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OIG Expands Protections Under the Anti-Kickback Safe Harbors and the CMP Exceptions

On December 7, 2016, the Department of Health and Human Services Office of the Inspector General (OIG) published a final rule (Final Rule) [1] that amends the safe harbors to the federal Anti-Kickback Statute (AKS) [2] by modifying an existing safe harbor, adding new safe harbors and codifying existing statutory provisions that provide further protections from sanctions under the AKS with respect to certain payment practices and business arrangements.

The Final Rule also amends the exceptions to the civil monetary penalty rule [3] (CMP) regarding beneficiary inducements by codifying revisions to the definition of "remuneration" added by the Balanced Budget Act of 1997 [4] and the Patient Protection and Affordable Care Act, as amended (ACA) [5].

The Final Rule expands AKS and related CMP protections by: (1) extending the existing AKS cost-sharing safe harbor to pharmacies and emergency ambulance services; and (2) adding new safe harbors for: (a) arrangements between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs), (b) certain manufacturer drug discounts and (c) qualifying free or discounted local transportation.

Background on AKS and Safe Harbors

The AKS prohibits offering, paying, soliciting or receiving any "remuneration" in exchange for, or to induce, the referral of a patient for items or services covered by Medicare, Medicaid or other state health programs. The prohibition applies regardless of whether the remuneration is provided directly or indirectly, overtly or covertly, in cash or in kind. In addition, the Anti-Kickback Statute prohibits the solicitation or receipt of any remuneration in return for the activities described above. Because the AKS on its face is so broad, many relatively innocuous commercial arrangements could be viewed as violating the AKS. Thus, as part of the Medicare and Medicaid Patient and Program Protection Act of 1987, Congress directed the OIG to promulgate regulations specifying payment practices that will not be treated as criminal offenses under the AKS and will not provide a basis for exclusion from Medicare, Medicaid or other federal healthcare programs. The resulting regulations, referred to as the "safe harbor rules" [6], were intended to give guidance and comfort to providers who engage in certain narrowly prescribed business practices that Congress did not intend to prohibit by the AKS and, in some instances, should be encouraged by the federal government.

Background on CMP Exceptions

In 1981, Congress enacted the Civil Monetary Penalty Law (CMPL), [7] as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The CMPL authorized the Secretary to impose penalties and assessments on a person who defrauds Medicare or Medicaid or engages in certain other wrongful conduct. The CMPL also authorized the Secretary to exclude persons from Medicare and all state healthcare programs (including Medicaid). Congress later expanded the CMPL and the scope of exclusion to apply to all federal healthcare programs. The Secretary of the Department of Health and Human Services (Secretary) delegated the CMPL's authorities to OIG. [8] Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse. These new authorities were also delegated by the Secretary to OIG. Exceptions to the CMPL are incorporated in to the definition of "remuneration" as found in the CMP rules.

Expansion of AKS Safe Harbors

Protection for Cost-Sharing Waivers

The Final Rule significantly amends the existing safe harbor for *Waiver of beneficiary coinsurance and deductible amounts* [9] to create protection for a beneficiary's copayment, coinsurance or deductible (collectively "cost-sharing") amounts owed to a pharmacy or ambulance provider, subject to certain standards.

A. Pharmacy Cost-Sharing Waivers for Financially Needy Beneficiaries [10]

Under the Final Rule, a pharmacy may reduce or waive the cost-sharing amounts imposed under a federal healthcare program [11] if the waiver or reduction meets the following standards: (i) the waiver or reduction is not offered as part of an advertisement or solicitation; (ii) the pharmacy does not routinely waive or reduce cost-sharing amounts; and (iii) the pharmacy waives the cost-sharing amount only after (a) determining in good-faith that the individual is either in financial need or (b) fails to collect the cost-sharing amount after making reasonable collection efforts.

