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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 Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing

AGENCY: Office of Inspector General (OIG) HHS

ACTION: Proposed Rule

SUMMARY: This proposed rule would amend the safe harbors to the anti-kickback statute and the civil monetary penalty (CMP) rules under the authority of the Office of Inspector General (OIG). The proposed rule would add new safe harbors, some of which codify statutory changes set forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (ACA), and all of which would protect certain payment practices and business arrangements from criminal prosecution or civil sanctions under the anti-kickback statute. We also propose to codify revisions to the

definition of "remuneration," added by the Balanced Budget Act (BBA) of 1997 and ACA, and add a gainsharing CMP provision in our regulations.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m. Eastern Standard Time on [INSERT DATE 60 DAYS FROM PUBLICATION IN FEDERAL].

ADDRESSES: In commenting, please reference file code OIG-403-P3. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. Electronically. You may submit electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. By regular, express, or overnight mail. You may mail your printed or written submissions to the following address:

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P, Room 5269
Cohen Building
330 Independence Avenue, SW, Room 5269
Washington, DC 20201

Please allow sufficient time for mailed comments to be

received before the close of the comment period.

3. By hand or courier. You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to:

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue, SW, Room 5269
Washington, DC 20201

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff at (202) 619-1368.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on <http://www.regulations.gov> for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

FOR FURTHER INFORMATION CONTACT: Heather Westphal, Office of Counsel to the Inspector General, (202) 619-0335, for

questions relating to the proposed rule.

EXECUTIVE SUMMARY:

A. Need For Regulatory Action: MMA and ACA include exceptions to the anti-kickback statute, and BBA of 1997 and ACA include exceptions to the definition of "remuneration" under the civil monetary penalties law. OIG proposes to codify those changes here. At the same time, OIG proposes additional changes to make technical corrections to an existing regulation and proposes 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. Finally, the civil monetary penalties law includes a gainsharing CMP provision that has yet to be codified in regulations. We propose to interpret and codify that provision in this proposed rule.

B. Summary of Major Provisions

1. Anti-kickback Statute and Safe Harbors: We propose to 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 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 Medicare Advantage organizations and federally qualified health centers;
 - 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 propose to amend the definition of "remuneration" in the CMP regulations at 42 CFR 1003 by adding 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.

We also propose to codify the gainsharing CMP set forth in section 1128A(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7a(b)).

C. Costs and Benefits

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

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking is part of a rulemaking that was identified in the Unified Agenda by the title "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Safe Harbors Under the Anti-Kickback

Statute, Exclusion Authorities, and Civil Monetary Penalty Rules.” OIG has proposed additional rulemaking in the following areas: CMP authorities (42 CFR part 1003); inflation adjustment for CMPs (42 CFR part 1003); and exclusion authorities and the duties and responsibilities of State Medicaid Fraud Control Units (MFCUs) 42 CFR parts 1000, 1001, 1002, and 1006. Each of the proposed rules is a stand-alone, independent rule, and thus, one can comment meaningfully on this proposed rule independent of the proposed rules concerning CMP authorities, inflation adjustment for CMPs, exclusion authorities, or authorities and duties of the MFCUs.

I. Background

A. Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b), 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 (42

U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), 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 the Federal health care programs.

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 limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while

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 45110 (Aug. 8, 2006); and 72 FR 56632 (Oct. 4, 2007).

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 CMP² only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses. 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 the safe harbor regulations to be updated periodically to reflect changing

² Pursuant to section 1128A(i)(6)(B), any 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.

business practices and technologies in the health care industry.

Section 101 of MMA added a new section 1860D to the Act, establishing the Part D prescription drug benefit in the Medicare program. Section 101(e) of 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 conditions are met. In addition, section 237 of MMA added an exception to permit certain remuneration between Medicare Advantage organizations and federally qualified health centers.

ACA also includes a number of provisions that could affect liability under the anti-kickback statute. Section 3301 of ACA establishes the Medicare Coverage Gap Discount Program, codified at new section 1860D-14A of the Act (42 U.S.C. 1395w-114A). 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 ACA amends the anti-kickback statute to protect the discounts provided for under the Medicare Coverage Gap Discount Program.

