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Health Law Alert: OIG Releases Proposed Revisions to Anti-Kickback Safe Harbors and Civil Monetary Penalty Rules

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HEALTH LAW ALERT: OIG RELEASES PROPOSED REVISIONS TO ANTI-KICKBACK SAFE HARBORS AND CIVIL MONETARY PENALTY RULES

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The Department of Health and Human Services Office of Inspector General (OIG) recently released a proposed rule that revises safe harbors under the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) rules regarding beneficiary inducements and gainsharing arrangements. A link to the rule can be found at the bottom of this alert. We encourage readers to submit comments about the proposed rule by Dec. 2, 2014.

Anti-Kickback Statute Safe Harbors

Under the proposed rule, the OIG announced several new safe harbors along with revisions to a number of existing safe harbors:

- *New safe harbor for local transportation services*: The OIG proposes to add a safe harbor to protect free or discounted local transportation. In the past, the OIG has generally permitted the provision of transportation that is only of nominal value ($10 per item or service or $50 in the aggregate over the course of the year). In the proposed rule, the agency recognized that these limits may be overly restrictive. The proposed safe harbor would be available only when free or discounted "local" transportation services are provided to "established patients" by "eligible entities." "Local" would be defined as a distance of 25 miles or less. The term "eligible entity" would exclude organizations, such as DME suppliers and laboratories, which primarily rely on referrals from other providers for the bulk of their business. In addition, the restriction to "established patients" means that safe harbor protection would not be available to a practice that offers free or discounted transportation to new patients. Under the proposed rule, the patient must have selected the practice and attended an appointment prior to receiving an offer for transportation. The safe harbor would not protect an offer of transportation that is based on the type of treatment a patient might receive.

- *New safe harbors for certain cost-sharing waivers*: The OIG proposes to add two new safe harbors relating to cost-sharing waivers. The first would protect cost-sharing waivers for ambulance services, a frequent topic of past OIG advisory opinions. Protection would only apply to situations in which a government unit owns and operates the ambulance provider. Ambulance providers would be required to offer the reduction or waiver uniformly. The second safe harbor would protect Part D cost-sharing waivers by pharmacies. A pharmacy would qualify for protection if three conditions are met: (1) the waiver or reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive cost-sharing; and (3) before waiving 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.
- *Other Anti-Kickback Statute Changes:* The OIG announced several other proposed changes, including a new safe harbor for Medicare Advantage organizations and federally qualified health centers; a new safe harbor for Medicare Coverage Gap Discount Program; and revisions to the referral services safe harbor.

Civil Monetary Penalty Rules

The OIG proposes a number of changes to the CMP rules, including amending the definition of "remuneration." This is important because the issue of whether the Anti-Kickback Statute or CMP is implicated by an arrangement depends first on whether any "remuneration" has been provided. The OIG proposes to add the following exceptions to the definition of "remuneration:"

- *Remuneration that promotes access to care and poses a low risk of harm:* The OIG would add an exception that protects "any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs." The term "promotes access to care" means that the remuneration improves a beneficiary's ability to obtain medically necessary health care. "Low risk of harm" means the remuneration: (1) is unlikely to interfere with or skew clinical decision-making; (2) is unlikely to increase costs through overutilization or inappropriate utilization; and (3) does not raise patient safety or quality-of-care concerns. The agency seeks comments on all of this, including whether it should expand the exception to include non-clinical care that is reasonably related to a patient's medical care (i.e. social services) and whether it should include remuneration that promotes access to care for a defined beneficiary population, rather than a particular beneficiary.
- *Coupons, rebates, or retailer rewards:* Certain rewards would also be carved out from the definition of "remuneration." To qualify, three requirements must be met. First, the items or services must consist of "coupons, rebates, or other rewards from a retailer." While these terms largely have their common sense meanings, a "rebate" is interpreted as a return of payment that could never exceed the full payment amount. Second, providers are prohibited from discriminating or cherry-picking patients on the basis of health insurance status. The items or services must be offered on equal terms to the public. Finally, the offer of items or services cannot be tied to the provision of other items or services that are reimbursable by Medicare.
- *Financial-need-based exception:* This new provision would except from the definition of "remuneration" the offer or transfer of items or services for free, or at less than fair market value, after a determination that the recipient is in financial need. The OIG proposes several limitations to this provision, including

the restriction that the items or services cannot be offered through advertisement or solicitation. In addition, the items or services could not be tied to the provision of other reimbursable services.

- *Other Proposed Changes to the CMP:* The OIG also proposed an exception that would allow waivers of cost-sharing amounts for the first fill of a generic drug, as well as reductions in copayments for covered hospital outpatient services.

The OIG also proposes to revise the CMP restriction on "gainsharing" arrangements. The gainsharing rule prohibits hospitals from knowingly paying a physician to induce the physician to reduce or limit services provided to Medicare or Medicaid beneficiaries. The OIG noted that the expansive scope of this rule is problematic and may prohibit gainsharing arrangements that are in fact beneficial and cost reducing. In an effort to narrow the reach of the rule, the OIG proposes to codify the gainsharing CMP and adopt a narrow definition of the term "reduce or limit services." The OIG does not propose specific regulatory language, but instead solicits comments as to the parameters of this provision. Hospitals and physician groups that have struggled to implement arrangements that reward cost-sharing initiatives are encouraged to provide input on how the parameters of the gainsharing CMP should be defined.

The proposed rule to revise safe harbors under the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) rules regarding beneficiary inducements and gainsharing arrangements is also available online.

If you have comments or questions regarding the proposed rule, please contact Jesse Berg at jesse.berg@lathropgpm.com (612.632.3374) or Tim Johnson at timothy.johnson@lathropgpm.com (612.632.3208).