[1] 81 Fed. Reg. 88,368 (Dec. 7, 2016).
[2] 42 U.S.C. § 1320a-7b(b).
[3] 42 C.F.R. Part 1003.
[4] Balanced Budget Act of 1997, P.L. 105-33.
[5] Patient Protection and Affordable Care Act, P.L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152.
[6] 42 C.F.R. § 1001.95.
[7] Section 1128A of the Social Security Act; 42 U.S.C. 1320a–7a.
[8] 53 Fed. Reg. 12,993 (April 20, 1988).
[9] 42 C.F.R. § 1001.952(k).
[10] 81 Fed. Reg. 88,408 (to be codified at 42 C.F.R. § 1001.952(k)(3)) (*available at* Electronic Code of Federal Regulations).
[11] 81 Fed. Reg. 88,371 (Dec. 7, 2016).

The OIG declined to provide guidance on the number of cost-sharing waivers that would be considered "routine," and therefore, problematic. As pharmacies serve many different communities, including those with subsidy-eligible beneficiaries that are exempt from the prohibition against routine waivers, the OIG stated that it will not mandate or prohibit protocols to determine the number of waivers or reductions that pharmacies may develop to meet the safe harbor requirements. The OIG also declined to mandate specific guidelines for a pharmacy's good faith determination of financial need. The OIG emphasized that the guideline a pharmacy adopts must be reasonable and applied uniformly when performing the financial need assessment.

Additionally, the OIG emphasized that a pharmacy must make an effort to collect the cost-sharing amounts. While the copayment amount or the "historical inability" to collect for a particular beneficiary may be "factors that are considered in determining what reasonable collection efforts are," the pharmacy may not forego all collection efforts and must attempt to collect the cost-sharing amount. [12]

B. Cost-Sharing Waivers or Reductions for Emergency Ambulance Services [13]

The Final Rule also created a safe harbor related to a frequent topic of OIG Advisory Opinions. Specifically, this safe harbor permits coinsurance/deductible waivers or cost-sharing reductions by ambulance service providers for which Medicare pays under a fee-for-service payment system. The waiver or reduction of such cost-sharing responsibilities by an ambulance provider in connection with "emergency ambulance services" falls within the protection of this newly established safe harbor so long as the ambulance provider: (1) is owned and operated by a state, a political subdivision of a state or a tribal health organization; (2) is enrolled as a Medicare Part B provider of the emergency ambulance services; (3) offers the waiver or reduction of cost-sharing amounts in a uniform manner to all individuals; and (4) does not later claim the amount reduced or waived as bad debt or otherwise shift the burden to Medicare, a state healthcare program, other payers or individuals.

Importantly, the safe harbor only applies to emergency services, and privately owned ambulance providers do not qualify for safe harbor protection.

Protected Remuneration Between FQHCs and Medicare Advantage Organizations [14]

The OIG adopted a regulatory safe harbor to protect any remuneration between an FQHC (or an entity controlled by an FQHC) and MA organization pursuant to a written agreement that meets certain statutory requirements. [15] That statutory payment rule guarantees an FQHC a payment amount that at a minimum equals the amount the MA organization would make to a non-FQHC entity. Consistent with statutes, the safe harbor protects only payments related to an FQHC's treatment of MA organization enrollees and does not include a fair market value requirement.

Protection for Discounts by Manufacturers on Drugs Furnished to Beneficiaries Under the Medicare Coverage Gap Discount Program [16]

The OIG also added safe harbor protection for drug price discounts when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount program established under the ACA. [17] Under the Medicare Coverage Gap Discount, a manufacturer may offer discounts on drugs at the point of sale to an "applicable beneficiary" for an "applicable drug," and the drug manufacturer participates in, and is in compliance with, the requirements of the Medicare Coverage Gap Discount Program. An "applicable beneficiary" is an individual who, subject to a number of exclusions, has reached or exceeded the initial coverage limit for prescribed drugs, has not incurred costs for covered drugs in the year equal to the annual out-of-pocket threshold. [18] An "applicable drug" is a part D drug or licensed biologic, available to an applicable beneficiary through an applicable formulary or provided through an exception or appeal. [19]

OIG included these self-implementing statutory exceptions in its rulemaking for completeness. [20]

Free or Discounted Local Transportation [21]

The Final Rule also allows "eligible entities" to provide free or discounted local transportation to federal healthcare program beneficiaries to "established patients" in order to obtain medically necessary items or services so long as the eligible entities comply with the conditions of the regulation.

