OIG FINALIZES NEW AND AMENDED ANTI-KICKBACK AND CMP SAFE HARBORS [OBER|KALER]

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On December 7, 2016, the Department of Health and Human Services Office of the Inspector General (OIG) issued a final rule to establish new safe harbors under the anti-kickback statute and civil monetary penalty (CMP) rules, as well as update existing safe harbors. This Final Rule implements, with some modifications suggested by commenters, safe harbors that were initially proposed by the OIG in October 2014.

As discussed in our article on the proposed rule, the new rules will impact a variety of business practices in the health care industry. Protection under the anti-kickback safe harbors is extended in certain circumstances to cost-sharing waivers by pharmacies and for emergency ambulance services, remuneration between Medicare Advantage Organizations and federally qualified health centers, certain drug discounts, and free and reduced-cost local transportation services. With the exception of safe harbors for cost-sharing waivers for certain ambulance services and for free or discounted local transportation, all of the safe harbors are existing statutory exceptions to the anti-kickback statute. Protection under the CMP safe harbors is extended by adding additional exceptions to the definition of remuneration under the beneficiary inducement CMP.

Technical Correction to Referral Safe Harbor

Stylizing it as a “technical correction,” the OIG is finalizing 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 . . . .” (emphasis added). The OIG notes that this was the initial language in the 1999 safe harbor; however, a subsequent revision inadvertently changed the italicized language to address referrals or business generated “by either party for the referral service.” The technical correction in the Final Rule is intended to eliminate unintended ambiguity created by the existing language, which could support the interpretation that referral services may adjust their fees on the basis of the volume of referrals made to participants.

Cost-Sharing Waivers

In this Final Rule, the OIG is republishing its waiver of cost-sharing safe harbor to clarify certain aspects of the safe harbor and to adopt two new cost-sharing waiver safe harbors. The OIG reiterates its concerns about potentially abusive waivers of cost-sharing amounts under the anti-kickback statute, but indicates that the finalized modifications to the safe harbor protect cost-sharing waivers that “pose a low risk of harm” to federal health care programs. Among other things, the OIG adopts language to clarify that the safe harbor applies to waivers of coinsurance, copayments and deductibles under all federal health care programs, not just Medicare and Medicaid, provided that the standards of the exception are met. In addition, the OIG finalizes safe harbor protection for two new types of cost-sharing waivers, including (1) non-routine waivers of pharmacy cost-sharing amounts imposed under federal health care programs; and (2) waivers of cost-sharing amounts for certain emergency ambulance services, as described below.
Pharmacy Cost-Sharing Waivers

Under the proposed rule, the OIG had proposed to expand the cost-sharing safe harbor to protect certain waivers of cost-sharing amounts by pharmacies under Part D, consistent with a statutory exception to the anti-kickback statute added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The Final Rule, however, is much broader and expands safe harbor protection to not just waivers under Part D, but all federal health care programs. The OIG is careful to note that the safe harbor is nevertheless limited to pharmacies and does not protect, for example, waivers of copayments by physicians for Part B drugs.

The Final Rule includes a number of limitations and requirements that must be met to receive protection. First, the waiver or reduction of cost-sharing amounts must not be offered as part of an advertisement or solicitation. The OIG notes that the safe harbor is not intended to protect waivers that are offered as part of a “cost-saving program” and cannot be advertised, even for the lowest-income patients. The OIG suggests that stakeholders should interpret the terms *advertisement* and *solicitation* consistent with their common usage in the health care industry. As an example, information posted on a pharmacy website about waivers offered would be considered advertising, but responding to a patient inquiry about financial need would not. In response to comments regarding federally qualified health centers (FQHCs) and similar health centers, the OIG recognizes that, in certain circumstances, FQHCs and health centers are required to post their sliding fee schedules under Health Resources and Services Administration regulations. The OIG states that this would not constitute prohibited advertising of waivers; however, the OIG cautions that the communication may become prohibited advertising if the FQHC waives an amount that a patient would have been required to pay in accordance with the FQHC sliding fee schedule.

In addition to the foregoing, the safe harbor requires that, except for individuals eligible for certain cost-sharing subsidies under the Medicare statute, a pharmacy must not *routinely* waive or reduce cost-sharing amounts. The OIG declines to adopt a particular standard or definition for *routine* (e.g., a set percentage), and instead states it is a facts-and-circumstances analysis. The OIG suggests providers should consider prior OIG guidance on routine waivers, including the OIG's Special Fraud Alert, “Routine Waiver of Copayments or Deductibles Under Medicare Part B.”