We are proposing to incorporate into our regulations safe harbors for payment and business practices permitted

under MMA and ACA, as well as proposing 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.

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. The Secretary delegated the law's CMP authorities to OIG. 53 FR 12993 (April 20, 1988). Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse, many of which were also delegated by the Secretary to OIG.

2. The Definition of "Remuneration"

The BBA of 1997 and section 6402(d)(2)(B) of ACA amended the definition of "remuneration" for purposes of the beneficiary inducements CMP at section 1128A(a)(5) of the Act, as discussed below. We propose to incorporate these changes into the definition of "remuneration" under proposed § 1003.110³ (current § 1003.101).

3. The Gainsharing CMP

Pub. L. 99-509, the Omnibus Budget Reconciliation Act (OBRA) of 1986, authorized the Secretary to impose CMPs for certain incentive payments made to physicians by hospitals, risk-sharing health maintenance organizations (HMOs), and competitive medical plans. Over time, this provision, section 1128A(b) of the Act (the Gainsharing CMP), has been amended to repeal the provisions relating to HMOs and other

³ The Secretary proposed a reorganization of Part 1003. See Notice of Proposed Rulemaking RIN 0936-AA04, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules, published on May 12, 2014 (79 FR 27080) (CMP NPRM); this proposed rule uses the section designations proposed in the CMP NPRM, together with current section numbers.

risk-sharing entities and to make various other changes in terminology.⁴ See section 6003(g)(3) of Pub. L. 101-239, OBRA of 1989; section 4204(a)(3) and 4731(b) of Pub. L. 101-508, OBRA of 1990; and section 4201(c) of the BBA of 1997.

Section 1128A(b)(1) prohibits a hospital or a critical access hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician. A hospital or a critical access hospital that makes such payment and the physician who knowingly accepts such payment are subject to CMPs of not more than \$2,000 for each beneficiary for whom the payment is made.

II. Provisions of the Proposed Rule

A. Anti-Kickback Statute and Safe Harbors

Below is a description of the additional payment practices that we are proposing to incorporate under 42 CFR 1001.952 pursuant to the authorities cited under each heading and the rationale for their inclusion in this proposed rulemaking. Consistent with the criteria set forth in section 1128D(a)(2) for modifying and establishing safe

⁴ Requirements relating to physician incentive plans in HMOs and other risk-sharing entities are now set forth in section 1876(i) of the Act.

harbors, our goal is to protect beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk of harm associated with referral payments. We seek to strike an appropriate balance between protections for beneficial arrangements and safeguards to prevent unscrupulous individuals and entities from taking advantage of the safe harbors to increase costs to programs and patients or compromise quality of care. We seek comments on how best to do this with respect to all of our proposals below.

1. Referral Services

We propose to make a technical correction to the safe harbor for referral services, found at 42 CFR 1001.952(f). This safe harbor originally required that any fee a referral service charged a participant be "based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral service * * *". This language created an unintended ambiguity, such that the safe harbor could have been viewed as permitting referral services to adjust their fees on the basis of the volume of referrals they make to the participants. In

1999, we finalized a modification to the language 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 propose to make a technical correction and revert to the language in the 1999 final rule cited above.

2. Cost-Sharing Waivers

Generally, the reduction or waiver of Medicare or other Federal health care program cost-sharing amounts may implicate the anti-kickback statute. Our concern about potentially abusive waivers of cost-sharing amounts under the anti-kickback statute is longstanding. For example, we have previously stated that providers and suppliers that routinely waive Medicare cost-sharing amounts for reasons

unrelated to individualized, good faith assessments of financial hardship may be held liable under the anti-kickback statute. See e.g., Special Fraud Alert, 59 FR 65372, 65374 (Dec. 19, 1994). Such waivers may constitute prohibited remuneration to induce referrals under the anti-kickback statute, as well as violations of the CMP prohibition against inducements to beneficiaries, found in section 1128A(a)(5) of the Act. We propose 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. In addition, we note that subparagraph (k) is limited to reductions or waivers of Medicare and State health care program beneficiary cost-sharing. We are considering and solicit comments about expanding this safe harbor to protect waivers under all Federal health care programs, if applicable, and subject to each of the paragraphs below.

