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Life Sciences Health Industry

Analysis of HHS OIG Final Rule to Amend the Anti-Kickback Safe Harbors and CMP Rules on Beneficiary Inducements

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On December 7, 2016, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a final rule amending the safe harbors to the Anti-Kickback Statute (AKS) and the Civil Monetary Penalty (CMP) rules prohibiting beneficiary inducements. These changes protect certain practices and arrangements from criminal prosecution or civil sanctions under the AKS and/or the CMP (Final Rule).[1] The Final Rule follows a proposed rule published October 3, 2014 (Proposed Rule).[2] The Final Rule finalizes all of the AKS safe harbors proposed in the Proposed Rule, with certain modifications, and all of the beneficiary inducement CMP exceptions proposed in the Proposed Rule.

The AKS prohibits individuals or entities from knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward business reimbursable under federal health care programs. As required by Congress, the OIG has issued safe harbor regulations that identify business practices that are not subject to sanction under the AKS. The Final Rule makes the following changes to the AKS safe harbor regulations:

- Adds protection for free or discounted local transportation for medically necessary services and shuttle services meeting specified criteria
- Adds protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers
- Adds protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program
- Makes a technical correction to the existing safe harbor for referral services
- Adds protection for certain cost-sharing waivers, including pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries, and waivers

of cost-sharing for emergency ambulance services furnished by state- or municipality-owned ambulance services

The beneficiary inducement CMP prohibits offering or transferring remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider of Medicare or Medicaid payable items or services. In the Final Rule, the OIG amends the definition of "remuneration" in the CMP regulations at 42 C.F.R. Part 1003 to add exceptions that accord with statutory enactments covering the following:

- Copayment reductions for certain hospital outpatient department services
- Certain remuneration that poses a low risk of harm and promotes access to care
- Coupons, rebates, or other retailer reward programs that meet specified requirements
- Certain remuneration to financially needy individuals
- Copayment waivers for the first fill of generic drugs

As a matter of policy, the OIG does not apply the beneficiary inducement CMP to inexpensive gifts of nominal value that are not cash or cash equivalents. In 2000, the OIG announced its interpretation of "inexpensive" or "nominal value" to mean a retail value of no more than $10 per item or $50 in the aggregate per patient on an annual basis. On the same day that the OIG published the Final Rule, it separately issued a policy statement increasing these limits to $15 per item or $75 in the aggregate per patient per year.[3] Gifts to beneficiaries below these thresholds do not need to meet an exception to the beneficiary inducement CMP.

The Proposed Rule also included a proposal to codify in regulations the statutory "gainsharing" CMP set forth in section 1128A(b) of the Social Security Act, which prohibits a hospital or a critical access hospital from knowingly paying a physician to reduce or limit services provided to Medicare or Medicaid beneficiaries. However, after the Proposed Rule was published, Congress amended the law so that only payments to reduce or limit *medically necessary* services (as opposed to *any* services) are prohibited. As such, the OIG did not finalize in the Final Rule the proposed regulatory text or definitions related to the gainsharing CMP.

According to the OIG, the Final Rule is intended to "enhance flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse." The OIG also notes that it has taken changes in health care payment and delivery into account in finalizing the Final Rule. Yet, while the OIG recognizes that "the transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers," it concedes that the Final Rule "does not specifically address many emerging arrangements." While the OIG allows that many new relationships

do not implicate fraud and abuse laws or can fit within existing safe harbors or exceptions, it promises in the Final Rule to continue to monitor changes in the industry and consider whether additional rulemaking is needed.

The following is our analysis of the Final Rule.

Amendments to the AKS Safe Harbors

Local Transportation

Individual Transportation for Medically Necessary Services – In 2002, the OIG sought comments from the industry regarding the establishment of an exception to the definition of "remuneration" under the statutory beneficiary inducement prohibition that would allow for the provision of complimentary local transportation of a nominal value.[4] As explained in that solicitation for comments and in the Proposed Rule, Congress did not intend that the statutory prohibition would preclude free, local transportation of a nominal value.[5] Twelve years after the OIG's 2002 solicitation for comments, the agency proposed a regulatory safe harbor for free and discounted local transportation in the Proposed Rule, to apply to both the AKS and the beneficiary inducement prohibition.[6] The proposal largely codified a series of OIG Advisory Opinions related to complimentary transportation that the agency had issued over the years.[7]

