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Detailed Summaries of OIG Advisory Opinions – Calendar Year 2016

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January 6, 2016 – Notice of Modification of OIG Advisory Opinion No. 04-15

Modified Advisory Op. 04-15 (regarding grants provided by a nonprofit, charitable organization to financially needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies) and its first modification to reflect guidance regarding Independent Charity Patient Assistance Programs issued in the Supplemental Special Advisory Bulletin on May 21, 2014.

OIG provided notice that it was modifying Advisory Opinion No. 04-15 (Oct. 29, 2004), which discussed a charity's plan to operate a patient assistance program ("PAP") to subsidize, in whole or in part, the costs of prescription drug therapies incurred by financially needy patients suffering from certain chronic or life-threatening diseases. In the original advisory opinion, OIG determined the proposed PAP would not contribute grounds for imposition of sanctions since the subsidies were not likely to influence any beneficiary's selection of a particular provider and donors to the charity could not influence which patients received financial assistance. In 2008, OIG modified their opinion to allow the charity to provide donors with monthly aggregate patient data; modify their standard donation agreement to permit donors to terminate participation; and expand the charity's operations to provide assistance with additional disease categories.

On May 21, 2014, OIG issued a Supplemental Special Advisory Bulletin ("Supplemental Bulletin") that provided additional guidance regarding independent charity PAPs. *See* 79 Fed. Reg. 31,120 (May 30, 2014). Specifically, the Supplemental Bulletin addressed recent AKS-related concerns associated with independent charities' PAPs. First, OIG instructed that independent charities could not define disease funds so narrowly that the earmarking effectively becomes a "donor's subsidization of its own products." This could include situations where a charity operates a disease fund in a way that limits assistance to only a "subset of available products" rather than all FDA-approved treatments or a disease fund operates to cover only the products created by a certain manufacturer.

Second, OIG instructed that an independent charity PAP must determine eligibility according to reasonable, verifiable, and consistently applied measures of financial need. OIG noted that the cost of a particular drug is not an appropriate factor for financial need and that generous financial aid, in a context in which the subset of available drugs is limited to those created by a major donor, could draw more scrutiny. Finally, OIG affirmed that the actions charities certify in order to ensure independence from donors—for example, limiting the types of information it will provide to donors—serve as critical safeguards on which OIG relies in providing its opinions.

In response to the Supplemental Bulletin, the charity addressed OIG's concerns by making several certifications regarding three aspects of its plan:

1. The charity made several certifications regarding the definition of its disease fund, specifically promising not to define the disease in any way that would narrow the meaning of widely recognized disease states.

2. The charity made several certifications regarding the breadth of healthcare services it would financially assist, including that it would not provide copayment assistance for only one drug or therapeutic device, or any such product made or marketed by only one manufacturer. To prevent this possible outcome, in situations where one supplier dominates, the charity promised to support *all* prescription drugs and therapeutic devices used by a patient to manage her disease.

3. The charity made several certifications regarding the manner in which it would provide assistance. Specifically, the charity certified that it would not limit its aid to high-cost or specialty drugs, and it promised to employ a reasonable, verifiable, uniform, and consistently applied measure to determine financial aid.

To retain its favorable advisory opinion from OIG, the charity also proposed to:

1. Provide premium assistance to all qualifying enrollees;

2. Provide cost-sharing assistance for qualified applicants for therapeutic devices that treat underlying diseases;

3. Provide assistance with the cost of genetic testing;

4. Provide cost-sharing assistance with infusion services, including any office visits associated with the administration of certain medication therapies, such as chemotherapy treatment, utilized to treat the underlying disease covered by the fund;

5. Establish disease funds that would provide assistance only to qualifying federal health care program beneficiaries; and

6. Update its financial need criteria.

January 20, 2016 – Terminated OIG Advisory Opinion No. 08-17 (concerning a nonprofit, tax-exempt, charitable organization's arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with a certain disease)

OIG terminated Advisory Opinion No. 08-17 (Oct. 14, 2008) (modified on Oct. 27, 2010, and on Apr. 4, 2012), in which OIG concluded that a foundation's proposed arrangement to provide financial assistance to patients with cystic fibrosis who had health care coverage but could not afford the costs associated with their prescription drugs would *not* constitute grounds for imposition of civil monetary penalties or administrative sanctions. The foundation had ceased enrolling new patients as of Oct. 12, 2015.