Finally, the OIG provides that a pharmacy may waive cost-sharing amounts only after: (1) determining in good faith that an individual is in financial need; or (2) failing to collect cost-sharing amounts after making reasonable collection efforts.

With respect to financial need, the OIG declines to adopt a particular method for determining need, but suggests that providers must conduct a good faith, individualized, case-by-case analysis that is based on a reasonable set of uniformly applied income guidelines. In response to a comment, the OIG cautions that simply accepting a patient's statement that he or she is in financial need would be unlikely to meet the requirement of an individualized, good faith assessment.

With respect to reasonable collection efforts, the OIG states that it will interpret the requirement consistent with past guidance as “efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients.” Moreover, the OIG cites as instructive the definition of *reasonable collection efforts* set forth in CMS's Provider Reimbursement Manual, which requires providers to issue a bill to the patient and take other actions such as subsequent billings, collection letters and telephone calls. The OIG cautions that it cannot envision a scenario in which a pharmacy's preemptive determination not to pursue any collection efforts would satisfy this condition.

**Waivers of Cost-Sharing for Certain Emergency Ambulance Services**

The OIG finalizes its proposal to extend safe harbor protection to waivers of cost-sharing amounts associated with certain emergency ambulance services provided by ambulance providers or suppliers owned and operated by a state, political subdivision or a tribal health care program. As noted in the proposed rule, the OIG has issued a number of favorable advisory opinions regarding reductions or
waivers of copayments and deductibles for state- or municipality-provided emergency ambulance services and continues to receive such requests.

In order to qualify for the safe harbor, the emergency ambulance services must meet four conditions. First, the provider or supplier must be “owned and operated by a State, a political subdivision of a State, or tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act.” Thus, safe harbor protection is not generally extended to municipalities that contract with private ambulance companies. The OIG notes, however, that if a state or municipality uses its residents’ tax dollars to pay a private ambulance company an amount that is actuarially equivalent to the resident's copayment amounts, the anti-kickback statute would not be implicated since the residents would ultimately be paying for the services.

Second, the ambulance provider must be engaged in providing an “emergency response,” and safe harbor protection is not extended to non-emergency transports, which the OIG views as “too high risk” for safe harbor protection at this time. The OIG defines emergency response by reference to 42 C.F.R. § 414.605, which includes “responding at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system.” The OIG recognizes that transportation of psychiatric patients may qualify if, for example, the patient is a threat to himself, herself or others and an emergency transport is necessary to an emergency department or psychiatric hospital.

Third, the cost-sharing waivers must be offered on a uniform basis to all individuals who are transported, except a state, municipality or tribe may limit such waivers to residents or tribal members as applicable. The OIG notes that an ambulance provider or supplier cannot discriminate or limit waivers on any patient-specific basis, except for residency. Thus, for example, an ambulance provider couldn't limit waivers on the basis of insurance or financial status.

Finally, the OIG prohibits an ambulance provider or supplier from shifting the costs of the waivers onto any other federal health care program, other payors or individuals. The safe harbor further prohibits the provider from later claiming the amount reduced or waived as bad debt for payment purposes under a federal health care program.

**Protection of Certain Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers**

The MMA added a new statutory exception to the anti-kickback statute that protects remuneration between an MA organization and a FQHC, or an entity controlled by an FQHC, so long as the remuneration is provided pursuant to a written agreement as described in section 1853(a)(4) of the Social Security Act. The Final Rule adopts a regulatory safe harbor that is consistent with the exception.

**Protection for Discounts by Manufacturers for Certain Drugs under the Medicare Coverage Gap Discount Program**

Under the Medicare Coverage Gap Discount Program (MCGDP), prescription drug manufacturers may enter into agreements with the Secretary of the Department of Health and Human Services that enable the manufacturers to provide select beneficiaries with access to discounts on drugs at the point of sale. In this Final Rule, the OIG formally adopts a safe harbor regulation to protect discounts to the price of “applicable drugs” furnished to “applicable beneficiaries” through the MCGDP, so long as the manufacturer is in full compliance with the MCGDP requirements.

