

HHS OIG Adopts New Anti-Kickback Safe Harbor and Civil Monetary Penalty Exceptions

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On December 7, 2016, the Department of Health and Human Services (HHS), Office of Inspector General (OIG), issued a final rule that will have a widespread impact on health care service providers, medical transport providers, drug manufacturers and pharmacies, among others. The final rule creates additional safe harbors under the anti-kickback statute and revises the definition of "remuneration" under the civil monetary penalties rules. These new provisions enhance the ability of providers to implement programs to eliminate barriers to care. The final rule will take effect on January 6, 2017.

Revisions to the Anti-Kickback Statute

The anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce or reward the referral of business reimbursable under Federal health care programs. Because the statute could cover potentially innocuous commercial arrangements, Congress carved out certain "safe harbors" to describe practices that would not be subject to criminal penalties, and OIG has promulgated additional safe harbors.

Changes to Existing Safe Harbor for Cost-sharing Waivers

The safe harbor regulations enumerated at 42 C.F.R. §1001.952(k) include exceptions to the term "remuneration," allowing the waiver or reduction of certain patient cost-sharing obligations. Previously enacted cost-sharing waiver exceptions include waivers for some amounts owed to a hospital for inpatient hospital services, and amounts owed by individuals who qualified for subsidized services or amounts paid to federally qualified health care centers or certain other qualified health care facilities. The December 2016 final rule expands these existing safe harbors, which previously covered cost-sharing waivers issued to Medicare or State health program beneficiaries, to cover cost-sharing waivers issued to all Federal health care program beneficiaries, which includes Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), TRICARE, the Veterans Health Administration (VHA) program, and the Indian Health Service (IHS) program.

The December 2016 final rule also adds two new exceptions to the term "remuneration" for cost-sharing waivers by pharmacies and emergency ambulance services, along with three other safe harbors, discussed below.

Waivers or Reductions by Pharmacies

The final rule allows for pharmacies to reduce or waive cost-sharing amounts imposed under a Federal health care program if the waivers or reductions are not offered as part of an advertisement or solicitation. The ban on advertisement and solicitation is intended to deny safe harbor protection for potentially abusive steering arrangements. Waivers or reductions offered to certain individuals eligible for Medicare Part D subsidies need only meet the no-advertising, no-solicitation requirement to fall within this safe harbor. For waivers or reductions offered to individuals not eligible for subsidies, the pharmacy must meet several additional requirements. It must not routinely waive or reduce cost-sharing amounts, and must only waive the cost-sharing amounts "after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts." Providers should note that this rule only applies to pharmacies, and thus would not allow a physician to waive cost-sharing for Part B drugs.

For beneficiaries who are not already receiving subsidies, pharmacies will have to formulate their own financial need assessments under this rule and also make "reasonable collection efforts." The guidelines from the final rule state that providers must "make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases." To comply with this provision of the rule, pharmacies should either institute or clarify an existing written policy and provide training to personnel involved in cost-sharing waivers. Reasonable collection efforts are "those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients."

Waivers or Reductions for Emergency Ambulance Services

The final rule also allows for cost-sharing reductions or waivers for emergency ambulance services. This safe harbor extends only to emergency ambulance services furnished by a state, municipality, or federally recognized Indian tribe. After commenters pushed for amounts owed under Medicaid and other Federal health care programs to be covered, the final rule expanded the application of the safe harbor as requested.

Unlike the pharmacy cost-sharing waivers, waivers for emergency ambulance services must not take into account insurance or financial status of the beneficiary. In addition, the ambulance provider must not shift costs to a Federal health care program: for example, by upcoding services or providing medically unnecessary services. The safe harbor only applies to emergency services; nonemergency transportation was deemed too high of a risk to be protected by the safe harbor.

Free or Discounted Shuttle Service and Local Transportation

The final rule also adopts a new safe harbor that will allow eligible entities to provide free or discounted local transportation or shuttle services as long as they meet the requirements of 42 C.F.R. § 1001.952(bb). An eligible entity is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items, such as durable medical equipment suppliers, pharmaceutical companies and pharmacies. The final rule breaks down transportation into two categories: (i) transportation in the form of a "shuttle service" provided by an eligible entity, and (ii) other transportation offered to Federal health care program beneficiaries.

