

## HEALTH CARE LAW ALERT

### OIG Issues Year-End CMP and Anti-Kickback Regulatory Amendments and Updated Policy Statement

On December 6, 2016, the Office of Inspector General (OIG) issued two final rules which together amended the civil monetary penalty (CMP or penalty) rules and added/clarified certain of the anti-kickback law safe harbors. In addition, on December 7, 2016, the OIG updated the dollar amounts for what it will consider to be gifts of “nominal value” that need not satisfy an exception to the CMP rules.

#### **Civil Monetary Penalties**

The December 6, 2016 amendments to the CMP regulations established the following additional conduct that will subject a person or organization to possible penalties, assessments and exclusion from federal health care programs:

- Failing to grant OIG timely access to records;
- Ordering or prescribing while the person doing the ordering/prescribing is excluded from the applicable program;
- Making false statements, omissions, or misrepresentations in an enrollment application;
- Failing to report and return an overpayment; and
- Making or using a false record or statement that is material to a false or fraudulent claim.

The changes also provide an alternate methodology for calculating penalties and assessments for employing excluded individuals and clarify liability guidelines.

In addition, the definition of “remuneration” for purposes of the CMP regulations now incorporates the statutory exceptions for:

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

Finally, on December 7, 2016, in a non-regulatory written policy statement, the OIG announced that as of that date, it will consider gifts to beneficiaries with a retail value of not more than \$15 per item or \$75 in the aggregate annually per patient, to be of “nominal value” and, thus, not subject to CMP liability. The OIG last issued a determination on this topic in April of 2000, at which time it set the limits at \$10 per item and \$50 in the aggregate. The OIG reiterated, however, that the gifts in question may not be cash or cash equivalents.

### **New Anti-Kickback Safe Harbors**

The amended regulations corrected certain existing safe harbors to the anti-kickback law as well as adding new safe harbors, as follows:

- Made a technical correction to the existing safe harbor for referral services;
- Created a new safe harbor for certain beneficiary cost-sharing waivers, including:
- Pharmacy waivers of cost sharing for financially needy beneficiaries; and
- Waivers of cost sharing for emergency ambulance services furnished by State or municipality owned ambulance services.
- Created a new safe harbor for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs);
- Created a new safe harbor for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- Created a new safe harbor for free or discounted local transportation services that meet specified criteria.

The final rules are available on the Federal Register website at:

<https://www.federalregister.gov/documents/2016/12/07/2016-28293/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-the-office-of-inspector> and

<https://www.federalregister.gov/documents/2016/12/07/2016-28297/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-the-safe-harbors-under-the>.

The non-regulatory policy statement on “nominal value” is available on the OIG website at:

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>

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