**Local Transportation Safe Harbor**

In addition to the foregoing, the OIG also finalizes a new safe harbor to protect free or discounted local transportation services provided to federal health care program beneficiaries pursuant to its authority at section 1128B9b(3)(E) of the Act. As far back as 2002, the OIG solicited public comment on issues related to the provision of complimentary transportation. At that time, the OIG acknowledged that in enacting section 1128A(a)(5) of the Act, Congress intended that the statute did not preclude the provision of complimentary local transportation of nominal value. Nominal value at the time was interpreted to mean no more than $10 per item or service or $50 in the aggregate over the course of a year. The OIG
recently released a Policy Statement [PDF] that increases this cap to $15 per item or service or $75 in the aggregate per patient on an annual basis. Even with this increase, this cap may be overly restrictive in the context of complimentary local transportation.

Following the OIG's proposal of a possible safe harbor in 2014, the industry was operating with a sense of uncertainty regarding what transportation services would be considered permissible. The Final Rule addresses these longstanding concerns by finalizing a safe harbor that modifies certain elements from the proposal. The new safe harbor permits free or discounted local transportation made available by an “eligible entity” to federal health care program beneficiaries if certain criteria are met, including providing free transportation to “established patients” for medically necessary services within a local area. The OIG also included separate criteria for “shuttle service” transportation that do not include some of the limitations contained in the first provision of the safe harbor.

Free Local Transportation Generally

In response to the comments received in response to the proposed rule, the OIG modified some elements of safe harbored arrangements and clarified points raised by commenters. For example, the OIG notes that the safe harbor is available for transportation of a patient both to a provider or supplier of services and back to a patient's home if the conditions of the safe harbor are met. Additionally, the OIG does not require that the transportation be planned in advance. A transportation program can apply its own terms for patient eligibility for free or discounted transportation services as long as such eligibility is not based on a status of being federal health care program recipient or not. The OIG believes that the safe harbor effectively balances the potential benefits of a properly structured program against the possible risks.

Eligible Entity

An eligible entity for purposes of the safe harbor includes any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items. The OIG specifically discussed DME suppliers and pharmacies as examples that provide items rather than services and, as such, would not qualify for this safe harbor. The OIG is concerned that individuals and entities that primarily supply health care items generally do not play a role in ensuring patient access to other providers. Rather, the provision of free transportation, if permitted, could present a heightened risk of using such transportation to generate referrals in a way that increases costs for patients and federal health care programs.

Although the OIG considered excluding certain groups of providers or suppliers in the proposed rule, the proposal was not finalized. Rather, the preamble provides examples of individuals and entities included in the definition of eligible entity, such as dialysis facilities, physical therapists, and home health agencies. However, the OIG includes a warning that home health agencies have posed heightened risk of program abuse and they must be sure to make note of safe harbor for protection for transportation services offered.

In recognition of the variety of entities that may not directly render health care services to patients, such as health plans, MA organizations, MCOs, accountable care organizations (ACOs), clinically integrated networks, and charitable organizations, the OIG clarified that these groups are not among the entities excluded from the definition of eligible entity and are therefore eligible to provide transportation.

Established Patient

The proposed definition of established patient did not include free transportation to new patients, rather it applied to patients who had selected a provider or supplier and had attended an appointment with that provider or supplier. Commenters noted that patients often need transportation to their first appointment, particularly those who have not seen a primary care physician in years or those who are newly insured. In response to the commenters' concerns, the OIG attempted to balance the risk of the transportation services being used as a patient recruiting tool with the benefit of ensuring safe transport to and from medically necessary services. Under this final safe harbor an established patient is a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who previously attended an
appointment with the provider or supplier. This change allows a patient to be considered an established patient at the time the patient initiates contact and would permit the provision of transportation services to even the first appointment.

It is possible for others to initiate contact with a provider or supplier on behalf of a patient who would then be considered an *established patient*. Another person, such as a family member, a case manager, or a provider or supplier where a patient is attending an appointment, who has been given permission to do so, can schedule an appointment on behalf of the patient to meet this criterion of the safe harbor. The OIG clarifies by noting that a case manager (i.e., someone coordinating a patient's care) scheduling an appointment and asking if transportation might be available is different than a provider or supplier reaching out to the patient (or to the patient's case manager) and asking to have a new patient come in, linked with an offer of transportation. The first would be protected (if all other conditions of the safe harbor are met), and the second would not be.

For eligible entities such as health plans, ACOs and health systems that do not have *established patients* because patients do not receive health care from them, any transportation services they provide will be to another provider or supplier. The patient must be an *established patient* with that other provider or supplier for safe harbor protection.

