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HEALTH LAW

Expert Analysis

New Anti-Kickback Law 'Safe Harbors' Proposed

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Within the dense and complex Patient Protection and Affordable Care Act (ACA) are significant provisions that are intended to incentivize health care providers to furnish better quality care at lower costs, and conversely, to penalize providers for poor quality care or care that was not medically necessary. The problems of poor quality or unnecessary care were caused, in part, by the fee-for-service payment system that was in effect for generations. The fee-for-service model unfortunately offered the wrong incentives to dishonest or poor quality providers to maximize revenue by maximizing services regardless of the quality or the medical necessity of the services provided.

As our payment systems have moved away from the fee-for-service model, however, a kind of Catch-22 has developed whereby certain types of incentive payments and business arrangements that would improve the quality of care and provide needed assistance to indigent patients could actually run afoul of the federal fraud and abuse laws, including the Anti-Kickback Statute (AKS),[1] and potentially trigger their drastic penalties.

Anti-Kickback Statute

As we have discussed in previous columns, the AKS is a broadly worded law that prohibits the knowing and willful solicitation, offer, payment or acceptance of remuneration of any kind (including but not limited to kickbacks, bribes or rebates) directly or indirectly, in cash or in kind for:

- Referring an individual for a service or item covered by Medicare, Medicaid or any other federal health benefit program; or
- Purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease or order of any good, facility, service or item reimbursable under a federal health benefit program.

Violation of the AKS is a felony with penalties that include up to five years imprisonment, a $25,000 fine, and exclusion from participation in Medicare or other federal health benefit programs.

The law's very broad wording encompasses not only obvious problems like kickbacks, but also certain practices that would otherwise be perfectly legitimate and in fact would benefit patients and other program beneficiaries. Recognizing this, the statute authorizes the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) to promulgate regulations creating so-called "safe harbors" for legitimate practices that would otherwise be prohibited under the AKS.

Safe Harbors

The OIG recently issued proposed regulations[2] that would create new carefully worded safe harbors to the AKS and the Civil Monetary Penalty (CMP) provisions of the Social Security Act[3] for certain payment practices and business arrangements that will arise in connection with implementation of the ACA. In doing so, the OIG is recognizing the need for more flexibility if the implementation of the ACA's quality improvement provisions are to succeed, while also keeping a tight lid on what otherwise might easily become abusive and exploitive practices.

The proposed rule would make a technical correction to the existing safe harbor for certain paid referral services[4] and to expand the existing safe harbor permitting certain kinds of waivers of Medicare co-insurance and deductibles[5] to encompass waivers by pharmacies under 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's definition of "remuneration" (i) any remuneration between a federally qualified health center and a Medicare Advantage Organization; (ii) discounts offered to a beneficiary in the so-called "donut hole" under Part D; and (iii) free or discounted local transportation so that a beneficiary can obtain needed health care.

The proposal to expand the safe harbor for cost-sharing waivers would allow a pharmacy to waive Part D cost-sharing 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.

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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

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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 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 a pharmaceutical company;
- 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 Penalties

Unlike the AKS, which prohibits remuneration of any kind for referrals of Medicare or Medicaid patients or for the generation of business involving any item or service payable by Medicare, Medicaid or other federal health benefit programs, the Anti-Inducement Act (AIA)[6] of the CMP statute prohibits offering "inducements" to program beneficiaries when the offeror knows or should know that the inducements are likely to influence the patient's selection of particular providers, practitioners or suppliers. The OIG proposes to add new exceptions to the AIA's prohibitions.

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 who files a suit under the federal False Claims Act[7] 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.

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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. Examples of what might qualify as reasonably connected to medical care include:

- 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 Prescription Drug Plan 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 is engaged in prohibited "gainsharing" under the AKS. The intent of this prohibition 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 carefully review the new safe harbors when they are issued in final form, and hew as closely as possible to the wording of the safe harbors for maximum protection.

1. 42 U.S.C. §1320a-7b(b).
2. 79 Fed. Reg. 59717 (Oct. 3, 2014).
3. 42 U.S.C. §1320a-7a.
4. 42 C.F.R. 1001.952(f).
5. Id. at 1001.952(k).
6. 42 U.S.C. §1320a-7a(a)(5).
7. 31 U.S.C. §3729.

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