Under this new safe harbor, an "eligible entity" is any individual or entity, except individuals or entities that primarily supply healthcare items, including but not limited to, durable medical equipment suppliers or pharmaceutical companies. The safe harbor protects round trip transportation from a patient's home to a provider or supplier of services as long as the following conditions are met: (a) eligible entities have a set policy regarding the availability of free or discounted local transportation assistance, the policy is applied uniformly and consistently, and availability is not determined in a manner related to the past or anticipated volume or value of federal healthcare program business; (b) the mode of transportation cannot include air, luxury and ambulance-level transportation; (c) the transportation assistance cannot be publicly advertised or marketed to patients or others who are potential referral sources, marketing of healthcare items or services cannot occur during the course of the transportation, and drivers or others involved in arranging the transportation cannot be paid on a per-beneficiary-transported basis; (d) the eligible entity is prohibited from shifting the associated costs to Medicare, a state healthcare program, other payers or individuals; (e) the individual receiving the transportation benefit is an "established patient" of the eligible entity; and (f) the distance one-way traveled is no more than 25 miles from the healthcare provider or supplier, or 50 miles if the patient resides in a rural area.

[12] 81 Fed. Reg. 88,374 (Dec. 7, 2016).
[13] 81 Fed. Reg. 88,407 (to be codified at 42 C.F.R. § 1001.952(k)(4)) (*available at* Electronic Code of Federal Regulations).
[14] 81 Fed. Reg. 88,408 (to be codified at 42 C.F.R. § 1001.952(z)) (*available at* Electronic Code of Federal Regulations).
[15] See 42 U.S.C. § 1395w-23(a)(4), 42 U.S.C. § 1395l(a)(3)(B).
[16] 81 Fed. Reg. 88,408 (to be codified at 42 C.F.R. § 1001.952(aa)) (*available at* Electronic Code of Federal Regulations).
[17] Patient Protection and Affordable Care Act, P.L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Section 3301(d); 42 U.S.C. § 1395w-114a.
[18] 42 U.S.C. § 1395w-114a(g)(1).
[19] 42 U.S.C. § 1395w-114a(g)(2).
[20] 81 Fed. Reg. 88,378 (Dec. 7, 2016).
[21] 81 Fed. Reg. 88,408 (to be codified at 42 C.F.R. § 1001.952(bb)) (*available at* Electronic Code of Federal Regulations).

A patient is considered to be an "established patient" for purposes of this safe harbor after he or she selects and initiates contact with a provider or supplier to schedule an appointment (e.g., telephone call). Under the Proposed Rule, only patients who had selected a provider or supplier and had attended an appointment with the provider or supplier were deemed to be "established." Because the eligible entity is not permitted to market the transportation services, OIG believes that making transportation available to new patients who contact the provider or supplier on their own initiative is sufficiently low risk to warrant safe harbor protection.

The OIG clarified that an eligible entity offering free or discounted local transportation need not require transportation to be planned in advance. Further, a transportation program can use vouchers rather than having the transportation provided directly by the eligible entity in the form of a shuttle service (discussed below) or other mode of transportation.

The safe harbor also protects the offering of a shuttle service by eligible entities. The term "shuttle" refers to a vehicle (except for air, luxury or ambulance) that runs on a set route and on a set schedule. Of note, the "established patient" requirement does not apply to shuttle services. However, shuttle transportation must remain "local," meaning that there are no more than 25 miles between any stop on the route and any stop at a location where healthcare items or services are provided, or within 50 miles if the patient resides in a rural area. The marketing prohibitions also apply to shuttle services, except that the shuttle schedule and stops may be posted in public. All of the remaining requirements of the safe harbor (e.g., eligible entity requirements, other marketing restrictions and the prohibition on cost-shifting) apply to shuttle service offerings.