For shuttle services, the shuttle must not be air, luxury, or ambulance-level transportation; it must not be marketed or advertised; no marketing of health care items and services may occur during the ride; the driver must not be paid on a per-beneficiary-transported basis; the distance between the farthest stops must not be more than 25 miles or 50 miles in a rural area; and the eligible entity should not engage in cost-shifting onto any Federal health care program or other payer.

In order to offer transportation to Federal health care program beneficiaries, eligible entities must meet five requirements. First, the availability of the free or discounted local transportation services must be set forth in a policy, applied uniformly and consistently and not determined in a manner related to volume or value of Federal health care business. Second, the transportation must not be air, luxury, or ambulance-level transportation. Third, the eligible entity must not market or advertise the transportation services, nor may it market health care items and services during the course of transportation. Drivers cannot be paid on a per-beneficiary-transported basis. Fourth, the eligible entity must only make the transportation available to established patients.

With respect to the fourth requirement, an established patient includes an established patient of the eligible entity providing the transportation, where the eligible entity is a provider or supplier of health care services. It also includes an established patient of the provider or supplier to or from which the individual is being transported. Patients can be considered "established" as early as when they contact the provider or supplier on their own initiative. Providers must not, however, reach out to a new patient offering services coupled with free transportation. The destination must be within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area. Fifth, the eligible entity that makes the transportation available must bear the cost of the transportation services and not shift the burden onto Federal health care programs, other payers, or individuals.

In practice, hospitals and other eligible entities will be able to provide some forms of transport services for their patients without fear of violating the anti-kickback statute, so long as they meet the applicable safe harbor requirements laid out above.

Protected Remuneration between FQHCs and Medicare Advantage

The final rule establishes another safe harbor that will protect any remuneration between a federally qualified health center (FQHC) (or an entity controlled by such a health center) and a Medicare Advantage (MA) organization pursuant to a written agreement required by § 1853(a)(4) of the Social Security Act. To comply with § 1853(a)(4), the payment to the FQHC must not be less than the level and amount of payment that the MA organization would make to a non-FQHC entity. Note that the statute does not include a fair market value requirement. Relationships between FQHCs and third-party entities may qualify for the remuneration exception if they are consistent with requirements of § 1853(a)(4). Remuneration between an FQHC and an independent practice association (IPA) would fall within the safe harbor in a situation where the IPA stands in the shoes of the MA organization pursuant to an indirect contract arrangement.

Provision of free space by the FQHC to the MA organization would not be covered by the safe harbor, because arrangements must be related to MA plan enrollees being treated at the FQHC. Similarly, financial support from the MA to the FQHC for outreach services or infrastructure costs, for example, would not be covered.

Medicare Coverage Gap Discount Program

The final rule creates a new safe harbor that supplements the already-existing statutorily-based Medicare Coverage Gap Discount Program, which allows prescription drug manufacturers to enter into an agreement with the Secretary of HHS to provide access to discounts on drugs at the point of sale. "Applicable drugs" furnished to "applicable beneficiaries" under the Medicare Coverage Gap Discount Program will not be considered remuneration. The safe harbor cross-references the definitions of "applicable drug" and "applicable beneficiary" as listed at § 1860D-14A of the Social Security Act.

The December 2016 final rule modifies the proposed rule by requiring that manufacturers be "in compliance with the requirements of the Medicare Coverage Gap Discount Program," rather than "in full compliance with all requirements" of the program. OIG states that "minor, technical instances of non-compliance should not preclude safe harbor protection," allowing manufacturers some flexibility with respect to minor violations of the program, such as missing a payment deadline by one day. However, "[a] manufacturer that knowingly and willfully provided discounts without complying with the requirements of the Medicare Coverage Gap Discount Program could be subject to sanctions, unless such discounts are protected by another safe harbor."

Technical Revision of the Anti-Kickback Statute

The final rule makes a technical correction to the safe harbor found at 42 C.F.R. § 952(f), pertaining to referral services. The language was changed inadvertently in 2002 to say ". . . business otherwise generated by either party *for the referral service* . . ." and is now changed back to the 1999 language, ". . . business otherwise generated by either party *for the other party*" (emphases added).

