

OIG Proposes Revisions to Safe Harbors and CMPs

The Department of Health and Human Services (HHS) Office of Inspector



General (OIG) recently published a proposed rule that provides new and modified regulatory safe harbors to the Anti-Kickback Statute (AKS), amends regulatory provisions related to enforcement of the Beneficiary Inducement Civil Monetary Penalty (CMP) rules, and adds a gainsharing CMP provision. The proposed rule affects a wide range of health care business arrangements including free transportation services, retailer reward programs, referral services and cost-sharing waivers. **OIG Goals** According to OIG, its goal in proposing these changes “is to protect beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk of harm associated with referral payments.” **OIG Proposed Changes** *Proposed New AKS Safe Harbors:* Designed to protect certain payment practices and business arrangements from criminal prosecution or civil sanctions, including:

- Referral services
- Reductions or waivers of cost-sharing amounts owed under federal health care programs
 - Financially needy Medicare Part D
 - Emergency ambulance services
- Remuneration between Medicare Advantage (MA) organizations and Federally Qualified Health Centers (FQHCs)
- Medicare Coverage Gap Discount Program
- Certain free or discounted local transportation services provided to federal health care program beneficiaries

Proposed Changes to the Beneficiary Inducement CMP: Intended to protect arrangements that offer beneficiaries incentives to engage in wellness or treatment regimens or that improve or increase beneficiary access to care.

- Copayment reductions for certain hospital outpatient department services (OPD)
- Certain remuneration that promotes access to care and poses a low risk of harm
- Retailer reward programs that meet certain requirements
- Financial-need-based exception

- Waivers of cost-sharing for the first fill of generic drugs

Gainsharing Updates: The OIG recognized that gainsharing can be beneficial and the rule attempts to narrow the prohibitions currently covered. It seeks comments specifically on these topics:

- Is the interpretation of the prohibition on payments to reduce or limit services as including payments to limit items used in providing services appropriate?
- Should a hospital's decision to standardize certain items be deemed to constitute reducing or limiting care?
- Should a hospital's decision to rely on protocols based on objective quality metrics for certain procedures ever be deemed to constitute reducing or limiting care?
- Should a hospital desiring to standardize items or processes as part of a gainsharing program be required to establish certain thresholds based on historical experience or clinical protocols, beyond which participating physicians could not share in cost savings?
- If "reduce or limit services" is defined, should the regulation include a requirement that the hospital and/or physician participating in a gainsharing program notify potentially affected patients about the program?

What This Means for You As a health care provider you have the ability to influence the outcome of this rulemaking. You have until December 2nd, 2014 to provide comments to the Proposed Rule. If you have questions about how these changes could affect your organization, please contact one of our experienced health care attorneys. Image: Thinkstock/belchonock *This article is very general in nature and does not constitute legal advice. Readers with legal questions should consult with an attorney prior to making any legal decisions.