DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936-AA06

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

AGENCY: Office of Inspector General (OIG), HHS

ACTION: Final rule.

SUMMARY: In this final rule, OIG amends the safe harbors to the anti-kickback statute by adding new safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. The OIG also amends the civil monetary penalty (CMP) rules by codifying revisions to the definition of "remuneration," added by the Balanced Budget Act (BBA) of 1997 and the Patient Protection and Affordable Care Act, Public Law 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (ACA). This rule updates the existing safe harbor regulations and enhances 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.

DATES: These regulations are effective on [INSERT DATE 30 DAYS AFTER PUBLICATION]

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SUPPLEMENTARY INFORMATION:

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Executive Summary

A. Purpose of the Regulatory Action

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and ACA include exceptions to the anti-kickback statute, and the BBA of 1997 and ACA include exceptions to the definition of "remuneration" under the civil

monetary penalties law. The OIG is codifying those changes here. At the same time, OIG is finalizing additional changes to make technical corrections to an existing regulation and to add new safe harbors to the anti-kickback statute to protect certain services that the industry has expressed an interest in offering and that we believe could be, if properly structured and with appropriate safeguards, low risk to Federal health care programs.

B. Summary of the Major Provisions

1. Anti-Kickback Statute and Safe Harbors

In this final rule, we amend 42 CFR 1001.952 by modifying certain existing safe harbors to the anti-kickback statute and by adding safe harbors that provide new protections or codify certain existing statutory protections. These changes include:

- a technical correction to the existing safe harbor for referral services;
- protection for certain cost-sharing waivers, including:
- pharmacy waivers of cost-sharing for financially needy beneficiaries; and

- waivers of cost-sharing for emergency ambulance services furnished by State- or municipality-owned ambulance services;
- protection for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs);
- protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- protection for free or discounted local transportation services that meet specified criteria.

2. Civil Monetary Penalty Authorities

We amend the definition of "remuneration" in the CMP regulations at 42 CFR part 1003 by interpreting and incorporating certain statutory exceptions for:

- 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; and
- copayment waivers for the first fill of generic drugs.

In addition, because the original language in the introductory paragraph of the definition of "remuneration" referred only to "coinsurance and deductible amounts," we have added the word "copayment" for consistency with the other text that we proposed and are finalizing.

C. Costs and Benefits

There are no significant costs associated with the regulatory revisions that would impose any mandates on State, local, or tribal governments or on the private sector.

I. Background

A. The Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (the Act), the anti-kickback statute, provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of

up to $25,000 and imprisonment for up to 5 years. Violations may also result in the imposition of CMPs under section 1128A(a)(7) of the Act, program exclusion under section 1128(b)(7) of the Act, and liability under the False Claims Act (31 U.S.C. 3729-33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93 (section 1128B(b)(3)(E) of the Act), which specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would

specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under Federal health care programs. In authorizing the Department of Health and Human Services (Department or HHS) to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended that the safe harbor regulations be updated periodically to reflect changing business practices and technologies in the health care industry.

Section 205 of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, established section 1128D of the Act, which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act provides that, in modifying and establishing safe harbors, the Secretary of Health and Human Services (Secretary) may consider whether a specified payment practice may result in:

- an increase or decrease in access to health care services;
- an increase or decrease in the quality of health care services;
- an increase or decrease in patient freedom of choice among health care providers;

- an increase or decrease in competition among health care providers;
- an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in the cost to Federal health care programs;
- an increase or decrease in the potential overutilization of health care services;
- the existence or nonexistence of any potential financial benefit to a health care professional or provider, which benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arrange for a referral of health care items or services to a particular practitioner or provider;
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing safe harbors in various areas.[1] These provisions have been developed "to

[1] 56 FR 35952 (July 29, 1991); 61 FR 2122 (Jan. 25, 1996); 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); 66 FR 62979 (Dec. 4, 2001); 71 FR

limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements." (56 FR 35952, 35958 (July 29, 1991)). Many of the safe harbors create new exemptions, while other safe harbors interpret exceptions already promulgated by statute.

Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. We note, however, that compliance with a safe harbor insulates an individual or entity from liability under the anti-kickback statute and the beneficiary inducements CMP[2] only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

Section 101 of the MMA added a new section 1860D to the Act, establishing the Part D prescription drug benefit in the Medicare program. Section 101(e) of the MMA amends section 1128B(b)(3) of the Act to permit pharmacies to waive or reduce cost-sharing imposed under Part D as long as specified

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45110 (Aug. 8, 2006); 72 FR 56632 (Oct. 4, 2007); 78 FR 78751 (Dec. 27, 2013).

[2] Pursuant to section 1128A(i)(6)(B), a practice permissible under the anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the beneficiary inducements CMP.

conditions are met. In addition, section 237 of the MMA added an exception to permit certain remuneration between MA organizations and FQHCs.

The ACA also includes a number of provisions that could affect liability under the anti-kickback statute. Section 3301 of the ACA establishes the Medicare Coverage Gap Discount Program, codified at section 1860D-14A of the Act. Pursuant to this program, prescription drug manufacturers have entered into agreements with the Secretary to provide certain beneficiaries access to discounts on drugs at the point of sale. Section 3301(d) of the ACA amends the anti-kickback statute to protect the discounts provided for under the Medicare Coverage Gap Discount Program.

In this final rule, we incorporate into our regulations safe harbors for payment and business practices permitted under the MMA and ACA, as well as new safe harbors pursuant to our authority under section 14 of the Medicare and Medicaid Patient and Protection Act of 1987 to protect practices that we view as posing a low risk to Federal health care programs as long as specified conditions are met. We considered the factors cited by Congress in promulgating the safe harbors in this final rule. We believe the safe harbors in this rule further the goals of access, quality, patient choice, appropriate utilization, and competition, while protecting against increased costs,

inappropriate steering of patients, and harms associated with inappropriate incentives tied to referrals.

B. Civil Monetary Penalty Authorities

1. Overview of OIG Civil Monetary Penalty Authorities

In 1981, Congress enacted the CMP law, section 1128A of the Act, as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The law authorized the Secretary to impose penalties and assessments on persons who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMP law also authorized the Secretary to exclude persons from Federal health care programs (as defined in section 1128B(f)(1) of the Act) and to direct the appropriate State agency to exclude the person from participating in any State health care programs (as defined in section 1128(h) of the Act). Congress later expanded the CMP law and the scope of exclusion to apply to all Federal health care programs, but the CMP applicable to beneficiary inducements remains limited to Medicare and State health care program beneficiaries. Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse.

2. The Definition of "Remuneration"

The BBA of 1997 and section 6402(d)(2)(B) of the ACA amended the definition of "remuneration" for purposes of the beneficiary inducements CMP at section 1128A(a)(5) of the Act, as discussed below. In this final rule, we are incorporating these changes into the definition of "remuneration" under § 1003.110.

C. Summary of the 2014 Proposed Rulemaking

On October 3, 2014, we published in the Federal Register (79 FR 59717) a Notice of Proposed Rulemaking (Proposed Rule) setting forth certain proposed amendments to the safe harbors under the anti-kickback statute and proposed amendments to the CMP exceptions. With respect to the anti-kickback statute, we proposed a technical correction to the existing safe harbor for referral services; 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; protection for certain remuneration between MA organizations and FQHCs; protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and protection for free or discounted local transportation services that meet specified criteria. With the exception of the proposed safe harbors for cost-sharing waivers for certain emergency ambulance

services and for free or discounted local transportation, all of the proposed safe harbors already were statutory exceptions to the anti-kickback statute (or revisions to existing safe harbors). We proposed five new exceptions to the beneficiary inducements CMP related to 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; and copayment waivers for the first fill of generic drugs. The latter four exceptions emanated from exceptions to the CMP included in the ACA, and some of them included multiple conditions.

We solicited comments on interpretations of each of the anti-kickback safe harbors and CMP exceptions to ensure that we protect low-risk, beneficial arrangements without opening the door to abusive practices that increase costs or compromise patient choice or quality of care.

In the Proposed Rule, we also proposed to add a regulation to reflect section 1128A(b) of the Act (the Gainsharing CMP). The Gainsharing CMP is a self-implementing law that, at the time we issued the Proposed Rule, prohibited hospitals and critical access hospitals (CAHs) from knowingly paying a physician to

induce the physician "to reduce or limit services" provided to Medicare or Medicaid beneficiaries who are under the physician's direct care, and prohibited the physician from accepting such payments. As we have explained in various guidance documents over the years,[3] the Gainsharing CMP prohibited payments to reduce or limit services, not only payments to reduce or limit "medically necessary" services. Without a change in the statute, we continued to believe that we could not read a "medically necessary" element into the prohibition. However, in the Proposed Rule, we stated our intention to consider a narrower interpretation of the term "reduce or limit services" than we have previously held.

D. Summary of the Final Rulemaking

In finalizing this rule, we are mindful of the impact of delivery system and payment reform on Federal health care programs and the changing relationships between providers in delivering better care, smarter spending, and improved health. Congress intended the safe harbors to evolve with changes in the health care system, and we believe this final rule balances additional flexibility for industry stakeholders to provide

[3] See, e.g., the Special Advisory Bulletin titled "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries", available at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm

efficient, well-coordinated, patient-centered care with protections against fraud and abuse risks. We also believe this rule advances the needs of providers and patients in rural areas and expect that it will have a beneficial effect in promoting improved access to quality care in rural and other underserved areas. The transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers. Many of those new relationships do not implicate our statutes or may be structured to fit in existing exceptions and safe harbors, including those addressed in this final rule. We have taken changes in payment and delivery into account in this final rule. This final rule does not specifically address many emerging arrangements (though, as we note above, some of those arrangements can fit in existing protections). We intend to continue to monitor changes in the industry, technology, and clinical care and consider whether additional rulemaking is needed to foster high-quality, efficient, patient-centered care. We will continue to seek stakeholder input as appropriate, and we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending.

Safe harbors and exceptions, along with advisory opinions, are long-standing tools for addressing the evolution of health

care business arrangements under the fraud and abuse laws. More recently, Congress granted the Secretary limited authority to waive certain fraud and abuse laws under Title XI and XVIII of the Act as necessary to carry out and test new payment and delivery models and demonstration programs in Medicare and Medicaid. Specifically, under the ACA, the Secretary has such waiver authority for, among others, the Medicare Shared Savings Program (MSSP) pursuant to section 1899 of the Act and testing models under section 1115A of the Act.[4] This waiver authority creates a new tool for addressing the application of the fraud and abuse laws to business arrangments in a changing health care landscape. Parties participating in these models may use available waivers, if all waiver conditions are met. Alternatively, they are free to look to any available safe harbors or CMP exceptions for protection of arrangements they may undertake. They would not need to comply with both sets of requirements.

We are finalizing all of the anti-kickback statute safe harbors that we proposed, with certain modifications suggested by commenters. We also are finalizing all of the beneficiary inducement CMP exceptions that we proposed. Although we did not

[4] The waivers are posted on the CMS Web site, available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.

propose regulatory text in the Proposed Rule for the exception for remuneration that promotes access to care and poses a low risk of harm, we did propose and solicit comments on interpretations of the statutory terms "promotes access to care" and "low risk of harm" to programs and beneficiaries. We are finalizing these proposals as regulatory text, as explained in greater detail below. We also note that we are removing the "or" that previously appeared between the third and fourth exceptions, now that we are adding five exceptions to the end of the definition of "remuneration."

With respect to the Gainsharing CMP, approximately six months after the Proposed Rule was published, Congress amended the law. Congress passed the Medicare and CHIP Reauthorization Act of 2015 (MACRA) in April 2015. Section 512(a) of MACRA amended the language to insert the words "medically necessary" before "services," so that now only payments to reduce or limit medically necessary services are prohibited by the law. Because of the amendment to the statute, we are not finalizing the regulation text, as proposed (nor are we finalizing the definition of "hospital" that we had proposed adding to section 1003.101 (as proposed to be redesignated as section 1003.110) to complement the Gainsharing CMP proposal). We note that this statutory provision is self-implementing, and no regulatory

action is required to make the change enacted in MACRA effective. However, we may in the future codify the new statutory language in our regulations.

II. Summary of Public Comments and OIG Responses

A. General

We received responsive comments from 88 distinct commenters, including, but not limited to, individuals, trade associations, providers, and suppliers. Many of these individuals and entities provided comments on multiple topics. Commenters generally supported our proposals, but many commenters recommended certain changes or requested certain clarifications. We have divided the public comment summaries and our responses into sections pertaining to the individual safe harbor or CMP exception to which they apply.

B. Anti-kickback Statute and Safe Harbors

1. Referral Services

We proposed to make a technical correction to the safe harbor for referral services, found at 42 CFR 1001.952(f). In 1999, we finalized a modification to the language of the safe harbor to clarify that the safe harbor precludes protection for payments from participants to referral services that are based

on the volume or value of referrals to, or business otherwise generated by, either party for the other party. See 64 FR 63518, 63526 (Nov. 19, 1999). During subsequent revisions to the safe harbor by which we intended to make a technical correction clarifying that OIG's exclusion authority applied to all Federal health care programs rather than only to Medicare and State health care programs, the language in § 1001.952(f)(2) inadvertently was changed to "* * * or business otherwise generated by either party for the referral service * * *." See 67 FR 11928, 11929 and 11934 (Mar. 18, 2002). Therefore, we proposed to make a technical correction and revert to the language in the 1999 final rule cited above. We received no comments on this proposal and intend to make the proposed revision in this Final Rule.

Comment: We received one comment on a different aspect of this safe harbor. A commenter recommended that OIG modernize the safe harbor to permit the use of online, Internet-based tools, as these are the more common modes of communication and can better promote quality patient care.

Response: The commenter's request is outside the scope of this rulemaking. We note, however, that the safe harbor does not exclude the use of online tools. Should we determine in the future that online referral sources need additional or different

protection, we may consider revisions to the safe harbor to further facilitate the use of these tools at that time.

2. Cost-Sharing Waivers

While reiterating our concerns about potentially abusive waivers of cost-sharing amounts under the anti-kickback statute, in the Proposed Rule, we proposed to modify § 1001.952(k) by adding two new subparagraphs to protect certain cost-sharing waivers that pose a low risk of harm and make technical corrections to the introductory language to account for new subparagraphs. We also noted that subsection (k) is limited to reductions or waivers of Medicare and State health care program beneficiary cost-sharing and solicited comments about expanding this safe harbor to protect waivers under all Federal health care programs, if applicable, and subject to terms of each type of cost-sharing waiver in subsection (k).

Comment: Several commenters supported the expansion of the safe harbor in subsection (k) of § 1001.952 to protect waivers of cost-sharing obligations for all Federal health care programs. One commenter stated that this expansion would increase patient access to care, treatment, and therapy.

Response: We believe that expanding the scope of subsection (k) to all Federal health care programs, if

applicable, is appropriate. We note that subsection (k) protects waivers of specific types of cost-sharing, some of which cannot be read to apply to all Federal health care programs. For example, subparagraph (k)(1) protects only cost-sharing waivers for inpatient hospital services paid on a prospective payment system. Thus, it would protect waivers of cost-sharing of that type, but the safe harbor might not apply to all Federal health care programs due to varying methods of payment. To make this and the change described below, we are republishing subparagraph (k) in its entirety.

Comment: A commenter requested that we change the language in the first sentence of subparagraph (k) from "coinsurance or deductible" to "copayment, coinsurance, or deductible."

Response: We had proposed to make certain technical corrections to this introductory paragraph to account for the new subparagraphs we proposed to add. Given that we proposed to include the language suggested by the commenter in new subparagraph (k)(3) regarding waivers of Part D cost-sharing, we believe it is reasonable to include this change in the introductory paragraph as well. We have revised the language accordingly in this final rule.

a. Part D Cost-sharing Waivers

In the Proposed Rule, we proposed a new paragraph at § 1001.952(k)(3) reflecting an exception to the anti-kickback statute at section 1128B(b)(3)(G) of the Act, which was added by section 101 of the MMA. Consistent with the statute, we proposed language that would protect a pharmacy waiving Part D cost-sharing if: (1) the waiver or reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive or reduce the cost-sharing; and (3) before waiving or reducing the cost-sharing, the pharmacy either determines in good faith that the beneficiary is in financial need or the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so. If, however, the waiver or reduction of cost-sharing is made on behalf of a subsidy-eligible individual (as defined in section 1860D-14(a)(3) of the Act), then conditions (2) and (3) above are not required. Because the statute incorporates by reference the three conditions stated above from section 1128A(i)(6)(A) of the Act, we proposed to interpret those conditions consistent with our regulations incorporating them in paragraph (1) of the definition of "remuneration" at 42 CFR § 1003.110. We also cautioned providers, practitioners, and suppliers that safe harbors protect individuals and entities from liability only under the anti-kickback statute and the beneficiary inducements CMP, and that they still must comply with other laws,

regulations, and Centers for Medicare and Medicaid Services (CMS) program rules.

Scope of Safe Harbor

Comment: Two commenters requested that the safe harbor for waivers or reductions of Part D cost-sharing obligations by pharmacies be expanded to the Medicaid program. These commenters noted that expanding the safe harbor to Medicaid beneficiaries would benefit low-income patients who often cannot obtain needed health care services because they cannot afford their cost-sharing obligations.

Response: Because we have expanded subsection (k) to apply to all Federal health care programs, where applicable, we have determined that it is appropriate to expand this paragraph as well. Thus, we are not limiting the safe harbor to waivers of Part D cost-sharing. However, we emphasize that this is a safe harbor applicable to pharmacies and does not protect, for example, waivers by physicians for copayments for Part B drugs. In addition, we are retaining the statutory requirement that pharmacies seeking to rely on this safe harbor may forego the individualized financial need assessment only for subsidy-eligible individuals (as defined in section 1860D-14(a)(3) of the Act).

Comment: One commenter suggested that the proposed safe harbor is more restrictive than the statutory exception. The commenter requested that we expand the safe harbor for waivers of cost-sharing obligations for covered supplies under Part B and for cost-sharing obligations for items and services imposed under Part C. The commenter stated that we have the statutory authority to apply the safe harbor beyond Part D, and asserted that by limiting the safe harbor to Part D plans we would create a competitive disadvantage for MA plans who cannot offer the same "cost-saving programs."

Response: We respectfully disagree that the safe harbor that we proposed was more restrictive than the statutory exception; the language of the proposed safe harbor was entirely consistent with the statutory exception. Nevertheless, as we explained above, we are finalizing a safe harbor that protects reductions or waivers by pharmacies of Federal health care program cost-sharing, rather than limiting the protection to waivers of Part D cost-sharing, as long as all requirements of the safe harbor are met.

In addition, we note that this safe harbor is not applicable to anything characterized as a "cost-saving program" as we understand the term. This safe harbor permits pharmacies to waive cost-sharing on an unadvertised, nonroutine basis after

an individualized determination of financial need (or a failure to collect after reasonable collection efforts). It is not meant to, and would not, protect waivers that are advertised as part of a "program" to waive copayments. Finally, the safe harbor protects waivers given at the pharmacy level, not the plan level. Thus, there should be no effect on competition among plans. The safe harbor does not affect the ability of Part D plan sponsors, MA organizations offering Medicare Advantage prescription drug (MA-PD) plans, or other plans to reduce beneficiary cost-sharing obligations as a matter of plan design, nor does it affect their ability to share the cost of such reductions with pharmacies through negotiation of drug prices.

Comment: One commenter suggested that we expand the safe harbor to permit MA plans and pharmacies to develop joint cost-sharing waiver initiatives for dual-eligible beneficiaries and that we allow these waivers for dual-eligible beneficiaries to be routine and advertised. The commenter asserted that its proposed expansion of the safe harbor would be at little or no cost to Federal health care programs.

Response: We decline to accept the commenter's suggestion. The statute expressly states that the waivers cannot be advertised, even for the lowest-income patients. However, as

also explained above, MA plans and pharmacies are free to negotiate reduced cost-sharing as part of benefit designs, and MA plans are free to market plan benefits consistent with CMS marketing guidelines.

Comment: One commenter asserted that the regulatory safe harbor does not match the scope of the statute and suggested we broaden the safe harbor to implement congressional intent.

Response: As explained above, despite the fact that we believe the proposed safe harbor was consistent with the statutory language, we have expanded protection in this final rule to include waivers by pharmacies under all Federal health care programs, as long as the waivers meet all elements of the safe harbor.

Advertising

Comment: One commenter expressed concern that the proposed restrictions on advertising and solicitation violate pharmacies' First Amendment rights to free speech, and asserted that these restrictions therefore should be eliminated. As an alternative, the commenter recommended that OIG impose no more than the least restrictive limits on pharmacies' free speech that are necessary to advance a substantial government interest.

Response: The regulatory safe harbor finalized in this final rule is intended to be consistent with subparagraph (G)

added to section 1128B(b)(3) of the Act by the MMA. Section 1128B(b)(3)(G) of the Act cites to the conditions specified in clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act. In turn, clause (i) requires that the waiver or reduction of any cost-sharing obligation not be offered as part of any advertisement or solicitation. This prohibition on advertising of covered incentives, waivers, or other item or service has been in the statute since it was enacted in the Health Insurance Portability and Accountability Act of 1996. The safe harbor is consistent with the statutory exception, and we cannot ignore the conditions that Congress explicitly included. Moreover, we do not believe that the restriction on advertising, as a condition of an exception to a statutory provision, is unconstitutional. The exception does not require or prohibit any conduct. Advertising would not violate the anti-kickback statute by itself; any programs that are advertised simply would not be eligible for protection under the exception and would be subject to a case-by-case review under the anti-kickback statute. As explained elsewhere in this rulemaking, our interpretation of the statutory prohibition on advertising is no broader than necessary to preclude communications that create a high risk of abusive steering arrangements under the fraud and abuse laws.

Comment: Several commenters that represent entities such as health centers designated by CMS as FQHCs assert that these types of FQHCs are required by section 330 of the Public Health Service Act to offer a schedule of fees or payments for the provision of their services as well as a corresponding schedule of discounts, which apply on the basis of a patient's ability to pay. In addition, according to the commenters, the Health Resources and Services Administration (HRSA), which administers the Health Center Program, requires these health centers (designated by CMS as FQHCs) to use multiple methods (e.g., signage and registration processes) to inform patients of the sliding fee discount programs. These commenters are concerned that certain activities that are necessary to meet these notification requirements could be construed as advertising, which would exclude these entities from protection under the safe harbor. The commenters suggest clarifying that communications about a FQHC's sliding fee discount program are not an advertisement or solicitation of Part D cost-sharing waivers for purposes of the safe harbor.

Response: We understand HRSA obligates health centers to make patients aware of their sliding fee discount programs, and such communications would not constitute advertising for the purpose of this rule. However, depending where a patient falls

on the sliding scale, he or she often still will have a copayment for items or services received at the FQHC. A FQHC would not need to avail itself of this safe harbor for waiving a pharmacy copayment unless it waives the amount that the patient would have been obligated to pay according to the FQHC's sliding scale. That potential waiver would not be protected by the safe harbor if it were advertised.

Comment: Three organizations focused on access to health care for Alaska Natives and American Indians asserted that the restriction on advertisements prohibits providers from informing low-income patients and/or rural patients about affordable health care options while they are receiving care at a health care facility. According to the commenters, these patients are difficult to contact because they are geographically isolated, elderly, and have limited means of communication, and these patients oftentimes are more likely to forgo services they cannot afford. To address their concerns, the commenters requested that OIG amend the regulation to exclude the following materials from the terms "advertisement" and "solicitation" for all patients: (1) information given by a provider to a patient in person; (2) a notice of patient rights on provider Web sites related to charity care or similar opportunities; and (3) any information transmitted directly to a patient as part of a

reminder of upcoming appointments or a statement of benefits and coverage.

Response: Although we appreciate the commenters' concerns, we decline to adopt their suggested language narrowing the scope of the terms "advertisement" and "solicitation." We agree that it is important for patients to receive information about their health care options, and that not all information provided to beneficiaries is advertising or solicitation. Stakeholders should interpret the terms "advertisement" and "solicitation" consistent with their common usage in the health care industry. This particular safe harbor relates to cost-sharing waivers by pharmacies. Information posted on Web sites regarding such waivers offered by pharmacies generally would be advertising, while responding to an inquiry from, or discussing financial need with, a particular patient in person generally would not be. However, whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances.

"Routine" Waivers

Comment: One commenter asked us to confirm that a pharmacy does not routinely waive cost-sharing obligations as long as the pharmacy does not automatically waive cost-sharing amounts for beneficiaries of government programs. The same commenter also

recommended that OIG exclude any waivers provided to private-pay patients and subsidy-eligible individuals in assessing whether a pharmacy routinely waives cost-sharing obligations. Finally, the commenter suggested that OIG provide flexibility for pharmacies when they establish protocols for employees to use in determining whether a cost-sharing waiver is appropriate. Three commenters asked for clarification as to what constitutes "routine" waivers of Part D cost-sharing obligations in the context of FQHCs. According to these commenters, waivers or reductions in cost-sharing obligations under Part D frequently occur at FQHCs because of the low-income populations served at these facilities.