Technical Correction to Referral Safe Harbor [22]

As a technical correction, the OIG finalized an amendment to the second standard of the referral service safe harbor to clarify that any payments participants make to the referral service must not be based on "the volume or value of any referrals to or business otherwise generated by either party for the other party . . . ." [23] The prior language "for the referral service" may have supported an ambiguous interpretation that referral services may adjust their fees on the basis of the volume of referrals made to participants.

Expanded Protections for CMP Beneficiary Inducement

Exceptions to the CMP rules are incorporated into the definition of "remuneration." [24] The Final Rule adds five new exceptions.

1. Copayment Reductions for Certain Outpatient Department Services [25]

The OIG proposed a cost-sharing exception permitting reduction in the copayment amount for some or all covered hospital outpatient department services to no less than 20% of the Medicare fee schedule in its Proposed Rule. This cost-sharing exception builds upon Section 4523 of the Balanced Budget Act of 1997 (the BBA), which prompted the Secretary of the Department of Health and Human Services to establish a copayment reduction procedure. [26] In the Final Rule, the OIG added the exception into the definition of "remuneration" using substantively identical language to the statutory language.

2. Certain Remuneration That Poses a Low Risk of Harm and Promotes Access to Care [27]

The Final Rule adds a new interpretive exception that aligns with an existing statutory exception protecting "any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." [28] The OIG noted that "[t]his exception should be read in the context of more specific exceptions and safe harbors," and it would look to those exceptions "to determine if remuneration poses a low risk of harm." Certain arrangements that do not meet the exceptions for a safe harbor or exception may be protected under this exception. Any entity asserting such protection for its arrangements has the burden of demonstrating sufficient facts and analysis for the OIG to determine that the arrangement fits within the exception.

This exception builds off of specific aspects of the statutory language. The OIG defined "care" to mean items and services that are payable by Medicare, Medicaid or a state health program, but does not include a medically necessary qualifier. The OIG defined "promotes access" to limit the exception to only remuneration that "improves a particular beneficiary's ability to obtain medically necessary items and services" for a defined beneficiary population, but not on an individual patient-by-patient basis. The OIG clarified that its interpretation of items or services that "promote access to care" captures giving patients the opportunities to remove socioeconomic, education and other barriers to access necessary care; while excluding items or services that purely reward patients for accessing care. Furthermore, remuneration associated with a coordinated care arrangement that meets the requirement of being low risk and assists patients to access necessary care can fit within this exception.

[22] 81 Fed. Reg. 88,407 (to be codified at 42 C.F.R. § 1001.952(f)) (*available at* Electronic Code of Federal Regulations).
[23] 81 Fed. Reg. 88,371 (Dec. 7, 2016).
[24] 81 Fed. Reg. 88,409 (Dec. 7, 2016) (to be codified at 42 C.F.R. § 1003.101) (*available at* Electronic Code of Federal Regulations).
[25] *Id.*
[26] *See* 42 C.F.R. § 419.42.
[27] 81 Fed. Reg. 88,409 (Dec. 7, 2016) (to be codified at 42 C.F.R. § 1003.101) (*available at* Electronic Code of Federal Regulations).
[28] Section 1128A(i)(6)(F) of the Social Security Act; 42 U.S.C. § 1320a-7a(i)(6)(F).

In addition to promoting access to care, remuneration must pose a low risk of harm to federal healthcare programs for protection under this exception. The OIG finalized its proposed interpretation of a "low risk of harm to Medicare and Medicaid beneficiaries and Medicare and Medicaid program" to mean that the remuneration must: "(1) be unlikely to interfere with, or skew, clinical decision-making; (2) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient-safety or quality-of-care concerns." [29] In its commentary, the OIG cautioned that certain forms of remuneration (such as cash, cash equivalents and copayment waivers) and, specifically, remuneration provided in connection with marketing, are unlikely to be considered by the OIG to be low risk.