Part D Cost-Sharing Waivers by Pharmacies

As noted in section I.A above, MMA specifically amended section 1128B(b)(3) of the Act by adding a new subparagraph (G) that excepts from liability under the anti-kickback statute waivers or reductions by pharmacies (including pharmacies of the Indian Health Service, Indian

tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Medicare Part D, as long as certain conditions are met. These conditions are specified in clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act, and we propose to interpret them consistent with our regulations interpreting these conditions in paragraph (1) of the definition of "remuneration" at § 1003.101.

We propose to add a new § 1001.952(k)(3) reflecting this exception to the anti-kickback statute. Thus, consistent with the statute, a pharmacy waiving Part D cost-sharing qualifies for safe harbor protection if: (1) the waiver or reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive the cost-sharing; and (3) before waiving the cost-sharing, the pharmacy either determines in good faith that the beneficiary has a 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. We reiterate, however, that compliance with the conditions of this safe harbor, as with all safe harbors, protects a

individual or an entity from liability only under the anti-kickback statute and the beneficiary inducements CMP, pursuant to section 1128A(i)(6)(B) of the Act. Providers, practitioners, and suppliers still must comply with other laws, regulations, and Centers for Medicare & Medicaid Services (CMS) program rules.

Cost-Sharing Waivers for Emergency Ambulance Services

Over the years, we have received many advisory opinion requests concerning the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a State or a political subdivision of a State, resulting in many favorable advisory opinions (that is, approving of such arrangements). Notwithstanding the vast body of favorable advisory opinions, we continue to receive similar requests for advisory opinions each year. In light of this, pursuant to our authority under section 1128B(b)(3)(E) of the Act, we propose to establish a safe harbor to protect those reductions or waivers that meet all the conditions enumerated in § 1001.952(k)(4).

First, we propose 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 tribe⁵ and be the Medicare Part B provider or supplier of the emergency ambulance services. We note that items and services that are paid for directly or indirectly by a government entity (i.e., "free services") generally are not reimbursable by Medicare,⁶ so we also propose to limit the safe harbor protection to situations in which a provider's or supplier's reduction or waiver of coinsurance or deductible is not considered to be the furnishing of services paid for directly or indirectly by a government entity, subject to applicable exceptions promulgated by CMS. CMS has explained that certain cost-sharing waivers do not constitute the provision of free services:

A [State or local government] facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment.⁷

Notwithstanding the use of the term "facility," CMS has confirmed that this provision would apply to an ambulance provider or supplier that was owned and operated by a State or a political subdivision of a State and that was the

⁵ 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.

⁶ See 42 CFR § 411.8.

⁷ CMS Medicare Benefit Policy Manual, Pub. No. 100-02, ch. 16, § 50.3.1.

Medicare Part B provider or supplier of the emergency ambulance services.

We also would require that the ambulance provider or supplier offer the reduction or waiver on a uniform basis, without regard to patient-specific factors. In addition, we propose to include an express prohibition against 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 onto Medicare, a State health care program, other payers, or individuals. We solicit comments on these proposed conditions.

For purposes of this safe harbor, we plan to interpret the term "ambulance provider or supplier" as a provider or supplier of ambulance transport services that furnishes emergency ambulance services. The term would not include a provider or supplier of ambulance transport services that furnishes only nonemergency transport services, because the safe harbor would only apply to the waiver of cost-sharing in connection with emergency ambulance services. We plan to interpret "emergency ambulance services" in a manner consistent with the definition given to that term in 42 CFR 1001.952(v)(4)(iv). We solicit comments on this interpretation and on whether these terms need to be

expressly defined in the regulatory text of this safe harbor.

Finally, we are considering 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 solicit comments on this consideration, and on what additional or different safeguards, if any, might be required to protect against fraud, waste, and abuse.