In the Final Rule, the OIG finalizes a safe harbor at 42 C.F.R. § 1001.952(bb) for local transportation to enable an established patient to be transported to a provider or supplier of services and back to a patient's home to receive medically necessary services. Specifically, under the safe harbor, remuneration does not include free or discounted local transportation made available by an eligible entity to federal health care program beneficiaries if all of the following requirements are met:

1. The availability of the free or discounted local transportation services:
    - is set forth in a policy, which the eligible entity applies uniformly and consistently;[8] and
    - is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;
2. The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;
3. 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;[9]

4. The eligible entity makes the free or discounted transportation available only:

    - to an individual who is: (1) an established patient of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services;[10] 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;[11] and

    - for the purpose of obtaining medically necessary items and services.[12]

5. 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 program, other payers, or individuals.

Eligible Entities

Citing fraud and abuse concerns, the OIG used a narrow definition of "eligible entity" in the Proposed Rule, proposing to exclude suppliers of items and certain groups of providers or suppliers of services that may be more likely to offer transportation to their patients in exchange for referrals, such as durable medical equipment (DME) suppliers, pharmaceutical companies, laboratories, and home health agencies.

In the Final Rule, the OIG defines "eligible entities" 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."

Under this definition, eligible entities are those that provide *services* (or services and items), but not those that provide *items*. In the Final Rule, the OIG notes that physical therapists, dialysis facilities, home health agencies, and laboratories are therefore eligible entities, but pharmacies and pharmaceutical manufacturers are excluded from the definition because they primarily provide items. The OIG also clarifies that entities that do not directly render health care services to patients, such as health plans, MA organizations, MCOs, ACOs, clinically integrated networks, and charitable organization, are not excluded from the definition of eligible entity, and are eligible to provide transportation under this safe harbor.

Established Patients

In the Proposed Rule, the OIG proposed to limit the safe harbor to "established patients," but it did not define that term. Instead, in the Proposed Rule's preamble discussion, the OIG noted that a patient would be "established" once a patient had selected a provider or supplier, and had attended an appointment with that provider or supplier.[13]

In the Final Rule, the OIG defines the term "established patient" as a "person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment [sic], or who previously has attended an appointment with the provider or supplier." This established-patient requirement does not apply to shuttle service transportation, further discussed below.

According to the OIG, the definition is intended to offer flexibility to improve patient care while limiting the risk of the transportation being used as a recruiting tool, or to bring patients in for unnecessary services. Therefore, the OIG is finalizing a definition that includes new patients (or their representatives) who contact the provider or supplier on their own initiative. The safe harbor does not protect transportation provided as a result of a provider or supplier reaching out to a patient (or the patient's case manager) and asking to have a new patient come in via offered transportation.

The safe harbor does not require documentation that the patients receiving transportation are established patients, but the OIG notes that maintaining such documentation may be "best practice" to demonstrate compliance with the safe harbor.

Shuttle Transportation Services – In the Proposed Rule, the OIG sought comments on whether to separately protect a second form of transportation furnished to beneficiaries akin to a shuttle service. In the Final Rule, the OIG separately protects free or discounted local transportation made available by an eligible entity in the form of a "shuttle service" – a transportation service that runs on a set route and on a set schedule – if all of the following requirements are met:

1. The shuttle service is not air, luxury, or ambulance-level transportation;
2. 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;
3. 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, the distance may be up to 50 miles between that that stop and all providers or suppliers on the route; and
4. 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.

As the OIG noted in the Final Rule, some of the safeguards applicable to the safe harbor for local transportation for medically necessary services also apply to the safe harbor for shuttle transportation services, while others do not. For example,

the shuttle transportation services' safe harbor is not limited to established patients, does not mandate where the shuttle may or may not make stops, and permits use of the shuttle for reasons other than to obtain health care items or services.

Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers

In the Proposed Rule, the OIG proposed incorporating into the AKS regulations, at a new 42 C.F.R. § 1001.952(z), a statutory exception to the AKS created by section 237 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Previously, section 237 of the MMA added a provision to the then-existing statute governing contracting with Medicare Advantage (MA) organizations to the effect that any agreement between such an organization and a federally qualified health center (FQHC) must require "a level and amount of payment" for services by the MA plan to the FQHC "that is not less than the level and amount of payment" the MA plan would pay to another, non-FQHC entity for similar services. Section 237 also added a provision to the then-existing version of the AKS itself that excluded from the scope of that statute's prohibitions "any remuneration between a [FQHC] (or an entity controlled by such a health center) and a MA organization pursuant to a written agreement" described in the existing statute governing payment to MA organizations.

