



OIG Releases Proposed Rule Expanding Anti-Kickback Safe Harbors

R. Michael Barry

On October 3, 2014, the Office of the Inspector General (“OIG”), Department of Health and Human Services, published a proposed rule that, if adopted, would make changes to 42 C.F.R. § 1001.952—the safe harbor provisions of the Federal Anti-Kickback Statute. The changes are aimed at “protect[ing] certain payment practices and business arrangements from criminal prosecution or civil sanctions under the anti-kickback statute” that “[OIG] believe[s] could be, if properly structured and with appropriate safeguards, low risk to Federal health care programs.” 79 Fed. Reg. 59,719 (October 3, 2014).

The proposed rule would include a technical correction to the existing safe harbor for referral services. In addition, the new rule would add new protections for providers by way of newly proposed safe harbors. The proposed rule includes:

- A new safe harbor protection for certain cost-sharing waivers, including:
 - Pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries; and
 - Waivers of cost-sharing for emergency ambulance services furnished by State- or municipality-owned ambulance services;
- A new safe harbor protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers;
- A new safe harbor protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- A new safe harbor protection for free or discounted local transportation services that meet specified criteria.

By modifying and adding protections, OIG states that it is fulfilling the intent of Congress to update the safe harbor regulations periodically to reflect changing business practices and technologies in the health care industry.

OIG also proposes to amend the definition of “remuneration” under the civil monetary penalty provisions of the law (42 C.F.R. § 1003) to include a wider set of statutory exceptions for:

- Copayment reductions for certain hospital outpatient department services;
- Certain remuneration that poses a low risk of harm and promotes access to care;
- Coupons, rebates, or other retailer reward programs that meet specified requirements;
- Certain remuneration to financially needy individuals; and
- Copayment waivers for the first prescription fill of generic drugs.

In addition, OIG proposes to codify the gainsharing civil monetary penalty provision in 42 U.S.C. § 1320a-7a(b), which generally prohibits a hospital from incentivizing physicians to limit services provided to Medicare or Medicaid patients with money inducements. The changes would reflect OIG’s recognition (a) that gainsharing can be beneficial under certain circumstances and (b) of the

reduced risks that come with technology that tracks the benefits of cost-saving care.

OIG's proposal would codify changes that were included in the Medicare Prescription Drug Improvement, and Modernization Act of 2003; the Balanced Budget Act of 1997; and the Affordable Care Act. Comments must be delivered by no later than 5 p.m. Eastern Standard Time on December 2, 2014.

Mr. Barry acknowledges Alex Foster who assisted in the preparation of this article. Mr. Foster is a recent graduate of the University of Virginia School of Law and an employee of Arnall Golden Gregory LLP in our Healthcare law practice. Mr. Foster is a resident in our Atlanta, Georgia office but is not yet admitted to practice.

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