Response: In the Proposed Rule, we explained that we would interpret the conditions in section 1128A(i)(6)(A) of the Act consistent with the regulations interpreting these conditions in paragraph (1) of the definition of "remuneration" at § 1003.110. Stakeholders would be well advised to review our guidance on routine waivers of cost-sharing obligations,[5] as well as our guidance on the same condition in the first exception to the definition of remuneration at § 1003.110.[6] First, we do not confirm the commenter's suggestion that waivers are not routine unless they are "automatic." We believe that a waiver or

[5] See, e.g., Special Fraud Alert, 59 FR 65372 (Dec. 19, 1994), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.
[6] 65 FR 24400, 24404 (Apr. 26, 2000).

reduction could be common enough to be "routine" without being automatic. We decline to adopt the commenter's recommendation to define whether waivers of cost-sharing obligations for private-pay patients and subsidy-eligible individuals count in analyzing whether a pharmacy is routinely waiving Federal health care program cost-sharing obligations. Because of the different makeups of different communities, we do not believe it is appropriate to assign a specific number or percentage of patients to the concept of "routine." While we agree that safe harbor protection would not be denied on the basis of waiving cost-sharing for privately insured or subsidy-eligible patients, if those waivers were advertised as, for example, "insurance accepted as payment in full," then such a program would be suspect. We note, however, that waivers offered to subsidy-eligible patients are exempt from the prohibition against offering routine waivers. This safe harbor sets forth the conditions pharmacies must satisfy to qualify for protection when waiving copayments; we are not mandating (or prohibiting) protocols pharmacies may develop to meet those conditions. Whether a pharmacy waives cost-sharing obligations routinely, and thus fails to satisfy a requirement of the safe harbor, depends on the facts and circumstances. We address waivers by FQHCs in response to a more specific comment above.

Financial Need Assessments

Comment: A commenter recommended that OIG provide pharmacies with a uniform, objective standard of financial need to use in meeting the requirement that pharmacies determine in good faith that a beneficiary has a financial need. The commenter requested that we require pharmacies to verify the beneficiary's income (e.g., by reviewing wage statements) prior to waiving his or her Part D cost-sharing obligations. Another commenter requested guidance from OIG as to the methods pharmacies may use to make good faith determinations that individuals are in financial need. According to this commenter, individual assessments are not practical because of the volume of prescriptions that pharmacies dispense, and the commenter asserted that the cost of these individualized assessments would oftentimes be greater than the copayment amount to be waived. For purposes of this safe harbor, the commenter suggested that OIG allow pharmacies to accept as true a patient's statement that he or she is in financial need. Three commenters asked that we confirm that a FQHC's annual assessment of an individual's eligibility for its sliding fee discount program would meet the safe harbor's requirement to make a good faith determination of financial need.

Response: This safe harbor incorporates conditions (i) through (iii) of section 1128A(i)(6)(A) of the Act, and in the

Proposed Rule we proposed to interpret them consistent with the regulations interpreting these conditions in paragraph (1) of the definition of "remuneration" at § 1003.110. When we finalized that definition, commenters requested guidance as to what constitutes "financial need," and we made the following observations:

> We are not specifying any particular method of determining financial need because we believe what constitutes "financial need" varies depending on the circumstances. What is important is that providers make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. We do not believe that it is appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need.

65 FR 24404 (Apr. 26, 2000). This guidance applies equally to the same requirement in this safe harbor. We decline to mandate

specific guidelines, in part, to permit pharmacies the flexibility to determine an appropriate method for their patient population and for their business. By way of example only, one pharmacy might choose to apply a multiple of the poverty guidelines, which take into account family size, for determining financial need, while another pharmacy might prefer to take into account a combination of the poverty guidelines, adjusted for the cost of living in the pharmacy's locality, plus family medical expenses. We emphasize, however, whatever guideline is applied by the pharmacy must be reasonable and applied uniformly. If an entity, such as a FQHC, conducts annual assessments of financial need that are performed on a "good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases," then the entity would not need to perform a second assessment to meet this criterion of the safe harbor. Finally, we find it unlikely that the commenter's suggestion that pharmacies that simply accept as true a patient's statement that he or she is in financial need would meet the criteria of an individualized, good faith determination that the patient is in financial need. We understand that there is a cost involved in performing a financial need assessment. We note that pharmacies are not required to waive copayments, nor are they required to perform financial need assessments for subsidy-eligible

individuals. For all beneficiaries for whom the pharmacy desires to waive a copayment and be protected by this safe harbor, performing a financial need assessment is an important safeguard. A pharmacy might do this by verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant (e.g., pay stubs, tax forms, or evidence of other expenses), or some combination thereof. While we are not requiring any specific documentation of financial need, we do expect that entities offering these reductions or waivers would do so in accordance with a set policy that is reasonable and uniformly applied. Moreover, if an entity were under investigation and asserted this exception as a defense, it would have to be able to demonstrate compliance with the requirement to make an individualized, good faith determination of financial need. A written policy describing the reasonable standards and procedures used for establishing financial need, together with evidence that this written policy was followed, would be useful in making such a demonstration.

Reasonable Collection Efforts

Comment: Under the second option in subsection (3)(ii)(B) of the safe harbor, a pharmacy must fail to collect the copayment, coinsurance, or deductible after making reasonable collection efforts. One commenter asserted that the "reasonable

collection efforts" standard should account for the fact that many cost-sharing obligations are small and the costs associated with collection efforts would exceed the amount owed by the beneficiary. The commenter suggested that pharmacies be able to forgo collection efforts and still meet this condition of the safe harbor if the beneficiary has a "smaller than average" cost-sharing amount or when past collection efforts indicate the costs of collection efforts are greater than the projected recovery amounts.

Response: Like the requirement for a pharmacy to conduct a good faith determination of a beneficiary's financial need, we indicated that we would interpret the reasonable collection efforts requirement consistent with our regulations interpreting that same condition in paragraph (1) of the definition of "remuneration" at § 1003.110. In previous guidance on this condition, we stated that "'reasonable collection efforts' are those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients." 65 FR 24404 (Apr. 26, 2000). In other contexts, we also have cited to the CMS Provider Reimbursement Manual's description of "reasonable collection efforts," which requires providers to issue a bill for the patient's financial obligations, and also includes: "other actions such as subsequent billings, collection letters and telephone calls or

personal contacts with this party which constitute a genuine, rather than a token, collection effort."[7] These concepts apply to this new safe harbor. We note that we cannot envision a scenario in which a preemptive decision by a pharmacy not to request payment from a patient (in the absence of a determination of financial need) or pursue any collection efforts could meet this condition. The amount of the copayment or historical inability to collect cost-sharing amounts for a particular beneficiary might be factors that are considered in determining what reasonable collection efforts are, but they do not justify forgoing all collection efforts.

Comment: According to three commenters, Indian Health Service (IHS) facilities are statutorily prohibited from charging cost-sharing amounts to Alaska Natives and American Indians, and the commenters further state that tribal health programs do not charge any cost-sharing amounts to Alaska Natives and American Indians "on principle." These commenters are concerned that creating a narrow safe harbor for pharmacies (and for ambulance services in subsection (4)) to waive or reduce cost-sharing obligations implies that tribal health programs are violating the Federal anti-kickback statute if they waive cost-sharing obligations for Alaska Natives and American

[7] See Provider Reimbursement Manal (CMS Pub. 15-1) § 310.

Indians in other situations. The commenters requested that OIG include language in the safe harbor that would permit facilities operated by IHS, an Indian tribe, a tribal organization, or an urban Indian organization to waive cost-sharing amounts for any individual eligible to receive services from IHS and still comply with the Federal anti-kickback statute.

Response: The language requested by the commenters regarding cost-sharing waivers for other services is outside the scope of this rulemaking. This safe harbor is limited to implementing the exception in subparagraph (G) of section 1128B(b)(3) of the Act, which includes waivers or reductions of cost-sharing obligations imposed by pharmacies of IHS, Indian tribes, tribal organizations, and urban Indian organizations. We note, however, that if an entity is statutorily prohibited from collecting a copayment from a particular patient, there is no copayment to be "waived" and thus no protection needed for a copayment waiver.

Comment: A commenter requested clarification that § 1001.952(k)(3) applies to reductions of cost-sharing obligations, not just waivers.

Response: We agree with the commenter that subsection (3) applies to waivers or reductions of copayments, coinsurance, or deductible amounts, and we have revised the text accordingly.

b. Cost-sharing Reductions or Waivers for Emergency Ambulance Services

We proposed to establish a safe harbor to protect reductions or waivers of cost-sharing owed for emergency ambulance services for which Medicare pays under a fee-for-service payment system and meets the following conditions: (1) the ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a federally recognized Indian tribe; (2) the ambulance provider or supplier is the Medicare Part B provider or supplier of the emergency ambulance services; (3) the reduction or waiver is not considered the furnishing of free services paid for directly or indirectly by a government entity; (4) the ambulance provider or supplier offers the reduction or waiver on a uniform basis, without regard to patient-specific factors; and (5) the ambulance provider or supplier does not later claim the amount reduced or waived as bad debt or otherwise shift the burden to Medicare, a State health care program, other payers, or individuals. We solicited comments on these criteria and related issues. We are finalizing certain aspects of the rule as we proposed it, but we are making certain modifications in response to comments that we received.

Owned and Operated by the State

We proposed to require that the ambulance provider or supplier be owned and operated by a State, a political subdivision of a State, or a federally recognized Indian tribe[8] and be the Medicare Part B provider or supplier of the emergency ambulance services. We also proposed to limit the safe harbor protection to situations in which a provider's or supplier's reduction or waiver of cost-sharing amounts is not considered to be the furnishing of services paid for directly or indirectly by a government entity,[9] subject to applicable exceptions promulgated by CMS. We solicited comments on these conditions.

Comment: Two commenters noted that the proposed waiver excluded ambulance services operated by tribal organizations authorized by federally recognized Indian tribes to carry out health programs on their behalf. The commenters stated that the Indian Self-Determination and Education Assistance Act (ISDEAA) permits Indian tribes to authorize tribal organizations and inter-tribal consortiums to carry out ISDEAA functions, which can include ambulance services. The commenters noted that tribal health organizations might be the only ambulance providers or suppliers in a tribal area. Thus, the commenters recommended using the phrase "tribal health program, as that

[8] Section 104 of the Federally Recognized Indian Tribe List Act of 1994, Pub. L. No. 103-454, 108 Stat. 4791, requires the Secretary to publish a list of all federally recognized Indian tribes on an annual basis.
[9] See 42 CFR § 411.8.

term is defined in section 4 of the Indian Health Care Improvement Act" (25 U.S.C. § 1603) instead of "federally recognized Indian tribe."

Response: We are accepting the commenter's recommendation and have revised the text accordingly. The ambulance services described by the commenters are the type that we intended to protect when we proposed to protect ambulance providers or suppliers owned and operated by a federally recognized Indian tribe.

Comment: Some commenters requested that we expand the safe harbor to include nongovernmental ambulance providers or suppliers under certain conditions. Some commenters requested that we protect nongovernmental ambulance providers or suppliers when they contract with a State or municipality, and the State or municipality pays the cost-sharing amounts otherwise due from beneficiaries to the ambulance company through an actuarially determined amount of the residents' tax revenues. Another commenter asked us to protect nonprofit ambulance companies that otherwise comply with the safe harbor if they operate a waiver program under which beneficiaries pay an annual subscription fee that reasonably approximates what the ambulance company would have collected in cost-sharing amounts from subscribers.

Another commenter requested that we protect hospital ambulance services that provide emergency transports.

Response: We are finalizing our requirement (with the amendment discussed above) that protects only ambulance providers and suppliers owned and operated by a State, a political subdivision of a State, or tribal health program, as that term is defined in section 4 of the Indian Health Care Improvement Act. As we explained in the preamble to the Proposed Rule, municipalities cannot contract with private ambulance companies and require them to waive their residents' cost-sharing. However, when a State or municipality contracts with a private ambulance company, and the State or municipality uses its residents' tax dollars to pay the ambulance company an amount that is actuarially equivalent to the residents' copayments, the anti-kickback statute would not be implicated. For an example of such an arrangement, please see OIG Advisory Opinion No. 13-11. If the anti-kickback statute is not implicated, no safe harbor is necessary. Subscription arrangements referenced by the other commenter are distinct from arrangements in which the State or municipality pays the ambulance company. We believe that these arrangements should be subject to a case-by-case determination, rather than protected by a safe harbor. Moreover, we did not contemplate these

arrangements in the Proposed Rule and therefore could not finalize any regulatory text to protect them, even if we believed they should be protected. Likewise, we did not propose to protect waiver of cost-sharing by hospital-operated ambulance services.

Not Furnishing Free Services

We proposed to include a requirement that the reduction or waiver not be considered the furnishing of free services paid for directly or indirectly by a government entity. We explained that items or services that are paid for directly or indirectly by a government entity generally are not reimbursable by Medicare. CMS has a policy holding that State or local government facilities (including ambulance providers or suppliers) that reduce or waive charges for patients unable to pay, or charge patients only up to their Medicare and other health insurance coverage, are not considered to be providing free services. We proposed to incorporate this condition into the safe harbor. In response to the following comment, we are modifying this condition.

Comment: One commenter suggested that we eliminate the condition related to the waiver not constituting free services paid for by a government entity. The commenter gave several reasons for this recommendation, including the commenter's

belief that inclusion of the requirement is superfluous, that ambulance providers and suppliers should not have to review authority quoted in other sources (such as advisory opinions) to interpret a rule, and that the language is vague.

Response: We agree with the commenter's recommendation to an extent, but we reach our conclusion for different reasons. As the commenter correctly states, several of our advisory opinions regarding ambulance cost-sharing waivers include the cited language from CMS guidance. In the context of an advisory opinion, we generally are analyzing an arrangement that potentially implicates a fraud and abuse statute, such as the anti-kickback statute, but may not fit into an exception or safe harbor. As we stated in one such opinion, OIG Advisory Opinion No. 06-07, "since Medicare would not require the Municipal Ambulance Provider to collect cost-sharing amounts from municipal residents, we would not impose sanctions under the anti-kickback statute where the cost-sharing waiver is implemented by the Municipal Ambulance Provider categorically for bona fide residents of the Municipality." In other words, we relied on CMS guidance to ensure that the arrangement we approved was low risk. In the context of a safe harbor, however, while we need not rely on other guidance, we also want to ensure that the conduct we are protecting is low risk and

does not permit a practice that would be prohibited by a different law. Because we understand the conduct does not violate CMS requirements, as long as ambulance providers and suppliers are in compliance with the other provisions of this safe harbor, we believe this condition can be removed.

Offered on a Uniform Basis Without Regard to Patient-Specific Factors

We proposed to require that the ambulance provider or supplier offer the reduction or waiver on a uniform basis, without regard to patient-specific factors. We are finalizing this condition, with certain textual revisions for additional clarity.

Comment: We received one comment recommending that we eliminate the phrase "without regard to patient-specific factors." The commenter suggested that OIG did not enumerate what such factor could be, and that the phrase is ambiguous.

Response: While we agree that we did not provide a list of patient-specific factors in the Proposed Rule, we decline to eliminate the concept from the safe harbor. However, we have modified the language, as explained below. This condition includes two prongs that should be read together: the waivers must be offered on a uniform basis, and the waivers (and the policy) should not be based on patient-specific factors. We

intended "patient-specific factors" to include anything other than residency in the municipality or other governmental unit providing the ambulance service. We understand from the many advisory opinions we have issued in this context that tax revenue from residents is often attributed to cover residents' cost-sharing. We clarified the text of the final rule to eliminate any confusion on that point: an ambulance provider or supplier could waive cost-sharing amounts for all residents, but charge cost-sharing amounts to nonresidents. However, the ambulance provider or supplier cannot discriminate on the basis of any factor other than residency or, if applicable, tribal membership. For example, an ambulance provider or supplier cannot waive cost-sharing amounts for patients transported for an emergency that required only outpatient treatment, but charge cost-sharing amounts for patients transported for a condition that requires hospitalization (or vice versa). They cannot choose whether to waive cost-sharing on the basis of the patient's age. Under this particular safe harbor, they cannot waive cost-sharing on the basis of insurance or financial status. In other words, this safe harbor protects only routine waivers of cost-sharing by the entities specified, where the waivers do not take into account or require any case-by-case, patient-specific determinations (other than residency or tribal membership, as explained above).

No Cost-Shifting

We proposed to prohibit claiming the amount reduced or waived as bad debt for payment purposes under Medicare or a State health care program or otherwise shifting the burden of the reduction or waiver to Medicare, a State health care program, other payers, or individuals.

Comment: One commenter asked OIG to clarify what activities would be considered to be cost-shifting. The commenter suggested that ambulance providers or suppliers do not appear to have an opportunity to shift costs to Medicare, because Part B emergency ambulance services are paid on a fee-for-service basis. The commenter also requested clarification that prohibited "cost-shifting" would not include differentials in payment amounts based on a fee schedule (e.g., if a private insurer pays more for emergency ambulance transports than Medicare pays).

Response: First, we confirm that commenter's understanding that accepting a higher fee schedule amount from a private insurer would not constitute cost-shifting (assuming the fee schedule is either a standard fee schedule for the insurer or was not specifically requested by the ambulance provider or supplier to recoup costs it may lose by waiving copayments). As for the larger question of cost-shifting, we can imagine many

ways an ambulance provider or supplier could shift costs to a Federal health care program (e.g., by upcoding services, providing medically unnecessary services, or other illegal or inappropriate means). While each method of cost-shifting or making up for costs could be an independent ground for sanctions, we include it in the safe harbor to clarify that it would also result in the copayment waivers losing protection.

Definitions

For purposes of this safe harbor, we proposed to interpret the term "ambulance provider or supplier" as a provider or supplier of ambulance transport services that furnishes emergency ambulance services, which would not include a provider or supplier of ambulance transport services that furnishes only nonemergency transport services. We proposed to interpret "emergency ambulance services" in a manner consistent with the definition given to that term in 42 CFR 1001.952(v)(4)(iv). After considering comments received, we are finalizing modified versions of these definitions.

Comment: One commenter recommended that we expressly include ambulance providers and suppliers that are enrolled in Part A as well as Part B of Medicare.

Response: We decline to adopt the commenter's specific recommendation. We understand that emergency ambulance services, as we use that term in this regulation, are covered under Part B. However, with respect to the Medicare program, Part A could cover transportation between facilities and not generally emergency calls that would result in service by the types of ambulance providers and suppliers included in this safe harbor. As we explain below, however, we are expanding this safe harbor to include other Federal health care programs. Thus, we are removing the clause that specified that the ambulance provider or supplier be the Medicare Part B provider or supplier of emergency ambulance services.

Comment: One commenter suggested relying on a different definition for "emergency ambulance services." Rather than cross-referencing a definition found in another safe harbor, the commenter recommended using the following definition of "emergency response" found in Medicare regulations: "Emergency response means responding at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call." 42 CFR § 414.605. The commenter recommended revising the condition regarding emergency ambulance

services as follows: "The ambulance provider or supplier is the Medicare Part B provider or supplier of the emergency ambulance services, meaning the provider or supplier engaged in an emergency response, as defined in 42 CFR § 414.605."

Response: We had solicited comments about interpreting "emergency ambulance services" in a manner consistent with the definition given to that term in 42 CFR 1001.952(v)(4)(iv). We believe that the commenter provided a helpful recommendation that we are incorporating into this final rule. We agree that it makes more sense to include a definition directly within the text of this safe harbor, and that the definition proposed by the commenter, while capturing similar elements to the definition we proposed, is more aligned with the purpose of this safe harbor than the definition we proposed.

Comment: One commenter requested that we protect psychiatric emergency transportation. Another commenter requested protection for cost-sharing waivers for ambulance transports that do not qualify as "emergency" transports, but that are initiated based on a provider's judgement that the patient requires specialized transportation.

Response: We decline to expand the safe harbor to protect cost-sharing waivers for either of these suggested forms of transportation, to the extent that the transports do not meet

the definition of "emergency response" set forth in the regulation. As a threshold matter, we did not propose either of the suggested policies. The safe harbor is limited to waivers for emergency transports, and we believe waivers in connection with nonemergency transports are too high risk to be protected by a safe harbor at this time. We note, however, that the regulation does not necessarily exclude transportation of psychiatric patients. For example, if a psychiatric patient is a threat to himself, herself, or others, and an emergency transport is necessary (to a hospital emergency department or psychiatric hospital), cost-sharing waivers for the transportation could be protected.

Expansion to Other Federal Health Care Programs

We solicited comments about whether to include reductions or waivers of cost-sharing amounts owed under other Federal health care programs (e.g., Medicaid) in the safe harbor. We are finalizing a safe harbor that includes such reductions and have made appropriate modifications to the proposed regulation.

Comment: Several commenters supported expanding the safe harbor to apply to waivers of cost-sharing owed under other Federal health care programs, especially Medicaid. Commenters suggested that such an expansion would allow ambulance providers and suppliers to treat all patients equally. Certain commenters

note that IHS facilities are statutorily prohibited from charging copayments to Alaska Natives and American Indians, and tribal health programs do not charge such amounts to Alaska Natives and American Indians on principle. The commenters asked that we clarify that those waivers do not violate the anti-kickback statute.

Response: We agree with the commenters that requested expansion of protection to all Federal health care program beneficiaries. We see no greater risk under the anti-kickback statute in allowing such waivers for beneficiaries of other programs, if they are allowed for Medicare beneficiaries. We note, however, the safe harbor protects practices only under the Federal anti-kickback statute; to the extent that such waivers are prohibited under a payment policy or other law or regulation (e.g., a particular State Medicaid program), this safe harbor would provide no protection for violations of those laws, regulations, or requirements. With respect to the prohibition on IHS facilities charging cost-sharing to Alaska Natives and American Indians, as we explain in response to a similar comment above, if an entity is statutorily prohibited from collecting a copayment from a particular patient, there is no copayment to be "waived."

Textual Revisions

We received comments regarding two omissions in the Proposed Rule: (1) we inadvertently omitted "provider or" from the proposed text of subparagraph (iv); and (2) we inadvertently omitted tribes in one of the descriptions of ambulances operated by a State or a political subdivision of a State. We confirm that these were inadvertent and are corrected, as applicable, in this final rule.

3. Federally Qualified Health Centers and Medicare Advantage Organizations.

We proposed to incorporate into our safe harbors a statutory exception to the anti-kickback statute at section 1128B(b)(3)(H) of the Act, which was added by section 237 of the MMA. This exception protects "any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a MA organization pursuant to a written agreement described in section 1853(a)(4) [of the Act]." Section 1853(a)(4) of the Act (which should be read in conjunction with section 1857(e)(3) of the Act, as described below) generally describes the payment rule for FQHCs that provide services to patients enrolled in MA plans that have an agreement with the FQHC. We are finalizing the language that we proposed. Commenters generally supported the safe harbor, and specific comments are addressed below.

Comment: One commenter did not support the Medicare requirement for MA plans to pay FQHCs at the same level and amount that they pay other providers. The commenter states that each provider gets different rates based on a variety of different factors, and the commenter does not support limiting the ability of a MA plan to weigh those factors and determine payment rates.

Response: This comment is outside the scope of this rulemaking. The commenter is referencing a payment rule, while this rule relates to protecting certain remuneration under the anti-kickback statute.

Comment: One commenter supports the safe harbor, but recommends two qualifications: (1) that the level and amount of payment to the FQHC not exceed levels or amounts for similar providers; and (2) that the safe harbor also apply to remuneration and payment whether the services are provided at the FQHC or by a provider who contracts to provide services through a contract with the FQHC.

Response: With respect to the first suggestion, the safe harbor protects remuneration paid pursuant to an agreement described in section 1853(a)(4) of the Act between a MA organization and a FQHC. Section 237 of the MMA specifies that agreements described in section 1853(a)(4) must provide for a

level and amount of payment to the FQHC that is not less than the level and amount of payment that the MA organization would make for such services if the services had been furnished by an entity other than a FQHC. The safe harbor protects payments made pursuant to such agreements, and the law sets a minimum, but not a maximum, payment level to be specified in the applicable agreements. The additional qualification suggested by the commenter varies from this statutory requirement. With respect to the second suggestion, the statute specifically applies to remuneration between FQHCs and MA organizations that have certain written contracts; it does not reach remuneration between FQHCs and third-parties. However, if the arrangement between the FQHC and the third-party provider is consistent with the requirements of section 1853(a)(4), the fact that the services were provided by a third-party entity would not disqualify the remuneration between the FQHC and the MA organization from protection under the safe harbor.

Comment: Two commenters request that we clarify whether four specific types of arrangements would be protected under this safe harbor: (1) all remuneration between a MA organization and a health center, without regard to amounts typically paid to other providers or fair market value; (2) the provision of free space by the FQHC to the MA organization

(e.g., free conference room space for the MA organization to offer sales presentations to potential enrollees); (3) financial support from the MA organization to the FQHC (e.g., for conducting outreach activities, purchasing health information technology, and funding infrastructure costs), even when the support is based on the number of health center patients enrolled in the MA organization; and (4) remuneration between a health center and an IPA when the IPA stands in the shoes of the MA organization pursuant to an indirect contract arrangement between a health center and MA organization recognized by CMS regulations.

Response: Some of these examples would be protected by the safe harbor, but others would not be. We reiterate, however, that not every arrangement between two parties implicates the anti-kickback statute. If an arrangement does not implicate the statute, then no safe harbor is necessary to protect it. Moreover, entities seeking to provide remuneration to a FQHC should also consider whether the safe harbor at 42 CFR § 1001.952(w), which addresses transfers of certain items, services, goods, donations or loans to FQHCs, could apply. With that said, we address the potential protection of each example under this safe harbor in turn.

The first example could be protected under this safe harbor, if the commenter's use of the term "all remuneration" is understood in the context of what the safe harbor protects (payment for certain FQHC services). The statutory exception was added by section 257(d) of the MMA. Section 257(c) of the MMA specified the following payment rule (added in 1857(e)(3)): "in any written agreement described in section 1853(a)(4) between [an MA organization] and [FQHC], for a level and amount of payment to the [FQHC] for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by [an] entity providing similar services that was not a [FQHC]." The statute does not include a fair market value requirement; it provides for a minimum level of payment by the MA organization. Thus, the safe harbor protects payment for FQHC services that meet this requirement. It does not, however, protect "all remuneration" that the parties might exchange. The second example of remuneration—providing free space—would not be protected by this safe harbor. The safe harbor protects payments related to FQHCs treating MA plan enrollees, not arrangements unrelated to MA plan enrollees being treated at the FQHC. The same analysis applies to the third example: financial support for the FQHC is outside the scope of what the safe harbor protects. Finally, we confirm that the fourth

example would come within the ambit of the safe harbor with respect to the requirement that the FQHC have a written agreement with the MA plan. CMS has interpreted the requirements related to services provided to MA plan enrollees as including indirect contracts. Specifically, in a 2005 final rule, CMS stated: "[w]e interpreted section 237 of the MMA to mean that any Medicare FQHC furnishing covered FQHC services to MA plan enrollees would be eligible for supplemental payments regardless of whether they have a direct contract with a MA organization or contract with another entity (for example, a medical group) that has a direct contract with the MA organization to treat its enrollees." 70 FR 70116, 70268 (Nov. 21, 2005). Because this safe harbor is in place largely because of a payment rule, we believe it is reasonable to rely on the interpretations applicable to that payment rule.