Accordingly, the Proposed Rule proposed excluding from potential AKS enforcement any remuneration between an MA organization and an FQHC that meets the foregoing requirements – i.e., that is pursuant to a written agreement between the two requiring the MA plan to pay the FQHC at rates no lower than those the plan pays to other types of providers for similar services. The Final Rule finalizes this proposal.

In recognition of the key role FQHCs play in serving the poor and medically underserved, federal law requires the Centers for Medicare & Medicaid Services (CMS) to make supplemental payments to such centers for services they render to MA plan members to cover the portion of the center's costs not covered by the MA plan's reimbursement. The new regulatory exclusion at 42 C.F.R. § 1001.952(z) furthers the policy goal of supporting FQHCs by limiting their potential AKS liability, while also ensuring that MA plans cover their fair share of the cost of operating such centers, which otherwise would become the responsibility of CMS under the supplemental FQHC payment program.

Manufacturer Discounts Under Part D Coverage Gap Discount Program

The 2010 health reform legislation, the Patient Protection and Affordable Care Act (ACA), included a statutory exception to the AKS for discounts provided by pharmaceutical manufacturers under the Medicare Part D Coverage Gap Discount Program (CGDP). Under this program, manufacturers agree with CMS to provide discounted prices to certain Medicare beneficiaries at the point of sale, while they are in the so-called "donut hole."

As proposed in the Proposed Rule, the Final Rule codifies this exception in the safe harbor regulations at 42 C.F.R. § 1001.952(aa). Under the new safe harbor, "remuneration" does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the CGDP, as long as all the following requirements are met:

1. The discounted drug meets the definition of "applicable drug" under the CGDP;
2. The beneficiary receiving the discount meets the definition of "applicable beneficiary" under the CGDP; and
3. The manufacturer of the drug participates in, and is in compliance with the requirements of, the CGDP.

While there can be little question that an AKS exception is appropriate for these statutorily mandated discounts, manufacturers might take issue with the fact that OIG has drafted the safe harbor to apply only to discounts provided to "applicable beneficiaries" on "applicable drugs" (each as defined under the CGDP), since manufacturers do not control the provision of the discounts—rather, they must pay the amounts invoiced to them for CGDP discounts by CMS' third-party administrator, subject to limited audit and appeal rights.

Technical Correction to Referral Services Safe Harbor

The Final Rule makes a technical correction to the referral services safe harbor at 42 C.F.R. § 1001.952(f), which provides that payments (or other exchanges of value) between a participant (i.e., the person or entity that receives referrals through the arrangement) and a referral service (i.e., the person or entity that is making referrals to the participant) are not remuneration for purposes of the AKS, provided that the arrangement meets the safe harbor's four requirements. The OIG previously made this same change in 1999, but then inadvertently undid the change in 2002.[14]

As finalized, the second of the four requirements of the safe harbor is now that "any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by *either party for the other party* for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs."[15] Previously, the relevant phrase was "*either party for the referral service*," which was a source of confusion. As amended, the safe harbor makes clear that the volume or value of referrals or business otherwise generated "*by either party for the other party*" cannot affect the referral service's fee to participants.

In the Final Rule, the OIG also notes that it received a comment recommending that OIG modernize this safe harbor to permit the use of online, Internet-based tools. Although outside the scope of the rulemaking, the OIG does nonetheless

confirm in the Final Rule that the safe harbor does not exclude the use of online tools, and notes that it may consider revisions to the safe harbor in the future if it determines that online referral sources need additional or different protection.

Cost-Sharing Waivers

The AKS may be implicated by the reduction or waiver of Medicare or other federal health care program cost-sharing amounts, and OIG has consistently expressed concerns regarding providers and suppliers that routinely waive Medicare cost-sharing amounts unrelated to individualized, good faith assessments of financial hardship. The OIG has long maintained that such waivers may constitute prohibited remuneration to induce referrals under the AKS or improper beneficiary inducements under the CMP.

Nonetheless, certain waivers arguably pose a low risk of harm to federal health care programs, while benefitting patients and enhancing the efficient and effective delivery of health care. Recognizing this, OIG finalized its proposal to modify 42 C.F.R. § 1001.952(k) to protect certain cost-sharing waivers related to Part D and emergency ambulance services, further discussed below. In the Final Rule, the OIG also expands the scope of 42 C.F.R. § 1001.952(k) to all federal health care programs, recognizing that the safe harbor may not apply to all federal health care programs because of the varying methods of payment. The OIG also revises the regulatory language to define "cost-sharing" to include "copayment, coinsurance, or deductible" (previously, the reference was limited to "coinsurance or deductible").