January 20, 2016 – Terminated OIG Advisory Opinion No. 10-06 (concerning a patient assistance program that assists underinsured patients with their prescription drug co-payment obligations)

OIG terminated Advisory Opinion No. 10-06 (May 20, 2010), in which OIG concluded that a corporation's arrangement to award financial assistance to needy patients in connection with premium and cost-sharing obligations associated with their prescription drug coverage would *not* constitute grounds for the imposition of civil monetary penalties or administrative sanctions. The corporation never implemented the arrangement and indicated that it does not intend to do so in the future.

January 25, 2016 – OIG Advisory Opinion No. 16-01

Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

OIG evaluated a proposal by an insurance company offering Medicare Supplemental Health Insurance ("Medigap") policies to participate in an arrangement with a preferred hospital organization ("PHO"), which has contracts with hospitals in a nationwide network. Under the arrangement, the network hospitals would provide discounts of up to 100 percent on Medicare Part A inpatient hospital deductibles incurred by the insurance company's Medigap plan policyholders. For each discount from a network hospital, the insurance company would pay the PHO a fee for administrative services. Further, the insurance company would use to savings from the discounts to provide a premium credit of $100 to policyholders that use a network hospital for an inpatient stay.

OIG stated that two potentially applicable AKS safe harbors would not protect the proposed arrangement:

1. The safe harbor for waivers of beneficiary coinsurance and deductible amounts specifically excludes such waivers when they are part of an agreement with an insurer. *See* 42 C.F.R. § 1001.952(k)(1)(iii).

2. The safe harbor for reduced premium amounts offered by health plans requires health plans to offer the same reduced cost-sharing or premium amounts to all enrollees. *See* 42 C.F.R. § 1001.952(l)(1). But under the proposed arrangement, the discounts would be available only to policyholders who used network hospitals.

Nevertheless, OIG found the risk of fraud and abuse to be minimal for six reasons:

1. The discounts and premium credits would not affect Medicare payments because Part A payments for inpatient services are fixed (i.e., independent of and unaffected by patients' cost-sharing obligations).

2. The proposed arrangement would be unlikely to increase utilization. Without the discounts, it would be Medigap insurance and not the patients themselves that would be covering the cost-sharing obligations. In other words, the discounts would be effectively invisible to policyholders.

3. The proposed arrangement would be unlikely to unfairly affect competition among hospitals since participation in the PHO's network is open to any hospital meeting Medicare certification and state law

requirements.

4. Clinicians' professional medical judgment would remain unencumbered since no remuneration would flow to the clinicians.

5. Policyholders would be permitted to select providers without regard to their network participation status and without incurring additional liability or a penalty.

6. The $100 premium credit would have "substantially the same purpose and effect" as differentials in coinsurance and deductible amounts as part of a benefit plan design, which are exempted from the definition of "remuneration" for purposes of the general prohibition on inducements to beneficiaries. Relatedly, because savings realized from the proposed arrangement would be reported to state insurance rate-setting regulators, the arrangement would have the potential to lower costs for all policyholders.

March 1, 2016 – OIG Advisory Opinion No. 16-02

Regarding a state academic medical center that offers pregnant women (1) transportation aid to and from the campus hospital for delivery; and (2) short-term lodging near the campus hospital.

OIG evaluated a proposal regarding a state academic medical center that, in limited circumstances, sought to provide pregnant women with (1) transportation to and from the hospital campus for their obstetric care and deliveries and (2) short-term lodging near the hospital campus. The center operates 12 hospital-based clinics that provide prenatal care in specific counties in the state. The clinics primarily serve low-income women and confer care without considering a patient's ability to pay. Generally, a patient begins receiving prenatal care at the clinic within her community, but in some medical situations, a patient may desire to deliver at the hospital campus.

OIG concluded that it would not pursue administrative sanctions under either the AKS or the civil monetary penalty statute for five reasons:

1. The arrangement would benefit clinic patients because it would provide patients without financial means the opportunity to deliver at a hospital familiar with their particular medical histories.

2. The limited nature of the aid: patients would only receive a modest amount of aid, which the hospital would only provide in narrow circumstances.

3. The hospital would not consider whether a patient participates in a federal health care program when distributing aid under the arrangement.

4. The hospital would not attempt to claim costs associated with this program as "bad debt" or shift the financial burden of these programs to Medicare or Medicaid.

5. A state academic medical center sought to operate the program, and states are responsible for promoting the well-being of their citizens.