4. Medicare Coverage Gap Discount Program

Section 3301 of the ACA establishes the Medicare Coverage Gap Discount Program, codified at section 1860D-14A of the Act. Under this program, prescription drug manufacturers enter into an agreement with the Secretary to provide certain beneficiaries access to discounts on drugs at the point of sale. Section 3301(d) of the ACA amends the anti-kickback statute by adding a new subparagraph (J) to section 1128B(b)(3) of the Act to

protect the discounts provided for under the Medicare Coverage Gap Discount Program, which we proposed to incorporate into our safe harbor regulations.

We proposed to protect a discount in the price of an "applicable drug" of a manufacturer that is furnished to an "applicable beneficiary" under the Medicare Coverage Gap Discount Program under section 1860D–14A, as long as the manufacturer participates in and is in full compliance with all requirements of the Medicare Coverage Gap Discount Program. We proposed to incorporate by reference the definitions of the terms "applicable beneficiary" and "applicable drug" that were added by a new section 1860D-14A(g) of the Act. Commenters generally supported our proposal. Specific comments and recommendations are addressed below.

Comment: Some commenters noted that a safe harbor is unnecessary, because the statutory exception is sufficient.

Response: We acknowledged in the Proposed Rule that the statutory exception was self-implementing. However, for the sake of completeness, we generally incorporate and interpret statutory exceptions in our safe harbor regulations.

Comment: Several commenters objected to our proposal to require that manufacturers be "in full compliance with all

requirements of" the Medicare Coverage Gap Discount Program to qualify for safe harbor protection. Commenters expressed concern that minor administrative or technical non-compliance could open manufacturers up to liability. For example, one commenter provided hypotheticals under which a manufacturer met all requirements, except did so one day late. A commenter suggested that neither the ACA nor the anti-kickback statute support the requirement that a manufacturer be in compliance with the all requirements of the program. Another commenter asserted that we exceeded our rulemaking authority by including this requirement.

Response: Although we disagree with the commenter who asserted that we do not have the authority to require compliance with the very program that this safe harbor aims to protect, we do agree with commenters who suggested that minor, technical instances of non-compliance should not preclude safe harbor protection. Thus, we are revising the language to reflect that manufacturers must be in compliance with the Medicare Coverage Gap Discount Program. While we do not contemplate that missing a payment deadline by one day would subject a manufacturer to sanctions under the anti-kickback statute, the safe harbor only protects discounts offered in connection with this program. A manufacturer that knowingly and willfully provided discounts

without complying with the requirements of the Medicare Coverage Gap Discount Program could be subject to sanctions, unless such discounts are protected by another safe harbor.

Comment: One commenter suggested that the definitions of "applicable beneficiary" and "applicable drug" are too narrow, because they apply only to beneficiaries enrolled in, and drugs that are covered by, prescription drug plans and MA-PD plans. The commenter asserts that the exception should be expanded to encompass Medicare reasonable cost contractors under section 1876 of the Act that offer a Part D supplemental benefit.

Response: We decline to adopt the commenter's suggestion at this time. We proposed to incorporate the statutory definitions used in establishing the Medicare Coverage Gap Discount Program into the safe harbor regulation, and we intend to rely on those definitions.

5. Local Transportation

Pursuant to our authority at section 1128B(b)(3)(E) of the Act, we proposed to establish a new safe harbor at 42 CFR 1001.952(bb) to protect free or discounted local transportation services provided to Federal health care program beneficiaries.

In the Proposed Rule, we proposed to protect free or discounted local transportation made available by an "eligible entity" to established patients (and, if needed, a person to

assist the patient) to obtain medically necessary items or services. We also sought comments on a second form of transportation that would be akin to a shuttle service. We proposed a number of conditions on offering or providing protected free or discounted local transportation services, and proposed definitions of certain terms, such as "eligible entity," "established patient," and "local." Overall, we received substantial support for implementing a safe harbor to protect local transportation. Many commenters urged us to include (or decline to include) certain safeguards within the final regulation. With certain modifications described below in response to the comments we received, we are finalizing a safe harbor at § 1001.952(bb) for local transportation for established patients.

General Comments

We received a number of comments generally in support of the proposed safe harbor, and others requesting specific changes or clarifications.

Comment: Several commenters expressed general support for the concept of free or discounted local transportation, and for proposing it as a safe harbor that would cover all Federal health care program beneficiaries. Commenters stated the proposal would increase access to care. Commenters gave

examples of patients who would benefit, such as those who cannot drive or take public transportation after a procedure, or isolated/homebound patients. One commenter noted that Congress expressly stated that the beneficiary inducement prohibition was not intended to prohibit complimentary local transportation and urged OIG to consider the needs of certain patient populations (like mental health and substance abuse patients). One commenter supported our proposal to eliminate the nominal value restriction with respect to transportation.

Response: We acknowledged in the Proposed Rule that Congress did not intend to preclude the provision of local transportation of nominal value in the context of the beneficiary inducements CMP. (See 79 FR 59717, 59721). However, the anti-kickback statute does not have any exceptions for items or services of nominal value. With that clarification, we agree that a safe harbor is warranted to protect complimentary local transportation that meets certain requirements that limit the risk of fraud and abuse.

Comment: One commenter recommended that we cover transportation whether planned in advance or for ad hoc services that arise unexpectedly, and whether provided directly or through vouchers. Other commenters requested that we expressly

state that the safe harbor also protects transportation back to a patient's home.

Response: We agree with the commenters. First, the safe harbor would protect transportation both to a provider or supplier of services and back to a patient's home, as long as all conditions of the safe harbor are met. Next, an eligible entity offering free or discounted local transportation need not require that transportation be planned in advance. Further, a transportation program could use vouchers rather than having the transportation provided directly by the eligible entity. However, we reiterate that the transportation cannot take the form of air, luxury, or ambulance-level service and must meet other requirements described herein to be protected under the safe harbor.

Comment: One commenter requested that OIG clearly define the situations in which free transportation can be provided and clearly outline the process for determining patient eligibility.

Response: We have set out the conditions under which free transportation will be protected in this final rule. We have provided explanations of each condition, and examples where we believe them to be helpful. Individuals and entities seeking to offer transportation and be protected by the safe harbor should apply these conditions and guidance to their desired program.

We decline to mandate specific eligibility terms or a set list of situations under which transportation would be protected, beyond what we specify in this final rule.

Comment: One commenter recommended a more narrowly defined safe harbor, particularly with respect to dialysis providers. The commenter expressed concern that larger, well-funded dialysis providers may increase their volume by routinely providing transportation, thus hurting smaller providers. The commenter recommended protecting transportation for dialysis patients only on an infrequent basis and in accordance with policies that the commenter believes the OIG should clearly outline. Some commenters asked that we clearly state that dialysis facilities would not be required to provide free transportation. Other commenters recommended that dialysis facilities should be allowed to offer transportation only in certain circumstances, such as when a beneficiary suddenly finds him- or herself without transportation to or from a dialysis facility, for beneficiaries with intermittent lack of reliable transportation, or for certain emergent purposes.

Response: First, we reiterate that safe harbors are voluntary. This safe harbor does not require any individual or entity to offer free or discounted local transportation services; it sets forth conditions and limitations on providing

such transportation. With respect to the other comments in the paragraph above, we decline to adopt the commenters' suggestions. We do not believe that this safe harbor should have additional restrictions tailored to a specific patient population, such as dialysis patients. Any time a provider or supplier is permitted to give something for free or reduced cost to beneficiaries, there is a risk that such a program will affect competition, because entities with greater financial resources might be in a better position to provide the "extras." However, we believe that the combination of requirements in the safe harbor will mitigate that risk and appropriately balances the risks against the potential benefits of a well-designed and properly structured transportation program. For example, the prohibition on advertising constrains the use of free or discounted transportation as a marketing tool, and the mileage limitations serve to limit, to some degree, the cost of the transportation provided. In addition, we believe this safe harbor will save Federal health care programs money in the very population cited by the commenter; dialysis patients are a population that has been identified as contributing to the increasing costs of nonemergency ambulance transportation and would benefit from local transportation furnished by providers.[10]

[10] See MedPAC, *Report to the Congress: Medicare and the Health Care Delivery*

Comment: One commenter was concerned that eligible entities might demand concessions from their existing transportation vendors, despite the prohibitions on cost-shifting. The commenter requested that we clarify that contracts between eligible entities and transportation vendors are subject to existing "OIG guidelines."

Response: While we are unsure which "OIG guidelines" the commenter is referencing, we do confirm that nothing in the safe harbor exempts contracts between eligible entities and transportation vendors from complying with all applicable fraud and abuse laws for terms of an arrangement that are not protected by this safe harbor. For example, an eligible entity may not require an ambulance company to provide free or discounted transportation to its patients as a condition of receiving referrals.

Eligible Entity

We proposed that the safe harbor protect only transportation offered or provided by an "eligible entity." We

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System (June 2013), Chapter 7, *available at http://www.medpac.gov/documents/reports/chapter-7-mandated-report-medicare-payment-for-ambulance-services-%28june-2013-report%29.pdf?sfvrsn=2.* In fact, the report notes that: "[i[f there are concerns about the availability of transport to dialysis treatment, an approach other than using ambulance transport is needed. One possibility would involve dialysis facilities providing local transportation services to their patients" and notes the necessity of a safe harbor to permit such transportation. Id. at 187.

proposed to define "eligible entity" as any individual or entity, except individuals or entities (or family members or others acting on their behalf) that primarily supply health care items (including, but not limited to, durable medical equipment (DME) suppliers or pharmaceutical companies). We specifically solicited comments on excluding other entities that provide primarily services, such as laboratories or home health agencies, that we posited might be more likely to offer transportation in return for referrals, resulting in both steering and overutilization. We stated we were considering excluding home health care providers from safe harbor protection when they furnish free or discounted local transportation to their referral sources, but not excluding them from protection when they provide such transportation to sources that do not refer to home health care providers, such as pharmacies.

Comment: One commenter requested that we consider the competitive advantages/disadvantages to providers being able to provide free transportation (e.g., physical therapy providers who do in-home versus office visits). Another commenter asked that physical therapists expressly be allowed to provide free transportation. Commenters suggested including health plans, coordinated care entities, clinically integrated networks, managed care organizations (MCOs), and risk-bearing entities as

eligible entities, and urged that MA plans should be able to include transportation subsidies in their CMS bids. One commenter requested that pharmacies be included, to accommodate transportation to and from the pharmacy, and another asked that dialysis providers expressly be included.

Response: We proposed to exclude from the definition of eligible entities suppliers of items, and potentially certain groups of providers or suppliers[11] of services that might be more likely to offer transportation to their patients in exchange for referrals. Physical therapists and dialysis facilities provide services, and we did not propose to exclude them. Pharmacies, however, primarily provide items and thus would be excluded from the definition. Many types of entities that may not directly render health care services to patients, such as health plans, MA organizations, MCOs, accountable care organizations (ACOs)[12], clinically integrated networks, and charitable organizations are not among the entities excluded from the definition of

[11] In this safe harbor, we use the term "supplier" as it is defined for purposes of Medicare. That is, "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare." 42 CFR § 400.202. We are excluding suppliers of items, but including most suppliers of services (e.g., physicians), in the term "eligible entity."

[12] We note that the term "ACO" may be used differently in different sectors and programs to describe a variety of types of entities that consist of a collection of providers or suppliers working together to coordinate care. As explained elsewhere in this final rule, some ACOs participate in the MSSP or certain CMS demonstration programs or models that are subject to oversight and have waivers of certain fraud and abuse laws. Other entities called "ACOs" do not participate in the MSSP or CMS demonstration programs or models and may not be subject to the same safeguards.

eligible entity and thus are eligible to provide transportation. However, one condition of the safe harbor prohibits shifting the cost of the transportation onto, *inter alia*, Federal health care programs. Thus, for example, to the extent that a MA plan's inclusion of the transportation program in its bid would affect costs to Federal health care programs or affect reimbursement, then we decline to adopt the commenters' suggestion. With that said, we recognize that MA organizations are permitted to include transportation as a supplemental benefit to its enrollees when such transportation meets certain requirements. As we have explained in other places, safe harbors do not create liability for parties; they protect arrangements that would otherwise be prohibited by the anti-kickback statute. To the extent that MA organizations are transparently offering transportation as a supplemental benefit, as permitted under the MA program, this safe harbor would not be necessary to protect those arrangements. With respect to effects on competition, we do not believe that the safe harbor will unfairly affect competition among providers and suppliers and, in fact, may encourage competition and improve patient access to care if transportation assistance enables patients to access a wider range of providers and suppliers from which to receive care.

Comment: One commenter recommended not permitting any health care providers or suppliers to provide transportation services, unless the provider or supplier is willing to transport the patient to other providers or suppliers of similar services. The commenter believes the safe harbor should protect only transportation services that transport a beneficiary to the provider or supplier of his or her choice.

Response: We respectfully disagree with the commenter's proposal, to the extent that it would apply to a provider who offered transportation only to its own premises. First, we believe the fact that the patient is established with the provider or supplier of service implies that the patient has, in fact, chosen that provider or supplier. We discuss the limitations on constraining patient choice in the context of one eligible entity transporting the patient to another provider or supplier elsewhere in this final rule.

Comment: Some commenters disagreed with our proposal to partially or fully exclude home health agencies from the definition of eligible entities. These commenters suggested that home health agencies are a critical link for patients to get to necessary appointments--some of which could be to referral sources. One commenter suggested that allowing home health agencies to provide transportation to a primary care

provider will help patients who did not have a primary care provider before requiring home health services. One commenter stated that home health agencies are tasked with providing comprehensive care, and providing transportation can help reduce hospital readmissions and help physicians comply with face-to-face requirements. A commenter stated that home health agencies also can help patients pick up prescriptions when caregivers are not available. One commenter suggested that home health agencies be required to develop and document eligibility criteria, which must be unrelated to referral source, supplier, or type of treatment. One commenter recommended allowing home health agencies to be eligible entities for certain circumstances, such as when a patient cannot transport himself or is exhibiting serious symptoms requiring transport to a doctor who already has been treating the patient. Another commenter agreed with the concept expressed in the Proposed Rule of excluding home health agencies from transporting patients to their referral sources. Similarly, another recommended a facts-and-circumstances analysis for home health agencies. One commenter suggested that excluding whole categories of providers and suppliers unfairly penalizes legitimate entities, and that the other requirements in the proposed safe harbor provide sufficient safeguards.

Response: For many of the reasons cited by commenters, we have concluded that home health agencies should not be excluded from the definition of "eligible entity." Individuals who provide home health services already travel to the patient's home and have regular communication with both the patient and the patient's health care providers or practitioners. In addition, patients eligible for home health services may be particularly in need of transportation, which home health agencies may be in a unique position to provide. We are aware, however, that home health agencies have historically posed a heightened risk of program abuse, and take this opportunity to remind all eligible entities that, to be protected by this safe harbor, the provision of transportation must be for medically necessary services and comply with all other conditions of the safe harbor. Moreover, the fact that transportation is potentially protected by this safe harbor would never insulate it from scrutiny as part of an investigation. For example, we have investigated schemes in which home health agencies recruited beneficiaries and transported them to physician offices to obtain prescriptions and renewals of prescriptions for home health services that they did not need. The provision of transportation, in such an instance, would be considered as part of a scheme to submit false claims for unnecessary services.

Comment: One commenter supported excluding DME suppliers and pharmaceutical manufacturers for the reasons stated in the Proposed Rule. Another commenter recommended against excluding suppliers of items, but suggested imposing additional limitations on those suppliers to curtail fraud and abuse. One commenter opposed excluding pharmaceutical manufacturers, and provided examples of situations in which it argued pharmaceutical manufacturers should be permitted to provide local transportation (e.g., when patients should be accompanied home after receiving an infused drug treatment). One commenter objected to excluding suppliers of items, calling it an unjustified bias. This commenter believed that these suppliers and manufacturers do not pose a heightened risk of steering and suggested that OIG did not adhere to guidelines for establishing safe harbors. Despite agreeing with concerns we expressed, another commenter disagreed with excluding particular types of entities, suggesting that other safeguards in the safe harbor should offer sufficient protection. This commenter requested that, if we do exclude certain types of entities, we clarify that entities that offer both items and services (e.g., a hospital that also has laboratory or pharmacy) could transport its patients to receive those both the items and services.

Response: We agree with the commenters that support excluding suppliers of items from the definition of "eligible entity." Unlike physicians, hospitals, or other providers and suppliers of services, suppliers of items generally do not play a role in ensuring that patients have access to other providers and suppliers. They certainly can play a role in assisting a patient obtain transportation by bringing the need to the attention of, for example, the patient's physician, practitioner, or hospital. We are finalizing a rule that excludes only suppliers of items from the definition of eligible entity; we are not excluding home health agencies or laboratories. We respectfully disagree with the suggestion that we did not take into account the factors set forth by Congress to consider when developing safe harbors. We continue to believe, as we stated in the Proposed Rule, that allowing individuals and entities that primarily supply health care items to offer transportation to patients presents a heightened risk of using such transportation to generate referrals, potentially in a way that increases costs for patients and Federal health care programs. Entities that sell items, such as pharmaceutical manufacturers, generally do not need to furnish transportation to their own location. Offers by a pharmaceutical manufacturer to transport patients to physicians who are the manufacturer's referral sources could influence that referral source's decision

to prescribe one drug over another. For example, a physician might be influenced to prescribe an expensive branded infusion drug in preference to a less expensive drug, if the manufacturer of the more expensive drug offered transportation to the patients who received it so that they can get to their appointments with the physician. Such a program could both influence the physician to choose a particular item and increase costs to Federal health care programs—two factors cited by Congress to consider when developing safe harbors—without necessarily increasing quality or patient choice. With respect to entities that primarily provide services, but also provide items, we confirm the commenter's understanding. That is, an entity, such as a hospital, could offer transportation to its established patients to its own location for items or services provided by the entity (such as for obtaining items at the hospital's on-site pharmacy).

Established Patients

We proposed to require that the free or discounted local transportation services be available only to "established patients." We proposed that a patient would be "established" once the patient had selected a provider or supplier and had attended an appointment with that provider or supplier. In contrast, we proposed not to protect transportation offered to

new patients. We received a number of comments on this proposal and have decided to modify our interpretation of the term "established" as it is used in the safe harbor.

Comment: Though acknowledging and agreeing with our efforts to prevent eligible entities from using free or discounted local transportation as a recruiting tool, a number of commenters asked us to consider the impact of the established patient requirement on patients who have not seen a primary care doctor in years, including patients who are newly insured or FQHC patients. Several commenters recommended that we deem a patient to be "established" once the patient selects the provider and calls to schedule an appointment. These commenters urged that many newly insured patients may need help getting to their first appointment, and that in some cases, the first appointment may be critical or urgent (e.g., a mental health patient whose communication indicates a need for prompt treatment). Other commenters suggested that limiting transportation availability to established patients will deter patients from changing providers.

Response: We agree with the thrust of the comments. The purpose of limiting the local transportation offers to established patients is 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. Because the eligible entity is not permitted to market the transportation services, we believe that making transportation available to new patients who contact the provider or supplier on their own initiative is sufficiently low risk to warrant safe harbor protection. Thus, a patient can be "established" for purposes of this safe harbor after he or she selects and initiates contact with a provider or supplier to schedule an appointment. If a patient is unable to call a provider or supplier himself, or has otherwise given consent for a person (e.g., a family member, a case manager, or a provider or supplier where the patient is attending an appointment) to schedule appointments for him, then a request for an appointment made on behalf of the patient is sufficient to meet this criterion. We reiterate that transportation cannot be used as a recruiting tool. Thus, we view a case manager (i.e., someone coordinating a patient's care) reaching out to schedule an appointment and asking if transportation might be available as being entirely 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, coupled with an offer of transportation. The former would be protected (if all other conditions of the safe harbor are met), and the latter would not be.

Comment: We received questions about the scope of an entity with which a patient might be "established." One commenter inquired whether a patient became established after a visit with a practice, or only as to the particular provider or supplier the patient had seen. Another thought the preamble suggested that a patient could be "established" only with a practice, and suggested that the patient should be "established" within a health system or network of providers. Similarly, we received a question about whether a single visit to a hospital "establishes" the patient for all future visits. Commenters asked how the "established patient" requirement would work with integrated entities (e.g., whether a patient would be "established" within a whole system). Another asked whether a patient would be established at one dialysis facility, or others under common ownership (e.g., if the patient usually receives dialysis at one facility but needs to reschedule an appointment at a different local facility). A commenter suggested that the safe harbor should protect both new and established patients of FQHCs. One commenter expressed a concern about steering, such as if a hospital or large practice could choose to offer transportation only to their own ancillary practices.

Response: We understand the commenters' concerns and requests for clarity regarding the provider or supplier with

whom a patient is established. We believe that some of these issues are resolved by our conclusion that a patient is "established" with any provider once an initial appointment is made. Thus when a patient makes an appointment (including a rescheduled appointment), an eligible entity may offer transportation regardless of whether the patient has received services from that eligible entity in the past. We recognize, however, that when and with whom a patient is an "established patient" remains pertinent with respect to the commenter's concern regarding steering. We also recognize that eligible entities that do not directly provide health care services (e.g., health plans, ACOs, health systems, etc.) would not have "established patients," because patients do not receive health care from them. Such entities always would be considered to be providing transportation to another provider or supplier, and the patient must be "established" with that other provider or supplier. An eligible entity that is a health care provider or supplier may make transportation to its own location available to its own established patients, without offering transportation to the patients of other providers. However, the safe harbor requires that the availability of transportation not be determined in a manner related to past or anticipated volume or value of Federal health care program business. So, if an eligible entity chooses to make transportation available for

services provided by others, it must provide the transportation to the provider or supplier of the patient's choice, subject to restrictions that an eligible entity can impose that are unrelated to referrals, as discussed below. Thus, if a patient is being discharged from the hospital, and the hospital is willing to transport the patient to followup visits with a cardiologist, the hospital cannot make that offer contingent on the patient choosing a cardiologist affiliated with the hospital. We note, the eligible entity can have various limits on transportation policies. For example, the eligible entity might be willing to transport patients only within a 10-mile radius of its location, or willing to transport patients only to primary care providers, or only for visits included in a discharge plan. These types of limitations are acceptable and do not limit patient choice or steer to particular providers or suppliers.

We interpret the commenter's question about how the "established patient" requirement would work with integrated entities as asking whether a patient who is established with a particular physician practice, for example, is also established with respect to the entire integrated health care system of which that practice is a part. If so, then the system would be able to provide transportation limited to entities within the

system. We understand that integrated entities, health systems, and others would prefer to transport patients only to their own affiliated locations. At this time, we are not protecting such limited transportation offers to individual patients. We will continue to monitor the changing landscape and could consider new or revised safe harbors in the future. We do note that shuttles protected under this safe harbor are not subject to the established patient requirement. Thus a health care system could offer a shuttle service to the public that made stops at its own facilities, but not at any health care facilities outside the system. We also note that an ACO or similar entity may assist its affiliates in providing transportation (e.g., by having a fleet of vehicles available for the use of its affiliates in transporting their patients). In this situation, the transportation would be provided by the affiliates, who could limit the transportation offers to their own patients. However, the safe harbor requires that eligible entities (in this case, the affiliates) bear the cost of the transportation they provide. This could be done by, for example, having the affiliates pay to the ACO a fixed amount per mile or per trip for their transported patients. We decline to require any particular method of calculating these costs, as long as the method reasonably compensates the ACO for the transportation provided. We note that, alternatively, ACOs in the MSSP and

certain CMS demonstration programs may use waivers of the fraud and abuse laws to cover some transportation arrangements, provided all waiver conditions are met.

Comment: A number of commenters raised general concerns that the "established patient" requirement was unnecessary, too restrictive, burdensome, or an arbitrary limit to care. One commenter suggested it should apply only to physicians, and another stated it should not apply to home health agencies. Others advocated it might prevent new patients from seeking care, or from attending new appointments, including hospital registration. An additional commenter urged us to consider that the requirement will create barriers to entry in the health care system, especially with Medicaid expansion. Several commenters expressed a concern that it would be burdensome or impossible to screen patients to ensure that only established patients used a shuttle around a hospital or extended campus.

Response: We believe that the revised interpretation of "established" should address many of these concerns. Further, except for the limited exception for ACOs and other eligible entities that do not have patients of their own, we do not see any reason to exempt certain categories of providers and suppliers from the requirement to offer transportation only to established patients. By allowing transportation to be offered

to patients after the patient has an appointment, we believe we have removed the barriers to transportation to new patients that commenters described. We also note, most Medicaid programs include coverage for some form of non-emergency transportation services, which further reduces the likelihood that the established patient requirement will result in significant barriers to entry in the Medicaid program. As discussed in greater detail below, when transportation is in the form of a shuttle service, the established patient requirement does not apply.

Comment: One commenter recommended we include family and friends of skilled nursing facility (SNF) patients, as we approved in OIG Advisory Opinion 09-01. The commenter suggests that such transportation facilitates SNF residents keeping community ties.