Part D Cost-Sharing Waivers and Reductions by Pharmacies – The MMA included a statutory exception to the AKS for waivers of Part D cost-sharing by pharmacies that meet certain requirements. In the Proposed Rule, the OIG proposed to add a regulatory safe harbor at 42 C.F.R. § 1001.952(k)(3) reflecting the statutory exception. The basic requirements of the proposal were as follows:

1. That the waiver not be offered as part of an advertisement or solicitation;
2. That the pharmacy does not routinely waive cost-Part D sharing; and
3. That the waiver is provided only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing despite making reasonable collection efforts.

However, consistent with the statutory exception, requirements (2) and (3) would not apply to waiver of cost-sharing for Part D low-income, subsidy-eligible individuals.

In the Final Rule, the OIG finalizes its proposal so that waivers and reductions of Part D cost-sharing obligations by pharmacies that meet the requirements noted above will be protected. As with all 42 C.F.R. § 1001.952(k)-protected cost-sharing waivers, this new safe harbor is not limited to Part D cost-sharing, but now applies to all federal health care programs. However, the safe harbor is applicable to

pharmacies only, and does not protect waivers by physicians for copayments of Part B drugs, nor any MA or other plans' "cost-saving programs."

As in the Proposed Rule, the OIG continues to stress in the Final Rule that this safe harbor protects only against AKS liability and the beneficiary inducement CMP provisions – a particular practice could still implicate other CMS program rules (such as chapter 5 of the Prescription Drug Benefit Manual).

Emergency Ambulance Services Cost-Sharing Waivers by Certain Ambulance Providers and Suppliers – In multiple advisory opinions, the OIG has approved the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a state or political subdivision of the state. However, no safe harbor expressly protected such arrangements. In the Proposed Rule, the OIG proposed to establish a new safe harbor at 42 C.F.R. § 1001.952(k)(4) to protect such arrangements, and in the Final Rule the OIG finalizes the same.

Under the new safe harbor, reductions or waivers of cost-sharing owed to an ambulance provider or supplier for emergency ambulance services for which a federal health care program pays under a fee-for-service payments system are protected if the following requirements are met:

1. The ambulance provider or supplier is owned and operated by a state, a political subdivision of a state, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;
2. The ambulance provider or supplier is engaged in an emergency response;
3. The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or tribal members, or to all individuals transported;[16] and
4. The ambulance provider or supplier does not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

Amendments to the Beneficiary Inducement CMP

Under section 1128A(a)(5) of the Social Security Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services, may be liable for CMPs of up to $10,000 for each wrongful act. In the Proposed Rule, the OIG proposed to add five new exclusions to the beneficiary inducement CMP regulations, four of which emanated from statutory provisions contained in the ACA. The Final Rule incorporates these changes

into the definition of "remuneration" under the applicable regulations (42 C.F.R. § 1003.110).

Copayment Reductions for Outpatient Department Services

The CMP regulations include an exception that permits hospitals to give reductions in copayment amounts for certain outpatient department (OPD) services. In the Proposed Rule, the OIG proposed to update the statutory citation to the definition of "covered OPD services" included in the regulations, and having received no comments regarding this proposal, the OIG finalizes this change in the Final Rule, so that the regulations now refer to the current statutory section (section 1833(t)(8)(B) of the Social Security Act).

Promotes Access to Care and Presents a Low Risk of Harm to Beneficiaries and Federal Health Care Programs

The ACA included an exception that protects "any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." In the Proposed Rule, the OIG proposed certain interpretations of this statutory language, and also solicited comments on a number of aspects of the statutory language, including what constitutes "care," what it means to "promote access to care," and what type of remuneration poses a low risk of harm.

Under the Final Rule, 42 C.F.R. § 1003.110 is amended to provide that the following is not considered "remuneration" and is therefore not subject to the beneficiary inducement CMP:

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—

1. Being unlikely to interfere with, or skew, clinical decision making;
2. Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
3. Not raising patient safety or quality-of-care concerns.[17]

Pursuant to the relevant statutory language, this exception requires an assessment of (1) whether the remuneration at issue promotes access to care (i.e., improves a beneficiary's ability to obtain payable items and services), and (2) if so, whether it poses a low risk of harm to beneficiaries and programs.