March 18, 2016 – OIG Advisory Opinion No. 16-03

Regarding the use of a "preferred hospital" network as part of Medigap policies, whereby two insurance companies would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

Similar to the proposal evaluated in Advisory Opinion No. 16-01 (and other proposals in previous years), OIG evaluated a proposal by two insurance companies owned by the same corporate parent. The insurers offer Medigap policies and proposed to participate in an arrangement with a PHO that has contracts with hospitals in a nationwide network. Under the arrangement, the network hospitals would provide discounts of up to 100 percent on Medicare Part A inpatient hospital deductibles incurred by the insurers' Medigap plan policyholders. For each discount from a network hospital, the insurers would pay the PHO a fee for administrative services. Further, the insurers would use to savings from the discounts to provide a premium credit of $100 to policyholders that use a network hospital for an inpatient stay.

As in Advisory Opinion No. 16-01, OIG stated that the AKS safe harbors for waivers of beneficiary coinsurance and deductible amounts and for reduced premium amounts offered by health plans would *not* protect the proposed arrangement. Nevertheless, OIG found the risk of fraud and abuse to be minimal for the same reasons outlined in Opinion No. 16-01.

April 6, 2016 – Termination of OIG Advisory Opinion No. 06-09 (concerning a nonprofit, tax-exempt, charitable organization's proposals to subsidize Medicare Part D premium and cost-sharing obligations owed by financially needy patients with end-stage renal disease and chronic kidney disease)

OIG terminated Advisory Opinion 06-09 (Aug. 18, 2006), in which OIG concluded that a charity's proposal to subsidize the Medicare Part D premium and cost-sharing obligations owed by financially needy patients suffering from end-stage renal disease and chronic kidney disease would not constitute grounds for imposition of civil monetary penalties or administrative sanctions. But the charity currently has no program to subsidize Medicare Pare D premium and cost-sharing obligations and indicated that there were no plans to resume or implement such a program in the future.

April 19, 2016 – OIG Advisory Opinion No. 16-04

Regarding the use of a "preferred hospital" network as part of Medigap policies, whereby three insurance companies would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

Similar to the proposals evaluated in Advisory Opinions 16-01 and 16-03 (and other proposals in previous years), OIG evaluated a proposal by three affiliated insurance companies that offer Medigap policies. The insurers proposed to participate in an arrangement with a PHO that has contracts with hospitals in a nationwide network. Under the arrangement, the network hospitals would provide discounts of up to 100 percent on Medicare Part A inpatient hospital deductibles incurred by the insurers' Medigap plan policyholders. For each

discount from a network hospital, the insurers would pay the PHO a fee for administrative services. Further, the insurers would use to savings from the discounts to provide a premium credit of $100 to policyholders that use a network hospital for an inpatient stay.

As in Advisory Opinion No. 16-01, OIG stated that the AKS safe harbors for waivers of beneficiary coinsurance and deductible amounts and for reduced premium amounts offered by health plans would not protect the proposed arrangement. Nevertheless, OIG found the risk of fraud and abuse to be minimal for the same reasons outlined in Opinion No. 16-01.

May 3, 2016 – OIG Advisory Opinion No. 16-05

Regarding the use of a "preferred hospital" network as part of Medigap policies, whereby an insurance company would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

Similar to the proposals evaluated in Advisory Opinions 16-01, 16-03, and 16-04 (and others in previous years), OIG evaluated a proposal by an insurance company offering Medigap policies to participate in an arrangement with a PHO that has contracts with hospitals in a nationwide network. Under the arrangement, the network hospitals would provide discounts of up to 100 percent on Medicare Part A inpatient hospital deductibles incurred by the insurance company's Medigap plan policyholders. For each discount from a network hospital, the insurance company would pay the PHO a fee for administrative services. Further, the insurance company would use to savings from the discounts to provide a premium credit of $100 to policyholders that use a network hospital for an inpatient stay. The arrangement would apply to all of the insurance company's Medigap plans except those that (1) fall under the category of Medicare SELECT policies and (2) do not cover any portion of the Part A deductible.

As in Advisory Opinion No. 16-01, OIG stated that the AKS safe harbors for waivers of beneficiary coinsurance and deductible amounts and for reduced premium amounts offered by health plans would not protect the proposed arrangement. Nevertheless, OIG found the risk of fraud and abuse to be minimal for the same reasons outlined in Opinion No. 16-01.

