OIG Finalizes New and Expanded Anti-Kickback Safe Harbors, Issues Guidance Regarding Nominal Gifts

In an uncertain health care environment following the presidential election, the Department of Health & Human Services Office of Inspector General ("OIG") finalized a new rule expanding existing safe harbors to the federal anti-kickback statute and adding new safe harbors. In describing the final rule, the OIG emphasized the importance of care coordination and elimination of barriers to patient care. The final rule was published on December 7, 2016 (81 FR 88368). On the same date, the OIG issued a bulletin regarding gifts of nominal value to Medicare and Medicaid beneficiaries.

According to the OIG, the new and amended anti-kickback safe harbors provide greater flexibility to health care providers and businesses, specifically in their ability to offer benefits that promote access to services and "efficient, well-coordinated, patient-centered care."

These safe harbors allow providers to eliminate certain barriers to care and improve access to health care services. For example, the safe harbor for local transportation will allow providers to offer free transportation or shuttle services that meet the new regulatory requirements to established patients within a 25-mile radius of the provider (or 50 miles for patients in rural areas). Being able to offer transportation to patients is expected to improve patient outcomes and reduce costs associated with inefficient care coordination, as patients who are able to travel to regular, nonemergency appointments will forego utilizing emergency rooms for basic treatment at the highest possible cost.

In addition to local transportation programs, the final rule addresses the following:

- Medicare Part D cost-sharing waivers;
- Reductions or waivers of cost-sharing for ambulance services;
- Remuneration between federally qualified health centers ("FQHCs") and Medicare Advantage plans; and
- Discounts of applicable drugs provided under the Medicare Coverage Gap Discount Program.

Local Transportation

As briefly described above, health care service providers now have greater flexibility in providing local transportation, shuttle services, or transportation vouchers to "established patients" without risk of violating the anti-kickback statute, as long as providers satisfy the following conditions.

Transportation services must be offered pursuant to a policy consistently applied by an "eligible entity." "Eligible entities" are broadly defined as "any individual or entity, except individuals or entities … that primarily supply health care items" (such as DME suppliers or pharmaceutical companies). In its commentary, the OIG confirms that health care service providers such as physicians, hospitals, home health agencies, physical therapists, and dialysis facilities are eligible entities.

Free local transportation may be offered to "established patients," defined as either "a person who has selected and initiated contact to schedule an appointment with a provider or supplier …, or who previously has attended an appointment with the provider or supplier." The OIG dropped its proposed definition of an "established patient" as a patient who had attended an appointment with the provider, recognizing that newly insured patients, FQHC patients, or patients with urgent needs may require assistance in attending their first appointment. Because the providers are prohibited from publicly marketing free transportation services (discussed below), the risk of use of transportation services as a recruiting tool for new patients is reduced, according to the OIG.

The eligible entity cannot publicly advertise or market its transportation or shuttle services. Providers may post shuttle routes and schedules, but cannot otherwise advertise local transportation or utilize its drivers as advertisers of health care services. Drivers (or others) cannot be compensated on a per-patient basis.

The safe harbor is limited to "local" transportation, defined as no more than 25 miles from the health care provider, or 50 miles if the patient resides in a rural area. Rural and urban areas are defined (by Metropolitan Statistical Area and specifically named counties) in the regulation.

Finally, the costs of the transportation services must be borne by the provider and cannot be shifted to the Medicare program, other payers, or individuals.

In response to commenters, the OIG stated that the safe harbor does not require that transportation arrangements be made in advance. A transportation program could take the form of vouchers provided to patients, rather than a fixed shuttle service or other system. Unsurprisingly, the free transportation cannot be via air, luxury, or emergency transport services.

Medicare Part D Cost-Sharing Waivers

Certain waivers of beneficiary copayments, coinsurance, and deductible amounts by pharmacies for federal health care program beneficiaries are now excluded from the definition of prohibited "remuneration" under the anti-kickback statute. Pharmacies may now waive Medicare Part D cost-sharing requirements if the following conditions are met: (1) the pharmacy does not advertise the waiver or include the waiver as part of a beneficiary solicitation; (2) the pharmacy does not waive beneficiary obligations or reduce beneficiary costs on a routine basis; and (3) the pharmacy makes a good faith, individualized determination of the beneficiary's financial need, or the pharmacy has made reasonable efforts to collect the cost-sharing amounts.

The OIG stated that the new rule would protect "certain cost-sharing waivers that pose a low risk of harm," which is expected to improve accessibility to Part D benefits.

Reductions or Waivers for Cost-Sharing for Ambulance Services

In a similar vein, a new safe harbor protects waivers of cost-sharing amounts for ambulance services. An ambulance provider may waive or reduce beneficiary cost-sharing amounts in connection with Medicare fee-for-service payments for emergency transportation if: (1) the provider is state-owned and operated (or owned and operated by a municipality or federally recognized Indian tribe); (2) the provider is enrolled as a Medicare Part B provider (or supplier); (3) the provider offers the reduction or waiver uniformly to all patients; and (4) the provider does not later claim that an amount was reduced or waived as bad debt, or otherwise attempt to shift the cost of emergency transportation.

Remuneration between FQHCs and Medicare Advantage Plans

A further revision to the definition of "remuneration" under the new rule excludes "any remuneration between a federally qualified health center (or entity controlled by such a health center) and a Medicare Advantage organization pursuant to a written agreement ..." The new language generally permits payments to FQHCs for services to patients enrolled in Medicare Advantage plans.

In response to commenters, the OIG declined to expand the safe harbor or provide further specifically permitted arrangements, while reminding stakeholders that the safe harbor for transfers of certain services, items, or goods to FQHCs, and donations or loans to FQHCs, would continue to apply.

Drug Discounts

The new rule also addresses discounts of "applicable drugs" to "applicable beneficiaries," as defined in the Medical Coverage Gap Discount Program. The Medicare Coverage Gap Discount Program permits drug manufactures to make discounts available to Medicare beneficiaries for applicable Part D drugs while the patients are in the Part D coverage gap, otherwise known as the "donut hole." Manufacturers may enter into agreements with CMS to offer these discounts.

While commenters pointed out that a regulatory safe harbor was unnecessary, as the current statutory exception for the discount program was self-implementing, the OIG nonetheless finalized this safe harbor for the sake of "completeness."

Gifts of Nominal Value

In addition to finalizing the safe harbors to the anti-kickback statute, on December 7, the OIG also issued a general policy statement regarding what constitutes a gift of "nominal value" to a federal health care program beneficiary. In 2000, the OIG stated that any gift with a retail value of no more than $10 per item or $50 in the aggregate annually per patient would be permitted and would not be considered prohibited remuneration to the beneficiary. The OIG updated those figures and now considers a gift of "nominal value" to have a retail value of no more than $15 per item and $75 in the aggregate annually per patient. The OIG bulletin reminds providers that gifts to beneficiaries cannot be cash or cash equivalents (*i.e.*, gift cards).

If you have questions about this Client Alert, please contact Andrea Musker, Rebecca Freed, or the Buchalter lawyer with whom you normally consult.

Andrea Musker is an Attorney in the Health Care Law Practice Group based in the Firm's Los Angeles office.
Direct: 213.891.5145
Email: amusker@buchalter.com

Rebecca Freed is an Attorney in the Health Care Law Practice Group based in the Firm's San Francisco office.
Direct: 415.227.3512
Email: rfreed@buchalter.com