Response: This section of the safe harbor is intended to address transportation for patients to obtain medically necessary services. While transportation of family and friends can serve important patient interests, as we recognized in OIG Advisory Opinion 09-01, we do not believe that this section of the safe harbor is the place to address that concern in the context of SNF patients, or other patients who would benefit from visits from family and friends. We are separately

protecting shuttle services under this safe harbor. Thus a SNF or other provider would be able to offer a shuttle on a set route that could accommodate friends and family of residents. For other arrangements that do not meet all requirements of the safe harbor, the SNF could seek an advisory opinion.

Comment: Commenters urged us to ensure that the safe harbor is available for post-acute patients. For example, one commenter asked whether a SNF could transport a patient to its facility after the patient selected the facility, but before signing the admission agreement. Another commenter asked us to confirm that hospitals could provide transportation to ensure that post-discharge followup care was received. Another commenter was concerned about patients who come to the Emergency Department (ED) by ambulance. The commenter asserted that, whether or not those patients are admitted, they may need a ride home.

Response: We believe that each of the examples provided above could be protected by the safe harbor. Our revised interpretation of "established" would permit the SNF to transport the patient to its facility, as long as the patient selected the facility first on his or her own initiative (or through the patient's representative), whether or not an actual agreement had been signed. However, transportation for

marketing purposes, offered to a patient who has not yet selected the facility, would not be protected by the safe harbor. A hospital providing transportation to its discharged patients for followup care would be protected under either interpretation of "established;" if the patient was admitted to the hospital or received outpatient care there, then the patient was an established patient of the hospital. The Proposed Rule had proposed protecting, and we are finalizing a rule that will protect, transportation offered by one provider or supplier to convey patients to or from another provider or supplier (so long as other requirements are met). Likewise, the safe harbor could protect transporting a patient home from an ED visit: a patient who has received a service is an established patient, and transportation of such a patient could be protected by this safe harbor.

Comment: One commenter requested that we define "new patient," while other commenters asked whether one visit was sufficient to be established with the provider or supplier. Another commenter asked whether providers must document that transported patients are "established." Other commenters suggested that we establish an exception, or include fewer restrictions, for patients in MA plans because, the commenters

assert, there is a lower risk of steering or overutilization in these plans.

Response: We believe we have addressed most of these comments through the revised interpretation of "established" patient. We confirm here that the safe harbor does not require documentation that the patients receiving transportation are established patients. However, maintaining documentation that demonstrates compliance with the safe harbor may be best practice.

Comment: Some commenters argued that the established patient requirement does not consider patients with emergent situations (e.g., an ESRD patient who needs to go to a new facility for a vascular access problem, or a patient who just discovered potential HIV infection). Commenters suggested that the safe harbor allow for transportation to be provided to new patients with emergent conditions because other safeguards mitigate risk. Another commenter specifically requested an exception process to address situations where one provider must transport a patient to another provider to reduce the risk of an emergency department visit or a hospital admission.

Response: We believe that the safe harbor, as it is being finalized, is sufficient to cover emergent situations, including situations that would prevent a hospital visit. If a patient

has an emergent condition, needs a service, and reaches out to a provider or supplier to schedule an appointment and expresses concern about his or her ability to get to that appointment, the provider or supplier can offer transportation. Using an example provided by commenters, if a patient is at an ESRD facility and needs to get to a vascular access clinic, but has no way to get there, the safe harbor would be available to protect transportation offered by either the ESRD facility or the vascular access clinic. First, because the patient is established with the ESRD facility, the ESRD facility could transport him to the vascular access clinic, provided all other conditions of the safe harbor are met. Second, the patient could call the vascular access clinic to make an appointment and ask if transportation is available (or a call could be made on the patient's behalf, at the request of the patient or the patient's representative). By reaching out and making the appointment, the patient would be established with the clinic for purposes of being eligible for transportation.

Purpose of Transportation

We proposed and solicited comments on conditions related to the purpose of the transportation and the location to which a patient could be transported. Specifically, we proposed that protected transportation be for "the purpose of obtaining

medically necessary items or services," but we solicited comments on whether eligible entities also should be protected under the safe harbor if they provide free or discounted local transportation for other purposes that relate to the patient's health care (e.g., to apply for government benefits, to obtain counseling or other social services, or to get to food banks or food stores). We proposed to allow an eligible entity to provide free or discounted local transportation services to the premises of another health care provider or supplier, as long as the eligible entity does not make the free or discounted local transportation available only to patients who were referred to it by particular health care providers or suppliers, and as long as the offer of transportation is not contingent on a patient's seeing particular providers or suppliers who may be referral sources for the eligible entity offering the transportation. We received several comments on these proposals.

Comment: Several commenters recommended that transportation be allowed for purposes that relate to health care, and that such concept be interpreted broadly. For example, commenters recommended allowing transportation for non-clinical, but health-related activities (e.g., obtaining counseling or other social services, getting to food banks/stores, applying for government benefits). Another

commenter recommended allowing transportation for other services if the purpose of the services support care coordination and adherence to the patient's plan of care. One commenter supported the provision of transportation services for a variety of purposes, including those that are non-clinical but reasonably relate to an individual's health care and would be beneficial to the patient (e.g., a risk-bearing provider might offer transportation to an exercise program, mental health counselor, or healthy grocery store).

Response: We decline to extend safe harbor protection to transportation for purposes other than to obtain medically necessary items or services at this time. A transportation program offered by a provider or supplier inherently poses a risk both of inducing patients to get items or services that they might otherwise not have obtained and to get the services from that provider or supplier. In the case of transportation for medically necessary items or services, we think that risk is acceptable. However, we believe the risk is too high when the transportation for an individual (as opposed to a shuttle) is for non-health-related purposes.[13] First, whether the patient's

[13] We note, however, transportation for non-medical purposes would not violate the statute if it is not for the purpose of inducing individuals to obtain federally reimbursable items or services.

destination is really health-related would be difficult to determine, e.g., if it is a shopping center that includes, in addition to a food store, a movie theater and other retailers. Transportation for food shopping or other non-medical reasons also might be more frequent than transportation for medical appointments, which would give larger providers a significant competitive advantage over smaller entities or individual suppliers. Nevertheless, as described below, an eligible entity could operate a shuttle service that includes stops at locations that do not relate to a particular patient's medical care. In addition, we will continue to monitor new payment models and methods of coordinated care that increase quality and reduce costs, and we will consider whether permitting transportation to non-medical services that are part of coordinated care arrangements or are related to improving health care, would be appropriate in a future rulemaking.

Comment: One commenter noted that we proposed prohibiting eligible entities from making transportation available only to patients referred by particular providers or suppliers. This commenter recommended that we also prohibit eligible entities from discriminating based on insurance type (e.g., limiting transportation to Medicare patients).

Response: As the commenter correctly observed, we proposed prohibiting limiting transportation offers to patients referred by particular providers or suppliers. We also proposed requiring that the availability of the free or discounted transportation be determined in a manner unrelated to the past or anticipated volume or value of Federal health care program business. If transportation were offered only to Federal health care program beneficiaries, then it would be unlikely to meet this latter requirement. If an eligible entity transported only Federal health care program beneficiaries to itself, or only transported Federal health care program beneficiaries to other providers or suppliers, it would appear that the availability of the transportation took into account the volume, as well as possibly the value, of Federal health care program business. However, an eligible entity could take into account an individual patient's need for transportation, even if this resulted in the transportation being disproportionately made available to elderly or low-income patients who are more likely to be Federal health care program beneficiaries. It would be necessary for the determination of transportation to be made on an individual basis, however, and not on the basis of insurance type. For example, a geriatric practice might provide transportation almost exclusively to Medicare beneficiaries where most of its practice is Medicare beneficiaries, so long as

the practice does not discriminate based on insurance type. In other words, any non-Medicare patients of the practice must be eligible for transportation assistance on the same terms as the Medicare patients.

Comment: Some commenters suggested that allowing transportation from one provider to another is essential, and gave the example of a hospital transporting a patient to affiliated post-acute sites. Another commenter supported transportation from one provider to another, as long as the patient is established with one of the providers. According to one commenter, excluding transportation to referral sources would limit the availability of transportation, given how many organizations and providers are part of "intertwined referral networks." Another commenter recommended that, if health systems, health plans, ACOs, or other integrated networks are permitted to be eligible entities, they should not be permitted to restrict transportation to providers or suppliers in their own networks. Another commenter suggested the opposite: that integrated care systems should not have to transport patients to non-network providers, and that such a requirement would discourage hospitals from offering transportation.

Response: We agree with commenters that allowing one eligible entity to transport patients to another provider or

supplier is important. We intend to protect this transportation, as long as it meets all other requirements in the safe harbor. We wish to clarify that, if the patient is being transported to a different provider than the eligible entity that is providing the transportation, and the eligible entity providing the transportation is itself a provider or supplier of federally payable services, then there must be an established patient relationship between the eligible entity providing the transportation and the patient being transported, as well as an established patient relationship between the patient and the provider to which the patient is being transported. For example, a hospital that has discharged a patient (and therefore has an established relationship with the patient) may provide transportation for the patient to an appointment with a physician for followup care. In these circumstances, the hospital has an interest in ensuring that the patient is seen for followup care, in order to avoid complications and possible readmission. The hospital may not, however, offer to transport a patient with whom it has no established relationship (either as an inpatient or outpatient) either to the hospital's own facilities or to the facilities of a different provider or supplier. If a provider with no

established relationship with a patient provides or offers to provide transportation,[14] there is a risk that a purpose of the transportation is to market its own services to the patient or induce referrals from the provider to whom the patient is being transported. As explained above, 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 relationship with a patient in order to provide transportation that is protected by this safe harbor.

We did not propose to exclude transportation to referral sources, other than potentially in the context of entities that we were considering fully or partially excluding from the definition of "eligible entity" (e.g., our proposal to exclude home health providers from providing transportation to their referral sources). Under the Proposed Rule, and as we are finalizing in this final rule, an eligible entity can transport patients to another provider or supplier that is a referral source; the transportation offer, however, cannot be contingent on the patient choosing a referral source. For example, a hospital could offer transportation services to its established patient diagnosed with cancer who needs to see an oncologist. The hospital would need to provide transportation to any

[14] We note that the considerations are different, as explained below, in the context of a shuttle service.

oncologist that the patient chooses (subject to the hospital's policy on distance), not only to the oncologists who are referral sources for the hospital. This restriction holds true in networks. For example, if a hospital will transport a patient to a clinical laboratory, radiology provider, or specialist, the patient must have the freedom to choose the provider or supplier; the hospital cannot make the offer of transportation contingent on the patient using a clinical laboratory, radiology provider, or specialist in its network. The hospital can, however, set restrictions on the distance it is willing to transport the patient.

Comment: One commenter disagreed with our proposal to exclude from safe harbor protection free or discounted local transportation that an eligible entity makes available only to patients who were referred to the eligible entity by certain providers or suppliers. The commenter recommended allowing an eligible entity to limit transportation only to patients from particular providers in the context of ACOs in the MSSP. The commenter notes that ACOs participating in the MSSP do not benefit from increased referrals or overutilization, because the goal of that program is to improve quality while lowering Medicare cost growth. The commenter suggested that this condition should not apply to MSSP ACOs because such ACOs are

designed to reduce spending, not increase it. Thus, increased referrals should not be a concern.

Response: We are not adopting the commenter's suggestion. CMS administers the MSSP pursuant to section 1899 of the Act. In addition, CMS operates a number of models pursuant to its authority under section 1115A of the Act. The MSSP and some of the models operated pursuant to section 1115A of the Act have waivers of certain fraud and abuse laws, including the anti-kickback statute. Parties involved in the MSSP or models under 1115A authority may not need this safe harbor to provide transportation, if they meet all the conditions set forth in an applicable waiver for the program in which they are participating.

Need for Transportation

In the Proposed Rule, we sought comments on whether we should require eligible entities to maintain documented beneficiary eligibility criteria. After consideration, we are finalizing a requirement that eligible entities have a set policy regarding the availability of transportation assistance, and must apply that policy uniformly and consistently. However, eligible entities are not required to maintain individualized documentation for each patient to whom transportation is provided. While not required to be protected under the safe

harbor, maintaining such documentation would be a best practice to demonstrate compliance with the requirements of the policy and the consistent and uniform application.

Comment: Some commenters maintained that providers should not be required to have established criteria that patients must meet to qualify for transportation. One commenter suggested it would be intrusive and would discourage patients from seeking transportation. One commenter suggested transportation should be available to all patients, plus family members and friends who are involved in a patient's care. Others agreed that it is acceptable, appropriate, or even crucial to require providers to have policies regarding financial or transportation need. One commenter supported community-based need criteria, rather than individual need. Another commenter believed that the criteria should be based on the availability of and access to transportation, or to a driver willing to transport the patient. Another agreed with requiring the provider to maintain criteria, but urged OIG to avoid burdensome requirements or extensive documentation (e.g., a provider should be allowed to use Medicaid as a proxy for showing financial need). This commenter also recommended allowing different ways to show need (e.g., risk of missing treatment, certain medications making them unable to drive). One commenter stated that eligible entities

should be able to set caps on the amount of transportation provided (e.g., an annual cap on the use of transportation services).

Response: As stated above, we have determined that eligible entities must maintain a consistent policy for offering free or discounted transportation. We decline to mandate the parameters for this policy, other than the fact that it must comply with other terms of this safe harbor (including distance, and the prohibition on transporting only to referral sources), and must be applied uniformly and consistently. For example, one practice might have a policy to ask any patient who schedules any procedure that inhibits the patient's ability to drive himself or herself home whether that patient needs local transportation assistance. Another practice might offer local transportation assistance to any patient who has a history of missing appointments. Other providers or suppliers might have specific need criteria. Another provider might have a policy of never offering transportation unless the patient specifically states that he or she cannot get to an appointment due to a lack of transportation. We believe that the other requirements in this safe harbor should protect Federal health care programs and beneficiaries, and that eligible entities should have the flexibility to develop policies to suit their patient populations' needs within those requirements. However, certain

eligibility criteria would not be appropriate. For example, we do not agree that a patient's status as a Medicaid (or Medicare) beneficiary should be used as a proxy for establishing transportation need, in part because this would result in transportation being offered on the basis of volume or value of Federal health care program business. If the eligible entity has a need-based policy, the fact that a patient is a Medicaid (or Medicare) beneficiary does not establish that he or she has a need for transportation; nor does the fact that a patient is not a Medicaid (or Medicare) beneficiary establish a lack of transportation need. For example, a Medicaid beneficiary may have ready access to affordable public transportation, while a patient with more financial resources may not. While eligible entities are free to tailor their transportation programs to the needs of their own patient populations and communities (including setting caps on available transportation), they may not do so in a way that is linked to status as a Federal health care program beneficiary.

Comment: Several commenters stated that requiring eligibility documentation or a screening process for each patient would be burdensome and would cause delays in the availability of transport. Some commenters cited privacy concerns. Others stated that documentation requirements will

deter providers from offering the transportation. Others agree with documentation of need, with one commenter suggesting it is necessary for OIG oversight. One commenter suggested that patient need should be established by patient self-declaration, but that such need should be noted in the patient record or discharge plan. Another supported "reasonable" documentation of need.

Response: As we explain above, an eligible entity offering transportation must do so consistently and uniformly, in accordance with its own policy. If an entity believes that an inquiry as to transportation need raises privacy concerns, the entity is free to offer transportation without regard to need, as long as it does so consistently. We agree with commenters that documenting need for each patient could be burdensome, particularly for eligible entities that have a more generous transportation assistance program. We are not requiring entities to document transportation assistance provided, if it is in compliance with the eligible entity's policy (but again, we suggest it might be best practice to do so).

Modes of Transportation

We proposed to limit the form of permissible transportation by excluding air, luxury, and ambulance-level transportation

from safe harbor protection. Commenters generally agreed with this proposal.

Comment: Several commenters generally agreed with our proposals to exclude air, luxury and ambulance-level transportation. One commenter agreed with excluding those types of transportation, but recommended that we consider patient needs (e.g., some patients may be capable of riding a bus, while others might need a taxi). Some commenters requested clarification that the safe harbor extends to third-party public transport. One commenter noted that excluding air transport is limiting for patients who must travel long distances for quality care, while another commenter suggested we should protect air travel if that is the usual mode of transportation in the area. Another commenter suggested that unadvertised ambulance transport should be available when no other option is available. Some commenters requested that chair cars be permitted.

Response: We are finalizing our original proposal. We agree that transportation in vehicles equipped for wheelchairs (other than ambulances) and third-party transportation, including public transportation, would be protected if it meets the other criteria of the safe harbor. While there may be individual cases (or communities) that justify air or ambulance-level transportation, those situations would need to be considered on

a case-by-case basis. We recommend that providers or suppliers seeking to use alternate forms of transportation request an advisory opinion.

Comment: One commenter generally supported the proposal to permit a shuttle service but suggested that few, if any, restrictions be placed on hospital shuttle service transportation offered in the 30-day post-discharge or 7-day post-ED-visit timeframes.

Response: We recognize the importance of post-discharge care for patients. While the commenter used the term "shuttle service," transportation geared to post-discharge care is less likely to be in the form of a shuttle and more likely to be offered to the patient on an individualized basis. As described in detail below, we are separately protecting shuttle services, and those services are subject to fewer restrictions than transportation offered to a particular patient on an individualized basis.

Comment: Several commenters expressed a concern that it would be burdensome or impossible to screen patients to ensure that only established patients used a shuttle around a hospital or extended campus.

Response: In this final rule, we expressly state that eligible entities offering a shuttle service would not be required to limit the service to established patients.

Marketing

We proposed several conditions related to marketing in connection with offering free or discounted local transportation. We proposed that the transportation assistance could not be publicly advertised or marketed to patients or others who are potential referral sources, that no marketing of health care items or services could occur during the course of the transportation, and that drivers or others involved in arranging the transportation could not be paid on a per-beneficiary-transported basis. We are finalizing these proposals, with certain clarifications.

Comment: Commenters noted that signage on vehicles is important for safety. One commenter suggested that vehicles should be allowed to include signs and pamphlets about services to be received.

Response: As we stated in the Proposed Rule, we agree that signage designating the source of the transportation on vehicles used to transport patients (or shuttles available to non-patients) is an important safety feature and would not be

"marketing," for purposes of the safe harbor. However, we respectfully disagree that providers should be able to post signs or give patients pamphlets or other marketing or informational materials during transport. Any discussion of services that patients may receive should come from the health care provider or supplier, not the transportation provider. Information about other services that the provider or supplier might offer is precisely the type of marketing this restriction strives to prevent. We are willing to protect transportation that helps patients get the care they need; we are not willing to protect transportation that is used as a sales tool.

Comment: One commenter recommended that MA organizations or other risk-bearing entities be allowed to advertise publicly the availability of transportation. The commenter states that such advertisements would reduce costs, and may be the only way to get the information to low-income populations.

Response: Individuals or entities seeking to avail themselves of this safe harbor may not advertise the availability of the transportation. However, as explained above, we do not believe that all transportation offered by organizations such as a MA organization would require the protection of this safe harbor (e.g., when the transportation is being provided as a supplemental benefit). Every entity would

need to evaluate the terms of a transportation program, on a case-by-case basis to determine whether the statute is implicated. If it is not, safe harbor protection would be unnecessary.

Comment: Several commenters requested that we clarify that providers are permitted to distribute information to patients who may need transportation but would not otherwise know it is available. Commenters variously suggested, for example, that providers be able to offer transportation proactively to patients who might need it, or permit statements that transportation is available subject to certain conditions. One commenter inquired whether information could be on the provider's Web site or in printed materials. Another suggested the requirement should be sufficiently flexible to allow patients to learn about opportunities for transportation.

Response: We agree with commenters that informing patients that transportation is available is not marketing, if it is done in a targeted manner. For example, if a patient learns that he or she needs to come to a followup appointment, or is scheduling a procedure that might require a safe ride home, it would be permissible to ask if the patient has a reliable mode of transportation. However, providers and suppliers should not advertise the availability of free or discounted transportation

(including on Web sites or in printed materials distributed to the public). As we explain below, this rule is slightly different for shuttle services.

Comment: One commenter agreed that a provider or supplier could pay drivers or others involved in arranging the transportation on a mileage or other fixed-rate basis, but not per-beneficiary-transported. Another requested that the safe harbor permit providers or suppliers to offer nominal public transportation fees (e.g., bus fare) to individual patients. Another commenter advocated that we permit providers and suppliers to reimburse patients directly, through vouchers, or through cash reimbursement.

Response: We agree with the commenters' suggestions, which largely support our proposals. If transportation is offered via a driver or private company hired by the eligible entity, that eligible entity cannot pay the driver or person/entity involved in arranging for the transportation on a per-patient-transported basis (although it could pay on the basis of total distance traveled by a vehicle). However, if transportation is provided in the form of nonprivate transportation (such as taxi or bus), the transportation would be paid for or reimbursed to individual patients through, for example, taxi vouchers or bus fare, or

cash reimbursement if the patient has a receipt to show that he or she incurred the cost of the transportation.

Comment: One commenter requested clarification as to whether acknowledging donors constitutes marketing (e.g., a sign in the vehicle saying "donated by ABC Chevrolet").

Response: In the Proposed Rule, we proposed prohibiting the marketing of health care items and services. We are finalizing this proposal. If a donor is a health care provider or supplier, or makes, markets, or sells health care items or supplies, an acknowledgment of that donor's contribution would be prohibited. If the donor is not a health care provider or supplier, or does not sell or provide health care items or supplies, the acknowledgement would not violate that condition of the safe harbor.

"Local" Transportation

As we explained in the preamble to the Proposed Rule, this safe harbor is intended to protect "local" transportation. We proposed that if the distance that the patient would be transported is no more than 25 miles, then the transportation would be deemed to be "local." We solicited comments on whether 25 miles is an appropriate distance, whether 25 miles should be a fixed limitation rather than a distance "deemed" to comply with the safe harbor, and other reasonable methods for

interpreting the term "local." In response to comments, and as described in more detail below, we have decided to have separate distance limits for rural areas and urban areas. We defined "rural area" as an area that is not an "urban area," as defined in this rule. We defined "urban area" as: (a) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (b) the following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. These definitions are intended to be consistent with the physician self-referral law definitions of the same terms.

Comment: Some commenters proposed specific distances that are farther than 25 miles. Proposals included 35 miles, 50 miles, and 100 miles. Some of these commenters proposed allowing the transportation at least within this expanded distance or to the closest facility capable of providing the necessary care. Many commenters recommended considering a greater distance than 25 miles for providers and suppliers in rural or underserved areas, where patients travel much greater

distances to access appropriate care. Commenters noted that CAHs must be at least 35 miles away from the nearest hospital or other CAH. Certain commenters suggested that providers serving rural or medically underserved communities should be exempt from any mileage limits. One commenter gave this example: In a rural area, a patient might go to a hospital for an outpatient procedure that could be done in an office; if the office is farther away than the hospital but transportation is allowed, the patient could receive care in a less expensive setting.

Response: This final regulation maintains the proposed 25-mile distance for patients in an urban area but expands the definition of "local" to 50 miles for patients in a rural area, as defined in this rule. The 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).

We arrived at our determinations of 25 and 50 miles after considering input from commenters and additional consultation with our government partners. We reviewed the United States Department of Agriculture (USDA) Economic Research Service's (ERS) data on Frontier and Remote (FAR) ZIP code areas, developed using data from the 2010 census. In an article describing these FAR levels (of which there are four), ERS

explained that "[h]ealth care access is the primary policy issue motivating this research."[15] FAR level one includes ZIP codes in which the majority of the population lives 60 minutes or more from an urban area[16] of 50,000 or more people. FAR level four breaks down the travel time to other areas: not only are the majority of those residents 60 minutes or more from urban areas with 50,000 or more people, they are 45 minutes or more from urban areas of 25,000-49,000 people, 30 minutes or more from urban areas of 10,000-24,999 people, and 15 minutes or more from urban areas of 2,500-9,999 people. According to the article, 6.5 percent of the U.S. population is classified as FAR level one, while 1.7 percent is classified as FAR level four (and thus, 93.5 percent of the population would not be classified as FAR). We note, MSAs contain at least one urbanized area of 50,000 or more people. In conjunction with this data, we reviewed a Working Paper titled "Geographic Access to Health Care for Rural Medicare Beneficiaries" that presented research and data on how far rural patients had to travel to access health care.[17] This paper included both median distance in miles

[15] John Cromartie, David Nulph, and Gary Hart, *Mapping Frontier and Remote Areas in the U.S.*, Amber Waves, Dec. 2012, Vol. 10, Issue 4, available at: http://www.ers.usda.gov/media/960626/datafeature.pdf.

[16] The cited research uses the term "urban area" as described in this preamble, which is not necessarily the same as "urban area" as defined in the final regulation.

[17] Leighton Chan, MD, MPH, L. Gary Hart, PhD, David C. Goodman, MD, *Geographic Access to Health Care for Rural Medicare Beneficiaries* (WWAMI Rural Health Research Center, Working Paper #97, April 2005).

and median time in minutes and presented the data in different categories: selected diagnoses (e.g., dementia, congestive heart failure, fractures, malignant neoplasms) and procedures (e.g., intubation for emergency, cardiac surgery, radiation oncology, general medical exam, dialysis). All diagnoses presented showed a median distance under 50 miles. Only two procedures showed a median distance over 50 miles, and those were for patients considered "isolated rural," defined in this paper as "in or associated with a rural town of fewer than 2,500." We believe that expanding the distance to 50 miles for patients in rural areas should protect transportation that meets the vast majority of patients' needs, while still being "local" for their communities.