May 9, 2016 – OIG Advisory Opinion No. 16-06

Regarding a proposal for a health system to purchase the remaining ownership interest in a group purchasing organization ("GPO") to become the GPO's sole owner while also wholly owning a number of the GPO's participants.

A group purchasing organizations ("GPO") is an entity that helps providers realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts and contracts with manufacturers, distributors, and other vendors. GPOs' contracting services are financed in part by "administrative fees" paid to GPOs by vendors. Generally, the fees are based on a small percentage of the values of sales to GPO members. In 1986, Congress sanctioned the GPO model for health care programs by creating an AKS safe harbor for supplier-paid administrative fees. *See* 42 C.F.R. § 1001.952(j).

A health system initially owned a GPO with over 84,000 members (hospitals, nursing facilities, clinics, physician practices, laboratories, home care or equipment organizations etc.) in equal shares with another entity. After a series of corporate mergers and stock sales, the health system acquired 95 percent of the GPO. OIG evaluated a proposal by the health system to purchase the remaining five percent ownership interest in the GPO to become its sole owner. The health system would also then own or operate approximately 800 of the 84,000 GPO members. Under the proposed arrangement, the GPO would continue operating as before, including negotiating with vendors regarding products and pricing to be offered to the GPO's members and receiving administrative fees from vendors.

OIG concluded that the discounts that the GPO negotiates from vendors on behalf of its members and any administrative fees passed through the GPO to members as rebates may be protected by the safe harbor for discounts. *See* 42 C.F.R. § 1001.952(h). But the administrative fees obtained by the GPO from vendors would not be protected by the safe harbor for GPOs. *See* 42 C.F.R. § 1001.952(j). The safe harbor's definition of a "GPO" excludes entities with members that are "subsidiaries of a parent corporation that wholly owns the GPO." Under the proposed arrangement, the health system would wholly own the GPO and approximately one percent of the GPO's members would become its subsidiaries. In other words, the proposed arrangement would cause the GPO to fall outside the definition of a "GPO" that would be protected by the GPO safe harbor.

Nevertheless, similar to its conclusion for a comparable proposal in Advisory Opinion No. 12-01 (Mar. 15, 2012), OIG found the risk of fraud and abuse to be acceptably low. In crafting a specific definition of a "GPO" for purposes of the AKS safe harbor, OIG wanted to prevent entities from establishing wholly owned subsidiaries as GPOs to be able to extract fees from vendors in exchange for referrals. The proposed arrangement, however, presents a different situation for three reasons:

1. The members that are completely owned by the same entity that also would completely own the GPO constitute a mere one percent of the GPO's total membership.

2. The GPO certified that all members are, and would continue to be, subject to GPO contract terms and conditions negotiated on the same basis as members unaffiliated with the health system. In other words, all GPO members, whether owned by the health system or not, would receive the same treatment and discounts.

3. The GPO certified that, despite the proposed ownership change, the GPO would continue to operate as a purchasing agent for a group of individuals and entities unrelated to the GPO.

May 12, 2016 – Modification of OIG Advisory Opinion No. 10-07

Modifies OIG Advisory Op. 10-07 (concerning a nonprofit, tax-exempt, charitable organization's proposal to provide assistance with cost-sharing obligations to financially needy individuals, including Medicare and Medicaid beneficiaries, diagnosed with certain specified diseases) and its first modification to reflect guidance regarding Independent Charity Patient Assistance Programs issued in the Supplemental Special Advisory Bulletin on May 21, 2014.

OIG provided notice that it was modifying Advisory Opinion No. 10-07 (June 3, 2010), which discusses a charity's plan to (1) operate a PAP that provides cost-sharing assistance for specialty medications to patients diagnosed with multiple sclerosis, cancer, or rheumatoid arthritis, and (2) maintain a separate fund for costs

associated with genetic testing. Similar to its conclusion for the proposal in Advisory Opinion No. 04-15, OIG originally determined that there was a low risk that donor contributions or financial assistance to patients would influence any federal health care program beneficiary's selection of a particular provider, practitioner, supplier, product, or test. Further, OIG stated that there appeared to be a minimal risk that donor contributions would improperly influence referrals by the charity. In 2011, OIG modified their opinion to allow the charity to (1) establish a process to create new assistance funds for additional diseases; and (2) provide assistance not just with cost-sharing obligations and genetic testing, but also with health insurance premiums.