Civil Monetary Penalties

The civil monetary penalties law authorizes the Secretary of HHS to impose penalties and assessments on persons who defraud Medicare or Medicaid or engage in certain other prohibited conduct. Such conduct could lead to those persons or entities being excluded from Federal health care programs (a term that includes State health care programs). The December 2016 final rule applies to one specific provision of the civil monetary penalties, which imposes penalties on any person who "offers to or transfers remuneration to any individual eligible for benefits" under a Federal health care program "that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part" by a Federal health care program.

The December 2016 final rule carves out five new exceptions to the definition of remuneration in the provision above.

Reduction in Copayment for Certain Outpatient Services

The rule adds a straightforward cost-sharing exception that allows for reduction in the copayment amount for covered outpatient department services under § 1833(t)(8)(B) of the Social Security Act. This cost-sharing exception adds to the already-existing regulation that allows for differentials in coinsurance and deductible amounts as part of a benefit plan design for the payers of such amounts, with any differentials disclosed in writing to all beneficiaries, third party payers and providers. The foregoing safe harbor does not apply to physician practice billing.

Remuneration That Poses a Low Risk of Harm and Promotes Access to Care

A provider can avoid civil monetary penalties when it provides items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. The inclusion of "items and services" revises the earlier proposed language, "medically necessary health care items and services." However, OIG stated it will not permit remuneration that would be likely to influence a patient to access unnecessary care. For example, cash and cash equivalents would not meet the criteria for the exception. Importantly, the items or services provided need not be items or services that are eligible to be paid by Medicare or Medicaid. Therefore, nonclinical items that improve a beneficiary's access to Federal health services could be eligible. Examples listed include telemedicine capability, health and wellness-related technology, smartphone applications, home monitoring devices, nutritional services, health and wellness coaching, Internet classes, and discount programs that tie health and wellness achievements to the receipt of retail items and services.

The items or services provided must be analyzed in accordance with several factors listed in the regulations. Namely, the items and services must (i) be unlikely to interfere with, or skew, clinical decision making, (ii) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization, and (iii) not raise patient safety or quality-of-care concerns.

Retailer Rewards and Discounts

Retailers may offer or transfer items or services for free or less than fair market value, without being subject to civil monetary penalties. The items or services must consist of coupons, rebates, or other rewards from a retailer; must be offered or transferred on equal terms available to the general public, regardless of health insurance status; and must not be tied to the provision of other items or services reimbursed in whole or in part by a Federal health care program.

The preamble to the final rule states that remuneration need not be of "nominal value" to fall under this category, but also that remuneration of "nominal value" might not meet the criteria of the exception if, for example, it is tied to the provision of items or services reimbursed by a Federal health care program.

Remuneration to Financially Needy Individuals

The regulations also provide for a financial-need-based exception to the definition of remuneration. There may be some overlap between this provision and the exception for remuneration that poses a low risk of harm and promotes access to care. Under this provision, a person may offer or transfer items or services for free or less than fair market value if: the items or services are not offered as part of an advertisement or solicitation and are not tied to the provision of other items or services reimbursed in whole or in part by a Federal health care program; there must be a reasonable connection between the items or services and the medical care of the individual; and the person providing the items or services must determine in good faith that the individual is in financial need.

Similar to the anti-kickback safe harbor revision, OIG does not provide a uniform measure of need or threshold of assistance, and states that the determination of financial need should be done on an individual basis. No specific documentation is required, but a written policy would prove useful for a provider or supplier in any relevant investigation.

Copayment Waivers for the First Fill of Generic Drugs

A Medicare Part D Plan sponsor may waive any copayment for the first fill of a covered Part D drug that is either a generic drug or an authorized generic drug, as long as the waiver is included in the benefit design package submitted to CMS. The authorized generic drug exception was added between the proposed rule and the final rule. It is important to note that this is the only regulation that will apply beginning with coverage on or after January 1, 2018; the other regulations take effect on January 6, 2017.

Conclusion

The final rule provides greater legal certainty and flexibility for a variety of providers interested in eliminating barriers to care, especially those facing low-income patients.

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