**Purpose of Transportation**

The final safe harbor is available only for transportation for medically necessary items or services at this time. OIG is willing to consider comments that the purpose of free transportation should be interpreted more broadly to include non-clinical but health-related activities such as obtaining social services, getting to food banks and applying for government benefits. It is possible that the safe harbor will be expanded to other activities as part of the movement toward coordinated care efforts. In the interim, eligible entities could consider a shuttle service for these non-medically necessary services as discussed below.

An eligible entity that is a health care provider or supplier can choose to provide its established patients with transportation services to its own location without extending this service to patients of other providers. However, because the availability of transportation cannot be determined in a manner related to past or anticipated volume or value of referrals of federal health care program business, if an eligible entity chooses to make transportation available to health care services provided by others, the eligible entity must provide transportation to the patient's provider of choice.

If an eligible entity is transporting a patient to another provider or supplier and the transporting entity is itself a provider or supplier of federally payable services, the patient must have an established relationship with both the transporting entity and the provider to which he is being transported. In contrast, an eligible entity that does not itself provide health care services (including charitable organizations, health plans, and ACOs) is not required to have an established relationship with a patient to provide transportation protected by this safe harbor.

**Need for Transportation**

The OIG finalizes a requirement that eligible entities have a set policy regarding the availability of transportation assistance, and must apply that policy uniformly and consistently. The specific parameters of such a policy are not included in the safe harbor. The OIG notes that eligible entities can choose to provide transportation in a variety of permissible ways, including: only for primary care visits; for visits included in a discharge plan; or even within a smaller radius than the 25-mile local distance limit established in the safe harbor. The criteria the eligible entity establishes must be applied consistently, not be based on the past or anticipated volume or value of federal health care program business, and satisfy the other elements of the safe harbor.
The safe harbor does not require eligible entities to maintain individualized documentation for each patient to whom transportation is provided. It may be best practice to do so to demonstrate compliance with the requirements of the policy and the consistent and uniform application.

Although the eligible entity may establish a need basis for transportation services, it is not required. If an eligible entity does include such a requirement, the fact that a patient receives Medicare or Medicaid benefits cannot serve as a proxy for establishing need, as this could be seen as linking the provision of transportation services to the volume or value of federal health care program business.

Modes of Transportation

The final safe harbor excludes air, luxury and ambulance-level transportation as proposed. Transportation via vehicles equipped for wheelchairs, other than ambulances, as well as third-party transportation such as public transportation, are both eligible for safe harbor protection if the other criteria of the safe harbor are met. Situations that require air or ambulance transportation would need to be considered on a case-by-case basis.

Marketing

The OIG is concerned that the marketing of free transportation will be used as a means to generate referrals. The marketing limitations as well as the definition of established patient are meant to address these concerns. OIG makes clear that transportation assistance cannot be publicly advertised or marketed to patients or others who are potential referral sources. Additionally, no marketing of health care items or services can occur during the course of the transportation. This includes posters and pamphlets that discuss services that patients may receive from the health care provider or supplier. The OIG wants these discussions to occur directly with the health care provider or supplier and not the transportation provider. For purposes of the safe harbor, signage designating the source of the transportation on the vehicles used to transport patients is considered a safety feature and not marketing. Additionally, donors of transportation services or vehicles can be acknowledged only if the donor is not a health care provider or supplier, and does not make, market, or sell health care items or supplies.

Commenters asked for clarification on how providers are permitted to inform patients that transportation is available. The OIG noted that informing patients in a targeted manner that transportation is available is not marketing, but advertising on web sites or in printed materials distributed to the public would not qualify for the safe harbor. Asking a patient if they will have transportation home after a procedure that requires it would not be considered marketing for purposes of the safe harbor.

The safe harbor protects arrangements in which drivers or others involved in arranging the transportation are not paid on a per-beneficiary transported basis. Mileage-based compensation for drivers is one acceptable methodology.

Local Transportation

Because the OIG created this safe harbor to protect the provision of “local” transportation, a distance limitation is included in the regulations as was proposed, but the OIG included a separate distance limitation for rural areas. In urban areas, the patient may be transported within 25 miles of the health care provider or supplier to or from which the patient would be transported. This distance is increased to 50 miles in rural areas. This distance can be measured “as the crow flies” which would include any route within the specified radius, even if the chosen route is more than the mileage limitation when driven. An eligible entity can choose a shorter distance limit for the provision of free or discounted transportation; this simply establishes the safe harbor limit.

