicians refer patients to the center for designated health services (DHS), for which the center bills Medicare. Specifically, CMS determined whether or not the

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physicians' ownership/investment interests in the center satisfied the rural provider exception of the Stark law. Based on the certified facts and law discussed more fully below, CMS concluded that the physicians' ownership/investment interests in the DHS center satisfied the Stark law's rural provider exception.

The diagnostic center provided a variety of DHS services. The physician owners had been referring, and would continue to refer, Medicare patients to the center for these services.

In its analysis of the application of the rural provider exception to the ownership/investment interests of the arrangement, CMS points out that the rural provider exception applies only to ownership or investment interests in a DHS entity ? not to compensation arrangements. CMS concluded this requirement was met because the physician owners certified that no compensation arrangements existed between them and the DHS center.

CMS next noted that qualification for the rural provider exception requires compliance with both prongs of a two-part test. First, the DHS must be furnished in a rural area. CMS found compliance with this first prong because the physician owners certified that, since the clinic's inception, the county in which it had been, and would continue to be, located is one that the Office of Management and Budget had not designated as a Metropolitan Statistical Area (MSA). CMS determined that if an area has not been designated as an MSA, by definition, it is a rural area. The second prong of the two-part test requires that "substantially all" (defined as meaning not less than 75 percent) of the DHS must be furnished to patients residing in rural areas. CMS found this requirement met because the physician owners certified that on an annual basis at least 75 percent of the DHS provided by the DHS center had been, and would continue to be, furnished to patients residing outside an MSA. Consequently, CMS concluded that the physicians' ownership in the diagnostic center satisfied the rural provider exception to the Stark law. Finally, CMS cautioned that compliance with both prongs of this two-part test is an ongoing requirement for the exception to apply. Thus, should the center fail to comply with any one of the requirements, it would lose the protection of the exception. ■