

HEALTH CARE REGULATIONS ALERT

12/20/16

New Anti-Kickback Safe Harbors

By **Christina M. Kuta**, Associate

On December 7, 2016, the Department of Health and Human Services (HHS), Office of Inspector General (OIG), issued a final rule creating additional “safe harbors” for the Federal Anti-Kickback Statute (42 USC § 1320a-7b(b) et seq.) (AKS), which will go into effect January 6, 2017. Generally, the AKS prohibits the giving or receiving of remuneration in exchange for or to induce referrals for services and business payable by a federal health care program. The OIG has enumerated a number of “safe harbor” provisions since 1999. If an arrangement meets the requirements of a relevant safe harbor provision, any remuneration exchanged pursuant to such an arrangement is deemed not to violate the AKS.

Waivers or Reductions in Cost-Sharing by Pharmacies

This safe harbor will allow pharmacies to reduce or waive amounts owed by patients whose prescriptions are payable by a federal health care program. For patients who are eligible for subsidies under Medicare Part D, a pharmacy can offer a reduction or waiver in the patient’s out-of-pocket costs, as long as it does not advertise such a waiver or reduction or otherwise use it to solicit business. To meet the safe harbor for patients who are not eligible for subsidies, the pharmacy additionally must not *routinely* waive or reduce cost-sharing amounts and may only do so after determining in good faith that a patient has a financial need or has not made payment after collection attempts.

Emergency Ambulance Services

This safe harbor allows for reductions or waivers for “emergency” ambulance services (as defined by Medicare regulations) when the ambulance service is furnished by a government municipality or a federally recognized Indian tribe. Accordingly, privately owned ambulance providers do not qualify for safe harbor protection. The ambulance provider must offer any reduction or waiver uniformly to all transported persons without regard to a person’s financial ability, but it can decide not to apply a discount based on whether a person is a resident or non-resident of the municipality.

Shuttle Service and Local Transportation

This safe harbor allows certain entities to provide free or discounted transportation upon meeting certain requirements. Individuals or entities that supply health care items (for example, durable medical equipment providers or pharmacies) are unable to take advantage of this safe harbor, but a physician office is eligible.

A provider can offer shuttle-type service under the following circumstances:

- The shuttle is not determined to be a “luxury” or ambulance-level service;
- Availability is neither marketed nor advertised;
- No health care marketing is conducted during the transport;
- The shuttle driver is not paid on a per-person transported basis;
- The shuttle travels no more than 25 miles to its furthest stop (extended to 50 miles in rural areas); and
- The cost for shuttle service is not shifted to any federal payer

In addition to these requirements, a provider can offer non-shuttle transportation service if it also meets the following:

- Maintains a uniformly-applied policy setting forth when transportation services are provided and unrelated to the volume or value of any health care business; and
- The transportation is provided only to established patients

Remuneration Between an FQHC and Medicare Advantage

This safe harbor allows for certain payments between a Federally Qualified Health Center (FQHC) and a Medicare Advantage (MA) organization pursuant to a written agreement, as long as such payments are not less than what an MA may pay to a non-FQHC and are related to treatment of MA beneficiaries at the FQHC.

Medicare Coverage Gap Discount Program

This safe harbor provides that "remuneration," as defined in the AKS, does not include any price discounts given to certain beneficiaries for drugs under the "Medicare Coverage Gap Discount Program" (the Program). The Program allows participating manufacturers the ability to discount applicable drugs for those Medicare Part D beneficiaries who have reached the "coverage gap" or "donut hole" in their Medicare Part D coverage.

It is important to note that failure to meet a safe harbor provision does not equate to an automatic violation of the AKS. Such a determination requires a careful review of the specific arrangement at issue. We encourage you to contact one of the Roetzel attorneys listed below for a more detailed and necessary analysis of your specific circumstances, and how the AKS and other relevant regulations may apply.

Author

Christina M. Kuta
ckuta@ralaw.com

Additional Contacts

Ericka L. Adler
eadler@ralaw.com

Mazen Asbahi
masbahi@ralaw.com

Avery Delott
adelott@ralaw.com

David J. Hochman
dhochman@ralaw.com

Media Contacts

Wendy Castorena
wcastorena@ralaw.com

Ashley McCool
amccool@ralaw.com