We believe that a 25-mile distance should be sufficient for patients in urban areas to access quality health care, and can be fairly characterized as "local." We recognize that there may be areas within urban areas, as we are defininig that term in this regulation, that are generally underserved, or underserved as to particular types of health care services. However, we believe using definitions of "rural area" and "urban area" in this safe harbor that are consistent with definitions of the same terms used in connection with the physician self-referral law at 42 C.F.R. §§ 411.351 and 412.62(f)(1)(ii) will be

simplest for providers to work with and encourage the widest use of this safe harbor.

Individuals and entities anticipating a need to transport over longer distances and believing that they have sufficient safeguards in place to avoid abusive outcomes, such as steering of patients and inducements to obtain unnecessary care, may seek an advisory opinion for a determination on whether the program is sufficiently low risk.

We are sensitive to the fact that patients living in rural areas may have fewer health care providers and suppliers in their immediate areas, and that transportation might provide these patients with more choices and better access to quality care. We note that the requirement for a longer distance is that the patient resides in a rural area. Thus, the eligible entity (or the provider or supplier to whom the patient is transported) may or may not be in a rural area.

We believe that other suggestions provided by commenters are not appropriate for a safe harbor. For example, eliminating any kind of mileage or other limit would not give providers any kind of certainty as to whether they were offering "local" transportation, as required by the safe harbor. We also do not believe that a requirement that transportation be to the closest facility capable of providing treatment is appropriate. There is likely to be uncertainty as to whether any facilities were

closer to the patient, whether those facilities provide the needed service, whether such service is available within the time needed by the patient, and the like. We believe the two mileage limits that we are finalizing are sufficient to help patients access care while giving eligible entities a definite test to apply to determine whether their transportation assistance meets the "local" requirement of the safe harbor.

Comment: Several commenters proposed allowing a hospital or other provider to transport patients to the nearest facility capable of providing medically necessary items or service. Some commenters specifically cited specialized care (such as radiation oncology) or a specific facility type (e.g., for IHS beneficiaries, Indian tribe, tribal organization, or urban Indian organization health facility), which could be farther than 25 miles away. Some commenters proposed including the nearest facility as an alternate (i.e., 25 miles or to the nearest provider or supplier who can provide the care).

Response: As explained above, we have retained our proposed 25-mile limit for patients in an urban area, but have modified our original proposal to protect transportation up to 50 miles for patients located in rural areas. As we also explain above, a condition that limits transportation to the nearest provider or supplier could unnecessarily limit patient

choice, and application of such a standard could create a burden for patients or providers.

Comment: Certain commenters expressed a concern that a 25-mile limit could impede clinically integrated systems that span a greater distance from providing transportation among facilities in their systems.

Response: The purpose of this safe harbor is to protect free or discounted local transportation. We do not consider distances greater than 25 miles to be "local" in urban areas, or 50 miles in rural areas, for purposes of this safe harbor. We understand that there may be beneficial, low-risk transportation arrangements that the mileage limit will exclude from protection under the safe harbor. Entities desiring to implement an arrangement that implicates the statute and does not meet the terms of the safe harbor may submit an advisory opinion request so that we can determine, on a case-by-case basis, whether the arrangement is sufficiently low risk to be protected.

Comment: We received comments with a range of reasons to eliminate any fixed mileage limit. Commenters suggested that providers are in the best position to develop mileage criteria that reflect local characteristics; the distance is irrelevant, but transportation should be allowed only in certain circumstances (e.g., severe weather); any time or distance limit

is arbitrary, prescriptive, or too stringent; and any time or distance could be appropriate, depending on the facts and circumstances. Some commenters proposed using the provider's primary service area, or using longer distances for rural or medically underserved areas.

Response: While we understand that a set mileage limit is not a one-size-fits-all solution, we believe that a bright-line rule is easier for all parties to apply. Eligible entities will benefit from having the confidence that their arrangements fit within the safe harbor. We discuss our rationale for not implementing certain alternatives proposed by commenters elsewhere in this rule.

Comment: A number of commenters supported an approach referenced in the Proposed Rule of permitting transportation offered to patients within the primary service area of the provider or supplier (or other location) to which the patient would be transported. One of these commenters suggested defining "primary service area" as any jurisdiction from which the provider or supplier receives at least 10 percent of its patients. Some commenters noted that time or distance measurements vary too much in different areas (e.g., it could take an hour to travel 25 miles through an urban area, but only 20 minutes to cover the same distance in a rural area).

Likewise, argued a commenter, most of a provider's patients might be within a 25-mile radius in an urban area, but that same radius might include less than half of a provider's patients in a rural area.

Response: We considered this approach, but we maintain that using a mileage limit is more appropriate. We agree that time and distance measurements, and providers, suppliers, and patients within those time or distance limits, vary by region. However, we believe that by using a set mileage limit, which now includes the original 25-mile proposal as well as a 50-mile distance for patients in rural areas, we are balancing the need for patients to get local transportation for services, and the certainty that comes with a bright-line rule.

Comment: Certain commenters support the 25-mile limit as a "deeming" provision. In other words, 25 miles would always be acceptable, but greater distances would be permissible under appropriate circumstances (e.g., a rural or specialized facility that is farther than 25 miles away).

Response: While we have adopted fixed mileage limits for the reasons specified above, rather than the deeming concept that we proposed in the Proposed Rule, we did expand the distance to 50 miles for patients in rural areas. Again, these distance limits preserve the concept of "local" transportation,

while accommodating transportation needs greater than our original proposal of 25 miles for patients in rural areas. We may consider other types of transportation arrangements in future rulemaking.

Comment: One commenter does not believe "rural" or "underserved" should be defined, both because the commenter claims that federal definitions of "rural" fail to address communities' unique barriers, and because "local" should include the service line's service area.

Response: We are relying on a definition of "rural" for the rule that includes anything outside of an urban area, which is consistent with the definition of "rural area," as defined in the physician self-referral law.

Prohibition on Cost-Shifting

We proposed that the eligible entity bear the costs of the free or discounted local transportation services, and not shift the burden of these costs to Medicare, a State health care program, other payers, or individuals. Many commenters supported this requirement, but some asked for specific clarifications.

Comment: One commenter asked that we clarify that transportation offerors cannot shift costs to third-party

vendors (e.g., ambulance providers). One commenter recommended that transportation offerors be required to report incurred costs on cost reports to CMS.

Response: We do not believe it is feasible or necessary to require specifically in this final rule that transportation offerors not shift costs onto third-party transportation vendors. First, we believe that our proposed prohibition on shifting costs and requiring the transportation offeror to bear costs itself covers the commenter's concern. Moreover, this safe harbor protects only the offering, giving, soliciting, and receiving of the transportation. It does not protect behind-the-scenes arrangements to implement the transportation. Thus, if a hospital were to shift the costs of its transportation program to an ambulance provider under an explicit or implicit threat of withholding future referrals, such activity could still violate the anti-kickback statute and would not be protected under this safe harbor. Whether transportation costs should be reported on cost reports is outside the scope of this rulemaking; however, any reporting of the cost of transportation that would serve to shift such costs to Federal health care programs would take the transportation out of the protection of this safe harbor.

Comment: One commenter suggested that providers should be permitted to enter into cost-sharing arrangements with local or state entities, or with nonprofit organizations or charities. This commenter believes providers should not be required to bear the "full" costs. Another commenter noted that smaller practices should be able to pool resources to offer transportation.

Response: We agree that providers and suppliers should not have to bear the full cost of transportation, if they can get donations or contributions from appropriate sources. However, in the absence of an agreement among entities to share costs, entered into voluntarily and without any tie to referrals, the costs should not be shifted to any payer, individual, or other provider or supplier. This prohibition is not intended to bar entities from voluntarily joining together to offer transportation. Investing in transportation is not necessarily different than making any other investment (and donating transportation is not different than making any other donation). For example, a charity might donate a vehicle to a hospital, or a health system or an ACO might purchase vehicles that would be available for use by its providers or suppliers (at their cost pursuant to the safe harbor requirement that the eligible entity bear the costs of the transporation) to transport their patients

(i.e., the ACO or health system would not be acting as the eligible entity; the transporting provider or supplier would be). Any agreement parties enter into to make this investment would not be covered under this safe harbor (which protects the transportation itself), but it also would not disqualify the transportation from the protection of this safe harbor, as long as the terms of the agreement would not result in transportation that fails to meet the conditions of the safe harbor (e.g., if the agreement involved tying the availability of transportation to referrals). Parties would need to ensure that the agreement does not violate the anti-kickback statute or other fraud and abuse laws.

Shuttle Transportation

We sought comments on whether we should separately protect a second form of transportation akin to a shuttle service. We received a number of comments about offering a shuttle service, and which of our proposed safe harbor criteria should, or should not, apply to that form of transportation. In short, this final rule separately protects a shuttle service under the safe harbor. Some safeguards will be the same, and others will be different, compared to the more personalized form of transportation contemplated by this safe harbor. First, we interpret the term "shuttle" to be a vehicle (not air, luxury,

or ambulance) that runs on a set route, on a set schedule. Second, the "established patient" requirement will not apply to shuttle services. Third, we are not mandating where the shuttle can or cannot make stops, other than continuing to require that the shuttle transportation be local. Because we anticipate that shuttle routes may include multiple stops, "local" would mean that there are 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. Thus, if a health system runs a shuttle that stops at a hospital, a public transportation stop (the only stop in a rural area), a grocery store, and a clinic, all stops other than the public transportation stop must be within 25 miles of the hospital and the clinic (if measured directly, without regard for intervening stops), and the hospital and the clinic must be within 50 miles of the transportation stop in the rural area. Fourth, the marketing prohibitions apply to shuttle services, except that the schedule and stops can be posted. The rest of the requirements of the safe harbor (e.g., eligible entity requirements, other marketing, and the prohibition on cost-shifting) all apply to shuttle services. We summarize the comments received below and provide additional details.

Comment: A number of commenters expressly agreed with our proposal to allow shuttles, and others implicitly agreed by commenting on other requirements (such as the established patient requirement) in the context of a provider running a shuttle. One commenter requested that we clarify that providers and suppliers can contract with third parties to run shuttles. Another commenter requested protection of a shuttle, bus, or van route that includes neighborhoods served by a hospital, public transportation stops, and the hospital campus or other hospital campuses. One commenter urged us to require that a shuttle must transport patients to providers other than those affiliated with the eligible entity running the shuttle.

Response: We agree that shuttle vans or buses should be permitted under this safe harbor, and that some different safeguards should apply. We offer the following responses to specific comments. (1) We would not mandate who runs the shuttles (whether it is the eligible entity or a contractor of the eligible entity operating the shuttle service). (2) For various reasons, we are not requiring that the shuttle be limited to established patients. Unlike door-to-door transportation in which a driver is sent to pick up a specific patient, a shuttle would run on a regular route. We believe it would be burdensome if we required shuttle drivers to determine

whether individuals using the shuttle were established patients of one of the facilities where the shuttle would stop. Also, a shuttle service may be used for reasons other than to obtain healthcare items or services, or to obtain such items or services from a particular provider, practitioner, or supplier. For example, we expect many shuttles would be available to employees of the eligible entity or visitors to one of the eligible entity's facilities as well as to patients. If the entity furnishing the shuttle service chooses also to make it available to the general public, we do not believe that this would materially increase the potential for abuse. Other safeguards (e.g., restrictions on marketing) limit the risk that the shuttle would be used to recruit new patients. Should an eligible entity prefer to limit shuttle services to established patients, such a limitation would not be prohibited under this safe harbor. However, it is not a requirement. (3) We decline to adopt the recommendation that the shuttle be required to stop at providers unaffiliated with the provider or supplier offering the shuttle service. We are also not approving (or disapproving) particular types of stops as appropriate for a shuttle service. We believe that such requirements would be unworkable in a safe harbor. For example, if a hospital in an urban area offered a shuttle in roughly a 10-mile radius around the hospital, there could be dozens, if not hundreds, of

unaffiliated providers, practitioners, or suppliers on or near that route, as well as a variety of stops that are included primarily as patient pick-up locations. We believe the eligible entity offering the transportation is in the best position to determine the types of shuttle stops that are appropriate for the applicable community and that the safeguards included in the final rule are sufficient to mitigate risks associated with offering shuttle transportation.

C. Civil Monetary Penalty Authorities: Beneficiary Inducements CMP

When reviewing comment summaries and responses below, it is important to remember what the beneficiary inducements CMP prohibits, in contrast to certain other fraud and abuse laws, such as the anti-kickback statute. First, the beneficiary inducements CMP prohibits inducements only to Medicare and State health care program[18] beneficiaries. Second, it prohibits inducements to those beneficiaries only if the offeror knows or should know the inducement is likely to influence the beneficiary to receive a reimbursable service from a particular provider, practitioner, or supplier. Unlike the anti-kickback statute, which prohibits offering or giving remuneration to

[18] All references to "State health care program" in this final rule rely on the definition of that term found at section 1128(h) of the Act.

induce beneficiaries to order an item or service, the beneficiary inducements CMP is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner, or supplier. For example, if a hospital were to offer a beneficiary remuneration post-discharge to follow up with a physician (without regard to who that physician might be, and without recommending a particular physician or group), the beneficiary inducements CMP would not be triggered and no exception would be necessary. In contrast, an entity like a pharmaceutical manufacturer, which is not a provider, practitioner, or supplier, could nonetheless implicate the statute if it offered or gave remuneration to a beneficiary that it believed would be likely to induce the beneficiary to order an item or service from a particular provider, practitioner, or supplier (e.g., to choose a particular physician or pharmacy). With that background, the following section summarizes the comments we received on each of the exceptions proposed in the Proposed Rule.

1. Copayment Reductions for Outpatient Department Services

We proposed to incorporate the statutory exception set forth at section 1128A(i)(6)(E), which permits hospitals to give

reductions in copayment amounts for certain outpatient department (OPD) services. The statutory cite to the definition of "covered OPD services" was outdated, so we proposed to use the current statutory reference. We received no comments on this proposal, and we are finalizing it, as proposed.

2. Promotes Access/Low Risk of Harm

Section 1128A(i)(6)(F) of the Act includes 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 (as defined in section 1128B(f) and designated by the Secretary under regulations)."

We note that other exceptions to the beneficiary inducements CMP, and some safe harbors to the anti-kickback statute (which are incorporated by reference as exceptions to the beneficiary inducements CMP), may cover activities or arrangements that arguably "promote access to care and pose a low risk of harm to patients and Federal health care programs." This exception should be read in the context of those more specific exceptions and safe harbors: we would look to other applicable exceptions to consider whether the remuneration in question poses a low risk of harm. Thus, activities and arrangements that are addressed by another beneficiary inducements CMP exception or a safe harbor and meet the elements

of the applicable safe harbor or exception would be considered to be low risk under this exception. For example, one type of remuneration cited by numerous commenters that could promote access to care is free transportation. We have set out conditions in the anti-kickback statute safe harbor for local transportation that we believe are necessary for such transportation to be "low risk." If a local transportation arrangement did not meet the requirements of the safe harbor (e.g., it would be long-distance transportation, or transportation that is advertised), it would be unlikely to be low risk under this exception. However, we recognize that each arrangement should be subject to an analysis of the facts and circumstances. For example, if a transportation arrangement did not meet all conditions of the safe harbor, but had different safeguards in place, it could be low risk under this exception. We note, however, that this exception does not apply to the anti-kickback statute. Entities desiring to enter into transportation arrangements that do not meet the requirements of the anti-kickback safe harbor may wish to seek an advisory opinion.

For activities and arrangements that are not addressed by a more specific safe harbor or exception, anyone asserting this exception as a defense will have the burden of presenting

sufficient facts and analysis for OIG to determine that the arrangement promoted access to care and posed no more than a low risk of harm to patients and the Federal health care programs, as described in this Final Rule.

In the Proposed Rule, we proposed certain interpretations of the statutory language to inform our development of regulatory text. We also solicited comments on a number of specific aspects of the statutory language. The responsive comments fall into three general categories: (1) what constitutes "care;" (2) what it means to "promote access" to care; and (3) what type of remuneration poses a low risk of harm to patients and Federal health care programs. We also received questions about types of programs or arrangements that might meet the exception, or other general questions. We address these comments in turn, and we intend to strictly interpret the language of this exception, as described in detail below.

a. Promotes Access to Care

The Term "Care"

In the Proposed Rule, we characterized "care" as "medically necessary health care items and services." 79 FR 59717, 59725 (Oct. 3, 2014). We also solicited comments on whether we should interpret "care" more broadly to include nonclinical care that

is reasonably related to medical care, such as social services. Id.

Comment: Some commenters supported protecting remuneration that promotes access to nonclinical care that is reasonably expected to affect the patient's health (e.g., dietary counseling, social services). One commenter suggested that we should broaden our interpretation to include nonclinical care and protect any activity related to care that is encouraged through CMS's Medicare Star Ratings system. Another commenter recommended that the exception should include access to nonclinical services reasonably related to treating, managing, or preventing a condition identified in a published recommendation of the U.S. Preventive Services Task Force. Another commenter suggested that promoting access to nonclinical care fosters efficiency and quality improvement goals of integrated care arrangements.

Response: At a high level, we agree with the commenters who suggest that certain types of nonclinical items and services can improve overall health and help meet quality-improvement goals. However, after considering comments that expressly addressed this question, in combination with how this term affects other aspects of the exception, we do not agree that the term "care" in this exception should be expanded beyond items

and services that are payable by Medicare or a State health care program. For clarity, because some State health care programs (such as Medicaid) cover some services that are not strictly medical (such as personal care services for beneficiaries who are unable to care for themselves), we are revising the standard to encompass items and services that are payable by Medicare or a State health care program, rather than by reference to medical necessity. Thus, when we refer to "care" in the context of "access to care" throughout the following discussion, we mean access to items and services that are payable by Medicare or a State health care program for the beneficiaries who receive them.

In response to the comment regarding the Medicare Star Ratings system, we note that the activities encouraged under this system include many types of care, such as health screenings, vaccines, and managing chronic conditions. If the remuneration promotes access to care, and is low risk, it would be protected. The exception applies to a prohibition on remuneration that is likely to influence a beneficiary to order or receive items or services from a particular provider, practitioner, or supplier for which payment may be made by Medicare or Medicaid. As explained above, we believe it therefore follows that the "care" alluded to in the exception is

care provided by the particular provider, practitioner, or supplier, which is payable by Medicare or a State health care program. As further noted above, we are defining the term "access to care" as access to items or services payable by Medicare or a State health care program. We decline to define "care" more broadly because the statutory exception provides no guidance as to what constitutes "care," beyond that which is covered by these programs, or what other kinds of care should be included. Notwithstanding our conclusion on this point, we will continue to monitor the changing payment and health care delivery landscape for possible future exceptions. In addition, we emphasize that individuals and entities can still help and encourage beneficiaries to access nonpayable care without implicating the beneficiary inducements CMP. For example, individuals and entities can provide patients with objective information (such as educational materials or other resources) about community resources. Moreover, when items or services are not reimbursable by Medicare or State health care programs, the statute would be triggered only if the offeror of the remuneration knew or should have known that the remuneration was likely to influence a Medicare or State health care program beneficiary to receive reimbursable services from a particular provider, practitioner, or supplier. For example, a MA organization or a Part D plan could provide remuneration to its

enrollees to help them access nonpayable care, without implicating the beneficiary inducements CMP; MA organizations and Part D plans are not providers, practitioners, or suppliers, and under ordinary circumstances remuneration from them to access nonpayable items or services would not be likely to induce a beneficiary to use a particular provider, practitioner, or supplier for an item or service payable by Medicare. Likewise, an employee in a physician's office could work with Medicare or State health care program patients to refer them to resources in their communities (e.g., for assistance with housing, food, or domestic violence counseling). Providing these educational or informational services to patients would not implicate the beneficiary inducements CMP.

Comment: Commenters requested that the exception protect remuneration in the form of the provision of nonclinical items that improve medical care or are reasonably related to medical care. Among the nonclinical items commenters suggested should be permitted are health and wellness-related technology hardware and software, computer and smartphone applications, home monitoring devices, telemedicine capability, nutritional services (i.e., meals or meal preparation services), health and wellness coaching, mental or physical activity initiatives, social services, legal services, Internet classes, language

instruction, and discount programs that tie health and wellness achievements to the receipt of retail items and services.

Response: We note that the question of whether the form of remuneration can be a payable item or service is a different question from the "care" to which access is promoted by the remuneration. A number of commenters provided suggestions of beneficial items or services (i.e., forms of remuneration) that are nonpayable by Medicare or State health care programs. It is possible that any of the examples of remuneration above would not violate the CMP under appropriate circumstances. If the provision of an item or service is not likely to influence a beneficiary to choose a particular provider, practitioner, or supplier, it does not implicate the statute. The provision of remuneration that does implicate the statute could be protected by this or another exception, if all conditions of the exception are met. In evaluating a particular arrangement for the provision of remuneration to beneficiaries under this exception, we would consider whether the arrangement promotes access to care (i.e., items or services payable by Medicare or a State health care program) and is a low risk of harm to patients and Federal health care programs, in accordance with the guidelines set forth here.

Comment: Some commenters disagreed with limiting the exception to access to care in the form of items and services that are medically necessary. One commenter suggested that tying access to care to "medically necessary items and services" would exclude items or services given before seeing a doctor, because the provider would not necessarily know what services the beneficiary would require or whether such services are medically necessary. Two commenters suggested that the standard would be burdensome for health plans, pharmacy benefit managers, and OIG because it would require patient-specific reviews by individuals with medical expertise, and would exclude items that are "reasonably related" to medical care.

Response: We did not propose limiting the exception to remuneration that is medically necessary; the remuneration must increase the beneficiary's ability to obtain care and pose a low risk of harm. We do not believe the restriction we proposed would exclude items or services given before seeing a doctor. Remuneration may come from any individual or entity to facilitate a beneficiary's obtaining care, as defined herein, from a provider, practitioner, or supplier for the first time. For example, if a patient makes an appointment with a physician practice, the practice may send the patient a monitoring device (such as a blood pressure cuff, heart rate monitor, or purchase

code for a smartphone app) to collect health data before the appointment. As we explain above, we revised our interpretation of "care" from medically necessary items or services to items or services payable by Medicare or a State health care program. We do not believe it would be burdensome for health plans or others to be familiar with the types of items or services that are payable by these programs. Further, as we explain in greater detail below, we believe programs can be developed at the beneficiary-population level for greater efficiency. With that said, we would not protect remuneration that would be likely to influence a patient to access unnecessary care from a particular provider, practitioner, or supplier. As a separate matter, as we explain above, the remuneration itself does not need to be payable items or services; the remuneration must promote access to such care.

Comment: One commenter suggested that restricting the exception to remuneration that promotes access to medically necessary care conflicts with the suggestion that the remuneration could promote access to nonclinical care and is not required by statute.

Response: We agree that we could not adopt both standards. The standard that we are adopting protects remuneration that promotes access to care (items and services that are payable by

Medicare or a State health care program); we solicited comments on whether our proposal should be expanded to apply to remuneration that promotes access to nonclinical care (and poses a low risk of harm). For purposes of this exception, we believe a necessary safeguard to protect both patients and Federal health care programs is to limit the scope of the exception to remuneration that promotes access to items and services that are payable by Medicare or a State health care program. As we note elsewhere, we will continue to monitor the changing health care delivery and payment landscape, as well as changing understandings of the relationship between traditional health care services and non-traditional services that improve health, and consider whether additional or revised exceptions are necessary in the future.

The Term "Promotes Access"

We proposed that the exception would include only remuneration that "improves a particular beneficiary's ability to obtain medically necessary items and services." We solicited comments on multiple aspects of this proposal. We asked whether we 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 than it otherwise would be. As we explain in greater

detail below, many of the comments that we received proposing a broader interpretation sought protection for remuneration that could fit within our original proposal. After considering all of the comments, we decline to adopt a broader interpretation of "promotes access" than we proposed (subject to our revised definition of "care"), but we note that items or services that support or help patients to access care, or make access to care more convenient than it otherwise would be often would meet our original proposed interpretation. We also asked whether the remuneration would have to promote access to a particular beneficiary or whether it should also apply to a defined beneficiary population. We have determined that the exception should apply to remuneration that promotes access either to a particular individual or to a defined beneficiary population.

Comment: Some commenters supported protecting remuneration (including what some commenters characterized as programs to offer remuneration) to promote access to care for a particular beneficiary population, as well as individual beneficiaries. One rationale offered to expand the protection to remuneration that promotes access to care for a beneficiary population is to facilitate use of the exception operationally; the commenter suggested that lines can be blurred between what is offered on an individual basis versus what is offered to a defined group.

One commenter noted that a broader interpretation of the individual(s) for whom a program might promote access to care allows for the development of innovative programs. One commenter supported population-specific programs for free or discounted services, such as participation in smoking cessation, nutritional counseling, or disease-specific support groups.

Response: We agree with the commenters that the exception should apply to remuneration that promotes access to care for a defined beneficiary population, and not be limited to remuneration offered on an individual patient-by-patient basis. With that said, the form of remuneration does not matter (as long as it is an item or service, and not cash or a cash equivalent, and not a copayment waiver), and could include participation in smoking cessation, nutritional counseling, or disease specific support groups, but the remuneration would have to comply with the other prongs of the exception: it must promote access to items or services that are payable by Medicare or a State health care program (and pose a low risk of harm to patients and Federal health care programs). Such an analysis would depend on the facts and circumstances. For example, a primary care group practice might purchase and make available to its diabetic patients a subscription to a Web-based food and activity tracker that includes information about healthy

lifestyles. Depending on the cost of this subscription, it could constitute remuneration to the patient. This remuneration would promote access to care because it would help the patient understand and manage the interaction between lifestyle, disease, and prescribed treatment and would create a record that would facilitate interactions with the physician for future care-planning. In other words, the service is a tool that patients would use to access care and treatment because it helps them access improved future care-planning by their physican. In contrast, an ophthalmologist could not offer a general purpose $20 debit card to every patient who selected him as a surgeon to perform cataract surgery because the debit card does not help the patient access care, and remuneration that is cash or a cash equivalent[19] is not low risk.