OIG issued a Supplemental Special Advisory Bulletin regarding independent charity PAPs on May 21, 2014. In response to the Supplemental Bulletin, the charity addressed OIG's concerns by making several certifications regarding three aspects of its plan:

1. The charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of drug administration, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. The charity intends to maintain disease funds that would be limited to the metastatic stage of certain types of cancer.

2. The charity will not maintain any disease fund that provides copayment assistance for only one drug or only the drugs made or marketed by one manufacturer or its affiliates.

3. The charity will not limit its assistance to high-cost or specialty drugs. Instead, the charity will make assistance available for, at a minimum, all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state(s) covered by the fund.

4. The charity certified that it determines eligibility according to reasonable, verifiable, and consistently applied measures of financial need.

To retain its favorable advisory opinion from OIG, the charity also proposed to:

1. Establish funds that would serve only federal health care program beneficiaries;

2. Establish new funds that cover multiple disease states;

3. Allow donors to earmark their donations to any established fund; and

4. Provide additional assistance, including but not limited to premium assistance; cost-sharing assistance for related physician office visits, home visits, medical devices, and genetic tests (including diagnostic genetic tests); and incidental expenses related to receiving such treatment, such as child care, travel/transportation, lodging, and meals.

June 27, 2016 – OIG Advisory Opinion No. 16-07

Regarding a savings card program under which individuals that have prescription drug coverage under Medicare Part D receive discounts on a drug that is statutorily excluded from coverage.

OIG evaluated a proposal in which an entity would provide a savings card program under which individuals with prescription drug coverage under Medicare Part D could receive discounts for an erectile dysfunction drug—marketed and distributed by the entity—that is statutorily excluded from Medicare Part D coverage.

OIG concluded that the savings card program did not implicate the AKS for two reasons:

1. The discounts would not induce the purchase of specific items by reducing or eliminating federal health care beneficiaries' out-of-pocket costs for those items. In fact, the proposed arrangement would operate entirely outside the Medicare Part D benefit structure. The erectile dysfunction drug in question is not payable by Medicare Part D because it is statutorily excluded from coverage. So, even if an ineligible individual used the card, or a Part D beneficiary or a pharmacy filling a Part D beneficiary's prescription submitted a claim to a Medicare Part D plan for the drug, the claim would be denied. In other words, the statutory exclusion serves as an effective backstop that prevents the savings card program from inducing the purchase of a drug payable by Medicare Part D.

2. The discounts would not induce the recipients of federal health care benefits to purchase other items marketed by the entity in question. The entity certified that it would not use the savings card program as a vehicle to market other products it manufactures, markets, or distributes to federal health care program beneficiaries.

July 22, 2016 – Modification of OIG Advisory Opinion No. 10-12

Modifies Advisory Op. 10-12 (concerning a nonprofit, tax-exempt, charitable corporation's proposal to provide financially needy patients with grants to defray their cost-sharing obligations) to reflect guidance regarding Independent Charity Patient Assistance Programs issued in the Supplemental Special Advisory Bulletin on May 21, 2014.

OIG provided notice that it was modifying Advisory Opinion No. 10-12 (Aug. 30, 2010), which discussed a charity's proposal to operate a PAP, which would provide grants to financially needy patients to defray their cost-sharing obligations for drugs and devices to treat brain tumors as well as conditions incident to brain tumor treatment (e.g., chemotherapy-induced nausea, chemotherapy-induced anemia, chemotherapy-induced neutropenia, etc.). Similar to its conclusion for the proposals in Advisory Opinions 04-15 and 10-07, OIG originally determined that there was a low risk that donor contributions or patient grants would influence any federal health care program beneficiary's selection of a particular provider, practitioner, supplier, or product, or the selection of any particular insurance plan. Further, OIG stated that there appeared to be a minimal risk that donor contributions would improperly influence referrals by the charity, particularly as the charity planned to implement several safeguards to separate its non-PAP programs and services from the work it performs for the PAP.

OIG issued a Supplemental Special Advisory Bulletin regarding independent charity PAPs on May 21, 2014. In response to the Supplemental Bulletin, the charity addressed OIG's concerns by making several certifications regarding three aspects of its plan:

1. The charity will not define its disease fund by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of a widely recognized disease state.

2. The charity will not maintain a disease fund that includes only one drug or only the drugs made or marketed by one manufacturer or its affiliates.

3. The charity will not limit its assistance to high-cost or specialty drugs. Instead, the charity will make assistance available for all products approved by the FDA to treat a primary malignant brain tumor.