As an initial matter, in the Final Rule the OIG notes that this exception should be read in the context of more specific CMP exceptions and AKS safe harbors (which are incorporated by reference into the exceptions to the beneficiary inducements CMP), and that activities and arrangements that are addressed by and meet the elements of another applicable safe harbor or exception will be considered low risk under this exception. For example, a transportation arrangement that meets

all of the requirements of the AKS safe harbor discussed above related to local transportation would be low risk under this exception. However, if the arrangement did not meet all of the AKS safe harbor requirements, but had different safeguards in place, it *may* still be low risk under this exception (even if the AKS safe harbor is not available).

In addition, the Final Rule makes clear that if remuneration at issue is not likely or intended to induce a beneficiary to use a particular provider, practitioner, or supplier, the beneficiary inducements CMP will not be implicated in the first place (although the AKS may still be implicated).

Finally, in response to comments related to whether there should be special provisions for incentives offered by participants in CMS-sponsored initiatives and demonstrations, such as the Bundled Payment of Care Initiatives, the OIG confirms in the Final Rule that all entities seeking to rely on this exception must meet its terms.

"Care"

In the Proposed Rule, OIG characterized the term "care" as "medically necessary health care items and services," but solicited comments on whether it should interpret "care" more broadly to include care that is non-clinical but reasonably related to the patient's medical care, such as social services.

In the Final Rule, OIG declines to expand the term "care" beyond items and services that are payable by Medicare or a state health care program (e.g., Medicaid), but does not limit the term to strictly "medically necessary" services, recognizing that Medicaid covers some services that are not strictly medical (e.g., personal care services).

As finalized, the term "care" in the context of "access to care" means access to items and services that are payable by Medicare or a state health care program for the beneficiaries that receive them. As such, this exception protects remuneration that promotes access to items and services that are payable by Medicare or a state health care program.

The OIG makes clear that the type of care at issue is care provided by a particular provider, practitioner, or supplier. As noted above, individuals and entities (including health plans) can still help and encourage beneficiaries to access nonpayable care without implicating the beneficiary inducement CMP, as long as any remuneration associated with such assistance is not intended to induce a beneficiary to use a particular provider, practitioner, or supplier for an item or service payable by Medicare or a state health care program.

"Promotes Access"

In the Proposed Rule, OIG proposed that this exception would include only remuneration that "improves a particular beneficiary's ability to obtain medically necessary items and services," but solicited comments on whether it should

interpret "promotes access" more broadly to include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient. The OIG also solicited comments on whether remuneration would have to promote access to a particular beneficiary, or whether it should also apply to a defined beneficiary population.

In the Final Rule, the OIG declines to adopt a broader interpretation of the phrase "promotes access to care" than that proposed (subject to the finalized definition of "care" discussed above), but OIG does note that items or services that help or support patients' access to care, or make access more convenient that it otherwise would be, will often meet the originally proposed, and now finalized, interpretation. The OIG also finalizes that the exception applies to remuneration that promotes access either to a particular individual or a defined beneficiary population.

OIG's interpretation of items or services that "promote access to care" encompasses giving patients the tools they need to remove certain socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care, but does not include rewarding patients for accessing care, including compliance with a treatment plan, or inducements to seek care.[18] For example, if a patient had a health condition for which a smoking-cessation program was a payable service, a provider could offer free child care to the patient so that the patient could attend the program. Such remuneration would be protected by this exception because the patient might not be able to attend the program without child care assistance. However, the provider could not give movie tickets as a reward for attending the session, as movie tickets would not improve the patient's ability to attend the appointment.

Notwithstanding the foregoing and as noted above, the OIG makes clear in the Final Rule that inducements to comply with a treatment, rewards for compliance with treatment, incentives to seek preventative health services, or incentives to achieve certain health-related benchmarks offered to patients by individuals and entities (including health plans), will not implicate the beneficiary inducements CMP if such inducements or rewards do not influence a beneficiary to use a particular provider, practitioner, or supplier (although the AKS may still be implicated).

"Low Risk of Harm"

In the Proposed Rule, the OIG proposed that, for remuneration to involve a "low risk of harm" to Medicare and Medicaid beneficiaries and programs, 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.