This safe harbor would apply only to situations in which the governmental unit owns and operates the ambulance provider or supplier; it would not apply to contracts with outside ambulance providers or suppliers. For example, if a municipality contracted with an outside ambulance provider or supplier for rendering services to residents of its service area, the municipality could not require the ambulance provider or supplier to waive the collection from beneficiaries of out-of-pocket cost-sharing amounts unless the municipality paid the cost-sharing amounts owed or otherwise made provisions for paying them.

3. Federally Qualified Health Centers and Medicare Advantage Organizations

An individual enrolled in a Medicare Advantage (MA) plan may receive services from a federally qualified health center (FQHC) that has a written agreement with the MA plan. Section 237 of MMA amended 42 U.S.C. 1395w-27(e) by adding a new paragraph (3) regarding agreements between MA organizations and FQHCs. This new paragraph requires that the written agreement between the two entities specifically provide that the MA organization will pay the contracting FQHC no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity. Section 237 also added a new statutory exception to the anti-kickback statute at section 1128B(b)(3)(H) of the Act (42 U.S.C. 1320a-7b(b)(3)(H)). This exception protects "any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4) [of the Act]."⁸ We propose to incorporate this exception into the safe harbor regulations as new section 42 CFR 1001.952(z) and solicit comments on this proposal.

⁸ Section 1853(a)(4) of the Act (42 U.S.C. 1395w-23(a)(4)) generally describes the payment rule for FQHCs that provide services to patients enrolled in MA plans that have an agreement with the FQHC, including agreements required under 42 USC 1395w-27(e)(3).

4. Medicare Coverage Gap Discount Program

Section 3301 of 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 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. To codify this self-implementing exception in our regulations, this proposed rule would add a new paragraph (aa) to the existing safe harbor regulations at 42 CFR 1001.952.

This new paragraph (aa) would 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. The proposed regulation would incorporate by reference the following definitions of the terms "applicable beneficiary" and "applicable drug" which were added by a new section 1860D-14A(g) of the Act:

Applicable beneficiary means an individual who, on the date of dispensing a covered part D drug—

- (A) is enrolled in a prescription drug plan or [a Medicare Advantage Prescription Drug (MA-PD)] plan;
- (B) is not enrolled in a qualified retiree prescription drug plan;
- (C) is not entitled to an income-related subsidy under section 1860D-14(a); and
- (D) who—
 - (i) has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) during the year; and
 - (ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B).

Applicable drug means, with respect to an applicable beneficiary, a covered part D drug—

- (A) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and
- (B)
 - (i) if the sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
 - (ii) if the [prescription drug plan (PDP)] sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
 - or
 - (iii) is provided through an exception or appeal.

5. Local Transportation

Pursuant to our authority at section 1128B(b)(3)(E) of the Act, we propose 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. We explored this issue in the context of section 1128A(a)(5) in the past. According to the Act's legislative history, in enacting section 1128A(a)(5) of the Act, Congress intended that the statute not preclude the provision of complimentary local transportation of nominal value (H.R. Conf. Rep. No. 104-736 at 255 (1996)). We have interpreted "nominal value" to mean no more than \$10 per item or service or \$50 in the aggregate over the course of a year. (See 65 FR 24400, 24411; April 6, 2000.) As we previously indicated, we were concerned that this interpretation may be overly restrictive in the context of complimentary local transportation. Accordingly, we solicited public input on a number of issues as they related to a possible exception to section 1128A(a)(5) of the Act (via 1128A(i)(6)) for complimentary local transportation. (67 FR 72892; Dec. 9, 2002) (2002 Solicitation). However, ultimately we did not propose or finalize an exception for complimentary local transportation.

On the basis of our experience in the years since the 2002 Solicitation and our continued concern that our interpretation of "nominal value" in the context of

complimentary local transportation may be overly restrictive, we are proposing a safe harbor to the anti-kickback statute to protect not only certain free local transportation but also discounted local transportation that meets certain conditions. As explained above, by operation of section 1128A(i)(6)(B), practices permissible under the safe harbor would also be excepted from the definition of "remuneration" in section 1128A(i)(6) of the Act.