To retain its favorable advisory opinion from OIG, the charity also proposed to:

1. Modify the definition of its disease fund to cover drugs and devices to treat primary malignant brain tumors; and

2. Add a page of general resources on its websites that would include contact information for numerous programs and foundations to assist patients with primary malignant brain tumors, including contact information for the charity's own programs (while maintaining the independence of the PAP from the charity's non-PAP programs and services).

July 27, 2016 – OIG Advisory Opinion No. 16-08

Regarding an arrangement in which a hospice would make a supplemental payment to the nursing facilities in which the hospice's dually eligible patients reside when the nursing facilities—instead of the hospice—receive payment for patients' room-and-board expenses.

Generally, when a patient who is dually eligible for Medicare and Medicaid coverage elects hospice and resides in a nursing facility, Medicare is responsible for the patient's hospice care and Medicaid is responsible for the nursing facility room-and-board expenses. Medicare makes a per diem payment to the hospice for each day of care, while Medicaid must provide a payment for room and board in an amount equal to at least 95 percent of the state's Medicaid daily nursing facility rate—the rate the nursing facility would have received if the patient had not elected hospice. Typically, Medicaid pays the hospice for a dually eligible patient's room and board, and the hospice then passes this payment to the nursing facility at a negotiated rate.

OIG evaluated a proposal by a non-profit corporation licensed by the state to provide hospice care. The state in question has developed a managed care demonstration program under which participating managed care organizations ("MCOs") paid the room-and-board fee for dually eligible hospice patients directly to the nursing facility, thereby removing the hospice as a "pass-through payer." Under the proposed arrangement, the hospice would pay an additional payment to the nursing facility such that, when combined with MCOs' payments, the nursing facility receives the same amount that it would have received from Medicaid if the patient did not elect hospice.

OIG has previously approved hospices reimbursing nursing facilities for the room-and-board expenses of dually eligible hospice patients. But the agency has warned that any payments exceeding what the nursing facility would have received from the state's Medicaid program had the patient not been enrolled in hospice may be viewed as kickbacks to influence the selection of a hospice. *See* OIG Special Fraud Alert, Fraud and Abuse in Nursing Home Arrangements with Hospices (Mar. 1998).

While the hospice's supplemental payments to nursing facilities would constitute remuneration to potential referral sources, they would simply result in the nursing facility receiving, in total, the same amount—not more—that it would have received had the dually eligible hospice patient not elected hospice. So, instead of presenting a risk of fraud and abuse, the proposed arrangement would help to ensure that a nursing facility has no incentive to provide a lower level of room-and-board services or to discourage patients from electing hospice. As such, OIG determined that the proposed arrangement presents a low risk of fraud and abuse under the AKS.

September 23, 2016 – OIG Advisory Opinion No. 16-09

Regarding a proposal to install computerized point-of-care vaccine storage and dispensing systems in physicians' offices for the physicians' use.

OIG evaluated a manufacturer's proposal to enter into agreements with physicians to install the manufacturer's computerized point-of-care vaccine storage and dispensing system—in essence, a refrigerator system for vaccine storage—in the physicians' offices for their use. The refrigerator system would provide three benefits:

1. Selection of the correct storage environment for each vaccine based on the National Drug Code embedded in the vaccine's package barcode, which is scanned when the vaccine is loaded into the refrigerator system;

2. Electronic tracking and notification of expiration dates; and

3. Automated inventory counts, unit dose control, stock rotation, and temperature monitoring.

The manufacturer would also enter into fee agreements with certain manufacturers of "sole-source vaccines"—vaccines recommended for routine use in adults that are manufactured by a single manufacturer.

Under the proposed arrangement, the refrigerator system manufacturer would install the system in participating physicians' offices at no cost and would allow the physicians to use the refrigerator system free of charge, so long as they agreed to stock at least one sole-source vaccine made by a participating vaccine manufacturer. Sole-source vaccine manufacturers would pay the refrigerator system manufacturer a "per-dispense fee"—a fee for each unit of their vaccines stored and administered by a participating physician. The arrangement would only require *storage* of at least one sole-source vaccine; participating physicians would not be required to actually *administer* any quantity of such vaccines, and physicians would be free to exercise their independent medical judgment as to whether and to whom to administer a vaccine.