Rural area is an area that is not an urban area. An urban area is defined as a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or certain New England counties specified in the regulations.
The safe harbor does not require that patients be transferred to the nearest facility capable of providing the medically necessary items or services. The OIG expresses concern that such a condition could limit patient choice and that application of this standard could create a burden for patients or providers.

**Prohibition on Cost Shifting**

OIG includes an element of the safe harbor that makes clear that the eligible entity must bear the cost of free or local transportation services. The eligible entity cannot shift the cost to Medicare, a state health care program, other payers or individuals. An entity is not precluded from entering arrangements to partner with other parties to provide the transportation services as long as these arrangements are voluntary and not related to any explicit or implicit threat of withholding future referrals. The parties must ensure that the arrangement does not violate the anti-kickback statute or other fraud and abuse laws.

**Shuttle Transportation**

In the proposed rule, the OIG asked for comments on whether safe harbor protection should also be offered to transportation services that take the form of a shuttle service. OIG decided to protect this second form of transportation with some of the same safeguards of the more patient-specific transportation addressed in the first part of the safe harbor, as well as including some different criteria to consider.

The OIG made clear that *shuttle* only includes a vehicle (not air, luxury, or ambulance) that runs on a set route, on a set schedule. In contrast to the individual transportation services, a shuttle does not have an established patient requirement. Additionally, the OIG will not direct where a shuttle can or cannot make stops other than imposing a similar distance limitation. The OIG noted that this means, of the multiple stops a shuttle route may include, there can be no more than 25 miles between any stop on the route and any stop at a location where health care items or services are provided, when measured directly. If any stop is in a rural area, the distance would be up to 50 miles from that stop.

In contrast to other forms of transportation provided, a shuttle may be used for purposes other than to obtain health care items or services, or to obtain such services from a particular provider, practitioner, or supplier. Shuttles can be made available to employees, visitors and patients of an eligible entity. Although the eligible entity can choose to limit the shuttle service to established patients, the OIG does not believe that providing this service to the general public would increase the potential for abuse.

Shuttle services are subject to the same marketing prohibitions to receive safe harbor protection with a clarification that the schedule and stops can be posted. The other requirements of the safe harbor such as being provided by an eligible entity, other marketing limitations such as health care items and services not marketed during transportation, as well as the prohibition on cost shifting apply to shuttle services as well.

The Final Rule amends the CMP safe harbors by modifying the definition of *remuneration* as it relates to beneficiary inducement. The OIG proposed, and has now finalized, several additions to the exceptions to that definition. First, the Final Rule codifies in the regulations the statutory exception at 1128A(i)(6)(E) of the Act permitting hospitals to give reductions in copayment amounts for certain outpatient department services. Further, the OIG has created four additional exceptions.

**Copayment Reductions for Outpatient Department Services**

Section 4523 of the Balanced Budget Act of 1997 added a provision requiring the Secretary to establish a procedure to permit hospitals to elect to reduce copayment amounts for some or all covered hospital outpatient department services to no less than 20 percent of the Medicare fee schedule. The OIG proposed to codify this exception to the definition of *remuneration* by using language substantively identical to the statutory language. The OIG received no comments on the proposed rule, and it is finalized as proposed.
**Promotes Access/Low Risk of Harm**

The OIG has chosen to add an exception in keeping with the existing statutory exception which protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” The OIG recognizes that other exceptions to the beneficiary inducements CMP (and safe harbors to the anti-kickback statute) arguably overlap with this new exception. As such, the OIG indicates that the exception for promoting access with low risk of harm should be “read in the context of those more specific exceptions and safe harbors,” and that it would “look to other applicable exceptions to consider whether the remuneration in question poses a low risk of harm.” The OIG acknowledges that activities and arrangements that do not fit precisely into a safe harbor or an exception may well assert protection under this exception; however, the OIG also cautions that those doing so “will have the burden of presenting sufficient facts and analysis” before the OIG would conclude that the arrangement promotes access to care and poses a low risk of harm.

While the proposed rule did not provide regulatory text, the OIG offered its interpretation of the statutory language and solicited comments on what should be included within the meaning of both *promotes access to care and low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs.*

**Promotes Access to Care**

In the proposed rule, the OIG suggested that the phrase *promotes access to care* should be interpreted to mean that the remuneration provided “improves a particular beneficiary's ability to obtain medically necessary items and services.” However, the OIG solicited comments on whether it should expand that meaning to include “encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it would otherwise be.” The OIG is also considered whether the test for the exception should be that the remuneration promotes access to care for a *particular* beneficiary or for a defined beneficiary population. Finally, the OIG considered whether the term *care* may include non-clinical care such as social services.