The proposed safe harbor would protect free or discounted local transportation made available to established patients (and, if needed, a person to assist the patient) to obtain medically necessary items and services. We also seek comments on a second format of transportation that would be akin to a shuttle service. We are mindful that certain types of entities may have legitimate financial and patient care interests in the provision of local transportation to patients and that such transportation could, depending on the circumstances, benefit Federal health care programs through reduced costs and Federal beneficiaries through better care, access, and convenience. In an effort to foster these beneficial arrangements without permitting arrangements that negatively impact beneficiaries or Federal health care

programs, the safe harbor would impose a number of conditions on protected free or discounted local transportation services as set forth below.

(1) We propose to require that the free or discounted local transportation services be available only to established patients (as described in greater detail below) and be determined in a manner unrelated to the past or anticipated volume or value of Federal health care program business. This requirement is intended to reduce the risk that a health care provider or supplier could use a transportation program for the purpose of increasing business by transporting patients to its own premises or for the purpose of inappropriately inducing referrals from other providers or suppliers by transporting patients to theirs. We propose and solicit comments on a number of safeguards and limitations related to this proposed condition.

(a) We propose that the safe harbor protect free or discounted local transportation offered or provided by any individual or entity, except as provided below (for purposes of this safe harbor, an "Eligible Entity"), subject to meeting all proposed safeguards herein. The term "Eligible Entity" in the proposed safe harbor would not include individuals and 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) because we believe that there may be additional risk that these types of entities, which are heavily dependent upon practitioner prescriptions and referrals, would use transportation arrangements to generate business for themselves by steering transported patients to those who order their products. Moreover, these suppliers and manufacturers do not have the broader patient care responsibilities that, for example, hospitals, health systems, clinics, and physicians have, and thus they would seem to have less need to engage in free or discounted local transportation arrangements. We have similar concerns about the laboratory industry even though laboratories furnish services rather than items. Thus, we propose to exclude laboratories from the definition of "Eligible Entity" and solicit comments on that proposal.

For the same and other reasons, we are considering and solicit comments on whether certain other types of providers, suppliers of services, or other entities should be excluded, completely or partially, from protection as an Eligible Entity. In the context of partially limiting protection as an Eligible Entity, we are considering and

seek comments on whether certain types of health care providers or suppliers of services should not be protected when they provide free or discounted local transportation to other health care providers or suppliers who refer to them. For example, our oversight experience suggests that overutilization may be occurring in the home health industry. We are concerned that protecting the provision of free or discounted local transportation by home health care providers to physician offices that are actual or potential referral sources might result in both steering (inducing the physician to refer to that particular home health care provider) and overutilization in the form of unnecessary physician visits or unnecessary home health care prescriptions. To address this concern, we are 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 non-referral sources, such as pharmacies). We also solicit comments on whether home health agencies should be excluded from the definition of "Eligible Entity" entirely.

At this time, we propose that the safe harbor criteria apply equally to all Eligible Entities offering the

eligible forms of free or discounted local transportation services. In addition to considering whether to exclude certain types of providers or suppliers of services from protection as described above, we are also considering and solicit comments on whether there should be additional safeguards depending on the type of Eligible Entity offering the transportation services and, if so, what types of safeguards could be included to protect beneficial free or discounted local transportation arrangements while at the same time preventing abuses, such as overutilization, improper patient steering, or use of free or discounted local transportation to generate referrals, either referrals initiated by the transported patient or referrals from providers and others to whom the patients are transported.

(b) We propose and solicit comments on limiting safe harbor protection to free or discounted local transportation offered to established patients. Thus, for example, once a patient has selected an oncology practice and has attended an appointment with a physician in the group, the physician could offer transportation assistance to the patient who might have trouble reliably attending appointments for chemotherapy. However, safe harbor protection would not be available to a practice that offers

or provides free or discounted transportation to new patients.

