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## OIG Issues Proposed Rules Providing for New AKS Safe Harbors, CMP Changes

In the October 3 *Federal Register* ([79 FR 59717](#)), the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) published a proposed rule that would amend the safe harbor regulations to the Anti-Kickback Statute, as well as the civil monetary penalty (“CMP”) rules under the OIG’s authority (the “Proposed Rule”). Specifically, in addition to some minor technical tweaks to existing regulations, the OIG proposes to add new safe harbors manifesting from statutory changes in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, “ACA”). The Proposed Rule also proposes to amend the definition of “remuneration” added by the Balanced Budget Act (BBA) of 1997 and ACA, and to add a gainsharing CMP provision to the existing OIG regulations.

### Proposed New Safe Harbors

The OIG is proposing to amend the Anti-Kickback Statute’s implementing regulations to add safe harbors that provide new protections or codify certain existing statutory protections. Specifically, these changes include the creation of the following new safe harbors:

**1. Cost-Sharing Waivers:** The OIG is proposing to modify 42 C.F.R. § 1001.952(k)—an existing safe harbor that is limited to reductions or waivers of Medicare and state health care program beneficiary cost-sharing—by adding two new subparagraphs to protect certain cost-sharing waivers that pose a low risk of harm. The first new proposed cost-sharing waiver safe harbor is for pharmacy waivers of any cost-sharing imposed under Medicare Part D, as long as certain conditions are met (e.g., waiver/reduction not advertised, waivers not routinely given, and beneficiary determined to have financial need for waiver). The second new proposed cost-sharing waiver safe harbor is for reduction or waivers of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a state or municipality. Notably, the OIG is also soliciting comments whether to expand the entire cost-sharing waivers safe harbor to all federal health care programs.

**2. Remuneration between Medicare Advantage Organizations and Federally Qualified Health Centers (“FQHCs”):** The Social Security Act (the “SSA”) allows an individual enrolled in a Medicare Advantage (“MA”) plan to receive services from a FQHC that has a written agreement with the MA plan. The MMA further amended the SSA by requiring that the written agreement between the two entities specifically provide that the “MA organization pay the contracting FQHC no less than the amount that the plan would make for the same services if the services were furnished by another type of entity.” The MMA also created a new statutory exception to the Anti-Kickback Statute to account for these arrangements, which protects any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in the SSA. The OIG is now proposing to incorporate this exception into the safe harbor regulations as a new section 42 C.F.R. § 1001.952(z), and is seeking comments on this proposal.

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**3. Medicare Coverage Gap Discount Program Drugs:** Section 3301 of the ACA established the Medicare Coverage Gap Discount Program, under which prescription drug manufacturers enter into an agreement with the Secretary of HHS to provide certain beneficiaries access to discounted drugs at the point of sale. Section 3301 also amended the Anti-Kickback Statute to protect the discounts provided for under the program. The OIG now proposes to codify this exception in the safe harbor regulations by adding a new paragraph (aa) to 42 C.F.R. § 1001.952.

**4. Local Transportation Services:** The OIG is proposing to establish a new safe harbor at 42 C.F.R. § 1001.952(bb) to protect free or discounted local transportation services provided to federal health care program beneficiaries, provided the services meet certain conditions. The Proposed Rule also outlines the requirements for the proposed safe harbor including but not limited to: (1) limitations on new patient-provider relationships, (2) the types of providers/suppliers that can offer such transportation (to be defined as “Eligible Entities” under the proposed regulation), (3) the modes of transportation eligible for safe harbor protection (e.g., air, luxury, or ambulance-level transportation would not be eligible, as proposed), and (4) a 25-mile limitation on the distance deemed to comply with the proposed safe harbor. Perhaps most notably, the OIG is proposing that certain providers and suppliers, including DME suppliers, pharmaceutical companies and possibly home health agencies, not be eligible for this safe harbor, since the OIG believes these providers/suppliers are subject to overutilization and abuse of such transportation services. Significantly, the OIG notes the challenges in creating the most appropriate limitations and confines of this proposed safe harbor, and is requesting comments on all aspects of the proposed regulation.

#### **Changes to “Remuneration” Definition**

In addition to the proposed creation of new safe harbor protections, the OIG is proposing to amend the definition of “remuneration” in the CMP regulations (42 C.F.R. § 1003) by adding statutory exceptions for:

1. copayment reductions for certain hospital outpatient department services;
2. certain remuneration that poses a low risk of harm and promotes access to care;
3. coupons, rebates, or other retailer rewards programs that meet specified requirements;
4. certain remuneration to financially needy individuals; and
5. copayment waivers for the first fill of generic drugs.

Not surprisingly, these exceptions are very nuanced with detailed requirements being proposed for safe harbor protection eligibility, given the balancing act the OIG faces between protecting certain arrangements that offer beneficiaries incentives to engage in their care or improve their access to care, while guarding against the potential for abusive arrangements that offer vulnerable beneficiaries remuneration to induce them to obtain unnecessary, overly expensive, or low-quality items or services billable to Medicare or Medicaid.

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## Gainsharing CMP Provision

The Gainsharing CMP is a self-implementing law that prohibits hospitals and critical access hospitals from knowingly paying a physician to induce the physician to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the physician's direct care. The OIG proposed regulations to interpret the Gainsharing CMP back in 1994, although the proposed rule was never finalized. In 1999, the OIG issued a Special Advisory Bulletin related to gainsharing arrangements, which explained the broad prohibitions intended by the Gainsharing CMP that, in practice, operated to prohibit hospital incentive plans that involved payments to physicians to encourage reductions or limitations in items or services provided to patients under the physician's care.

Since that Special Advisory Bulletin, the OIG has issued 16 favorable Advisory Opinions on various gainsharing arrangements, demonstrating its recognition that certain gainsharing arrangements that emphasize accountability for providing high quality of care at lower costs can be beneficial. Accordingly, the OIG is proposing to codify the gainsharing prohibition itself, as well as to add definitions to key terms included in that prohibition, including "hospital" and "reduce or limit services." Notably, the OIG is not proposing text for the definition of "reduce or limit services" at this time, but is soliciting comments on areas of concern that will impact the formation of this definition.

Comments on all aspects of the Proposed Rule are due to the OIG by 5:00 p.m. Eastern Standard Time on December 2, 2014.

If you would like to know more specifics about the Proposed Rule, or you wish to submit comments to the OIG in response to the Proposed Rule, please contact any of Brownstein's health care attorneys, who would be glad to assist.

*This document is intended to provide you with general information regarding safe harbor regulations and civil monetary penalties. The contents of this document are not intended to provide specific legal advice. If you have any questions about the contents of this document or if you need legal advice as to an issue, please contact the attorneys listed or your regular Brownstein Hyatt Farber Schreck, LLP attorney. This communication may be considered advertising in some jurisdictions.*

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