The OIG noted that the comments it received on this aspect of the exception fell into two categories: (1) what constitutes “care,” and (2) what it means to “promote access” to care. With respect to the term *care*, the OIG declined to define the type of care beyond items and services that are payable by Medicare or Medicaid. However, as now drafted, the new rule does not include the term *medically necessary*—it simply requires that the care be payable by Medicare or Medicaid. The OIG also declined to adopt the broader, more specific definition of *promoting access*, i.e., “encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it would otherwise be,” but noted that the offer of items or services that do so “would meet [its] original proposed interpretation.” In addition, the OIG notes that the exception would apply to remuneration that promotes access to care for a particular beneficiary as well as a defined beneficiary population.

The OIG also clarifies that, while remuneration that simply rewards a patient for accessing or receiving care—including compliance with a treatment plan—does not promote access to care, the provision of items or services that remove obstacles to care or compliance with treatment plans are acceptable. In addressing many of the comments, the OIG offers several examples of remuneration that it views as “promoting access to care,” such as a subscription to a web-based food and activity tracker offered by a primary care group practice to its diabetic patients, free child care offered by a provider to allow a patient to attend a smoking-cessation program (assuming that the patient has the requisite health condition and the program offered is a payable service), an item that dispenses a medication at a certain time for a patient. These examples represent the offer of remuneration as a means of promoting access—either by improving future care planning (access to an online food and activity tracker for a diabetic patient) or eliminating obstacles to obtaining care (provision of child care) or compliance with a treatment plan (medication dispenser). The OIG also provides examples of remuneration that does not promote access, such as the offer of a $20 general use debit card or free movie tickets.
Low Risk of Harm to Beneficiaries and Program

In the proposed rule, the OIG noted that promoting access to care alone is insufficient to obtain protection under this exception and that it is equally important that any remuneration provided must also pose low risk to both beneficiaries and the federal health care program. The OIG therefore proposed to interpret the phrase **low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs** to mean that the remuneration “(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 exception as finalized adopts this interpretation.

In addressing comments, the OIG reiterates its view that remuneration provided in connection with marketing is not low risk; however, the OIG also notes that education materials are not considered to be remuneration, “even educational materials that include information about the qualifications of a particular provider.” Certain **forms** of remuneration are also not considered by the OIG to be low risk, including cash, cash equivalents, and copayment waivers that do not meet the conditions of the statutory and regulatory exceptions or applicable safe harbor. Free screenings or health care services that are not “simply marketing ploys,” and that “identify or assist with necessary care” would be considered low risk, so long as these services promote access to care.

Retailer Rewards Programs

The OIG proposed an exception to the definition of **remuneration** to reflect the revision enacted under the ACA permitting the offer or transfer of items or services for free or less than fair market value if (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 by the program. The Final Rule finalizes this language as proposed.

The OIG noted in its proposed rule that many retailers have been excluding federal health care program beneficiaries from incentive programs, even though the OIG had indicated its position that gifts worth no more than $10 and no more than $50 in the aggregate annually per patient do not violate the statute. This new exception, according to the OIG, “creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating a specific Federal law.”

Coupons, Rebates, and Other Rewards from Retailer

The OIG ultimately finalized its proposed interpretation that the term **retailer** has its “usual meaning,” i.e., a retailer is “an entity that sells items directly to consumers,” and that individuals and entities that primarily provide services are not considered retailers.

The OIG proposed to interpret **coupon** as “something authorizing a discount on merchandise or services;” **rebate** as “a return on part of a payment;” and **other rewards** as “free items or services, such as store merchandise, gasoline, frequent flyer miles, etc.” The OIG continues to interpret these terms as described, but notes that **rewards** may also include discounts.

Offered or Transferred Equally to the General Public, Regardless of Insurance Status

The OIG interprets the statutory criterion that the offer be made available to the general public to mean that a retailer must offer the items or services without discriminating or “cherry picking” individuals based on their health insurance status.