(c) We propose to allow free or discounted local transportation services to the premises of a health care provider or supplier, subject to certain limitations that we believe would reduce the risk of using the transportation services to increase referrals. First, the safe harbor would not protect free or discounted local transportation that an Eligible Entity makes available only to patients who were referred to it by particular health care providers or suppliers. Likewise, the safe harbor would not protect an offer of transportation that is contingent on a patient's seeing particular providers or suppliers who may be referral sources for the Eligible Entity offering the transportation. These restrictions would not prohibit Eligible Entities from setting limitations on the furnishing of free or discounted local transportation, but they would require that the limitations be unrelated to the volume or value of referrals. For example, a hospital could place a limit of 10 miles or a limit on the number of trips on its offer to transport a patient to another health care provider or supplier for the purpose of obtaining items or services necessary to avoid hospital readmissions. It could not, however, limit the

offer of transportation to patients who receive these items or services from the hospital's referral sources.

We are considering and seek comments on any additional safeguards that would be required to limit the risk of fraud and abuse associated with one health care provider or supplier providing transportation to the premises of another, as well as on whether one provider or supplier of services should be permitted to provide free or discounted local transportation to the premises of others at all. For example, if the safe harbor is to cover transportation provided by one health care provider to the premises of another, should it be required that the patient be an established patient of the provider or supplier to which the patient would be transported, as well as an established patient of the Eligible Entity offering the transportation? We also recognize that health systems, health plans, accountable care organizations, or other integrated networks of providers and suppliers might be Eligible Entities and might seek to establish a free or discounted local transportation program only among providers and suppliers within the system or network. We seek comments on the impact on those potential programs if we include, as conditions of safe harbor protection, the restrictions on offers of transportation set forth in this section. We are

considering whether, and if so, how, the safe harbor conditions should be modified to account for differences that may exist when these kinds of entities provide free or discounted local transportation. We are also considering whether, for these kinds of entities, safe harbor protection should apply only to free or discounted local transportation provided to destinations that are participating or network providers or suppliers; conversely, we are considering whether such entities should be permitted or required to provide free or discounted local transportation to non-network or non-participating providers or suppliers and, if so, under what conditions. Finally, if we were to have different standards applicable to entities that do not directly furnish health care services, we are interested in comments suggesting safeguards to prevent abuses such as overutilization, improper patient steering, and increased costs.

(d) We also propose to require that the offer or granting of free or discounted local transportation services not be based on the type of treatment a patient might receive. Under the proposed safe harbor, an Eligible Entity would be permitted to restrict offers of free or discounted local transportation to patients whose conditions require frequent or critical (e.g., follow-up

testing for a drug that has the potential for serious side effects) appointments, but who do not have reliable transportation. In practice, this means that a free or discounted local transportation offer might be restricted to patients with chronic conditions, or even, in some circumstances, to patients with a specific illness. However, limiting offers of transportation to patients who have been prescribed expensive treatments that are lucrative for the Eligible Entity offering the transportation (or a referral source, parent company, subsidiary, or other affiliated entity of the Eligible Entity) would not be protected. For example, an oncology group that offered an expensive radiation treatment in its office could not restrict its offers of transportation to patients who require the lucrative radiation treatments. The group could, however, offer transportation to patients who require frequent appointments to monitor their condition, even if some of those patients also would receive the radiation treatment. We solicit comments on this proposal.

(e) In addition, we are considering and seek comments on whether to require Eligible Entities to maintain documented beneficiary eligibility criteria, such as a requirement that the patient show transportation need

or financial need or that the transportation assistance would address risks associated with failure to comply with a treatment regimen. Offering transportation to patients solely on the basis of number of appointments, without regard to transportation need, raises the possibility that the offer might be based upon the volume of Federal health care program business and thus would not be protected.

(f) Finally, we are considering and solicit comments on whether Eligible Entities should be limited for purposes of safe harbor protection to providing transportation for medical purposes or if Eligible Entities should also 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 would not protect transportation for purposes wholly unrelated to health care, such as transportation to entertainment or sporting events. We note, however, that the anti-kickback statute prohibits offering or providing remuneration to induce referrals for or receiving items or services paid for by Federal health care programs. The provision of transportation for non-medical purposes, even by a provider or supplier of health care services, would

not necessarily violate the statute, depending on the facts and circumstances. For example, a hospital could potentially sponsor shuttle service between a housing complex and a grocery store without running afoul of the statute, if the service were available to all residents of the complex regardless of whether they were or would become patients of the hospital.

