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#### **OIG RELEASES PROPOSED RULE REVISING THE ANTI-KICKBACK STATUTE SAFE HARBORS AND CIVIL MONETARY PENALTY RULES**

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a proposed rule (the Proposed Rule), seeking changes to the federal Anti-Kickback Statute safe harbors (Safe Harbors) and the Civil Monetary Penalty (CMP) rules regarding beneficiary inducements and gainsharing. Many of the proposed changes are intended to implement provisions previously authorized by statute. The OIG is seeking public comment on the Proposed Rule, and such comments are due by December 2. The Proposed Rule is available [here](#).

#### **AKS Safe Harbors**

The Anti-Kickback Statute (AKS) makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of services reimbursable by a federal health care program. The OIG has created a number of regulatory Safe Harbors that protect an arrangement from prosecution under the AKS. The arrangement must satisfy all elements of the applicable Safe Harbor to be eligible for such protection. Arrangements that do not satisfy a Safe Harbor may be subjected to increased scrutiny for compliance with the AKS. With respect to the AKS, the OIG proposes the following:

- A new subsection to the existing waiver of beneficiary coinsurance and deductible amounts Safe Harbor that would permit pharmacies to waive Medicare Part D (Part D) cost-sharing amounts. To be eligible for the Safe Harbor, the waiver or reduction cannot be advertised or part of a solicitation; the pharmacy must not routinely waive cost-sharing amounts; and the pharmacy must determine that the beneficiary has a financial need for cost sharing or fail to collect the cost-sharing amount after making a reasonable effort to do so. If the individual is eligible for certain prescription drug subsidies, then only the advertising and solicitation restriction applies.
- A new subsection to the existing waiver of beneficiary coinsurance and deductible amounts Safe Harbor that would permit waivers or reductions in the cost-sharing amounts owed by Medicare Part B beneficiaries for emergency ambulance services. The proposed revision would only apply to waivers or reductions by emergency ambulance services owned and operated by a state, a political subdivision of a state (such as a county), or a federally recognized Indian tribe (Eligible Providers). Waivers of cost-sharing amounts by ambulance service providers under contract with Eligible Providers would not be eligible for protection under the Safe Harbor. Among other requirements, the waiver or cost reduction must be offered on a uniform basis without regard to patient-specific factors.
- A new Safe Harbor protecting free and discounted local transportation provided by an eligible entity to its patients who are beneficiaries of federal health care programs. An eligible entity is

an individual or organization, other than those individuals and organizations (and their family members) primarily engaged in supplying health care items such as pharmaceuticals or durable medical equipment. The transportation may only be provided for purposes of receiving medically necessary items or services within the eligible entity's "local" area. The OIG proposes that any transportation of 25 miles or less be deemed local. To be eligible for Safe Harbor protection, the transportation services cannot be determined in a manner that takes into account the past or anticipated volume or value of federal health care program business; the transportation services cannot be air, luxury, or ambulance-level transportation; the services cannot be marketed or advertised, and no marketing or advertising can occur by drivers providing the transportation; drivers cannot be compensated on a per-beneficiary basis; the services can only be made available to established patients and a person to assist a patient, if necessary; and the eligible entity cannot shift the cost onto Medicare, a state health care program, other payers, or individuals. The OIG is soliciting comments on a variety of topics relating to this proposed Safe Harbor, including the interpretation of the term "local" and whether additional safeguards should be imposed upon various types of eligible entities, such as whether home health care providers should be excluded in whole or in part from protection under the proposed Safe Harbor.

- Two new Safe Harbors to codify changes made to the AKS's statutory Safe Harbors. The first proposed new Safe Harbor protects remuneration between a Medicare Advantage (MA) organization and a Federally Qualified Health Center pursuant to a written agreement. The second new Safe Harbor permits prescription drug manufacturers to provide certain discounts on drugs without violating the AKS.
- A technical correction to the referral services Safe Harbor provides to clarify that fees charged by the referral service to a participant cannot be based on the volume or value of referrals or other business generated by one party for the other party. Currently, the Safe Harbor states that the fee cannot be based on fees generated by either party *for the referral service*. The OIG states that this language was inserted into the Safe Harbor in error, and seeks to revert back to the language in the Proposed Rule, which was included in an earlier version of the Safe Harbor.

#### **Revisions to the Civil Monetary Penalty Regulations**

In pertinent part, the CMP law and its implementing regulations prohibit providing remuneration to a Medicare or Medicaid beneficiary if such remuneration is likely to influence the selection of a particular provider or service that will be paid for, in whole or in part, by Medicare. The Proposed Rule includes several changes to the CMP regulations to codify changes made by statute. These changes include revising the definition of "remuneration" to include these exceptions:

- A hospital's reduction of copayments for hospital outpatient department services.
- Remuneration that is provided to promote access to care and presents a low risk of harm to patients or to federal health care programs. The OIG is considering a number of ways in which to interpret this new provision. The OIG proposes to interpret the phrase "promotes access to care" to mean that the remuneration increases a beneficiary's ability to obtain medically necessary health care. The OIG proposes to interpret the phrase "low risk of harm" to mean that the remuneration is unlikely to interfere with clinical decision making or increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization and does not raise quality of care or patient safety concerns.
- Coupons, rebates, and other rewards provided by retailers. Such rewards must be offered on the same terms to the public without regard to a person's health insurance status and may not be conditioned upon or otherwise tied to the purchase of items or services reimbursable by Medicare or Medicaid.
- Certain items or services provided to financially needy individuals on a free or reduced-cost basis. The person or entity providing such items or services must make a good-faith determination that the recipient is facing a financial hardship, and the items or services provided must be reasonably connected to the medical care of the recipient. The items or services cannot be offered as part of an advertisement or tied to the provision of other items or services reimbursable by a federal or state health care program.
- Waiver by a Part D plan sponsor or MA organization of an enrollee's copayment that would

otherwise be owed by MA enrollees for the first fill of a generic drug covered by Part D. The purpose of the revision is to reduce drug costs by encouraging the use of generic drugs. To be covered by the exception, the waiver must be included in the benefit design package submitted to the Centers for Medicare & Medicaid Services.

In addition to the proposed revisions to the definition of remuneration, the OIG also proposes changes to the gainsharing provisions of the CMP. Gainsharing prohibits hospitals from inducing a physician to limit the services the physician provides to Medicare or Medicaid beneficiaries. Many of the changes are intended to codify the statutory gainsharing provision into the regulations. In addition, in recognition of changing health delivery systems that encourage high-quality care to be provided at a lower cost, such as the Medicare Shared Savings Program and accountable care organizations, the OIG proposes to interpret the phrase “reduce or limit services” in a way that allows hospitals to change their practices to improve care and reduce costs without running afoul of the CMP. The OIG did not propose a definition of the phrase “reduce or limit services” in the Proposed Rule; however, it is seeking comment on whether such a definition should be included in the appropriate regulations.

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## **CMS ANNOUNCES NEW MEDICARE SHARED SAVINGS PROGRAM ACO MODEL**

The Centers for Medicare & Medicaid Services (CMS) recently announced the creation of a new accountable care organization (ACO) model, the ACO Investment Model, to support Medicare Shared Savings Program (MSSP) ACOs. The ACO Investment Model will provide upfront payments to participants and is designed to encourage the formation of ACOs in rural and underserved areas and to encourage existing MSSP ACOs to take on greater levels of financial risk. Participation in the ACO Investment Model is available to ACOs currently participating in the MSSP and those ACOs that will begin participating in the MSSP in 2016. More information on the ACO Investment Model is available [here](#).

### **Payment Structure**

Generally, under the MSSP, an ACO that generates sufficient savings and meets certain quality-of-care standards during a performance year receives a shared savings payment from CMS after the end of the performance year. Under the ACO Investment Model, CMS will make upfront and monthly payments to the participating ACOs. These prepayments are designed to provide ACOs with the capital needed to invest in the infrastructure required for a successful population health management program. New ACOs will receive a fixed upfront payment, a variable upfront payment, and a monthly payment. The variable upfront payment and monthly payment will be based on the number of beneficiaries prospectively assigned to that ACO. Existing ACOs will receive the variable upfront payment and the monthly payments. CMS has not yet provided the exact amount of these payments.

The upfront and monthly payments will be offset against the shared savings that an ACO earns during the course of its participation in the MSSP. If an ACO’s shared savings are insufficient to offset the full amount of CMS’s prepayments, CMS may pursue additional remedies against the ACO. The repayment obligations of an ACO that will join the MSSP in 2016, however, are limited to the total amount of the ACO’s shared savings as long as the ACO completes its MSSP or ACO Investment Model agreement period and does not enter into a second MSSP agreement.

### **Eligibility and Selection Criteria**

Participation in the ACO Investment Model is limited to MSSP ACOs whose first performance year started in 2012, 2013, or 2014 and ACOs that will join the MSSP in 2016. To be eligible, an ACO must meet the following criteria:

- The ACO has 10,000 or fewer prospectively assigned beneficiaries.
- The ACO does not include a hospital as an ACO participant, provider, or supplier unless the hospital is a critical access hospital or inpatient prospective payment system hospital with no more than 100 beds.
- A health plan does not own or operate the ACO or any part thereof.

- The ACO did not participate in the Advance Payment Model.
- If the ACO is currently participating in the MSSP, it must have completely and accurately reported its quality measures for the most recent performance year.

In selecting ACO Investment Model participants, CMS will give preference to ACOs that (1) have an exceptional financial need, that serve rural areas or currently underserved areas, (2) have a record of providing high-quality care, that have achieved financial benchmarks, (3) are committed to taking on greater financial risks, and (4) submit compelling proposals for their use of funds received through the ACO Investment Model program.

### **Application Deadlines**

ACOs that joined the MSSP in 2012 or 2013 and are interested in participating in the ACO Investment Model must submit applications to CMS by December 1. In the summer of 2015, CMS will begin accepting ACO Investment Model applications from ACOs that joined the MSSP in 2014 or that will join the MSSP in 2016.

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Please contact any member of the [Health Law Group](#) at Robinson+Cole if you have questions:

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