Comment: We received numerous comments generally supporting the concept of broadly interpreting the definition of "promotes access to care" to encompass encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it otherwise would be. Commenters suggested that the broader definition is justified, in light of the shift toward

[19] OIG considers "cash equivalents" to be items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores or for a certain purpose, like a gasoline gift card).

coordinated or integrated care that depends on patient engagement. Commenters further suggested that a more narrow definition could exclude many types of beneficiary incentives that would help patients to access care. Another commenter expressed concern with a broad definition, and recommended that OIG adopt a standard for medical necessity similar to the one Medicare uses and clarify how it would be enforced. Commenters suggested specific examples of types of remuneration that should fit into the definition of "promotes access" to care, such as transportation, self-monitoring tools, post-discharge contacts, and incentives to be proactive for health care needs.

Response: We believe that interpreting "promotes access to care" as improving a particular beneficiary's [or, as noted above, a defined beneficiary population's] ability to obtain items and services payable by Medicare or a State health care program is sufficiently broad. We appreciate the commenters' desire for a broad definition of "promotes access," and upon review of the comments, we have determined that some of the phrasing about which we solicited comments (e.g., "helping patients to access care" or "making access to care more convenient") could be included in the concept of improving a beneficiary's ability to access care. We recognize that there are socioeconomic, educational, geographic, mobility, or other

barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or services that "promote access to care" encompasses giving patients the tools they need to remove those barriers. As we discuss below, this interpretation would not, however, incorporate the concept of rewarding patients for accessing care; the exception protects items or services that should improve a patient's ability to access care and treatment, not inducements to seek care. Thus, some suggestions from commenters would not fit into our definition. Incentives to be proactive for health care needs might not improve a beneficiary's "ability" to access care (though we note, the preventive care exception[20] does protect incentives to seek preventive care). For example, if a patient had a health condition for which a smoking-cessation program was a payable service, under this exception, a provider could offer free child care to the patient so that the patient could attend the program, but the provider could not give the patient movie tickets or any other reward for attending a session or series of sessions. A patient might not be able to attend the appointment without child care assistance, but the movie tickets do not improve the patient's ability to attend the appointment. Other

[20] The "preventive care exception" is a statutory exception at section 1128A(i)(6)(D), and an exception to the definition of "remuneration" at 42 CFR § 1003.110.

examples provided by commenters could fit in the exception, under appropriate circumstances. Transportation assistance was a common request from commenters. If a provider, practitioner, or supplier offered local transportation or parking reimbursement to patients for appointments for items or services payable by Medicare or a State health care program, such remuneration would improve a beneficiary's ability to access that care.[21] Self-monitoring tools also could promote access to care. For example, a hospital might send a patient home with an inexpensive device to record data, such as weight or blood pressure, that could be transmitted to the hospital or the patient's physician. This remuneration could increase the beneficiary's ability to capture information necessary for followup care and to comply with the treatment plan. Post-discharge contacts limited to communications with the patient ordinarily would not constitute remuneration and thus would not require the protection of an exception to the CMP.

We also believe that the definition we are finalizing is broad enough to facilitate coordinated or integrated care. A goal of coordinated care is to improve the delivery of

[21] Note, however, that the remuneration must also be low risk. In this final rule, we have included a safe harbor to the anti-kickback statute that protects local transportation that meets certain requirements. As noted above, any remuneration that meets the requirements of a safe harbor is also excepted from the beneficiary inducements CMP. The safeguards set forth in that safe harbor would help ensure that the remuneration is low risk.

medically necessary care (and eliminate medically unnecessary care). If remuneration associated with a coordinated care arrangement meets the requirement of being low risk and helps the patient to access necessary care, the remuneration could fit in this exception. We recognize that the exception does not include inducements to seek care. However, we note that items of nominal value do not require an exception. See Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002 (2002 Special Advisory Bulletin), available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf. In the 2002 Special Advisory Bulletin, we stated our interpretation that the CMP permits inexpensive gifts (other than cash or cash equivalents) of no more than $10 in value individually or $50 in value in the aggregate annually per patient. Concurrently with the issuance of this final rule, we are announcing an increase in these limits, based on inflation, to $15 for an individual gift and $75 in value in the aggregate annually per patient. We are mindful that some CMS models permit incentives to seek care through waivers of the beneficiary inducement CMP. At the present time, methods used in these models are being tested to learn what might improve quality and patient outcomes without increasing costs. We will continue to monitor the results of such programs and

will consider whether new or expanded exceptions are warranted in the future.

Comment: One commenter suggested that the definition of "promotes access to care" should require compliance with a particular treatment plan, and prohibit suggestions of specific providers and suppliers.

Response: We respectfully disagree with both suggestions. First, the commenter seems to imply that the exception is available only after the patient has an established care plan. However, the exception also would protect remuneration that promotes access in the first instance, and thus no treatment plan would exist. With respect to the second suggestion, if there is no likelihood of influencing a beneficiary to use a specific provider or supplier, the statutory prohibition would not be triggered, and complying with an exception would not be necessary.

Compliance with a Treatment Plan

As we explain in responses to the various comments below, rewards for accessing care, including compliance with a treatment plan, do not "promote access" to care. However, remuneration that helps a patient comply with a treatment plan (i.e., removes an impediment or otherwise facilitates compliance

with a treatment plan) could promote access to care. The following comments and responses address these issues.

Comment: Several commenters recommended that the definition of "promotes access" should permit remuneration that promotes compliance with a treatment plan, or programs that promote adherence to medication therapy (in contrast to the previous comment, which suggested that a treatment plan should be required as a condition of any remuneration permitted by this exception). One such commenter said that, if permitted, the remuneration to promote compliance with a treatment plan must be part of a written followup plan.

Response: We agree that some forms of remuneration that remove impediments to compliance with a treatment plan could constitute promoting access to care and could fit within the exception (as long as the remuneration also is low risk, as explained below). Items that are mere rewards for receiving care, as opposed to items or services that facilitate access to that care, would not meet the definition of "promotes access" to care. For example, remuneration in the form of an item that dispenses medications at a certain time for a patient could meet the exception because it is a tool that enables the patient to access the right drugs at the appropriate dosage and time. Reimbursing parking expenses or providing free child care during

appointments also could promote access to care and help a patient comply with a treatment regimen. In contrast, offering movie tickets to a patient whenever the patient attends an appointment would not fit in the exception; such remuneration would be a reward for receiving care and does not help the patient access care, or remove a barrier that would prevent the patient from accessing care. We do not intend to require that remuneration that removes an obstacle to a patient's ability to comply with a treatment plan be part of a written followup plan because we do not believe that remuneration with this purpose should be different than any other remuneration permitted under the exception. In other words, if remuneration promotes access to care — whether the patient is at the beginning of the course of care or is in the middle of a treatment plan — and is low risk as described below, the remuneration can meet the exception.

Comment: We received a number of comments addressing our stated concern that rewards offered by providers or suppliers to patients purportedly for compliance with a treatment regimen pose a risk of abuse. Some commenters supported allowing remuneration that encourages patient participation and compliance. One commenter specifically requested that the exception include pharmacy programs that promote compliance with

medication regimens. Some commenters suggested that allowing targeted incentives would promote adherence and reduce utilization of high-cost services and support similar goals articulated in the ACA. Another commenter recommended that we avoid imposing specific safeguards, as long as the incentives do not steer patients to a particular provider or supplier. Some commenters note that incentive programs are effective in particular settings (e.g., the Alaska Native and American Indian community and in medication adherence programs). One commenter noted that similar programs, using incentives of nominal value, have been effective. Other commenters proposed specific safeguards, discussed further below.

Response: As we address above, we have determined that inducements to comply with treatment or rewards for compliance with treatment do not "promote access to care" and thus are not protected by this exception. We note however, that some of the comments above relate to activities that might not trigger liability under the statute. For example, if an incentive would not be likely to influence a patient to use a particular provider, practitioner, or supplier, the incentive would not implicate the beneficiary inducements CMP. Likewise, if the remuneration is of nominal value, it would not implicate the statute (again, because items and services with a low retail

value are unlikely to influence the beneficiary to choose a particular provider, practitioner, or supplier). If an individual or entity desires to offer a program that it believes would be beneficial but might implicate the beneficiary inducements CMP, the advisory opinion process remains available.

Comment: Some commenters submitted examples of remuneration that they believed should be allowed as incentives to comply with a treatment regimen. One commenter suggested that incentives such as computer/smartphone apps, gift cards, and fitness trackers would encourage compliance and that similar rewards were approved in advisory opinions, citing OIG Advisory Opinion Nos. 12-14 and 12-21. One commenter gave an example of a lottery: only patients who are in compliance with a treatment regimen may enter, and then even fewer will win (though the payout could be significant). Commenters offered a variety of examples of incentives or rewards that they believed should be protected under the exception, such as: rewards for routine exercise, gifts by health plans to incentivize enrollees to obtain preventive services or achieve benchmarks for controlling chronic conditions, discount programs that tie health and wellness achievements to the receipt of retail items and services, or rewards for positive outcomes (such as smoking cessation, losing weight). Another commenter requested that we

specify that the exception covers rewards for actual access to care, not just promoting access to care.

Response: We believe many of the examples offered could meet the exception, but we respectfully disagree with the commenter that suggests that the exception covers rewards for accessing care as opposed to promoting access to care. For example, smartphone apps or low-cost fitness trackers could, depending on the circumstances, promote access to care; they could be used to track milestones and report back to the treating physician. Gift cards that relate to promoting access to care (e.g., a gift card specifically for an item that would monitor the patient's health) could potentially fit into the exception as well. However, the examples structured as rewards (e.g., rewards for routine exercise) would not be covered. Similarly, it is unlikely that a lottery or raffle system that rewards compliance would promote access to care, as we interpret the term.[22] We will continue to monitor patient engagement incentives as they develop in the industry, including new CMS models, and may propose future rulemaking as results become known. We again note that no exception is necessary if

[22] A raffle, however, could be of nominal value and not implicate the statute. For example, if the prize would be worth $100, and there were 20 participants with an equal chance to win that prize, we would consider each chance to be worth only $5. Although the winner would receive the prize worth $100, that patient had only a 1 in 20 chance of winning it, so the chance was worth only $5. If lottery tickets are available for purchase by the public (e.g., a state lottery), however, we would consider the value be the purchase price.

remuneration offered to patients is not likely to induce the patient to select a particular provider, practitioner, or supplier, including items and services of nominal value, and that incentives to seek preventive care could be covered under the preventive care exception.

In responding to various aspects of the Proposed Rule, some commenters asked about health plans providing incentives to their members to seek preventive health services, or to achieve certain health-related benchmarks. If health plans (or other entities that are not providers, practitioners, or suppliers) offer these incentives to seek particular services without influencing members to use particular providers or suppliers, the beneficiary inducements CMP is not implicated. If the incentives would influence members to use a particular provider or supplier, then the same conditions and interpretations of this exception would apply to health plans that apply to providers, practitioners and suppliers. However, all individuals and entities remain subject to the anti-kickback statute, and remuneration not prohibited under the CMP could be prohibited under the anti-kickback statute. For example, if a pharmaceutical manufacturer offered rewards or incentives for treatment compliance (without regard to any provider or supplier furnishing treatment), it might not implicate the beneficiary

inducements CMP because the rewards would not incentivize the beneficiary to receive items or services from a particular provider or supplier, but it would implicate the anti-kickback statute because the remuneration could induce the beneficiary to purchase a federally reimbursable item.

Comment: Several commenters addressed the question of whether risk-bearing providers should be able to provide incentives for compliance with a treatment regimen. One commenter recommended that fee-for-service providers and suppliers should be allowed to provide remuneration to incentivize compliance, as certain ACO entities can. Another commenter recommended that providers taking on financial risk, such as some providers in ACOs, should be able to offer incentives. One commenter recommended that providers in fee-for-service alternative models (such as full or partial capitated models, ACOs outside of MSSP, medical homes, and others) be allowed to offer any kind of incentive (including cash equivalents) because the providers are rewarded on the basis of results rather than volume, and because patients are often assigned to providers (so the incentive wouldn't influence choice of provider).

Response: We believe that all individuals and entities seeking to rely on this exception should be required to meet the

same standards. We agree that the incentives are different with risk-bearing providers and suppliers and ACOs than they are with traditional fee-for-service providers and suppliers. However, those characteristics should make it easier for those entities to meet the standards of the exception. If they are accountable for cost and quality, it is more likely (but not guaranteed) that the remuneration would be low risk. We do not believe that they should be exempted from the standards by virtue of their organization as an ACO or risk-bearing provider, nor should they be permitted, by virtue of this exception, to provide incentives that do not promote access to care. Once again, however, we note that if the incentive would not influence the beneficiary to receive services from a particular provider, practitioner, or supplier, then it would not implicate the statute. In addition, if the incentive were to encourage a beneficiary to access preventive care, that remuneration could be protected under the preventive care exception.

Comment: Several commenters addressed the question of whether certain safeguards should apply to incentives given for compliance with a treatment regimen. One commenter disagreed with safeguards, especially dollar limits, on incentives for compliance with treatment regimens. The commenter said some entities cannot track dollar limits for coupons. Another

commenter recommended a $500 per beneficiary limit. One commenter proposed no dollar limit if the incentive is linked to health and wellness and has a reasonable connection to medical care, or a $100 limit if the item is not so linked. Another commenter generally suggested that the dollar amount should not be disproportionate to the patient's benefit from treatment. Another commenter suggested that dollar limits are arbitrary: an inexpensive app or device might be helpful for one patient, while another patient might need legal services or social services to get housing. One commenter recommended that the incentive should have a reasonable relationship with the treatment regimen. Commenters proposed a host of other safeguards for remuneration to incentivize or reward compliance with a treatment regimen. Some recommendations relate to documentation requirements (e.g., milestones reached, evidence of past noncompliance). Other commenters recommended that the incentives themselves must be related to care management. One commenter suggested that we require offerors to submit plans to CMS to evaluate effectiveness; if not shown to increase compliance, it would not be protected. Other commenters recommended against particular safeguards. For example, one commenter did not believe that the form of an incentive should be limited, or that the incentive itself should have to relate to medical care. Another commenter recommended against quality

or performance metrics. Another generally requested guidance on how the exception would protect incentives to engage in wellness or treatment regimens.

Response: Because we are not permitting incentives or rewards for compliance with a treatment regimen under this exception, some of the comments regarding incentives related to medically necessary care or treatment are moot. However, to the extent that some of the suggestions could apply to remuneration or programs that could fit within the exception, we address them in turn. First, we do not propose to include a specific dollar limit on remuneration to deem it "low risk." We agree with the commenter that noted that a very low value item might be appropriate for one patient, while the cost of an item or service that promotes access to care for a different patient could be more expensive. We also do not believe it is appropriate to require any kind of plan to be submitted to CMS, or to require any kind of reporting to qualify for the exception. Because the exception applies only to remuneration that promotes access to care (i.e., increases a beneficiary's ability to obtain items or services payable by Medicare or Medicaid), we assume the items or services, if obtained by the beneficiary, would be reflected in the beneficiary's medical record (whether remuneration was provided to the patient or

not). We include further discussion about the form of remuneration below.

b. The Term "Low Risk of Harm"

We proposed that for remuneration to be a "low risk of harm to Medicare and Medicaid beneficiaries and Medicare and Medicaid 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. We received general support from commenters regarding our approach to defining what it means to be a "low risk of harm" to patients and Federal health care programs. We also received a number of more specific comments and requests for clarification, which we detail below.

Comment: One commenter believed that strict controls were unnecessary for pharmacy programs for various reasons. First, the commenter noted that pharmacies ordinarily cannot dispense a prescription drug to a beneficiary unless a prescriber has determined that the drug is medically necessary and issued a prescription order, thus reducing the risk of unnecessary orders. The commenter further asserted that the risk of a pharmacy program increasing costs is also low in the pharmacy

context because pharmacy programs that promote medication adherence result in lower overall healthcare costs, and most pharmacy reimbursement rates are established by prescription drug plans (PDPs), MA plans and Medicaid Managed care plans, or are capped by Federal and State reimbursement limits. Finally, the commenter asserted that patient safety and quality of care issues are much less of a concern in the pharmacy context, because the Food and Drug Administration (FDA) ensures that medications dispensed by pharmacies satisfy stringent quality control requirements.

Response: We respectfully disagree that pharmacy programs should be subject to any fewer safeguards than other programs. Pharmacies are no less likely to try to induce beneficiaries to use their services (over the services of another pharmacy) than other providers or suppliers, and they also may encourage overutilization by unnecessarily refilling prescriptions or inappropriate utilization by encouraging switching to more expensive drugs. Controls on reimbursement and FDA requirements might place some limits on medically unnecessary services, but we remain concerned about quality of care and inappropriate utilization leading to increased costs.

Comment: One commenter was concerned that the second element (regarding increasing costs) might be too narrow with

respect to Part D and requested that costs should be viewed in the context of the totality of the patient's care.

Response: We understand the commenter's point and agree with its general premise. If a program promotes access to care, then care is more likely to be obtained. Therefore, some costs will increase, while others may decrease. For example, if a patient is discharged from the hospital with a prescription to manage newly diagnosed diabetes, cost to the Part D program might increase because of the new prescription, but overall health care costs may decrease because the patient will be managing a condition with the drug rather than having a higher chance of being rehospitalized. Thus, we agree that the harm to be avoided is an overall increase in health care costs. However, the condition we proposed was not that the remuneration be unlikely to increase costs at all, but that it be unlikely to increase costs through overutilization or inappropriate utilization. Incentives to access a higher level of care than necessary, or to use a higher cost brand name drug instead of a lower cost generic drug would not be low risk.

Comment: Some commenters generally agreed that valuable gifts in connection with direct or indirect marketing are not low risk. One commenter requested bright-line guidance regarding the distinction between educational activities and

marketing. The commenter suggested that "educational programs" focusing on the skills or qualities of particular providers should be excluded from protection under this exception, but that nonmarketing, *bona fide* educational materials should not considered marketing simply because they included a logo of a provider.

Response: As we discuss in various guidance documents, such as the 2002 Special Advisory Bulletin, we agree that remuneration given in connection with marketing is not low risk and therefore would not be protected under this exception. Such remuneration is, almost by definition, given for the purpose of influencing the choice of a particular provider, practitioner, or supplier, and may induce overutilization or inappropriate utilization. However, we do not consider educational materials alone (even educational materials that include information about the qualifications of a particular provider) to be remuneration. Thus, a provider or supplier may offer educational materials (such as written materials about disease states or treatments), or informational programs (such as a program to help patients with asthma or diabetes learn more about controlling their diseases) to patients or prospective patients without implicating the beneficiary inducement CMP. However, if a provider, supplier, or other entity offered patients attending

such a program an item or service (of more than nominal value), that the offeror knows or should know is likely to influence the patient to choose that provider or supplier, such remuneration would not be protected under this exception.

c. Other Examples and Comments

Comment: We received a number of comments providing examples of items or services that commenters believed should be protected by the exception. One type of remuneration could be categorized as health-care-related services. A sampling of remuneration that commenters suggested that we protect includes free- or reduced-cost health screenings (e.g., blood pressure or fall-risk screenings); charitable dental care; education programs (e.g., regarding diabetes or nutrition); post-discharge support; family support services; chronic condition management; education about insurance or medical leave benefits; lodging provided by a hospital the night before procedures; transportation to appointments; other services that help patients live within their own communities; discounts for copayments; and gift cards for ongoing medications. Some commenters recommended that screenings should not be conditioned on obtaining other services from the provider or supplier and should not be selectively offered (e.g., based on insurance type).

Response: We agree with the commenters' suggestions that free or reduced-cost health care screenings and services and discounts for drugs promote access to care and may be low risk. However some forms of remuneration (including cash or cash equivalents) would not be low risk, as we have indicated in previous guidance, such as the 2002 Special Advisory Bulletin. In addition, copayment waivers generally are not low risk. We note, however, that copayment waivers that meet certain conditions are separately protected under section 1128A(i)(6)(A) of the Act and 42 CFR § 1003.110 and 42 CFR § 1001.952(k). We also agree with comments suggesting that providing education or information about medical leave or insurance benefits would promote access to care and be low risk (and we believe that education or information alone would not qualify as "remuneration" at all.) Lodging before a procedure, or transportation to appointments, also could be protected under appropriate circumstances.[23] The local transportation safe harbor to the anti-kickback statute included in this rulemaking sets forth a number of factors that, taken together, would render transportation low risk. It would be prudent to structure any free or reduced-cost transportation arrangements to comply with the safe harbor because transportation to obtain

[23] For an example of an arrangement that included both lodging and transportation that we analyzed and found to be low risk, see OIG Advisory Opinion No. 11-01.

Federal health care program-covered items and services generally will implicate the anti-kickback statute. We note that many forms of free or reduced-cost services (e.g., free screenings at a health fair or charitable dental program, post-discharge support, chronic care management) could lead the patient to seek followup care with the provider or supplier that offered the free service.[24] Assuming the free screenings or health care services are not simply marketing ploys but rather identify or assist with necessary care, they could fit in the exception and be protected. Individuals and entities seeking to offer any of the listed items or services must determine, as an initial matter, whether they promote access to care (and if so, whether they are also low risk). For example, "family support services" could promote access to care (e.g., if they are in the form of child care offered during an appointment), but that term also could be more broad and include services that are not directly related to the patient accessing care. The same is true for "services that help patients live within their communities." Services such as transportation could be protected; services unrelated to helping the patient access care would not be.

[24] In addition, to the extent the services qualify as preventive services, the preventive care exception could be available. That exception to the beneficiary inducements CMP specifically permits the provision of preventive care as a form of incentive, as long as it is not tied to the provision of other reimbursable services. See § 42 CFR § 1003.110.

Comment: Commenters suggested a wide variety of tangible items that the commenters believe should be protected, such as health- or wellness-related technology (e.g., apps, or other items that would help patients record and report health data); discounted over-the-counter medication or medical supplies; free or discounted access to food services (e.g., Meals on Wheels); educational materials; food vouchers; mattress covers; vacuum cleaners; scales; air conditioners; medical devices (such as blood pressure cuffs); programmable tools that help with medication dosage, refill reminders, medical appointment reminders, or dietary suggestions; home monitoring devices; telemedicine capability; free or discounted glucose meters; incentives for scheduling (e.g., a dialysis facility giving an incentive to a retired patient to move his dialysis appointment earlier in the day so that a working patient can have an evening spot); and items that help manage clinical outcomes. Other commenters suggested that some items might not be low risk, such as a smartphone with a health data app. One commenter would like us to require a comparison of cost versus utility of the device for medical care.

Response: Many of these commenters' suggestions promote access to care, or remove obstacles to compliance with treatment regimens (e.g., free or discounted medications, supplies, or

devices; technology for reporting health data; scales; or programmable tools to help with medication dosage or refill reminders; telemedicine capability; certain incentives for scheduling, in extenuating circumstances[25]), and can be low risk under appropriate circumstances. Others promote access to healthy living (e.g., vacuum cleaners, air conditioners, mattress covers, food vouchers), but not necessarily access to "care."[26] If an individual or entity is unsure whether a particular item or service would fit in the exception, or knows that the program does not fit in the exception but nevertheless believes it should be protected, the advisory opinion process is available. We reiterate, however, if the remuneration is not likely to induce a patient to select a particular provider, practitioner, or supplier, no exception is needed with respect to the beneficiary inducements CMP.

Comment: Some commenters recommended allowing in-kind, but not cash, incentives of nominal value, as described in the 2002

[25] An inducement to one patient to move an appointment in order to promote access by a different patient could be protected by the exception, in limited circumstances. Under the commenter's example, Patient A is retired, and Patient B works during business hours. Patient A receives the incentive to remove a barrier (an appointment that conflicts with Patient B's job) to Patient B's access to care. Thus the incentive promotes Patient B's ability to receive care. However, offering remuneration to all of a provider's patients who agreed to accept appointments at certain times would not necessarily promote access to care and could pose more than a low risk of harm to Federal health care programs.

[26] We note that these forms of remuneration might be protected by a different exception if provided to beneficiaries in financial need. See discussion of proposed regulation interpreting section 1128A(i)(6)(H), below.

Special Advisory Bulletin. Others generally supported having some limits on the form or value of the incentive, but recommended considering what those limits would be in light of possible savings through the effective use of incentives. Other commenters recommended limiting the exception to providers who mainly serve low-income and rural patients so that other providers can't lure patients away without offering higher quality care.

Response: Consistent with our long-standing guidance, we agree with commenters who recommend that the remuneration cannot be cash or cash equivalents (such as checks or debit cards). We also explained above that the remuneration cannot take the form of copayment waivers (under this exception). We respectfully disagree that offerors should be limited to the monetary limits suggested in the 2002 Special Advisory Bulletin or the higher limits on nominal value we are announcing concurrently with this rule; we believe that higher-value remuneration can be warranted to promote access to care for some patients while remaining low risk. We also do not believe that the incentives protected by this exception should be limited to low-income and rural patients. While patients in those categories might be more likely to need remuneration to facilitate their access to care, many other patient populations also could have such a need. For

example, regardless of income or geography, patients might need a device that reminds them to take medication. Thus, we do not believe these suggested limitations would be appropriate.

Comment: One commenter was concerned that use of the term "patient" might not allow the exception to cover plan sponsors or Medicaid MCOs (the plan-enrollee relationship). The commenter requested that the exception specifically recognize the role played by sponsors or MCOs and protect these efforts from the prohibition.

Response: The statutory exception uses the term "patient," and the beneficiary inducements CMP prohibits influencing individuals to order or receive items or services payable by Medicare or a State health care program from a particular provider or supplier. At the time the individual would receive such item or service, the individual would be a "patient." As we explained above, plan sponsors or other insurers may not raise the same concerns as providers and suppliers that bill Federal health care programs. If incentives given by these entities are not likely to induce the patient to use a particular provider, practitioner, or supplier, the beneficiary inducements CMP would not apply. (We note that differentials in coinsurance and deductible amounts as part of benefit plan designs that encourage patients to use

in-network providers are protected by section 1128A(i)(6)(C) of the Act.)