Even though OIG has a longstanding concern with the provision of free goods or services to an existing or potential referral source, the agency concluded that it would not pursue administrative sanctions for five reasons:

1. There would be a low risk of unfair competition because the manufacturers' agreements with physicians and sole-source vaccine manufacturers would be non-exclusive. In other words, the proposed arrangement would not require physicians to store and administer a single vaccine chosen by the refrigerator system manufacturer.

2. Participating physicians could still store and administer sole-source vaccines from manufacturers with which there was no fee agreement.

3. The per-dispense fees would go to the refrigerator system manufacturer, rather than the physicians themselves, so the fees could not generate federal health care program business even though they would inherently reflect the volume or value of vaccines ordered and administered.

4. The proposed arrangement focuses on adult vaccines, which are administered in a limited manner. Unlike drugs that are necessary to treat illness and ongoing, chronic conditions, vaccines protect against preventable diseases that could lead to additional and more costly services.

5. Proper vaccine storage and management ensure that vaccines maintain their strength and effectiveness. So, the refrigerator system would facilitate physicians' efforts to administer adult vaccines.

October 11, 2016 – OIG Advisory Opinion No. 16-10

Regarding a local health care district's proposal to cooperate with another district to jointly fund the cost of a transportation coordinator to educate patients about local transportation options and subsidize certain forms of transportation for patients with financial need.

OIG evaluated a proposal regarding local health care districts cooperating together to fund the cost of a transportation coordinator to educate patients about local transportation options (e.g., public buses, curb-to-curb transportation for specific patient populations) and subsidize certain forms of transportation for patients with financial need. In particular, one district owns and operates a hospital within its boundaries and a clinic located within another district's boundaries approximately 25 miles away.

The two districts would cooperate in helping patients that receive services at the clinic get back and forth from the hospital. The transportation coordinator would provide travel instruction programs to train patients on using the local transportation system. The programs would be tailored to each patient's needs and could involve simply an overview of local transportation options, specific instructions on how to get from one location to another, or mobility device training for patients who must board and exit vehicles using wheelchairs or walkers. The two districts also would subsidize transportation costs with travel vouchers for patients who cannot afford to pay for transportation.

OIG concluded that remuneration would flow between the districts under the proposed arrangement, since both districts would be contributing to the cost of the transportation coordinator and for transportation subsidies that would benefit both districts. The issue would be that one district could be a referral source for the other, since, for example, the district in which the clinic is located could refer or recommend services offered by the other district's hospital. OIG determined, however, that the risk is low that the aforementioned remuneration would be for the purpose of inducing or rewarding referrals. All residents benefited by the districts' arrangement would

also be one district's patients. Since local health care districts are public agencies empowered to provide direct health care and to provide assistance in operating facilities or services, the arrangement would merely further the districts' mission.

Similarly, OIG determined that the remuneration to patients in the form of travel vouchers presented a low risk of fraud and abuse for three reasons:

1. The districts are public entities supported by taxpayer funds.

2. The vouchers would be for modest amounts—$0.50 to $2.50 per trip—and only available to patients that demonstrated financial need.

3. The districts' arrangement would not be advertised or marketed or targeted to particular patients or beneficiaries, so there was little risk that it could be used to recruit patients.

Less than two months after the issuance of Advisory Opinion No. 16-10, OIG published a final rule that added a new AKS safe harbor for free or discounted local transportation services provided to federal health care program beneficiaries if certain conditions are met. *See* 42 C.F.R. § 1001.952(bb); 81 Fed. Reg. 88,368 (Dec. 7, 2016). The safe harbor applies only to "established patients," although that can include a new patient who initiated contact with a provider to seek services. "Local" is defined to mean 25 miles in urban settings and 50 miles in rural settings, and the costs of the transportation cannot be shifted to a payer, provider, or supplier. The safe harbor does not protect air, luxury, or ambulance-level transportation, and the transportation services cannot be advertised or marketed. Similar conditions apply to transportation in the form of "shuttle service" (defined as a vehicle that runs on a set route with a set schedule). The safe harbor came into effect on January 6, 2017.

November 3, 2016 – OIG Advisory Opinion No. 16-11

Regarding the use of a "preferred hospital" network as part of Medigap policies, whereby an insurance company would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

Similar to the proposals evaluated in Advisory Opinions 16-01, 16-03, 16-04, and 16-05 (and others in previous years), OIG evaluated a proposal by an insurance company offering Medigap policies to participate in an arrangement with a PHO that has contracts with hospitals in a nationwide network. Under the arrangement, the network hospitals would provide discounts of up to 100 percent on Medicare Part A inpatient hospital deductibles incurred by the insurance company's Medigap plan policyholders. For each discount from a network hospital, the insurance company would pay the PHO a fee for administrative services. Further, the insurance company would use the savings from the discounts to provide a premium credit of $100 to policyholders that use a network hospital for an inpatient stay.