We are considering and solicit comments on whether the safe harbor should separately protect transportation supplied by an Eligible Entity, such as a hospital, in the form of bus or van service on regular routes that include neighborhoods served by the hospital, public transportation stops, and the hospital campus or other locations where referring physicians have offices. If we were to protect this type of transportation, protection would not necessarily be limited to established patients of an Eligible Entity. We recognize that certain communities may have a need for this type of service, but we also recognize that such a service presents opportunities for fraud and abuse. Thus, we solicit comments not simply on whether this type of service would be useful but also on what additional safeguards we could include to reduce the risk that Eligible Entities would use this service to bring in

patients for unnecessary services, leading to overutilization or compromised quality of care.

(2) We propose to limit the form of transportation by excluding from safe harbor protection air, luxury (e.g., limousine), and ambulance-level transportation.

(3) We propose and solicit comments on the following limitations, which would be designed to exclude from protection transportation that is, in reality, a means for providers and suppliers to pay for recruitment of patients. First, we propose to exclude from safe harbor protection transportation services that are publicly advertised or marketed to patients or others who are potential referral sources. Second, we propose that the safe harbor would not apply if Eligible Entities were to pay drivers or others involved in arranging the transportation on a per-beneficiary transported basis, rather than, for example, on an hourly or mileage basis. Third, no safe harbor protection would be available if marketing of health care items and services occurred during the course of the transportation. For purposes of this safe harbor condition, we would not consider signage on the vehicle designating the source of the transportation (e.g., the name of the hospital) to be "marketing."

(4) We propose to protect only local transportation services provided: (a) to the patient and, if needed, a family member or other person to assist the patient, to obtain medically necessary items or services and (b) within the local area of the health care provider or supplier to which the patient would be transported. We propose permitting the free or discounted local transportation to be extended to a family member, a friend, or other person involved in the patient's care. We recognize that it may be beneficial or necessary in some circumstances for the patient to be accompanied by another person, and we do not view this extension as increasing the risk of fraud and abuse. We do not intend to require that the need for a patient companion be documented, nor do we intend that transportation of a patient companion be required for the proposed safe harbor to apply to transportation of the patient.

Finally, we propose to limit the safe harbor to local transportation. In the interest of providing clear guidance, we propose 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 solicit comments on whether 25 miles is an appropriate distance for this deeming provision. We also solicit comments on

whether 25 miles should be a fixed limitation rather than a distance "deemed" to comply with the safe harbor.⁹

We recognize that a distance-based test is not a one-size-fits-all solution. Therefore, we are considering and seek comments on other reasonable methods for interpreting the term "local" either alone or in combination with the 25-mile deeming provision. For example, we are considering and solicit comments on:

- whether to allow a more expansive service area for patients who reside in rural or underserved areas, and if so, what the appropriate test should be and if "rural" or "underserved" should be defined;
 - If we were to include definitions, we solicit comments on: (1) defining "underserved" as being located either in a Health Professional Shortage Area or a Medically Underserved Area; and (2) using the definition of "rural" accepted by the Office of Rural Health Policy (i.e., all counties outside a Metropolitan Statistical Area (MSA), plus counties within MSAs with

⁹ If 25 miles is a fixed limitation, nothing beyond that distance would be "local" under the safe harbor, unless the final rule includes alternate tests. If 25 miles is deemed to be local, an Eligible Entity could still comply with the "local" requirement beyond 25 miles under appropriate facts and circumstances.

Rural-Urban Commuting Codes 4-10). We also solicit comments on alternate definitions for these terms;

- o If we were to deem a greater distance to be "local" in rural or underserved areas, we solicit comments on expanding the distance to 35 miles or to the nearest facility capable of providing medically necessary items and services, whichever is greater;
- whether to permit free or discounted local transportation to the nearest facility capable of providing medically necessary items and services, even if the beneficiary resides farther away than the proposed mileage limits would otherwise allow;
- whether travel time might be more appropriate than a distance-based method;
- whether the general approach used in the regulations governing exceptions to the self-referral prohibition related to compensation arrangements regarding "geographic area served by the hospital," which uses a calculation based on the contiguous ZIP Codes from which hospitals draw at least 75 percent

of their inpatients (see 42 CFR 411.357(e)(2)), would be useful; and

- whether a more general approach, such as transportation offered to patients within the primary service area of the provider or supplier (or other location) to which the patient would be transported, would be appropriate.