Comment: Commenters expressed differing views on whether incentives offered in connection with CMS programs or models to which a waiver of the CMP does not apply should be separately protected. One commenter suggested a specific exception for participants in payment and delivery models, including medical homes, bundled payments, or other care coordination models. Another suggested an exception for all risk-bearing entities (such as MCOs) because they are already accountable for cost. One commenter generally supported extending this exception to CMS demonstration programs. Another commenter disagreed, stating that separately protecting ACOs would cause an uneven playing field with large ACOs compared to smaller provider groups. Another commenter suggested a middle ground, noting that new payment models do not always meet the terms of the exception (promoting access and being low risk). Therefore, the commenter recommended, if the exception were to generally extend to these models, that the models must incorporate key principles to qualify as low risk, including quality metrics, transparency requirements, and mechanisms to support patient access to a full range of treatment options.

Response: We recognize that the Department is testing different models and methods for improving quality while reducing cost. We acknowledge that CMS's new models and demonstration programs have additional or different oversight and accountability than some other programs, such as traditional fee-for-service Medicare. Participants in some of these programs, such as the MSSP or the Bundled Payment for Care Improvement initiative have access to waivers of certain fraud and abuse laws, including the beneficiary inducements CMP, for certain arrangements. If a program does not have an applicable waiver, we believe that all entities seeking to rely on the exception must meet its terms. Parties with access to waivers may still elect to avail themselves of this exception if they meet all conditions.

Comment: A number of commenters noted that CMP exceptions are not incorporated into the anti-kickback safe harbors and requested a parallel safe harbor for this exception. One commenter specifically requested that adherence support incentives be included in a safe harbor, with suitable safeguards. Another commenter requested that a safe harbor be developed for certain MCOs that would be similar to the patient incentive waiver in MSSP. Another commenter requested that the exception be expanded to allow remuneration to providers (e.g.,

for remote patient monitoring). Another requested that the exception allow hospitals to help skilled nursing facilities or other long-term-care-facilities with portions of the cost of dispensing expensive medication.

Response: Commenters are correct that beneficiary inducements CMP exceptions do not provide protection under the anti-kickback statute. For a number of reasons, however, we decline to create a parallel safe harbor in this final rule. First, we did not propose such a safe harbor during this rulemaking and decline to adopt such a safe harbor without additional public comment. Further, this exception applies only to remuneration offered to beneficiaries, and we believe that the risk of fraud and abuse would be too high to generally protect remuneration offered to providers or suppliers under these standards. However, some such arrangements could be protected under existing safe harbors. For example, we proposed and are finalizing in this rule a safe harbor for local transportation. Commenters frequently mentioned transportation as needed for access to care. We will continue to monitor the changing health care delivery landscape and will consider appropriate safe harbors in the future. Any future proposals regarding additional safe harbors to protect specific types of remuneration that promote access to care and pose a low risk of

harm to Federal health care programs and beneficiaries would be made through notice and comment rulemaking. In the meantime, individuals or entities are able to request protection from sanctions under the anti-kickback statute for specific arrangements through our advisory opinion process.

3. Retailer Rewards

In the Proposed Rule, we proposed to incorporate into our regulations the statutory exception added by section 6402(d)(2)(B) of the ACA, which creates an exception to the beneficiary inducements CMP for retailer rewards programs that meet certain criteria. We proposed to use the statutory language as the text for our regulation, and we proposed interpretations of the terms "retailer" and "coupons, rebates, or other rewards;" what it means to transfer items or services on equal terms to the general public; and what it means for items or services to not be "tied to the provision of other items or services" reimbursed in whole or in part by the Medicare or Medicaid programs. We are finalizing the language, as proposed, and we set forth responses to comments received below.

General Comments

Comment: One commenter referred to OIG's existing guidance permitting gifts of nominal value, which permits items worth $10 or less, or items valued at $50 in the aggregate for a beneficiary on an annual basis. The commenter believes that, for a retailer rewards program that meets the three criteria for this exception set forth in section 6402(d)(2)(B) of the ACA, OIG could adopt a higher and more flexible standard than the existing nominal value standard. This comment appears to imply that the retail reward exception would be subject to some monetary value limit.

Response: As we have explained in previous rulemakings and guidance, and as we discuss in greater detail above, if remuneration (other than cash or cash equivalents) is "nominal in value," then it is not prohibited by the statute, and therefore no exception is necessary.[27] Thus, remuneration that meets the criteria set forth in the retailer rewards exception need not be nominal in value, and remuneration that is nominal in value need not meet the criteria of an exception.

Comment: A commenter wanted OIG to clarify that this provision of law preempts any analogous state restrictions on retailer rewards.

[27] See, e.g., the explanation of "nominal in value" concept in connection with the preventive care exception. 65 FR 24400, 24410-11 (Apr. 26, 2000).

Response: The retailer rewards exception creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating a specific Federal law: the beneficiary inducements CMP. It does not create an exception to or preempt any other Federal law or any State law (unless such State law incorporates the Federal law by reference).

Comment: One commenter argued that OIG should eliminate all penalties for the use of retailer rewards because the benefit to the beneficiary outweighs any benefit to the retailer. Another commenter suggested that OIG should clearly permit and protect incentives that combine components of different exceptions within the Proposed Rule. As an example, the commenter suggested that a patient adherence tool could be linked with a retailer reward program.

Response: The beneficiary inducements CMP prohibits certain inducements to Medicare and Medicaid beneficiaries and includes certain exceptions to that prohibition. The statute and its exceptions are designed to protect beneficiaries and Federal health care programs. The retailer rewards exception eliminates penalties under this law for reward programs that meet each of the exception's criteria; we decline to eliminate penalties for rewards programs that do not meet all of the

criteria of the exception. The same is true for other exceptions: remuneration that meets each of the criteria of any other exception are also protected. However, remuneration that implicates the statute and does not meet all criteria set forth in an exception may be subject to penalties. Further, remuneration will not be protected if it meets some criteria of one exception, and some criteria of a different exception. The remuneration needs to qualify for protection under only one exception, but it must meet all of that exception's criteria. It is possible that a patient adherence tool (depending on the type of "tool") could be a reward permitted under a retailer rewards program. However, it would have to meet all of the criteria, including not being tied to the provision of other items or services reimbursable by Medicare or State health care programs. Certain common items could be useful in patient adherence (e.g., scales, pill dispensers, books) and could be protected under the exception. A more detailed discussion of what might constitute "other rewards" appears below.

Coupons, Rebates, or Other Rewards from a Retailer

The first criterion of the statutory exception provides that the free or less-than-fair-market-value items or services must "consist of coupons, rebates, or other rewards from a retailer." We proposed to interpret these terms as follows: We

proposed to interpret "retailer" as an entity that sells items directly to consumers. We also proposed that individuals or entities that primarily provide services (e.g., hospitals or physicians) would not be considered "retailers," and we solicited comments on whether entities that primarily sell items that require a prescription (e.g., medical equipment stores) should be considered "retailers." We 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. We 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. We proposed to interpret "other rewards" primarily as describing free items or services, such as store merchandise, gasoline, frequent flyer miles, etc.

"Retailer"

Comment: Many commenters raised concerns or sought clarification about the proposed interpretation of "retailer." Commenters suggested that "retail community pharmacies" (as defined at section 1927(k)(10) of the Act[28]) and entities that

[28] The Medicaid statute states that the term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to

interact with or serve beneficiaries (including independent or small pharmacies and other suppliers) be included in the interpretation of "retailer" because excluding these entities would place them at a disadvantage compared to big box pharmacies. Others wanted clarification as to whether online retailers qualify as "retailers." Further, a commenter recommended that the term "retailer" not exclude any entity that sells a single category of products directly to individuals. Commenters asserted that the definition of "retailer" should not exclude entities that primarily sell items that require a prescription. Commenters were concerned that entities that sold a mix of items and services, including retail pharmacies, would have difficulty in determining whether they are retailers.

Response: We intend to finalize our proposal to interpret "retailer" in accordance with its commonly understood meaning: an entity that sells items directly to consumers. We continue to believe that a "retailer" does not include individuals or entities that primarily provide services. We believe that this interpretation can include independent or small pharmacies (and that pharmacies do not "primarily" provide services) and online retailers, and that it can include entities that sell a single

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patients primarily through the mail, nursing home pharmacies, long-term-care-facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

category of items. However, we reiterate that the retailer rewards program must meet all of the exception's criteria to be protected. 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.

Comment: One commenter sought clarification as to whether retailers are the only entities that can provider retailer rewards. Specifically, the commenter asked whether manufacturers could offer or transfer to patients any retailer rewards acquired or paid for by the manufacturer.

Response: As set out by Congress, the exception protects items or services "from a retailer." Thus, nonretailers, including manufacturers, may not provide retailer rewards under this exception.

Comment: Another commenter understood that physicians were not retailers but encourages efforts that allow physicians to understand when rewards would be available to their patients.

Response: Unlike some exceptions to the beneficiary inducements CMP, the retailer rewards exception does not

prohibit advertising or marketing. Retailers are free to inform physicians directly or through media outlets about the availability of their rewards programs.

Comment: Some commenters disagreed with interpreting retailer to exclude entities that primarily provide services. Specifically, some commenters stated that there is no statutory justification to differentiate retailers that primarily provide services and those that do not. These commenters believe that the distinction between the two groups is therefore unjustified and puts big box retailers at a competitive advantage over pharmacies that also provide services. In addition, a commenter stated that it is unclear whether the retail components of hospital systems (e.g., retail pharmacies) would be retailers. Another commenter had concerns about beneficiaries being excluded from rewards programs based strictly on their choice of pharmacy.

Response: As we explain above, we consider pharmacies to be retailers, whether the pharmacy is part of a "big box" retailer or is a stand-alone pharmacy. Most common definitions of "retailer" refer to selling "goods" to the public, not services. We did not propose to exclude entities that provide both items and services; we proposed to exclude individuals and entities that primarily provide services and thus typically

would not be considered to be retailers, such as physicians or hospitals. If a hospital system has a separate retail component, whether it is a convenience store or a pharmacy, then that component could have its own rewards program if it met the exception's remaining criteria.

"Reward"

Comment: Commenters supported a broad and flexible definition of "other rewards." One commenter believes that the proposed interpretation of "other rewards" as "primarily...describing free items or services" is too limited and should also include reduced-price items and services. Another commenter recommended that "other rewards" include in-kind benefits, including gift cards, educational information or programs, preventive care services, and retail-based initiatives to increase access to care (e.g., providing diabetes educational events to customers).

Response: Our Proposed Rule stated our belief that "other rewards" would "primarily" be in the form of free items or services; this was not a strict limitation. We believe the majority of reduced-price items or services would fall under the proposed interpretation of coupon or rebate. The concept of "other reward" is broad: if the item or service meets the three criteria listed in the regulation, it can be protected. As we

stated in the Proposed Rule, "other rewards" can include rewards such as gasoline discounts, frequent flyer miles, and items purchased in the retailer's store. To address specific examples provided by commenters, there is no reason why educational information or programs could not be "other rewards" (if they would be remuneration at all). Health care items or services can be "other rewards," but the reward cannot be in the form of a copayment waiver; copayment waivers would not meet the third criterion of the exception, as explained below.

Offered or Transferred on Equal Terms

The second criterion requires that the items or services be offered or transferred on equal terms to the public, regardless of health insurance status. We proposed that this criterion would exclude programs that are targeted to patients on the basis of insurance status (e.g., if a reward could be obtained only by Medicare beneficiaries).

Comment: Generally, commenters sought clarification as to the extent of the availability of the retailer reward to the general public that the OIG would require. Specifically, a commenter wanted clarification that it is appropriate for retailers to require consumers to complete an enrollment process as long as the related retailer rewards are offered on equal terms to the general public. One commenter recommended that

this criterion be interpreted in a manner that prohibits targeting individuals of a particular health plan. Similarly, another commenter stated that retailers should be allowed to mail or email retailer rewards to existing customers as long as the communication is not specifically targeting government beneficiaries (e.g., the commenter suggested that retailers should be able to offer a promotion targeted to patients with a particular disease state). Other commenters stated that the program should be broadly available to patients to discourage cherry picking and offered equally to the public regardless of health insurance status.

Response: The retailer reward must be offered to everyone regardless of health insurance status. The general public must have the same access to, and use of, the retailer reward as the retailer's insured customer base. This criterion does not, however, prohibit a retailer from having an enrollment process -- as long as the terms of enrollment, and the terms of earning and redeeming rewards, do not vary based on insurance status or plan. A rewards program targeted to patients with a particular disease state would need to meet the requirement that the reward not be tied to other reimbursable items or services, as described below.

Not Tied to Other Reimbursable Items or Services

The third statutory criterion, which we are finalizing here, requires that the offer or transfer of the items or services not be tied to the provision of other items or services reimbursed in whole or in part by Medicare or an applicable State health care program. We proposed that this criterion require the rewards program to attenuate any connection between federally reimbursable items or services both in the manner in which a reward is earned and in the manner in which the reward is redeemed. Thus, we proposed that the reward could not be conditioned on the purchase of goods or services reimbursed in whole or in part by a Federal health care program and should not treat federally reimbursable items and services in a manner that is different from that in which nonreimbursable items and services are treated. On the "redeeming" end of the transaction, we proposed that rewards programs in which the rewards themselves are items or services reimbursed in whole or in part by a Federal health care program would not be protected.

Comment: Some commenters believed that OIG's interpretation of the third criterion is overly restrictive. One commenter stated that this criterion should be interpreted to prohibit a retailer reward that focuses on health care items and services only when a discount on one covered health care item or service is tied to the purchase of a second "other"

covered health care item or service. Specifically, the commenter asserts that the statute does not require the reward to be equally applicable to health care and non-health care items or services. The commenter also does not believe that nonreimbursable items or services must be treated the same as reimbursable items or services when earning rewards. Therefore, the commenter disagreed with the statement in the preamble to the Proposed Rule that the reward (how it is earned or redeemed) should not treat federally reimbursable items and services in a manner that is different from that in which nonreimbursable items and services are treated. One commenter recommended that we not interpret the criterion to prohibit the reward from being tied to the provision of the same service. Another commenter asserted that the proposed interpretation would prohibit entities from offering rewards for adhering to therapy or drug regimens. With respect to prescriptions, another commenter believed that having the criterion apply to both the earning and redeeming side of the transaction to be unnecessary and counterproductive because patients should be encouraged and incentivized to obtain prescribed medicines and other medical products.

Response: We respectfully disagree with several of the commenters' interpretations of, and recommendations with respect

to, this criterion. The statutory criterion, which we adopt here, limits the exception as follows: "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 title XVIII or a State health care program (as defined in section 1128(h))." The "reward" cannot be tied to the provision of other reimbursable items. If a customer accumulates rewards (or preferentially accumulates rewards) based only on purchases of federally reimbursable items, the reward is tied to the provision of other reimbursable items because without purchasing those reimbursable items the customer would not earn a reward. Thus, for example, this criterion would not be met if a pharmacy had a rewards program that offered two points for every dollar spent on prescription copayments, but one point for every dollar spent elsewhere in the store. Likewise, if the reward were to take the form of a copayment waiver (or a $20 coupon off of a copayment), the reward would be tied to the purchase of a reimbursable item (the item for which the copayment is waived or discounted). In contrast, if the reward were a $20 coupon to be used on anything in the store, the coupon could, without violating the criterion, be redeemable a copayment. The coupon cannot, however, be limited to a reduction in price on a reimbursable item or service.

Comment: One commenter stated that the statute permits retailer rewards in the form of free or discounted health care items and services, not just non-health care items and services. A commenter asserted that the statute provides that retailer rewards may be offered as long as they are not tied to other covered items or services. The commenter sought confirmation that retailer rewards may take the form of discounts on covered health care services.

Response: As discussed above, the reward may not take the form of discounts specific to health care items or services that are reimbursed in whole or in part by Medicare or a State health care program. The reward can be a discount that could be used on anything in the store (including covered items or services), or can be specific to nonreimbursable items. If the retailer offered or gave a reward that was a free or discounted item or service covered by Medicare or a State health care program, but did not seek reimbursement for the item or service, the reward could be protected (as long as it was not tied to another reimbursed item). For example, a retailer could not have as a "reward" a free box of test strips that a patient could obtain only when filling an insulin prescription. However, if a retailer offered a rewards program such that if a patient spent a certain amount of money in the store over the course of the

year, the patient could obtain a blood pressure monitor for free, that blood pressure monitor could be a protected reward as long as the retailer did not bill Medicare or a State health care program for it.

Comment: One commenter supported OIG's proposal that offering a $20 coupon to transfer prescriptions would not meet this criterion because such a reward influences beneficiaries who may accept less effective medication, substandard service, or be unduly overcharged by the retailer.

Response: We agree with the commenter that coupons to transfer prescriptions would not be protected under this exception. However, we do not agree with the commenter's analysis. The commenter asserts that the remuneration should not be protected because it might influence the beneficiary to choose a particular provider. However, all rewards programs might influence a beneficiary to choose a particular provider or supplier; if the remuneration wouldn't be likely to influence a beneficiary to choose a particular provider or supplier, no exception would be necessary because the remuneration would not implicate the beneficiary inducements CMP. Thus, the exception, which mirrors the statutory language, protects rewards programs that meet specific criteria, even though they might influence a beneficiary to choose a particular provider or supplier, because

the criteria set forth in the exception provide sufficient safeguards to make the remuneration low risk. The remuneration used as an example by the commenter could not be protected by the exception because it fails to meet the criteria that prohibits tying the remuneration to purchasing a reimbursable item or service.

Comment: One commenter believed that OIG was inconsistent in its interpretation of similar criteria between the retailer rewards exception and the financial-need exception. According to the commenter, the financial-need exception requires the remuneration to have a connection to the patient's medical care and focus on health care items and services. With retailer rewards, the commenter stated that OIG did not focus on health care items and services. Instead, it applies the criterion to all items and services, including non-health care items and services.

Response: The financial-need-based exception has different criteria than the retailer rewards exception; both exceptions are statutory, and the statutory criteria are being finalized here. Both have a requirement that prohibits tying the offer or transfer of an item or service to the purchase of another reimbursable item or service. But in the financial-need-based exception, the item or service given must be reasonably related

to the patient's medical care. The statute does not include such a requirement in the retailer rewards exception. In the retailer rewards exception, a program could involve a rebate, a coupon for health and beauty items, or a free toy. As long as the customer is not required to purchase a federally payable item or service to earn or redeem the reward, the type of item or service is not limited. The section below on the financial-need-based exception explains the different requirements that apply to the remuneration protected under that exception.

4. Financial-Need-Based Exception

We proposed to incorporate a third new statutory provision, added at 1128A(i)(6)(H) of the Act, which excepts from the definition of "remuneration" the offer or transfer of items or services for free or less than fair market value if the items and services are not advertised or tied to the provision of other items or services reimbursed by the Medicare or State health care programs (including Medicaid); there is a reasonable connection between the items or services and the medical care of the individual; and the recipient has been determined to be in financial need. We proposed, and are finalizing, regulatory text that mirrors the statutory language. We will continue to assess the need for additional flexibility in the future.

Several commenters generally supported the proposed exception and the approach OIG took when interpreting the statutory terms in the Proposed Rule. Others, while generally supporting the exception, urged OIG to interpret it more expansively, allow additional flexibility, and not include certain restrictive criteria. We discuss these comments further below.

General

Comment: Some commenters noted that there could be overlap between this exception and the exception for remuneration that promotes access to care and poses low risk.

Response: We agree that there can be some overlap among exceptions. In addition to the exception cited by the commenter, the preventive care exception defined at 42 CFR 1003.110 shares some similarities with the financial-need-based exception. However, there are also distinctions among these exceptions. For example, the financial-need-based exception does not require that the remuneration "promote access to care," or "promote the delivery of preventive care," and those two other exceptions do not require that the recipient of the remuneration have a financial need. Remuneration might meet some criteria of multiple exceptions, but it is protected only if it meets all criteria of any one exception.

Comment: One commenter requested that the exception be carefully tailored to make clear that providers and suppliers are not required to provide free items or services to patients.

Response: The financial-need-based exception, like all other exceptions to the beneficiary inducements CMP, carves out certain things that otherwise would be prohibited remuneration from the definition of "remuneration," when certain conditions are met. The exceptions do not impose any affirmative obligations on providers or suppliers to provide free items or services, waive copayments, or implement any program that involves giving anything of value to beneficiaries; rather, the exceptions describe the circumstances under which such gifts or benefits are not prohibited by the beneficiary inducements CMP.

"Items or Services"

We proposed to interpret the term "items or services" to exclude cash or instruments convertible to cash.

Comment: One commenter expressly supported precluding providers from paying cash to patients.

Response: We agree with the commenter and intend to interpret "items or services" as excluding cash, or cash equivalents (instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards).

Prohibition on Advertising

We proposed to include the statutory requirement that the items or services offered or transferred under the exception may not be offered as part of any advertisement or solicitation. We received some comments and questions about this requirement.

Comment: One commenter, though recognizing that the prohibition on advertising is statutory, recommended that OIG not include it in the regulation, claiming that it violates the First Amendment to the Constitution. The commenter suggested that there is no legitimate reason to prohibit informing the public about programs that could reduce costs for financially needy patients. The commenter stated that if OIG keeps the prohibition, it should impose the least restrictive means necessary (e.g., allowing an entity to announce the availability and nature of the assistance, and directing the patient to other resources (such as a Web site or phone number) for more information.

Response: The prohibition on advertising of the incentive, copayment waiver, or other item or service has been in the statute for other exceptions since section 1128A(a)(5) was enacted in 1996. For the same reasons set forth above in connection with the safe harbor for Part D cost-sharing waivers, we respectfully disagree with the commenter's view that the advertising prohibition violates the First Amendment. As we

explain below, we believe this exception is intended to protect remuneration given on a case-by-case basis, when a need is identified. It is not intended to encourage patients to seek care (in contrast to the exception for remuneration that incentivizes preventive care). In the section above regarding the local transportation safe harbor, we explain that the prohibition on advertising does not prohibit a provider or supplier from informing patients that an item or service is available, when done in a targeted manner. For example, if a physician learns that a financially needy patient lives alone and has trouble remembering which medication to take at what time, the physician can offer the patient a tool or service to help. However, providers and suppliers wishing to avail themselves of the protection offered by this exception cannot advertise in the media, or post information for public display or on Web sites about the availability of free items or services that the provider or supplier would seek to have this exception protect.

Comment: Some commenters requested that OIG clarify that the sliding fee discount programs that FQHCs are required to communicate do not constitute marketing.

Response: As we acknowledge elsewhere in this final rule, we understand that health centers that have a FQHC designation

are required to make patients aware of the sliding fee discount program. Such required communications would not constitute marketing (for purposes of this exception), nor would the required discount program be prohibited remuneration under the CMP.

Not Tied to the Provision of Other Reimbursed Services

The statutory exception provides that the item or service being offered or transferred must not be tied to the provision of other reimbursed services. We proposed interpreting this limitation as not protecting offers or transfers of items or services that a provider or supplier conditions on the patient's use of other services that would be reimbursed by Medicare or a State health care program. We received comments and questions about this criterion.

Comment: Commenters requested clarification about how this condition applies to FQHCs and asked that we clarify that it does not extend to service discounts required from health centers designated as FQHCs. Another commenter noted that health centers designated as FQHCs are required to provide discounts on the basis of a patient's ability to pay, and asked that OIG clarify that FQHCs can continue to provide reimbursable services after providing such discounts.

Response: As we explain elsewhere in this final rule, we understand that health centers designated as FQHCs are required by law to establish sliding fee discounts for patients below certain income levels. Such billing policies were not prohibited before, and this exception would not change that. This exception only expands upon what providers and suppliers can do to help their patients in financial need.

Comment: Commenters asked about remuneration, such as lodging or transportation, that is expressly tied to receiving a service from a particular provider.

Response: Programs that offer lodging or transportation that is conditioned on receiving a particular service are "tied" to the particular service and would not be protected under this exception. However, other exceptions, such as the exception that allows remuneration that promotes access to care and poses a low risk of harm could apply, as could the anti-kickback safe harbor related to local transportation.

Comment: Some commenters requested clarification of "other" reimbursed services. One suggested that the remuneration can be connected to a reimbursable item or service, but can't be conditioned on the purchase of a second covered service. Another commenter asked us to clarify that the

provider could continue to provide treatment in the future, even after giving remuneration in the past.

Response: The statute, and the regulation text, as it is being finalized, does not protect offering or giving items or services that are tied to the provision of other reimbursable services. As discussed in greater detail below, the item or service must be reasonably connected to the patient's medical care. Thus, at a high level, we agree with the comment that the remuneration can be connected to a reimbursable service as long as it is not conditioned on the purchase of a reimbursable service. With the exception of items or services provided by FQHCs or certain other entities that are required by law to be discounted, it seems unlikely that the remuneration offered under this section would be discounted reimbursable items or services themselves. Other than waiving the copayment amount (which would not be protected by this exception but could be protected by the exception at section 1128A(i)(6)(A) of the Act), there is no easy way to discount a reimbursable item or service. It is possible that the provider or supplier could give the item or service for free, and not bill Medicare, a State health care program, or the beneficiary for it. For example, if a financially needy diabetic patient were to run out of test strips and needed an immediate supply before a refill

could be authorized, the pharmacist could give the patient an extra package of test strips and not bill the patient or payor for them. This free supply is not tied to another item or service, because, in the example, the patient could not get a refill at that time. The free supply does not require the patient to purchase a prescription or anything else from the pharmacy at that time or in the future. In other words, we recognize that providers or suppliers may have ongoing relationships with the patients to whom they may give free or discounted items or services under this exception. What this limitation prohibits is tying the purchase of a reimbursable item or service to the offer of the free item or service. Thus, using a different version of the example above, if the pharmacy had a practice of offering financially needy patients a free package of test strips (or any other item, whether or not it is reimbursable) each time the patient filled a prescription there, the remuneration would not be protected under this exception because it would be tied to filling the prescription.