As in Advisory Opinion No. 16-01, OIG stated that the AKS safe harbors for waivers of beneficiary coinsurance and deductible amounts and for reduced premium amounts offered by health plans would not protect the proposed arrangement. Nevertheless, OIG found the risk of fraud and abuse to be minimal for the same reasons outlined in Opinion No. 16-01.

December 5, 2016 – OIG Advisory Opinion No. 16-12

Regarding a laboratory's proposal to provide services consisting of the labeling of test tubes and specimen collection containers at no cost to certain dialysis facilities.

OIG evaluated a proposed arrangement in which a laboratory would provide services consisting of the labeling of test tubes and specimen collection containers at no cost to certain dialysis facilities with which it had service contracts. The dialysis facilities would use the tubes and containers to send specimens to the laboratory for testing. The laboratory would decide which dialysis facilities would be offered the labeling services based on whether the offer would be necessary to obtain or retain the facility's business.

Generally, the proposed arrangement might fall under the AKS safe harbor for personal services and management contracts, which is designed to protect most types of vendor arrangements. *See* 42 C.F.R. § 1001.952(d). But the safe harbor requires that the compensation paid for services be consistent with fair market value in an arms-length transaction. Under the proposed arrangement, the dialysis facilities would not pay any compensation to the laboratory even though labeling services have value for dialysis facilities.[1] So, the requirements for safe harbor protection would not be met.

OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the AKS and, accordingly, represented *more than a minimal risk of fraud and abuse* and might merit administrative sanctions. Since the laboratory conceded that it would offer the labeling services to the dialysis facilities when necessary to obtain or retain their business, there is an inference that the free labeling services would be intended to influence the facilities' selection of a testing laboratory. And such influence could be particularly profitable because dialysis patients typically need lifelong laboratory testing services associated with their dialysis services.

[1] Costs for labeling otherwise would be borne by the dialysis facility because such facilities do not receive reimbursement under the government's prospective payment system for administrative tasks associated with laboratory tests, such as labeling of test tubes or specimen collection containers. *See* 75 Fed. Reg. 49,029 (Aug. 12, 2010).

December 20, 2016 – OIG Advisory Opinion No. 16-13

Regarding (1) a proposal to waive cost-sharing obligations incurred by individuals for health care services required for participation in a government-funded clinical research study; and (2) the payment of a stipend to study participants for the time and effort required to participate in study visits.

OIG evaluated a university's proposal to waive patients' cost-sharing obligations (*i.e.*, copayments, coinsurance, and deductibles) associated with health care services required for participation in a government-funded clinical research study; and current arrangement of paying a stipend to study participants for the time and effort required to participate in study visits. The university had developed a clinical research study to determine whether proactively treating anal squamous cells that appeared abnormal on a Pap smear is effective in reducing the incidence of anal cancer in HIV-infected individuals over 35 years of age.

The university would waive patients' cost-sharing obligations to encourage eligible individuals to enroll in the study and to encourage study participants to remain compliant with the schedule of visits and services required by the study protocol. Since the study is a cancer *prevention* research study and not a cancer *treatment* trial, participants may not have sufficient personal incentive to maintain compliance with their treatment plan. And without the waivers, study participation likely would be skewed towards patients for whom the cost-sharing obligations are negligible or not unduly burdensome (*i.e.*, wealthier individuals). Further, the university was already paying study participants $100 for every scheduled visit where high-resolution anoscopy is performed and $25 for visits where only anorectal swabs are collected.

Even though the proposed waiver and stipends implicated the AKS, OIG concluded that there was a minimal risk of fraud and abuse for three reasons:

1. The study was funded by a grant awarded by the National Cancer Institute, which selected a financially independent monitor to oversee the study.

2. The university certified that the study would aim to enroll a widely diverse group of participants and that the waiver and stipends were important towards achieving this aim and ensuring completion of the study.

3. The study is not intended to develop or benefit any specific commercial product or entity, so it is unlikely that waiver of patients' cost-sharing obligations will induce them to self-refer to the university for unnecessary medical services.