The Final Rule accepts this interpretation. In the Final Rule, the OIG also discusses risk with respect to marketing and educational activities and materials. The OIG

confirms that remuneration given in connection with marketing is not low risk and will not be protected by this exception, since such remuneration is given for the purpose of influencing the choice of a particular provider, practitioner, or supplier, and may induce overutilization or inappropriate utilization. In contrast, the OIG does not consider educational materials alone (even those that include information about a particular provider's qualifications) to be remuneration. As such, a provider supplier may offer educational materials or informational programs to patient or prospective patients without implicating the beneficiary inducement CMP.

The Final Rule otherwise discusses various examples of item or services proposed by commenters for protection by this exception, with the OIG noting that whether such items and services will be protected will depend on the applicable facts and circumstances. The OIG does confirm, consistent with its previous guidance, that the remuneration cannot be cash or cash equivalents, and cannot take the form of copayment waivers (under this exception).

Retailer Rewards Programs

The ACA includes an exclusion from remuneration for the offer or transfer of items for free or for less than fair market value through coupons, rebates or rewards from a retailer to the general public, regardless of payor status, as long as the remuneration is not tied to items and services reimbursable by federal health care programs.

In the Proposed Rule, the OIG proposed using that statutory language as the text for a corresponding regulation. The proposal was intended to address the practice of many retailers to exclude federal health care program beneficiaries from their rewards programs in order to avoid running afoul of OIG guidance on the beneficiary inducement CMP.[19] In the Final Rule, the OIG finalizes the proposed language. According to the OIG, this retailer rewards exception "creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating…the beneficiary inducements CMP."[20]

Under the Final Rule, 42 C.F.R. § 1003.110 is amended so that the definition of "remuneration" now excludes the offer or transfer of items or services for free or less than fair market value by a person if the following criteria are met:

1. The items or services consist of coupons, rebates, or other rewards from a retailer;

2. The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

3. 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 the program under Medicare or State health care programs.

Coupons, Rebates, or Other Rewards from a Retailer

The Proposed Rule included interpretations of the terms "retailer," "coupon," "rebates," and "other rewards." The Final Rule includes specific discussion of certain of these terms, but not all.

Retailer – ccording to the Final Rule, the term "retailer" should be interpreted in accordance with its "commonly understood meaning." That is, an entity that sells items directly to consumers, including independent or small pharmacies, online retailers, and entities that sell a single category of items.[21] "Retailer" does not include individuals or entities that primarily provide services (e.g., hospitals or physicians). This exception is limited to items or services "from a retailer," and therefore the OIG confirms that non-retailers, including manufacturers, may not provide retailer rewards under this exception. As a result, this exception does not protect a situation in which a manufacturer offers or transfers to patients any retailer rewards acquired or paid for by the manufacturer.

Other Rewards – In the Final Rule, the OIG confirms its position that "other rewards" is a broad concept and, although OIG expects these would primarily be in the form of free items or services, reduced priced items or services may also qualify. According to the OIG, "other rewards" include gasoline discounts, frequent flyer miles, items purchased in the retailer's store, educational information or programs, and health care items or services (except that the reward cannot be in the form of a copayment waiver, which would not meet the third criteria above).

Coupons and Rebates – The Final Rule does not include specific discussion of the terms "coupon" or "rebate," but the discussion in the Proposed Rule remains applicable. In the Proposed Rule, the OIG proposed to interpret a "coupon" as something authorizing a discount on merchandise or services, such as a percentage discount on an item or a "buy one, get one free" offer. The OIG proposed to interpret "rebate" as a return on part of a payment, with the caveat that a retailer could not "rebate" an amount that exceeds what the customer spent at the store.

Offered or Transferred on Equal Terms

According to the Final Rule, the second criteria of the new retailer rewards exclusion requires that the retailer reward is offered to everyone regardless of health insurance status, and that the general public must have the same access to, and use of, the retailer reward as the retailer's insured customer base. The OIG also clarifies that this requirement does not prohibit a retailer from having an enrollment process, as long as the terms do not vary based on insurance status or plan. In addition, a rewards program targeted to patients with a particular disease state may be offered, but it would need to meet the requirement that the reward not be tied to other reimbursable items or services.

Not Tied to Other Reimbursable Items or Services

With respect to the third criteria of this exclusion, the Final Rule confirms that the reward cannot be tied to the provision of other reimbursable items, both in the manner in which the reward is earned and redeemed. Permitted rewards include either discounts that could be used on anything in the store (among them covered items or services), or those that are specific to non-reimbursable items.