Reasonable Connection to Medical Care

We explained in the Proposed Rule that the requirement that remuneration offered have a "reasonable connection to the medical care of the individual" must be interpreted in the context of this particular exception. This exception is not

designed to induce the patient to seek additional care, but rather to help financially needy individuals access items or services connected to their medical care. We proposed interpreting "medical care" as the treatment and management of illness or injury and the preservation of health through services offered by the medical, dental, pharmacy, nursing, and allied health professions. We also proposed that for remuneration to be "reasonably connected" to medical care, it must be reasonable from a medical perspective and reasonable from a financial perspective. We received comments on each of these concepts.

Reasonable from a Medical Perspective

Comment: Some commenters argued that OIG should broadly interpret the idea of reasonable connection to medical care for FQHCs, in particular, since they provide their patients a wide variety of items (e.g., diapers, car seats, strollers, baby formula, school supplies, toys, food, clothing, books, weight monitors, gas cards, and glucose monitors).

Response: In the context of this particular condition, we decline to treat FQHCs any differently than other providers or suppliers. We recognize both that FQHCs treat a particularly vulnerable population and that the distribution of items mentioned by commenters very likely benefits that population.

However, this exception serves a particular purpose, the advancement of medical care for the financially needy individual, and therefore protects only remuneration related to a particular patient's medical care. Some of the examples above would not qualify (strollers, school supplies, and usually toys or clothing). Others possibly could qualify, depending on individual circumstances. It is possible, for example, that car seats, diapers, specialized clothing, baby formula or particular food items, books, weight monitors, gas cards, and glucose monitors could be reasonably connected to a particular patient's medical care (as explained in more detail in response to a later comment below). However, we note that other exceptions and published guidance could be applicable to items that do not qualify for this exception. For example, non-monetary remuneration of nominal value (as announced herein, $15 per item or $75 in the aggregate per year) is not prohibited. Likewise, under section 1128A(i)(6)(D), a health center (or other provider or supplier) can offer items or services to incentivize preventive care. Thus, a stroller or school supplies, among other items, can be offered to patients who attend necessary preventive care appointments.

Comment: Commenters urged us to deem remuneration to be reasonably connected to medical care when a medical professional

(e.g., a pharmacist, physician, care management team, or a generally accepted professional practice) determines it is connected to medical care, is important to patient success, or would benefit treatment or adherence to treatment.

Response: We agree that a medical professional is generally in the best position to determine that an item or service is reasonably connected to the care that professional is providing, including achieving a favorable treatment outcome. However, we emphasize that the medical professional must keep in mind the purpose of this exception when judging whether a reasonable connection to the patient's treatment exists. For example, the medical professional cannot give patients sporting equipment (such as a bicycle or basketball hoop) on the basis that the patient needs more exercise. Likewise, it would not be reasonable for a provider to give tickets to an entertainment event or a gift card for a spa on the basis that the patient is suffering from anxiety or depression.

Comment: Commenters made specific requests for a determination that certain items and services are reasonably connected to medical care, including transportation and lodging for a transplant patient and companion, bicycle helmets and other safety devices for children treated for injuries, and provision of most items connected to the wellness and health

needs of patients, such as blood pressure cuffs, patient engagement apps, biomonitoring devices, and mobile devices as necessary to meet patients' various health needs.

Response: All of the listed items or services could be reasonably connected to a particular patient's medical care. However, they might not meet other prongs of the exception. For example, providing lodging to a transplant patient might be reasonably connected to his or her medical care, but it also makes the offer of the free item or service (the lodging) contingent on receiving another service (the transplant) from the provider. 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. Further, the offer or transfer of the item or service must meet all criteria of the exception to be protected. We again note, however, that if the remuneration is nominal in value (as, for example, a patient engagement app might be), then it would not implicate the statute and would not need an exception to protect it.

Comment: Commenters made suggestions about general circumstances that would indicate remuneration is reasonably connected to medical care. One commenter agreed with circumstances we proposed (treatment benefit, lack of access to

treatment absent payment resources, and others). The commenter also recommended permitting remuneration that is likely to enhance treatment outcomes. Others recommended remuneration that could lead to preservation of health and avoidance of injury, or improvement of nutritional status. Similarly, some commenters recommended preventive measures and items that support the structure and function of the body. Others recommended interpreting the medical connection requirement broadly, to encompass anything that could advance or improve care. Some commenters supported our suggestion in the Proposed Rule that we develop criteria that take into account a patient's unique physical, behavioral, and financial circumstances. Another commenter noted that imposing specific standards to define "reasonably connected" would be detrimental to the goal of the exception, because "reasonable" is a subjective standard and should involve patient-specific determinations.

Response: We believe that the phrase "reasonable connection to medical care of the individual" can be interpreted broadly. It can 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). 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. For example, school backpacks, while beneficial to the children, are not connected to medical care. Those types of items might be permissible under a different exception (e.g., the preventive care exception, if a practice offered backpacks to children who come in for required vaccines), but not under this one. Sometimes it is clear that an item is not connected to medical care, while in other circumstances that same item might be covered. For example, giving toys to children typically will not be reasonably connected to medical care. However, for certain children (e.g., children experiencing developmental delays or recovering from certain illnesses or injuries that require therapy for fine motor skills), "toys" that reinforce treatment or aid in improving a health condition could be reasonably related to that individual patient's medical care. As we explain above, we believe that the medical professional working with the patient is in the best position to determine what is reasonably connected to his or her patient's medical care, but we emphasize that this exception does not protect items and services that are essentially for entertainment or other nonmedical purposes.

Reasonable Connection from a Financial Perspective

Comment: Some commenters recommended that we abandon the concept of remuneration having a reasonable connection to medical care from a financial perspective. One commenter suggested that this criteria does not appear in the statute, and financial criteria should affect only eligibility. Another commenter thought that the limit on "disproportionately large" remuneration would stifle the provision of assistance, and that we should rely on the medical aspect of reasonably connected to care.

Response: We decline to adopt the commenters' suggestion to abandon the condition of financial reasonableness. 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 (and also unlikely to be given in the absence of a tie to additional services). For example, if a practitioner is treating an obese patient, the patient might benefit from an item or service connected to weight loss. An item such as an expensive electronic tablet with a weight loss program app (along with all of the other functionality available on such a tablet) would not be reasonable financially, but a less expensive item (electronic or paper-based), with similar information for the patient related to his or her medical care, might be. Moreover, the concept of excluding remuneration of

disproportionately high value is not new; our regulatory exception to allow incentives for preventive care excludes "[a]n incentive the value of which is disproportionally large in relationship to the value of the preventive care service (i.e., either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care)." 42 CFR 1003.110.

Comment: Some commenters requested clarification of what it means to be disproportionately large. One asked that we provide detailed retail value limits, compared to the medical benefit to a beneficiary. Another commenter suggested that the term is ambiguous and asked about specific examples, such as providing disease management services or having a nurse follow up with a patient by telephone. Another commenter agreed that disproportionately large items and services could lead to inappropriate inducements but questioned where to draw lines. If the lines are too specific, they might disrupt the incentive to innovate (new technology might be developed that would meet congressional intent but would be precluded by use of certain language/restrictions).

Response: We decline to provide specific retail value for something that is disproportionately large. We also agree that we do not want to draw specific lines because needs vary among

patients, and technology changes over time. Something that is very expensive today might be inexpensive (but still useful) in 10 years. Moreover, certain items or services could prevent much larger medical costs in the long (or short) run. For example, following a hospital discharge, particularly in a post-surgical context, a hospital might provide a financially needy beneficiary with items or services to ensure his home is safe for his recovery. It is important to consider whether the cost of the item or service is proportional to the possible harm it is designed to prevent. For example, offering a diabetic patient compression stockings could be reasonable from a financial perspective, but paying for a subscription to a long-term meal preparation and delivery service for such a patient would not be. On the other hand, providing meal deliveries for a limited period of time after a patient is discharged after a debilitating procedure might be reasonable from both a medical and financial perspective. Disease management programs could fit in the exception. For example, if a physician practice or clinic had a disease management program for asthma, and gave asthma patients free items to monitor or manage their breathing or oxygen levels, or provided other services, and the free items or services met the other criteria of the exception, they would be protected.

Individualized Determination of Financial Need

We proposed to incorporate the statutory requirement that the items or services may be provided only "after determining in good faith that the individual is in financial need." We proposed to interpret this provision as requiring an individualized assessment of the patient's financial need, in good faith, on a case-by-case basis. We proposed that such an assessment would require the use of a reasonable set of income guidelines, based on objective criteria that would be uniformly applied. We further proposed that the individual or entity offering the items or services should have flexibility to consider relevant variables in setting standards. We noted that we were considering whether to require documentation of the financial need assessment as a condition of the exception.

Comment: Commenters who addressed the issue generally objected to the potential requirement that patient need be documented. Commenters suggested that detailed documentation is burdensome, may require extensive time and effort, and might deter providers from offering assistance.

Response: While we are not requiring any specific documentation of financial need, we do expect that entities offering these items would do so in accordance with a set policy that is uniformly applied. Moreover, if an entity were under

investigation and asserted this exception as a defense, it would have to be able to demonstrate compliance with the requirement to make a good faith determination of financial need. A written policy describing the standards and procedures used for establishing financial need, together with evidence that this written policy was followed, would be useful in making such a demonstration.

Comment: Several commenters suggested that entities be permitted to continue using their current processes for determining need. One commenter stated that some Medicaid programs require pharmacies to accept as true patient statements of inability to pay coinsurance amounts. Another recommended that FQHCs' assessments based on the sliding fee discount schedule should suffice. Some commenters suggested that hospitals have longstanding policies for determining need, and they should not be required to use a different process. One commenter supported an individualized determination, on a case-by-case basis, but recommended that the providers have flexibility to consider relevant variables.

Response: We agree with most of these comments. While the financial need determinations must be done on an individual basis, we are not mandating any particular basis for determining need. We do expect entities to have a set policy, based on

income or other factors, and to uniformly apply that policy. However, providers and suppliers have the flexibility to determine the appropriate policy for their own patient populations. We do not agree that a patient statement of financial need should suffice in every instance. A statement of inability to pay coinsurance may suffice for a Medicaid patient, because Medicaid patients have been screened for financial eligibility by the state. A provider may have other reasons to be comfortable in accepting a patient's own statement of financial need, such as being located in a low-income area and generally serving a financially needy patient population, or knowing that a particular family has very high medical expenses. However, a provider or supplier should not rely solely on a representation by the patient that he or she is in financial need, unless the provider or supplier has some independent basis for belief that such a representation is reliable.

Comment: One commenter recommended that OIG determine a uniform measure of need (e.g., a specific percentage of the Federal Poverty Level, as proven by individual tax forms or wage statements). Another recommended not requiring any documentation of need, unless a patient would receive over $500 in assistance annually.

Response: We decline to adopt a uniform measure of need, and we also decline to adopt a minimum threshold of assistance before a determination of need is required. This exception is intended to protect items and services that, under certain conditions, are given to financially needy patients. Thus, providers and suppliers must adopt a standard that can be reasonably considered to reflect financial need and cannot simply ignore the last condition of the exception. We also explained above that we do not intend to require specific documentation of the actual determination of need for each patient, but that providers or suppliers using this exception as a defense would need to be able to prove they complied with their own standards. For example, if a physician's policy was that any patient on Medicaid is qualified for assistance, the simple fact that the patient's file shows Medicaid as the payor is sufficient documentation. However, the income or wealth of patients with Medicare as a payor varies greatly. Thus, a provider or supplier offering items or services to a Medicare patient would need some method to determine whether the patient qualifies as financially needy under the standards set by the provider or supplier.

5. First Fill of a Generic

We proposed to incorporate into our regulations the fourth new provision added at section 1128A(i)(6)(I) of the Act, which excepts from the definition of "remuneration" the waiver by a PDP sponsor of a Part D plan or MA organization offering MA-PD plans of 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. We proposed to rely on the definition of "generic drug" in the Part D regulations at 42 CFR 423.4. Further, because CMS already permits these waivers as part of Part D and MA plan benefit designs, we proposed that sponsors desiring to offer these waivers to their enrollees would be required to disclose this incentive program in their benefit plan package submissions to CMS. We proposed that this exception would be effective for coverage years beginning after publication of the final rule. However, because this final rule is being published after the deadline for submission to CMS of benefit plan packages for coverage year 2017), this exception is applicable to coverage years beginning on or after January 1, 2018. We have revised the regulation text accordingly.

Those who commented on this proposal generally supported it. We address some specific comments and recommendations below.

Comment: One commenter asked that we revise the text of the regulation to ensure that it applies to all sponsors of Part D coverage.

Response: We did not intend to exclude any sponsors of Part D coverage from this exception. To ensure that the exception applies to all Part D sponsors, we have replaced the reference to "a sponsor of a Prescription Drug Plan under part D of Title XVIII or a MA organization offering a MA-PD Plan under part C of such title" with "a Part D Plan sponsor," as that term is defined in 42 CFR 423.4." For consistency with this change, we also replaced the reference to "Prescription Drug Plan or MA-PD Plan, repectively" with "Part D plan (as that term is defined in 42 CFR 423.4)."

Comment: One commenter asserted that the definition we proposed for "generic drug" (at 42 CFR § 423.4) would not include "authorized generics," which are defined at 21 CFR § 314.3. The commenter recommended we expand the definition to include authorized generics.

Response: As we explained in the preamble of the Proposed Rule, the purpose of this exception is to minimize drug costs by encouraging the use of lower cost generic drugs. As a form of lower cost generic drug, use of authorized generics would further this goal. Therefore, as long as these waivers are

included in the Part D Plan sponsor's benefit plan package submission to CMS, waivers of the first fill of authorized generics may be included in the exception as well. We have revised the language in the final rule to reflect this change.

Comment: One commenter asked OIG to remind PDP and MA-PD plans that pharmacy reimbursement must remain sufficient to provide Medicare beneficiaries adequate access to care. The commenter stated that plans should not simply waive copayment amounts, which the commenter asserts would be at no cost to the plan but great cumulative cost to the pharmacies. The commenter also suggests that these waivers could create a financial incentive for pharmacies not to dispense generic drugs.

Response: Part D Plan sponsors submit their plan designs to CMS and negotiate terms with their network providers. Pharmacies can choose whether to be in the network and accept those terms. OIG does not have a role in setting pharmacy reimbursement via the Part D Plan sponsors. This statutory exception, which we are incorporating into regulations, confirms only that Part D Plan sponsors offering such waivers would not violate the beneficiary inducements CMP.

Comment: One commenter supported our proposal to require advance disclosure of any copayment waivers in Medicare plan benefit packages, as well as transparency of such programs to

pharmacies, in order to allow pharmacies notice to decide if and how the pharmacies may agree to participate in Part D Plan sponsor's provider network and waiver program.

Response: We agree with the commenter that disclosure and transparency are important. We are finalizing the requirement that the waivers be included in the benefit design package submitted to CMS in the regulation.

D. Comments Outside the Scope of Rulemaking

We received several comments that are outside the scope of this rulemaking. For example, some commenters requested that we initiate new safe harbors, provide guidance on issues outside of the proposed safe harbors, and protect specific programs or initiatives outside of the proposed safe harbors. While we may consider these requests in future rulemaking, we also remind stakeholders that the advisory opinion process remains available for determinations on individual arrangements.

III. Provisions of the Final Regulation

This final rule incorporates most of the regulations we proposed in the Proposed Rule, but with some changes to the regulatory text.

We are finalizing, with certain revisions, both new safe harbors that we proposed in 42 CFR § 1001.952(k): one to

protect waivers or reductions in cost-sharing by pharmacies for financially needy beneficiaries, and one to protect waivers in cost-sharing for State- or municipality-owned emergency ambulance services. We also made a change was to the introductory language of subparagraph (k), expanding this safe harbor to all Federal health care programs. To implement the change where applicable, we are republishing subparagraph (k) in its entirety. We are finalizing the safe harbor to protect free or discounted local transportation, with some changes from the Proposed Rule. Two of the most frequent topics of comment were our interpretation of "established patient" and the distance limitation. In response to comments, we broadened our interpretation of "established patient" to encompass any patient who has made an appointment with the provider or supplier. We also revised our interpretation of "local" to include different distances for rural and nonrural areas, and we added a section applicable to shuttle services. We are finalizing the other safe harbors ((1) a technical correction to the referral services safe harbor; (2) arrangements between federally qualified health centers and MA organizations; and (3) discounts under the Medicare Coverage Gap Discount Program) as we proposed them in the Proposed Rule with minor, if any, changes.

We are finalizing all of the beneficiary inducements CMP exceptions, with certain changes. In the Proposed Rule, we did

not propose regulatory text for the exception for remuneration that promotes access to care but poses a low risk of harm to patients and Federal health care programs. However, we proposed to interpret "promotes access to care" to mean that the remuneration improves a particular beneficiary's ability to obtain medically necessary health care items and services. We proposed to interpret the requirement that remuneration pose a low risk of harm to Federal health care program beneficiaries and programs to mean that the remuneration must: (1) be unlikely to interfere with, or skew, clinical decision making; (2) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient safety or quality-of-care concerns. We are finalizing regulatory text that mirrors these proposals. The only changes we are making to any of the other four exceptions proposed in the Proposed Rule are the following changes to the exception relating to waivers of the copayment for the first fill of a generic drug: to incorporate a definition recommended by commenters of "Part D Plan sponsor;" to include "authorized generic drugs" in the exception; and to specify when the exception becomes effective.. Otherwise, the text of each exception in the final rule is the same that we proposed in the Proposed Rule.

We are not finalizing the gainsharing CMP regulation that we proposed. We had proposed to codify the gainsharing CMP set forth in section 1128A(b) of the Act, which, as of October 2014, provided penalties for hospital payments to physicians to "reduce or limit services" (not only medically necessary services) to Medicare or Medicaid beneficiaries. We solicited comments on a narrower interpretation of the term "reduce or limit services" than we have previously held. However, section 512(a) of MACRA amended the language in quotes to insert the words "medically necessary" before "services." Because of the amendment to the statute, we are unable to finalize the rule, as proposed. However, this statutory provision is self-implementing, and no regulatory action is required to make the change enacted in MACRA effective.

IV. Regulatory Impact Statement

We have examined the impact of this proposed rule, as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that

maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects, i.e., $100 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule would implement or codify new and existing CMP exceptions and implement new or revised anti-kickback statute safe harbors. The vast majority of providers and Federal health care programs would be minimally impacted from an economic perspective, if at all, by these proposed revisions.

The changes to the safe harbors and CMP exceptions would allow providers to enter into certain beneficial arrangements. In doing so, this regulation would impose no requirements on any party. Providers would be allowed to voluntarily seek to comply with these provisions so that they would have assurance that participating in certain arrangements would not subject them to liability under the anti-kickback statute and the beneficiary inducement CMP. These safe harbors and exceptions facilitate providers' ability to provide important health care and related services to communities in need. We believe that the aggregate

economic impact of the changes to these regulations would be minimal and would have no effect on the economy or on Federal or State expenditures.

Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than $100 million.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered small entities by having revenues of $7 million to $35.5 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The changes to the CMP exceptions and the the anti-kickback statute safe harbors would not significantly affect small providers as these changes would not impose any requirement on any party.

In summary, we have concluded that this final rule should not have a significant impact on the operations of a substantial

number of small providers and that a regulatory flexibility analysis is not required for this rulemaking.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. For the reasons stated above, we do not believe that any provisions or changes finalized here would have a significant impact on the operations of rural hospitals. Thus, an analysis under section 1102(b) is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million, adjusted for inflation. We believe that no significant costs would be associated with these revisions that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of $141 million (after adjustment for inflation) in any given year.

Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

V. Paperwork Reduction Act

The provisions of this final rule will not impose any new information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs — health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

Accordingly, 42 CFR parts 1001 and 1003 are amended as set forth below:

PART 1001—PROGRAM INTEGRITY — MEDICARE AND STATE HEALTH CARE PROGRAMS

1. The authority citation for part 1001 continues to read as follows:

AUTHORITY: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395w-104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 is amended by revising paragraphs (f)(2) and (k), and adding paragraphs (z), (aa), and (bb) to read as follows:

§ 1001.952 Exceptions.

* * * * *

(f) * * *

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants and is based only 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.

* * * * *

(k) Waiver of beneficiary copayment, coinsurance and deductible amounts. As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Federal health care program beneficiary's obligation to pay copayment, coinsurance or deductible (for purposes of this subparagraph (k) "cost-sharing") amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.

(1) If the cost-sharing amounts are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, the hospital must comply with all of the following three standards:

(i) The hospital must 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.

(ii) The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.

(iii) The hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the cost-sharing amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under Titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under Title V of the Act, the health care center or facility may reduce or waive the cost-sharing amounts for items or services for which payment may be made in whole or in part by a Federal health care program.

(3) If the cost-sharing amounts are owed to a pharmacy (including, but not limited to, pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:

(i) The waiver or reduction is not offered as part of an advertisement or solicitation; and

(ii) Except for waivers or reductions offered to subsidy-eligible individuals (as defined in section 1860D-14(a)(3)) to which only requirement in paragraph (k)(3)(i) of this section applies:

(A) The pharmacy does not routinely waive or reduce cost-sharing amounts; and

(B) The pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.

(4) If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all the following conditions are met:

(i) 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;

(ii) The ambulance provider or supplier engaged in an emergency response, as defined in 42 CFR 414.605;

(iii) The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and

(iv) The ambulance provider or supplier must 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.

* * * * *

(z) Federally Qualified Health Centers and Medicare Advantage Organizations. As used in section 1128B of the Act, "remuneration" does not include any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage organization

pursuant to a written agreement described in section 1853(a)(4) of the Act.

(aa) Medicare Coverage Gap Discount Program. As used in section 1128B of the Act, "remuneration" does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program established in section 1860D-14A of the Act, as long as all the following requirements are met:

(1) The discounted drug meets the definition of "applicable drug" set forth in section 1860D-14A(g) of the Act;

(2) The beneficiary receiving the discount meets the definition of "applicable beneficiary" set forth in section 1860D-14A(g) of the Act; and

(3) The manufacturer of the drug participates in, and is in compliance with the requirements of, the Medicare Coverage Gap Discount Program.

(bb) Local Transportation. As used in section 1128B of the Act, "remuneration" does not include free or discounted local transportation made available by an eligible entity (as defined in this paragraph (bb)):

(1) To Federal health care program beneficiaries if all the following conditions are met:

(i) The availability of the free or discounted local transportation services-

(A) Is set forth in a policy, which the eligible entity applies uniformly and consistently; and

(B) Is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

(ii) The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;

(iii) 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;

(iv) The eligible entity makes the free or discounted transportation available only:

(A) To an individual who is:

(*1*) An established patient (as defined in this paragraph (bb)) 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; and

(*2*) An established patient of the provider or supplier to or from which the individual is being transported;

(B) 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, as defined in this paragraph (bb); and

(C) For the purpose of obtaining medically necessary items and services.

(v) 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; and

(2) In the form of a "shuttle service" (as defined in this paragraph (bb)) if all of the following conditions are met:

(i) The shuttle service is not air, luxury, or ambulance-level transportation;

(ii) 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;

(iii) 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

(iv) 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.

Note to paragraph (bb): For purposes of this paragraph (bb), an "eligible entity" is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items; "established patient" is a person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment, or who previously has attended an appointment with the provider or supplier; "shuttle service" is a vehicle that runs on a set route, on a set schedule; "rural area" is an area that is not an urban area, as defined in this

rule;and "urban area" as: (a) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (b) the following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

3. The authority citation for part 1003 continues to read as follows:

AUTHORITY: 42 U.S.C. 262a, 1302, 1320-7, 1320a-7a, 1320b-10, 1395u(j), 1395u(k), 1395cc(j), 1395w-141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

4. In § 1003.110, the definition of "remuneration" is amended by revising the introductory text and paragraph (3) and adding paragraphs (5) through (9) to read as follows:

§ 1003.110 Definitions.

* * * * *

Remuneration, for the purposes of § 1003.1000(a) of this part, is consistent with the definition in section 1128A(i)(6) of the Act and includes the waiver of copayment, coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include:

* * * * *

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented;

* * * * *

(5) A reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the Act;

(6) 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—

(i) Being unlikely to interfere with, or skew, clinical decision making;

(ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

(iii) Not raising patient safety or quality-of-care concerns;

(7) The offer or transfer of items or services for free or less than fair market value by a person if—

(i) The items or services consist of coupons, rebates, or other rewards from a retailer;

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

(iii) 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 Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(8) The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) The items or services are not offered as part of any advertisement or solicitation;

(ii) 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 Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(iii) There is a reasonable connection between the items or services and the medical care of the individual; and

(iv) The person provides the items or services after determining in good faith that the individual is in financial need;

(9) Waivers by a Part D Plan sponsor (as that term is defined in 42 CFR 423.4) of any copayment for the first fill of a covered Part D drug (as defined in section 1860D-2(e)) that is a generic drug (as defined in 42 CFR 423.4) or an authorized generic drug (as defined in 21 CFR 314.3) for individuals enrolled in the Part D plan (as that term is defined in 42 CFR 423.4), as long as such waivers are included in the benefit design package submitted to CMS. This exception is applicable to coverage years beginning on or after January 1, 2018.

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DATED: August 3, 2016.

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Daniel R. Levinson

Inspector General

APPROVED: August 4, 2016.

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Sylvia M. Burwell

Secretary

Note: This document was received by the Office of the Federal Register on November 18, 2016.

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