OIG Proposes New Anti-Kickback Law and CMP Safe Harbors

Whenever the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issues proposed regulations regarding exceptions to the Anti-Kickback Statute (AKS), and the Civil Monetary Penalty (CMP) provisions of the Social Security Act, it's news. When the OIG proposes expanding those exceptions, it's big news. That is what the OIG did on Oct. 3, 2014[1] in proposing protections for certain payment practices and business arrangements in connection with the government payment changes under the Affordable Care Act (ACA).

Background

The ACA has numerous provisions aimed at aligning the way the government and private actors pay for healthcare. To better ensure that the AKS and the CMP provisions did not impede that re-alignment and ensure greater flexibility among those providing items or services under the government healthcare programs, the OIG has proposed expanding two existing AKS safe harbors, adding three new ones, and augmenting the exceptions to the CMP, under the Anti-Inducement Act (AIA) and Gainsharing provision. Comments to the proposed rule are due by 5 p.m. on Dec. 2, 2014.

ANTI-KICKBACK SAFE HARBORS

The proposed rule would make a technical correction to the referral services safe harbor (§ 1001.952(f)) and would expand the existing cost-sharing waiver safe harbor (§ 1001.952(k)) to encompass waivers by pharmacies that are under contract with a Prescription Drug Plan (PDP) under Medicare Part D and waivers by ambulance services that are owned by a governmental entity. The proposal would also add three new safe harbors, each of which would exclude from the AKS' definition of "remuneration" (i) any remuneration between a federally qualified health center and a Medicare Advantage Organization; (ii)

[1] 79 Fed. Reg. 59,717 (Oct. 3, 2014).

discounts offered to beneficiary in a "donut hole" under Medicare Part D; and (iii) free or discounted local transportation so that a beneficiary can obtain needed health care.

The proposal to expand § 1001.952(k),would allow a pharmacy to waive a PDP's a cost-sharing requirement if the pharmacy either (i) determines in good faith that the beneficiary has a financial need or (ii) fails to collect it after making reasonable efforts. The pharmacy may not routinely waive cost-sharing or mention waivers in its advertising or solicitations. The expansion of the cost-sharing waiver would also cover waiver of cost sharing for emergency ambulance services but only if the ambulance provider is owned by a State or municipality, and the waivers are offered on a uniform basis without regard to patient-specific factors.

The first of the three new proposed safe harbors would permit enrollees in Medicare Advantage (MA) plans to receive services from a federally qualified health center (FQHC) if the FQHC has a written agreement with the MA plan that provides that the MA plan will pay the FQHC no less than the level and amount of payment that the plan would make for the same services provided by another type of health care facility. The second new proposed safe harbor would permit a drug manufacturer to discount the price of an "applicable drug" that is furnished to an "applicable beneficiary" under the Medicare Coverage Gap Discount Program, as long as the manufacturer participates in and is in full compliance with all requirements of the Medicare Coverage Gap Discount Program.

The third new proposed AKS safe harbor, would if adopted, permit free or discounted transportation provided to patients, but only if:

- it is available only to established patients of the provider, and not at the outset to a new patient;
- it is determined in a manner unrelated to the past or anticipated volume or value of Medicare or Medicaid business;
- it must be provided by an "Eligible Entity" (*e.g.,* hospital) and not by entities such as a durable medical equipment supplier or pharmaceutical companies;
- it is not based on the type of treatment the patient receives;
- it is not publicly advertised or marketed to patients or potential patient referral sources;
- it is limited to local transportation (no more than 25 miles); and
- it is not "air, luxury (*e.g.,* limousine) [or] ambulance-level transportation."

The proposed rule would also require the Eligible Entity offering the transportation service to bear the costs of transportation itself, and not pass the cost along to Medicare, Medicaid, or other payors or individuals.

CIVIL MONETARY PENALITIES

Anti-Inducement Act

The OIG proposes to add exceptions to the prohibitions on offering "inducements" to Medicare or Medicaid beneficiaries when the offeror knows or should know that the inducements are likely to influence a Medicare or Medicaid patient's selection of particular providers, practitioners or suppliers. Although the AIA and the AKS both use the same operative word "remuneration," and although the OIG has never issued an advisory opinion blessing a proposed arrangement under the AIA, but not under the AKS, the OIG has nonetheless consistently taken the position that merely because an arrangement passes

muster under the AIA does not mean that it passes muster under the AKS. This was reiterated in the proposed rule and it makes no sense because even though an arrangement may be encouraged under an AIA exception, a *qui tam relator* can still claim that it is a technical violation of the AKS.

The proposed exceptions to the AIA are intended to protect certain arrangements that offer patient incentives to participate in wellness or treatment regimens or that improve or increase patients' access to care, including better care coordination. Accordingly, the OIG proposes to exclude from the definition of "remuneration" a hospital's reduction in the co-payment amounts for some or all covered outpatient department (OPD) services to no less than 20 percent of the Medicare OPD fee schedule amount. However, the hospital must meet certain conditions and requirements before doing so.

The OIG is proposing further exclusions from the definition of remuneration for certain charitable and other programs. It proposes to define "promotes access to care" as meaning that the remuneration improves a beneficiary's or a defined beneficiary population's ability to obtain medically necessary health care items and services. As examples, the OIG cites giving items that are necessary for patients to record and report health data, such as blood pressure cuffs or weight scales to those who could benefit from close monitoring of their blood pressure or weight. The OIG proposes to protect certain retailer rewards to patients, provided that the reward:

- consists of coupons, rebates or other rewards;
- is offered on equal terms to the public regardless of health insurance status; and
- is not tied to the provision of other items or services reimbursed in whole or in part by Medicare or Medicaid.

Another proposed exception is for items or services furnished for free or at less than fair market value after determining in good faith that the patient is in financial need and meets certain other criteria. The items or services have to be reasonably connected to the patient's medical care and include, by way of example:

- protective helmets and safety gear to hemophiliac children;
- pagers to alert patients with chronic medical conditions to take their drugs;
- free blood pressure checks to hypertensive patients;
- free nutritional supplements to malnourished patients with end-stage renal disease; and
- air conditioners to asthmatic patients.

The OIG notes that "financial need" does not have to be indigence, but can include "any reasonable measure of financial hardship."

Lastly, the OIG proposes to exempt waivers by a PDP sponsor of a Part D plan, or MA-PDP, of any co-payment that would otherwise be owed by their members for the first fill of a covered Part D drug that is a generic drug.

Gainsharing

A hospital that knowingly pays physicians to induce them to reduce or limit services provided to Medicare or Medicaid patients who are under the physicians' direct care are engaged in prohibited "gainsharing" under current law. The law's purpose is to prevent hospitals from paying physicians to

discharge patients too soon or otherwise taking actions that would inappropriately limit a patient's care. However, the OIG recognizes that certain types of gainsharing arrangements can be beneficial when they result in better quality of care and lower costs. The OIG notes that it looks for three types of safeguards when evaluating proposed gainsharing arrangements:

- measures that promote accountability;
- adequate quality control; and
- controls on payments that may change referral patterns.

Accordingly, the OIG intends to consider a narrower interpretation of the term "reduce or limit services" in the Gainsharing Civil Monetary Penalties regulations.

Conclusion

These are just some of the important considerations in the OIG's proposed regulatory revisions. Providers and payors, alike, should review the proposals carefully and submit their comments to the OIG by 5 p.m. on Dec. 2, 2014.

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