For example, a copayment waiver (or a $20 coupon off of a copayment) would not meet the third criteria of the exclusion because the reward is tied to the purchase of a reimbursable item (the item for which the copayment is waived or discounted). In contrast, a $20 coupon to be used on anything in the store would not be considered tied to other reimbursable items or services, even if the coupon was redeemable as a copayment, since the coupon is not limited to a reduction in price on a reimbursable item or service.

Similarly, coupons to transfer prescriptions are not protected under this exception because they tie the remuneration to purchasing a reimbursable item or service.

Financial-Need Based Exception

The ACA added an exclusion from prohibited remuneration for the offer or transfer of items or services for free or for less than fair market value to financially needy individuals if certain criteria are met. In the Final Rule, the OIG codifies this requirement in regulations and spells out the four statutory criteria.

Specifically, the term remuneration does not include the offer or transfer of items or services for free or less than fair market value by a person if the following requirements are met:

1. The items or services[22] are not offered as part of any advertisement or solicitation;
2. 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 care program;
3. There is a reasonable connection between the items or services and the medical care of the individual; and
4. The person provides the items or services after determining in good faith that the individual is in financial need.

Reasonable Connection to Medical Care

In order for remuneration to be "reasonably connected" to medical care, it must be reasonable from both a medical perspective and a financial perspective.

With respect to the first perspective, the OIG provides in the Final Rule that the concept of a reasonable connection to the medical care of an individual can be interpreted broadly, to include items related to prevention of illness or injury,

if specifically pertinent to a particular patient's medical care, as well as items related to medical treatment (e.g., extra bandages for wound care). In addition, items crucial to a patient's safety (such as car seats for infants) are reasonably connected to medical care. However, not everything beneficial to a patient is connected to medical care, according to the OIG. For example, school backpacks are beneficial to children but are not connected to medical care.

The exception is designed to be patient-specific, so whether something is reasonably connected to a patient's medical care must be determined on a case-by-case basis. The OIG recognizes that it is the medical professional working with the patient who is in the best position to determine what is reasonably connected to his or her patient's medical care.

With respect to remuneration having a reasonable connection to medical care from a financial perspective, if a provider or supplier gives remuneration that has a high financial value, it is less likely to be "reasonably" connected to the medical care. It is for this reason that the OIG finalizes its proposed concept of ensuring that the value of the items and services is not disproportionately large compared with the medical benefits. However, the OIG declines to provide a specific retail value for something that is disproportionately large. Instead, the provider or supplier must consider whether the cost of the item or service is proportional to the possible harm it is designed to prevent.

Individualized Determination of Financial Need

Under this exception, the items or services can only be provided after a good-faith, individualized assessment of the patient's financial need on a case-by-case basis. As finalized, the OIG will not require specific documentation of financial need. However, entities offering these items must do so in accordance with a set policy, based on income or other factors, that is uniformly applied. Providers and suppliers have the flexibility to determine the appropriate policy for their own patient populations.

Further, the Final Rule makes clear that while the financial need determinations must be done on an individual basis, OIG is not mandating any particular basis for determining need. In the Final Rule, the OIG declines to adopt a uniform measure of need (e.g., specific percentage of the Federal Poverty Level) and also declines to adopt a minimum threshold of assistance before a determination of need is required.

Waivers of Part D Cost-Sharing for First Fill of a Generic Drug

The ACA included a statutory exclusion from the beneficiary inducement CMP for waivers by Part D plan sponsors of a Part D enrollee's copayment for the first fill of a generic drug. In the Proposed Rule, the OIG proposed codifying this exception and does so in the Final Rule, applicable to coverage years beginning on or after January 1, 2018.

Under the new CMP exception, remuneration does not include waivers by a Part D Plan sponsor of any copayment for the first fill of a covered Part D drug that is a generic drug or an authorized generic drug for individuals enrolled in the Part D plan, as long as such waivers are included in the benefit design package submitted to CMS.

The purpose of this exception is to minimize drug costs by encouraging the use of lower cost generic drugs.

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By adding specific regulatory provisions and offering interpretations, the Final Rule provides clearer protection for a number of types of arrangements that the OIG and/or Congress had previously concluded should not result in sanctions under the AKS or the beneficiary inducement CMP. As a result, health industry participants now are able to structure these types of arrangements to comply with the regulatory requirements, resulting in greater comfort that their arrangements will not be found to violate these laws. On the other hand, not unexpectedly, the Final Rule did not break new ground by establishing AKS safe harbors or CMP exceptions that address emerging arrangements in the industry that are responsive to the transition from volume to value-based and patient-centered care. More flexibility from the OIG must await another day.