3. Retailer Rewards [30]

The OIG adopted the ACA's statutory text creating an exception to the beneficiary inducements CMP statute for retailer rewards programs that meet certain criteria. [31] A retailer rewards program may offer or transfer items for free or less than fair market value if: (a) the items or services consist of coupons, rebates or other rewards from a retailer; (b) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (c) 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 Medicare or a state health program. [32]

The OIG interprets "retailer" to be entities "that sell [ ] items directly to consumers . . . [and do not] primarily provide services," including both big-box stores with pharmacies and smaller, independent pharmacies. [33] These retailers may offer rewards that must not be copayment waivers. Additionally, these rewards must be available to everyone regardless of health insurance status, and must not be tied to the provision of items or services reimbursed by Medicare or a state healthcare program. For example, a reward of a $20 coupon that could be used on anything in the store would not violate the CMP, whereas a reward of federally reimbursable items stemming from the purchase of federally reimbursable items would violate the CMP.

4. Remuneration to Financially Needy Individuals [34]

The Final Rule incorporates a third new statutory provision that excepts from the definition of "remuneration" the offer or transfer of items or services for free or less than fair market value if the following requirements are met: (a) the items and services are not advertised or tied to the provision of other items or services reimbursed by the Medicare or state healthcare programs (including Medicaid); (b) there is a reasonable connection between the items or services and the medical care of the individual; and (c) the recipient has been determined to be in financial need. [35]

This exception, like others, does not impose any affirmative obligations on providers or suppliers to provide free items or services, waive copayments or implement any program that involves giving anything of value to beneficiaries; rather, this exception describes the circumstances under which such gifts or benefits are not prohibited by the beneficiary inducements CMP.

5. Copayment Waivers for the First Fill of Generic Drugs [36]

The OIG adopts another ACA statutory provision excepting from the definition of "remuneration" the waiver by a Part D Plan sponsor of any copayment for the first fill of a covered Part D drug. [37] The OIG states that the purpose of this exception is to "minimize drug costs by encouraging the use of lower cost generic drugs." [38] The Part D Plan sponsor must include the waiver in its annual benefit design package it submits to CMS if the sponsor will use it. This exception is applicable to coverage years beginning on or after January 1, 2018.

Effective Dates

The Final Rule became effective January 6, 2017.

Conclusion

While the AKS and CMP are often viewed by the healthcare and life science industries as impediments to improving the efficiency and innovation of healthcare delivery, the OIG in its Final Rule liberalizes those requirements by enhancing the flexibility of healthcare providers to engage in business arrangements that improve access to care, while still protecting federal programs and patients from fraud and abuse. In an environment where value-based reimbursement models and population health initiatives are the growing norm, the AKS and CMP exceptions under the Final Rule encourage hospitals, pharmacies, ambulance providers, Medicare Advantage Plans and FQHCs to collaborate and strategize among each other on efforts to better serve beneficiaries, members and patients alike.

[29] Fed. Reg. 88,406 (Dec. 7, 2016).
[30] 81 Fed. Reg. 88,409 (Dec. 7, 2016) (to be codified at 42 C.F.R. § 1003.101) (*available at* Electronic Code of Federal Regulations).
[31] Patient Protection and Affordable Care Act, P.L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Section 6402(d)(2)(B); 42 U.S.C. § 1320a-7a(i)(6).
[32] Social Security Act, Section 1128(h); 42 U.S.C. § 1320a-7(h).
[33] 81 Fed. Reg. 88399 (Dec. 7, 2016).
[34] 81 Fed. Reg. 88409 (Dec. 7, 2016) (to be codified at 42 C.F.R. § 1003.101) (*available at* Electronic Code of Federal Regulations).
[35] Social Security Act, Section 1128(i)(6)(H); 42 U.S.C. § 1320a-7a(i)(6).
[36] 81 Fed. Reg. 88409 (Dec. 7, 2016) (to be codified at 42 C.F.R. § 1003.101) (*available at* Electronic Code of Federal Regulations).
[37] Patient Protection and Affordable Care Act, P.L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, Section 6402(d)(2)(B); 42 U.S.C. § 1320a-7a(i)(6).
[38] 81 Fed. Reg. 88406 (Dec. 7, 2016).

If you would like more information about the Final Rule, or would like to discuss the implications of the Final Rule for your business or practice, please speak to one of the authors or your firm contact.

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