OIG Implements New Anti-Kickback Statute Safe Harbors and Civil Monetary Penalty Regulations

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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 to implement revisions to certain Anti-Kickback Statute (AKS) safe harbors, as well as revisions to the regulations corresponding to the Civil Monetary Penalties Law (CMPL).[1] Most importantly, the final rule adds five new AKS safe harbors, as well as five new exceptions to the CMPL. These new regulations and safe harbors become effective on January 6, 2017.

New AKS Safe Harbors

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program, and defines "remuneration" broadly to include the transfer of anything of value.[2] A violation of the AKS can also lead to liability under the False Claims Act (FCA)[3] and CMPL,[4] as well as exclusion from federal healthcare programs.[5] However, since 1991, the OIG has promulgated a series of safe harbor regulations to define practices that do not result in AKS violations given the unlikelihood of any fraud and abuse implications.[6] The OIG's regulatory AKS safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. In an effort to ensure that the safe harbors "evolve with changes in the health care system," the OIG published, as part of its December 7 final rule, five new AKS safe harbors.

A. Cost Sharing Waivers

As an initial matter, the final rule republishes subsection (k) of 42 C.F.R. § 1001.952 (the AKS safe harbor regulations) to expand the applicability of the safe harbor for the "waiver of beneficiary coinsurance and deductible amounts" to all Federal health care programs.[7] Moreover, the first two new safe harbors established by the final rule fall under the provisions relating to the waiver and cost-sharing reduction provisions of subsection (k). These two new safe harbors establish protections for: (i) Medicare Part D cost-sharing waivers; and (ii) cost-sharing reductions or waivers for emergency ambulance services.[8]

- Part D Cost-Sharing Waivers

For a pharmacy waiving a Medicare beneficiary's Part D cost-sharing payments, the new safe harbor provides protection to the pharmacy if: (a) the waiver or reduction is not advertised or part of a solicitation; (b) the pharmacy does not routinely waive or reduce the cost-sharing; and (3) before waiving or reducing the cost-sharing, the pharmacy either determines in good faith that the beneficiary is in financial need or the pharmacy fails to collect the cost-sharing amount after

1 81 Fed. Reg. 88368 (Dec. 7, 2016).
2 42 U.S.C. § 1320a-7b(b).
3 *Id.* at § 1320a-7b(g).
4 42 U.S.C. § 1320a-7a(a)(7).
5 42 U.S.C. § 1320a-7(b)(7).
6 *See* 42 C.F.R. § 1001.952.
7 81 Fed. Reg. 88368, 88371.
8 *Id.* at 88371-88377.

making a reasonable effort to do so.[9] However, the OIG notes that if such waiver or cost-sharing reduction is made on behalf of an individual eligible for a Part D subsidy (as defined by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003),[10] then conditions (b) and (c) above are not required.[11] Moreover, by finalizing a safe harbor that protects reductions or waivers by pharmacies of all Federal health care program cost sharing, the new safe harbor provides protection to pharmacies beyond waivers or cost-sharing reductions for only Part D beneficiaries. The OIG cautions, however, that "[t]his safe harbor permits pharmacies to waive cost-sharing on an unadvertised, nonroutine basis after an individualized determination of financial need (or a failure to collect after reasonable collection efforts)."[12] Thus, the safe harbor is "not meant to, and would not, protect waivers that are advertised as part of a 'program' to waive copayments."[13]

- Cost-Sharing Reductions or Waivers for Emergency Ambulance Services

The second new safe harbor created under subsection (k) applies to reductions or waivers of cost-sharing owed for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and meet the following conditions:

- the ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program;
- the ambulance provider or supplier engaged in an "emergency response;"
- the ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported, without regard to patient-specific factors; and
- the ambulance provider or supplier does not later claim the amount reduced or waived as bad debt or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.[14]

Although some commenters to the final rule requested that the OIG expand the safe harbor's protections to include nongovernmental ambulance providers in certain circumstances, the OIG declined such extension.[15] However, the OIG did note that "when a State or municipality contracts with a private ambulance company, and the State or municipality uses its residents' tax dollars to pay the ambulance company an amount that is actuarially equivalent to the residents' copayments, the [AKS] would not be implicated."[16] Where the AKS is not implicated, no safe harbor is required.

B. Federally Qualified Health Centers and Medicare Advantage Organizations

The third safe harbor added by the OIG protects "any remuneration between a federally qualified health center [FQHC] (or any entity controlled by such health center) and a Medicare Advantage organization pursuant to a written agreement described in section 1853(a)(4) of the [MMA]."[17] As noted in the final rule, section 1853(a)(4) of the MMA "generally describes the payment rule for FQHCs that provide services to patients enrolled in MA plans that have an agreement with the FQHC."[18]

In addressing one commenter, the OIG further notes that this new safe harbor does not protect "all remuneration" that the parties might exchange.[19] For example, the provision of free office or conference room space by the FQHC to the

9 *Id.* at 88371.
10 Pub. L. No. 108-173.
11 81 Fed. Reg. 88368, 88371.
12 *Id.* at 88372.
13 *Id.*
14 *Id.* at 88408.
15 *Id.* at 88375.
16 *Id.* (citing OIG Advisory Opinion No. 13-11 as an example).
17 *Id.* at 88377 (codified at 42 C.F.R. § 1001.952(z)).
18 *Id.*
19 *Id.* at 88378.