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1 81 Fed. Reg. 88,368 (Dec. 7, 2016). Available at https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf.

2 79 Fed. Reg. 59,717 (Oct. 3, 2014). Available at https://oig.hhs.gov/authorities/docs/2014/Safe_Harbor_Beneficiary_Inducements_Proposed_Rule.pdf.

3 Available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf.

4 67 Fed. Reg. 72,892 (Dec. 9, 2002).

5 H.R. Conf. Rep. No. 104–191 at 255 (1996).

6 79 Fed. Reg. 59,717, 59,722; 42 U.S.C. § 1320a–7a(i)(6)(B).

7 The OIG has issued a variety of Advisory Opinions discussing providers furnishing free transportation services to patients and their friends and family, such as OIG Advisory Opinion Nos.: 00-7, 07-02, 09-01, 11-01, 11-02, and 11-16. In addition, the OIG published a letter regarding complimentary local transportation programs on December 9, 2002, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/sabgiftsandinducements.pdf.

8 In the Final Rule, the OIG declines to mandate the parameters for this policy, other than the fact that it must comply with the terms of the safe harbor (including distance, and the prohibition on transporting only to referral sources), and it must be applied uniformly and consistently. 81 Fed. Reg. 88,385.

9 The OIG clarifies in the Final Rule that drivers may be paid on the basis of total distance traveled by a vehicle, and if the transportation is provided in the form of non-private transportation (e.g., bus or taxi), the transportation can be paid for or reimbursed to the individual patients through taxi vouchers, bus fare, or cash reimbursement if the patient has the necessary receipts. 81 Fed. Reg. 88,387.

10 An eligible entity that does not itself provide health care services (such as a charitable organization, health plan, ACO, or other entity) is not required to have an established patient relationship with a patient in order to provide transportation that is protected by this safe harbor. 81 Fed. Reg. 88,385.

11 In the Final Rule, the OIG explains that this mileage can be measured directly (i.e., “as the crow flies”), which would include any route within that radius (even if such route is more than 25 or 50 miles when driven). 81 Fed. Reg. 88,387.

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[12] In the Proposed Rule, the OIG requested comments on whether free or discounted transportation should be available for non-health-care-related trips, e.g., to obtain social services or to visit food banks. In the Final Rule, the OIG declines to extend the safe harbor protection to transportation for purposes other than to obtain medically necessary items or services. This same restriction does not apply to shuttle transportation. 81 Fed. Reg. 88,384.

[13] 79 Fed. Reg. 59,722.

[14] *See* 64 Fed. Reg. 63,518, 63,526 (Nov. 19, 1999); 67 Fed. Reg. 11,928, 11,929 and 11,934 (Mar. 18, 2002).

[15] 42 C.F.R. § 1001.952(f)(2)(emphasis added).

[16] With respect to this requirement (3), the Final Rule removes reference to providing the waivers "without regard to patient-specific factors," included in the Proposed Rule; but the OIG notes that this requirement (3) is still intended to ensure that the waivers do not take into account or require any case-by-case, patient-specific determinations (e.g., patient age, insurance, or financial status), while still allowing an ambulance provider or supplier to consider residency or tribal membership in granting waivers or reductions. That is, ambulance providers and suppliers can waive cost-sharing amounts for all residents, but charge cost-sharing amounts for nonresidents. 81 Fed. Reg. 88,376.

[17] 42 C.F.R. § 1003.110(6).

[18] Although this exception does not protect inducements to seek care, other CMP exceptions may apply. For example, the preventative care exception at 1128A(i)(6)(D) of the Social Security Act protects incentives to seek preventative care. *See also* 42 C.F.R. § 1003.110 (definition of "remuneration"). And, as noted above, items of nominal value do not require an exception, even if intended to cause a beneficiary to select a particular provider or supplier.

[19] *See* OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (2002) and OIG Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries, *supra*, note 3.

[20] 81 Fed. Reg. 88,399.

[21] With respect to entities that sell a single category of items, the OIG notes, "We believe that it may be difficult for an entity that primarily sells a single category of products to meet the criterion that the offer of items or services not be tied to other reimbursable services if, for example, the entity sells only (or mostly) items that are reimbursable by Federal health care programs." 81 Fed. Reg. 88,399.

[22] The term "items or services" exclude cash, or cash equivalents (i.e., instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards). 81 Fed. Reg. 88,402.