Not Tied to Other Reimbursable Items or Services

The criterion that the offer not be tied to other reimbursable items or services is not viewed by the OIG as creating a requirement that there be no connection whatsoever between the offer and the medical care of the individual; rather, the connection should be “attenuated.” That is, the reward cannot be conditioned,
on the front end, on the purchase of good or services reimbursed by a federal health care program. By way of example, the OIG indicates that a retail pharmacy cannot offer customers (that would include Program beneficiaries) two points for every dollar spent on prescription copayments, but one point for every dollar spent elsewhere in the store. Nor may the reward itself be an item or service that is reimbursed under a federal health care program. For instance, a customer should be allowed to redeem a coupon for anything purchased in the store rather than being restricted to using the coupon solely on the cost-sharing component of prescription purchases.

Financial-Need-Based Exception

The OIG proposed and has now finalized an exception to the definition of remuneration to reflect the revision enacted under the ACA permitting the offer or transfer of items or services for free or less-than-fair-market value after a determination that the recipient is in financial need and meets certain other criteria. This exception mirrors the statutory language. It is limited to the offer or transfer of items or services and does not include cash or instruments convertible to cash. The additional criteria set forth under the statute include: (1) the items or services may not be offered as part of any advertisement or solicitation; (2) the items or services are not tied to the provision of other items or services reimbursed by the Program; (3) there must be a reasonable connection between the items or services and the medical care of the individual; and (4) the items or services may be provided only after determining in good faith that the individual is in financial need.

In its proposal, the OIG noted that the second and third criteria should be considered together in order to provide any meaningful interpretation, and its discussion regarding these components of the exception is consistent with its interpretation of the exception relating to retail rewards programs discussed above. Again, while the free or below-fair-market-value items or services provided may not be tied to services reimbursable by Medicare and Medicaid, the OIG indicated that it is not necessary for there to be a “complete severance of the offer from the medical care of the individual.” The OIG viewed this exception as requiring a “dual consideration: Whether a reasonable connection exists from a medical perspective and whether a reasonable connection exists from a financial perspective. A reasonable connection exists from a medical perspective when the items or services would benefit or advance identifiable medical care or treatment that the individual patient is receiving. From a financial perspective, remuneration disproportionately large compared with the medical benefits conferred on the individual patient would not have a reasonable connection to the patient's medical care. Such remuneration gives rise to an inference that at least part of the transfer is being provided to induce beneficiaries to obtain additional services.”

In the Final Rule, the OIG provides some examples of items or services that might be “reasonable from a medical perspective,” including car seats, particular food items, weight monitors, glucose monitors, safety devices for children, etc., but cautions that reasonableness depends on individual circumstances. Moreover, the OIG emphasizes this 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.”

With respect to the requirement that the remuneration have a reasonable connection from a financial perspective, the OIG notes that remuneration of high financial value is less likely to be reasonably connected to the medical care, but, at the same time, declines to provide specific retail value limits because “needs vary among patients, and technology changes over time.”

With respect to the fourth requirement, that the items or services be provided only after determining in good faith that the individual is in financial need, the OIG continues to interpret this provision to mean that there is an individualized assessment of the patient's financial need on a case-by-case basis that is conducted in good faith. A “good faith” assessment would be one that utilizes a “reasonable” set of income guidelines that are (1) applied uniformly, (2) based on objective criteria, and (3) appropriate for the applicable locality. Further, “financial need” is not limited to indigence. The OIG considered, but declined to include, a requirement that there be specific supporting documentation, but recommends that entities be able to demonstrate compliance with the requirement to make a good faith determination of financial need and that “entities offering these items would do so in accordance with a set policy that is
uniformly applied.” Finally, the OIG declined to adopt a “uniform measure of need” or a “minimum threshold of assistance before a determination of need is required.”

Waivers of Cost-Sharing for the First Fill of a Generic Drug
The final addition to the statute was intended to “minimize drug costs by encouraging the use of lower cost generic drugs.” Under the exception, a PDP sponsor of a Part D plan or MA organization offering MA-PD plans may waive any copayment that would be otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug. This exception requires sponsors offering the waivers to disclose the incentive program in their benefit plan package submissions to CMS. The OIG proposed to make this exception effective for coverage years beginning after publication of the Final Rule, but because the rule was published after the deadline for submission of benefit plan packages to CMS, the effective date for this exception was extended to January 1, 2018.

1 42 C.F.R. § 1001.952(f).
2 42 C.F.R. § 1001.952(k).
4 See Provider Reimbursement Manual, § 310.
5 42 C.F.R. § 1001.952(bb).