OIG Proposes Revisions to Anti-Kickback Safe Harbors, Beneficiary Inducement Rules and Gainsharing Regulations

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PRACTICE AREAS
Health Care

On October 3, 2014, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a proposed rule to amend the safe harbors to the anti-kickback statute as well as the civil monetary penalty (CMP) rules. While much of the proposed rule codifies changes to the anti-kickback statute safe harbors already established by the Affordable Care Act (ACA) and the Medicare Modernization Act of 2003 (MMA), it also proposes two new safe harbors and makes technical corrections to an existing safe harbor. The OIG also proposes to narrow the definition of "remuneration" in the Beneficiary Inducement CMP laws as well as codify and interpret the gainsharing CMP rules set forth in section 1128A(b) of the Social Security Act.

ANTI-KICKBACK STATUTE SAFE HARBORS

The proposed rule would establish five safe harbors, three of which are based on pre-existing statutory exceptions. In addition, the proposed rule would make a technical correction to an existing safe harbor.

First, the proposed rule would create two new safe harbors with no pre-existing statutory basis:

- **Local Transportation:** A new safe harbor would be established to protect free or discounted local transportation services by an eligible entity to established patients provided that the following conditions are met:
    1. The availability of the transportation services is not determined in a manner related to the past or anticipated volume or value of referrals;
    2. The transportation services do not take the form of air, luxury, or ambulance-level transportation;
    3. The transportation services are not marketed or advertised, no marketing of healthcare items and services occurs during the course of the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary basis;

4. The eligible entity that makes the transportation available bears the costs of the transportation services and does not shift the burden onto other payers; and
5. The distance from the patient's location to the provider could be no more than 25 miles.

- **Cost-Sharing Waivers for Emergency Ambulance Services:** The proposed rule would also establish a safe harbor to protect reductions or waivers of cost-sharing amounts owed for emergency ambulance services to an ambulance provider provided that the ambulance provider or supplier (1) is owned and operated by the state, a political subdivision of the state, or a federally-recognized Indian tribe and is the Medicare Part B provider or supplier of the emergency ambulance services; and (2) offers the reduction or waiver on a uniform basis, without regard to patient-specific factors. The OIG is also proposing an express prohibition against claiming the amount reduced or waived as bad debt for payment purposes under Medicare or a State health care program, or otherwise shifting the burden of the waiver onto other payers. Finally, the OIG is considering whether to include waivers of cost-sharing amounts owed under other Federal healthcare programs, such as Medicaid, and is soliciting comments on this consideration.

Second, the proposed rule would also codify three safe harbors based on pre-existing statutory exceptions:

- **Part D Cost-Sharing Waivers by Pharmacies:** Consistent with changes set forth in the MMA, the rule would add a new safe harbor that would apply to waivers or reductions by pharmacies of any cost-sharing imposed under Medicare Part D as long as three conditions are met:
    1. The waiver or reduction is not advertised or part of a solicitation;
    2. The pharmacy does not routinely waive the cost-sharing; and
    3. Before waiving the cost-sharing, the pharmacy either determines in good faith that the beneficiary has a financial need or the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so.
- **Federally Qualified Health Centers and Medicare Advantage Organizations:** Consistent with provisions in the MMA, the rule would codify a safe harbor to protect any remuneration between a federally qualified health center (FQHC) and a Medicare Advantage (MA) organization pursuant to a written agreement requiring that the MA organization will pay the contracting FQHC no less than the level and amount that the plan would pay for the same services to another type of entity.
- **Medicare Coverage Gap Discount Program:** The rule would codify section 3301(d) of the ACA, which establishes a safe harbor to protect discounts on drugs to certain beneficiaries provided for under the Medicare Coverage Gap Discount Program. The safe harbor would protect a discount in the price of an "applicable drug" of a manufacturer that is furnished to an "applicable beneficiary" under the program, as long as the manufacturer participates in, and is in full compliance with, all requirements of the program. The safe harbor would incorporate the definitions of "applicable beneficiary" and "applicable drug" set forth in the ACA.

Finally, the rule would make the following technical correction to the existing safe harbor for referral services:

- **Referral Services:** The rule would amend the existing safe harbor for referral services to clarify that the safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either party for the other party* (italicized language would be added).

BENEFICIARY INDUCEMENT CMP

The Beneficiary Inducement CMP statute generally prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is likely to influence the beneficiary's selection of a provider. The proposed rule would codify the following five exceptions to the definition of "remuneration," which were added by the Balanced Budget Act of 1997 ("BBA") and the ACA:

- **Copayment Reductions for Hospital Outpatient Department Services:** The proposed rule would exclude from the definition of "remuneration" a reduction in the copayment amount for covered hospital outpatient department services under the BBA.
- **Promotes Access/Low Risk of Harm:** This exception would protect any remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs. For the purposes of this exception, remuneration "promotes access to care" if it improves a particular beneficiary's ability to obtain medically necessary health care items services. The OIG further proposes that the phrase "low risk of harm" means that the remuneration: "(1) is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns."
- **Retailer Rewards Programs:** This exception would exclude from the definition of "remuneration" any rewards pursuant to a retailer rewards program provided that the rewards are offered on equal terms available to the general public and the rewards are not tied to the provision of other items or services reimbursable by a Federal health care program. For example, a program in which a retailer rewarded a $20 coupon to any customer after spending $1000 at the store, even if a portion of that amount included copayments for prescription drugs, would be protected under this exception. However, a program that offered customers a $20 coupon to transfer their prescriptions to the store would not be protected, as the reward is tied to items reimbursable by Medicare.
- **Financial-Need-Based Exception:** Under this exception, the offer or transfer of items or services for free or at less than fair market value after a good faith determination that the recipient is in financial need would be permitted provided that:
    1. The items or services are not offered as part of any advertisement or solicitation;
    2. The items or services are not tied to the provision of other services reimbursable by Federal health care programs; and
    3. There is a "reasonable connection" between the items and services and the medical care of the individual.

- **Waivers for Cost-Sharing for the First Fill of a Generic Drug:** Under the proposed rule, Part D and Medicare Advantage prescription drug plan sponsors would be permitted to waive any copayment that would be otherwise owed by enrollees for the first fill of a covered Part D generic drug as long as such waivers are disclosed to CMS in the benefit design package.

GAINSHARING CMP

The proposed rule would codify and interpret the Gainsharing CMP law, set forth in section 1128A(b) of the Social Security Act, which prohibits hospitals from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries who are under the physician's direct care. Historically, this proscription was interpreted very broadly. However, in its proposed rule, the OIG indicates its intention to narrow the prohibition in light of the changing health care landscape, which has placed a "greater emphasis on accountability for providing high quality care at lower costs." The OIG further expresses that "gainsharing can be beneficial," and notes that it has approved 16 gainsharing arrangements through its advisory opinion process. Thus, the OIG is considering a narrower interpretation of the term "reduce or limit services." While the rule does not propose the text of this new definition, the OIG is soliciting comments regarding the new definition and how to balance its interests in protecting beneficiaries, while allowing low risk programs that further the goal of providing high quality care at lower costs.

WHAT THIS MEANS FOR PROVIDERS

The proposed changes to the safe harbors and CMP laws would give providers greater flexibility to enter into beneficial arrangements with the assurance that they will not be subject to penalties under these laws. The proposed rule reflects the OIG's continued effort to adapt its regulations to the changing health care landscape.

The OIG is soliciting comments concerning how to best implement several of these changes. Comments must be submitted to the OIG no later than December 2, 2014.

If you have any questions on the proposed rule and how you are affected, please contact an attorney in our Health Care Practice Group.