December 2016

OIG Recognizes New Local Transportation Safe Harbor and Exceptions to CMP in Updated Fraud and Abuse Regulations

On December 7, 2016, the Department of Health and Human Services Office of Inspector General (OIG) issued a long-awaited final rule (Final Rule) that expands the safe harbor regulations under the Anti-Kickback Statute (AKS) and codifies revisions to the definition of "remuneration" under the Civil Monetary Penalties Law (CMP). The Final Rule, which takes effect January 6, 2017, establishes a new safe harbor that protects free or discounted local transportation arrangements and also provides guidance on permissible forms of remuneration under the CMP's prohibition on certain inducements to federal health care program beneficiaries (Beneficiary Inducements CMP). The Final Rule largely implements changes consistent with the OIG's 2014 proposed rule (see our analysis here) but with important substantive modifications to the requirements for local transportation arrangements.

AKS LOCAL TRANSPORTATION SAFE HARBOR

The Final Rule establishes a new AKS safe harbor that protects free or discounted local transportation made available by an "eligible entity" to federal health care program beneficiaries as long as the following conditions are met:

1. The availability of the transportation services is set forth in a policy applied uniformly and consistently and is not determined in a manner related to the past or anticipated volume or value of federal health care program business.

2. The transportation is not provided via air, luxury, or ambulance-level transportation.

3. The transportation is not publicly marketed or advertised, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers, and drivers or others arranging for transportation are not paid on a per-beneficiary-transported basis.

4. The eligible entity makes the free or discounted transportation available only to an individual who is an "established patient" of the eligible entity if the eligible entity is a provider/supplier of health care items/services and, if applicable, of the provider/supplier to or from which the patient is to be transported.

The Final Rule defines an "established patient" as any person who has selected and initiated contact to schedule an appointment or who has previously attended an appointment with the provider/supplier in question.

5. The eligible entity makes the free or discounted transportation available only within 25 miles of the provider/supplier to or from which the patient is transported, provided that, if the provider/supplier is in a "rural area," the Final Rule extends that limit to 50 miles.

The Final Rule defines rural area as any area that is not an "urban area" (an urban area is a Metropolitan Statistical Area or New England County Metropolitan Area, or the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island).

6. The eligible entity makes the free or discounted transportation available only for the purpose of obtaining medically necessary items and services, although the Final Rule also affirms that transportation back to a patient's home is protected.

7. The eligible entity bears the costs of the free or discounted local transportation and does not shift the burden of such costs onto federal health care programs, other payers, or individuals.

"Eligible entity" includes any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items (for example, durable medical equipment suppliers or pharmaceutical manufacturers). An eligible entity can be a hospital or a physician, or can also be an entity that does not directly render health care services, such as a Medicare Advantage organization or an accountable care organization.

The Final Rule separately establishes protection under this safe harbor for shuttle services providing local transportation using a set schedule and route. Shuttle services must comply with all of the requirements described above, with two important exceptions: (1) shuttle services need not be operated in accordance with a policy that is applied uniformly and consistently, although implementation of such a policy may be advisable from a risk perspective, and (2) shuttle services need not be limited to established patients or for the sole purpose of obtaining medically necessary items and services (for example, employees and/or family-members may utilize the shuttles). A shuttle service must be local, however, and will qualify if there are no more than 25 miles between any stop and any location where health care items/services are provided along the shuttle's route (in urban areas or up to 50 miles in rural areas).

ADDITIONAL NEW SAFE HARBORS

The Final Rule also recognizes new AKS safe harbors related to certain arrangements, including (1) nonroutine waivers of beneficiary cost-sharing amounts (that is, copayments, coinsurance, or deductibles) owed to pharmacies under a federal health care program as long there is an individualized determination of financial need (or failure to collect after reasonable collection efforts) and the waivers are not marketed and (2) 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 for services.

BENEFICIARY INDUCEMENTS CMP

The Final Rule also codifies regulatory exceptions to the Beneficiary Inducements CMP enacted under the Patient Protection and Affordable Care Act (ACA). The Beneficiary Inducements CMP prohibits any person from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid-payable items or services. The

ACA excepted from the definition of "remuneration" under the CMP "any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs" as well as the offer or transfer of items or services for free or less than fair market value (1) in the form of coupons, rebates, or other retailer reward programs or (2) based on financial need.

The Final Rule interprets the exception for promoting access to care to apply to items or services that (1) improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid and (2) pose a low risk of harm to Medicare and Medicaid and beneficiaries of those programs by (a) being unlikely to interfere with, or skew, clinical decision making; (b) being unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (c) not raising patient safety or quality-of-care concerns.

The Final Rule also codifies regulatory exceptions to prohibited remuneration for the offer or transfer of items or services for free or less than fair market value by a person if one of these conditions is met:

1. The items or services consist of coupons, rebates, or other rewards from a retailer; the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Medicare or Medicaid.

2. The items or services are not offered as part of any advertisement or solicitation, the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Medicare or Medicaid, there is a reasonable connection between the items or services and the medical care of the individual, and the person provides the items or services after determining in good faith that the individual is in financial need.

In the Final Rule, the OIG finalized regulatory exceptions to the definition of remuneration under the CMP for copayment reductions by hospitals for certain outpatient department services and, in coverage years starting on or after January 1, 2018, for waivers by a Part D Plan sponsor of any copayment for the first fill of a covered Part D drug that is a generic or authorized generic drug as long as such waivers are included in the benefit design package submitted to CMS.

CMP INCREASES NOMINAL VALUE INTERPRETATION FOR GIFTS TO BENEFICIARIES

Relatedly, in an OIG Policy Statement released concurrently with the Final Rule, the OIG updated its long-standing interpretation of the term "nominal value" under the CMP to increase the applicable limits on items of nominal value from the current limits of $10 per item and $50 in the aggregate per patient annually. Consequently, as of December 7, 2016, the OIG will interpret nominal value as having a retail value of no more than $15 per item and $75 in the aggregate per patient annually, provided that items of nominal value may not under any circumstances be cash or cash equivalents.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

Lisa M. Boyle | Leslie J. Levinson | Brian D. Nichols

Melissa (Lisa) Thompson | Theodore J. Tucci | Pamela H. Del Negro

Meaghan Mary Cooper | Nathaniel T. Arden | Conor O. Duffy | Erica S. Youngerman

For insights on legal issues affecting various industries, please visit our Thought Leadership page

and subscribe to any of our newsletters or blogs.

Boston | Hartford | New York | Providence | Stamford | Albany | Los Angeles | Miami | New London | rc.com

Robinson & Cole LLP