MA organization would not be protected because the safe harbor "protects payments related to FQHCs treating MA plan enrollees, not arrangements unrelated to MA plan enrollees being treated at the FQHC.[20]

C. Medicare Coverage Gap Discount Program

Under the Medicare Coverage Gap Discount Program (established by the Affordable Care Act (ACA) in 2010), prescription drug manufacturers enter into an agreement with HHS to provide certain beneficiaries access to discounts on drugs at the point of sale.[21] The ACA itself provides protection for such discounts, which the OIG has now incorporated into its safe harbor regulations.[22] Specifically, the regulations now include protection for "a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program" so long as the following conditions are met: (a) the discounted drug meets the definition of "applicable drug" as set forth in the ACA;[23] the beneficiary receiving the discount meets the definition of "applicable beneficiary;"[24] and (c) the manufacturer of the drug participates in, and is in compliance with the requirements of, the Medicare Coverage Gap Discount Program.[25]

D. Local Transportation

The final AKS safe harbor added by the OIG's recent final rule protects "free or discounted local transportation" made available by an "eligible entity" either to Federal health care program beneficiaries (if all conditions are met) or in the form of a "shuttle service" (if all conditions are met).[26] For purposes of this safe harbor, "eligible entity" is defined as "any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items."[27]

In order for an eligible entity to provide such free or discounted local transportation services to Federal health care program beneficiaries, the following conditions must be met:

- the availability of the free or discounted local transportation services—
  - is set forth in a policy, which the eligible entity applies uniformly and consistently; and
  - is not determined in a manner related to the past or anticipated volume or value of Federal health care business;
- the free or discounted local transportation services are not air, luxury, or ambulance-level transportation;
- the eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;
- the eligible entity makes the free or discounted transportation available only:
  - to an individual who is either: (1) an established patient of the eligible entity providing the free or discounted local transportation, if the eligible entity is a provider or supplier of health care services; and (2) an established patient of the provider or supplier to or from which the individual is being transported;
  - 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; and
  - for the purpose of obtaining medically necessary items and services;

20 *Id.*
21 *Id.*; see also 42 U.S.C.A. § 1395w-114a (the Medicare Coverage Gap Discount Program).
22 81 Fed. Reg. 88368, 88378.
23 *See* 42 U.S.C.A. § 1395w-114a(g)(2) (providing the definition for "applicable drug").
24 *See id.* at § 1395w-114a(g)(1) (providing the definition for "applicable beneficiary").
25 81 Fed. Reg. 88368, 88378 (codified at 42 C.F.R. § 1001.952(aa)).
26 *Id.* at 88379 (codified at 42 C.F.R. § 1001.952(bb)).
27 *Id.*

- the eligible entity that makes the transportation available bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto any Federal health care programs, other payers, or individuals.[28]

As used in the safe harbor, "established patient" means "a person who has selected an initiated contact to schedule an appointment with a provider or supplier to schedule an appointment, or who previously has attended an appointment with the provider or supplier."[29]

In order for an eligible entity to provide such free or discounted local transportation services in the form of a "shuttle service," the following conditions must be met:

- the shuttle service is not air, luxury, or ambulance-level transportation;
- the shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;
- the eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area (as that term is defined in the safe harbor regulations), the distance may be up to 50 miles between that stop and all providers or suppliers on the route; and
- the eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.[30]

Comments to the newly-added "local transportation" safe harbor highlighted the benefits for the many beneficiaries who cannot drive or take public transportation after a procedure, or who may be isolated or homebound patients.[31] However, the OIG cautioned that the conditions set forth in the regulations should be closely followed by any eligible entity that provides such transportation services.[32]

II. New CMP Regulations

In addition to the new AKS safe harbors outlined above, the OIG further established new protections under the CMPL regulations pertaining to beneficiary inducements. In doing so, the OIG noted the differences between what beneficiary inducements the CMPL prohibits, in contrast to the AKS and other fraud and abuse laws. First, the CMPL prohibits inducements only to Medicare and State health care program beneficiaries.[33] Additionally, the CMPL prohibits inducements to those beneficiaries only if the offeror knows or should know the inducement is likely to influence the beneficiary to receive a reimbursable service from a particular provider, practitioner, or supplier.[34] Whereas the AKS prohibits the provision of remuneration in exchange for referrals (i.e., to induce beneficiaries to order an item or service), the CMPL "is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner, or supplier."[35]

The new regulations exclude from the CMPL's definition of "remuneration" the following types of payments or programs:

28 42 C.F.R. § 1001.952(bb)(1).
29 *Id.*
30 42 C.F.R. § 1001.952(bb)(2).
31 81 Fed. Reg. 88368, 88379.
32 *Id.*
33 42 U.S.C.A. § 1320a-7a.
34 *Id.*
35 81 Fed. Reg. 88368, 88390.

- Differentials in coinsurance and deductible amounts as part of a benefit plan design;
- A reduction of copayments by hospitals for certain outpatient department (OPD) services;
- 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 by—
    - Being unlikely to interfere with, or skew, clinical decision making;
    - Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
    - Not raising patient safety or quality-of-care concerns;
- The offer or transfer of items or services for free or less than fair market value if certain conditions are met;
- Waivers of copayment obligations for the first fill of generic drugs covered by Medicare Part D.[36]

By removing these payments and programs from the definition of "remuneration," the OIG has afforded such payments and programs protection from the CMPL, assuming all conditions are met.

III. Conclusion

In an effort to stay up-to-date with current health care trends, and to address concerns and questions received from providers, the OIG established new protections for certain payments and programs under both the AKS safe harbor regulations and the CMPL regulations. However, in order to remain compliant, health care providers and other entities seeking to implement or establish such programs should carefully review the necessary conditions and requirements, and should closely follow the language promulgated by the OIG.

36 *Id.* at 88409 (codified at 42 C.F.R. § 1003.110).

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