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NEW AKS SAFE HARBORS CREATE OPPORTUNITIES FOR PROVIDERS

On December 7, 2016, the Department of Health and Human Services Office of Inspector General ("OIG") released a final rule ("Final Rule") codifying new safe harbors to the Anti-Kickback Statute ("AKS") and new exceptions to the beneficiary inducement provisions of the Civil Monetary Penalties law ("CMP"). In the Final Rule, OIG focused its efforts on relaxing provisions of the AKS and CMP that prohibit health care providers from directly supporting beneficiaries either by waiving copayments, coinsurance or deductibles or by providing free or reduced price goods and services. While some of these provisions are already recognized by statute, others offer health care providers new flexibility in providing high-quality, low-cost health care to their communities. This announcement finalizes rules that CMS proposed in October 2014. Hall Render's analysis of that proposal can be found here. The Final Rule will go into effect on January 6, 2017.

In this article, we discuss the new AKS safe harbors. Hall Render's article on the new CMP exceptions can be found here.

BACKGROUND OF SAFE HARBORS

The Final Rule creates new safe harbors to the AKS. The AKS is a criminal statute that prohibits any person from offering, paying, soliciting or receiving anything of value in exchange for referring federal health care program business. Because the statute is so broadly written, Congress directed OIG to limit the AKS's reach by adopting "safe harbors" into the Code of Federal Regulations. Conduct that falls squarely within one of these safe harbors will not be subject to sanctions under the AKS, even though the conduct may potentially be capable of inducing referrals of business under federal health care programs. When new safe harbors are created, the range of permissible conduct is expanded, which creates more flexibility for health care providers. However, even if a safe harbor's elements are not satisfied, AKS liability only attaches to an arrangement where there is an actual purpose to induce referrals of federal health care program business.

DISCUSSION

The Final Rule creates five new AKS safe harbors and makes a technical correction to an existing safe harbor for referral services. If all the applicable requirements are met, the new safe harbors will protect conduct in the following areas.

- Pharmacy Cost-Sharing Waivers
- Public Ambulance Cost-Sharing Waivers
- Relationships between Medicare Advantage ("MA") Organizations and Federally Qualified Health Centers ("FQHCs")
- Medicare Coverage Gap Discount Programs
- Free or Subsidized Local Transportation Services

Of these, the Pharmacy Cost-Sharing Safe Harbor, the MA Organizations and FQHCs Safe Harbor and the Medicare Coverage Gap Discount Program Safe Harbor all existed already in statute. However, in adopting them as regulations as well, OIG directly responded to questions from the industry regarding how they will be interpreted and implemented. OIG relied on its general authority to protect low-risk, high-impact business arrangements when it created the Public Ambulance Cost-Sharing Safe Harbor and the Local Transportation Safe Harbor.

Each of these new safe harbors is discussed in more detail below.

Pharmacy Cost-Sharing Safe Harbor

The new Pharmacy Cost-Sharing Safe Harbor protects pharmacies that waive financially needy beneficiaries' coinsurance, copayment or deductible payments for drugs that are covered under a federal health care program (including both Medicare and Medicaid). It is important to note that this new safe harbor specifically applies to drugs provided by pharmacies; it cannot be relied upon by, for example, physicians (who often provide beneficiaries with drugs covered under Medicare Part B).

The Pharmacy Cost-Sharing Safe Harbor applies only to unadvertised, non-routine waivers granted on an individualized basis. Pharmacies should consult with legal counsel before adopting a cost-sharing waiver program based on the Pharmacy Cost-Sharing Safe Harbor because

there remains significant ambiguity in how it will be implemented. For instance, OIG declined to clarify when waivers occur frequently enough to be considered "routine," nor did it provide a uniform method for measuring a patient's financial need. Since practices that fall outside of any safe harbor could lead to criminal sanctions as long as the requisite intent is present, it is important to ensure that a pharmacy's program fits squarely within the safe harbor.

Public Ambulance Cost-Sharing Safe Harbor

Under the Public Ambulance Cost-Sharing Safe Harbor, state, municipal and tribal ambulance providers and suppliers (collectively, "Ambulance Providers") may reduce or waive beneficiaries' cost-sharing obligations for emergency services payable by a federal health care program on a fee-for-service basis. The reduction or waiver must be offered uniformly to all of the Ambulance Provider's residents or tribal members or to all individuals that the Ambulance Provider transports, and the cost of the waiver cannot be shifted to the federal government or any other individual or payer.

While the Public Ambulance Cost-Sharing Safe Harbor is limited in its scope, it could be a means for public entities that directly operate their own ambulance services to reduce the cost of those services to their community members. While the safe harbor is unlikely to apply to private entities providing ambulance services on behalf of public entities, OIG did not foreclose the possibility that a relationship between a private ambulance provider and a public entity may be structured so that it is not covered by the AKS at all.

MA Organizations and FQHCs Safe Harbor

The MA Organizations and FQHCs Safe Harbor, created in statute by the 2003 Medicare Prescription Drug, Improvement, and Modernization Act, protects any remuneration between an FQHC and an MA Organization pursuant to a written agreement between them. While affected organizations may already be utilizing the statutory safe harbor, OIG helped to better define its limits in the Final Rule. Under their written agreement, the MA Organization must provide the FQHC with a payment for services that is at least as much as it would provide to a non-FQHC but does not set a maximum limit on such payments. Furthermore, this safe harbor only protects monetary payments related to treatment for MA enrollees; in-kind goods, services and space unrelated to enrollees' treatments are not contemplated under the statue and are therefore not protected by the safe harbor. If the arrangement between them is properly structured, MA Organizations and FQHCs may utilize this safe harbor to inject additional funds into the FQHC to improve the quality of care for the community.

Medicare Coverage Gap Discount Program Safe Harbor

The Medicare Coverage Gap Discount Program ("Program") and its attendant safe harbor were established by the Affordable Care Act in 2010. Like the other safe harbors that were created in statute, OIG's codification of the Medicare Coverage Gap Discount Program Safe Harbor helps to define its limits and clarifies a path forward for providers. The Program makes manufacturer discounts available to eligible Medicare beneficiaries receiving applicable, covered Part D drugs while the beneficiaries are in the Part D coverage gap. In codifying this safe harbor, OIG limited the scope of its earlier proposal that drug manufacturers must be in full compliance with all requirements of the Program in order to receive the benefits of the safe harbor. OIG recognized that minor, technical or temporary noncompliance with the Program's requirements should not preclude safe harbor protection and removed the requirement that manufacturers be in "full" compliance.

Local Transportation Safe Harbor

Unlike several of the other safe harbors adopted in the Final Rule, the Local Transportation Safe Harbor was not already created in statute before OIG proposed it in 2014. In short, the safe harbor protects local, non-ambulance, non-luxury transportation provided to existing patients for the purpose of obtaining medically necessary services. Transportation may be provided on an as-needed basis or as a shuttle service. The Local Transportation Safe Harbor presents an opportunity for providers to help their patients get to their appointments, provided the requirements of the safe harbor are met.

PRACTICAL TAKEAWAYS

- The new AKS safe harbors are valuable tools for Medicare-enrolled entities to use when developing strategies for reducing the cost of care to patients, especially low-income patients.
- Although some of the safe harbors were already available to providers through the applicable statutes, their codification and OIG's commentary on them helps to ensure that providers will structure them appropriately under the law.

- While the four other new safe harbors are aimed at particular segments of health care providers, the Local Transportation Safe Harbor presents an opportunity for a wide range of Medicare-enrolled entities to reduce the cost of care for their patients and ensure that they receive regular, prompt care.

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