

OIG Creates New AKS Safe Harbors, Codifies Others

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On January 6, 2017, two new safe harbors to the federal anti-kickback statute (the “AKS”) will become effective pursuant to a final rule published by the United States Department of Health and Human Services Office of the Inspector General (the “OIG”) on December 7, 2016. The final rule also codifies safe harbors for certain AKS exceptions and makes a technical correction to the existing safe harbor for referral services. The OIG is authorized to promulgate safe harbors to protect various business arrangements from criminal prosecution under the AKS even though the arrangements potentially may be capable of inducing referrals of federal health care program business. The final rule as published in the Federal Register is available [here](#).

New Safe Harbors Created

The two new safe harbors share a focus on making medical-related transportation more affordable. The first new safe harbor protects reductions or waivers of a federal health care program beneficiary’s obligation to pay copayment, coinsurance or deductible (“cost-sharing”) amounts for emergency ambulance services provided by a state-, municipality- or tribal-owned ambulance supplier and paid for under a fee-for-service payment system if specified requirements are satisfied (e.g., the reduction or waiver must be offered on a uniform basis to all residents, tribal members or transported individuals). See 42 C.F.R. § 1001.952(k)(4). The second new safe harbor protects free or discounted local transportation provided by an “eligible entity” (i.e., any individual or entity, except for individuals or entities that primarily supply health care items) to federal health care beneficiaries in the form of a “shuttle service” if certain conditions are met. See 42 C.F.R. § 1001.952(bb).

AKS Exceptions Codified as Safe Harbors

The final rule also protects certain pharmacy reductions or waivers of cost-sharing amounts (see 42 C.F.R. § 1001.952(k)(3)), remuneration between a federally qualified health center (“FQHC”) and a Medicare Advantage (“MA”) organization and (see 42

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C.F.R. § 1001.952(z)), and discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program (see 42 C.F.R. § 1001.952(aa)).

Focus on Safe Harbor for Pharmacy Cost-Sharing Waivers

While all of the safe harbors are noteworthy, some additional commentary on the scope and requirements of the safe harbor for pharmacy cost-sharing waivers is warranted.

- First, the scope of the final rule's pharmacy cost-sharing waiver safe harbor includes both the Medicare Part D program and the Medicaid program, whereas the similar AKS statutory exception covers only Medicare Part D.
- Second, the OIG clarified in its comments to the final rule that the safe harbor requirement that the reduction or waiver not be part of an "advertisement or solicitation" would be violated by a pharmacy posting information on its Web site regarding the reduction or waiver, but generally would not be violated by responding to an inquiry from a particular patient in person.
- Third, with respect to the safe harbor requirement that the reduction or waiver not be "routine," the OIG stated in its comments that what is "routine" depends on the facts and circumstances of a particular case but that giving a reduction or waiver could be common enough without being automatic and still be routine.
- Fourth, the OIG declined to specify any particular method of determining whether a beneficiary has a "financial need," permitting pharmacies flexibility, by way of examples, to use a multiple of the poverty guidelines or to use a combination of the poverty guidelines plus family medical expenses. The key to satisfying the requirement is that the pharmacy must apply a reasonable determination method of financial need uniformly. And while not requiring a written policy describing the pharmacy's determination method, the OIG did say that having such a written policy, along with evidence that the policy was followed, would be "useful" in asserting the safe harbor's protection.
- Fifth, if a patient is not in financial need then the pharmacy must make "reasonable collection efforts" before waiving the cost-sharing amount. The OIG recognized in its comments that the amount of the copayment or the historical inability to collect from a particular patient might be factors in a pharmacy's decision regarding what collection efforts to take. However, a preemptive decision by a pharmacy not to request payment from, or not to pursue any collection efforts regarding, a particular patient would not satisfy this requirement.

Parties intending to fit within a particular safe harbor are advised to review all of the applicable requirements. In addition, as illustrated by the discussion of the safe harbor for pharmacy cost-sharing waivers above, reviewing the OIG's responses to comments in the final rule can help interpret the regulatory language.