We solicit comments on all of these possible approaches, and we will consider alternative suggestions as well.

(5) We propose requiring the Eligible Entity that makes the transportation available to bear the costs of the free or discounted local transportation services and not shift the burden of these costs onto Medicare, a State health care program, other payers, or individuals.

Moreover, safe harbor protection would not be available if the Eligible Entity providing the transportation and the destination provider or supplier had any referral agreement tied to the transportation. For example, if an ambulance supplier had an agreement with a hospital to provide certain free transports to hospital outpatients (e.g., via van service) in exchange for receiving the hospital's transports that are payable by Medicare Part B, the free transportation would not be protected.

B. Civil Monetary Penalty Authorities

This proposed rule would amend 42 CFR Part 1003 in two ways. First, we propose to amend the definition of "remuneration" related to the beneficiary inducements CMP to: (a) add a self-implementing exception that was enacted in BBA of 1997 but was never codified in our regulations; and (b) codify amendments that were enacted in ACA. Second, we propose to codify in our regulations the Gainsharing CMP by interpreting terms used in that statute and adding a definition of "hospital" to the regulations.

1. Beneficiary Inducements CMP

This proposed rule would add exceptions to the regulations at Part 1003 addressing the civil monetary penalties prohibition against offering inducements to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of particular providers, practitioners or suppliers.¹⁰ As we explained in footnote 2 above, one exception to the definition of "remuneration" for purposes of the beneficiary inducements CMP incorporates exceptions to the anti-kickback statute and the safe harbor regulations. However, no parallel exception exists in the anti-kickback statute. Thus, the exceptions in section 1128A(i)(6) of

¹⁰ For additional background on this provision, see 65 FR 24400 (Apr. 26, 2000).

the Act apply only to the definition of "remuneration" applicable to section 1128A.

Section 4523 of the BBA of 1997 added section 1833(t)(5)(B) of the Act, which required the Secretary to establish a procedure to permit hospitals to elect to reduce copayment amounts for some or all covered hospital outpatient department (OPD) services (as defined in section 1833(t)(1)(B)) to no less than 20 percent of the Medicare OPD fee schedule amount. The Secretary established the required procedures at 42 CFR 419.42.

Section 4523 of the BBA of 1997 also added subsection (D) to the definition of "remuneration" at section 1128A(i)(6) of the Act. That subsection, which was subsequently redesignated subsection (E), excluded from the definition of "remuneration" "a reduction in the copayment amount for covered OPD services under section 1833(t)(5)(B) [of the Act]." Id. Subsequent to the BBA of 1997, sections 201(a) and 202(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (106 Pub. L. 113) redesignated subsection 1833(t)(5) as section 1833(t)(8). A corresponding change to the reference at 1128A(i)(6)(E) was not made. We propose to codify the exception to the definition of "remuneration" at 1128A(i)(6)(E) in our regulations at proposed 42 CFR

1003.110 (current § 1003.101). We propose to adopt language identical to the statutory language, except that we propose to change the reference from 1883(t)(5)(B) to 1883(t)(8)(B) to reflect the redesignation of the originally referenced subsection. We believe that our proposed change is consistent with congressional intent and merely addresses an inadvertent oversight. We solicit comments on this proposal.

Section 6402(d)(2)(B) of ACA amends the statutory definition of "remuneration" at section 1128A(i)(6) of the Act by adding four new subparagraphs, (F)-(I), protecting certain charitable and other programs. We propose to amend the definition of "remuneration" in the regulations to include the new statutory exceptions. We believe these exceptions are intended to protect certain arrangements that offer beneficiaries incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care, including better care coordination. However, in structuring the proposals, we are also mindful of the significant potential for abusive arrangements that offer vulnerable beneficiaries (or, in some cases, cooperating beneficiaries) remuneration, whether in cash or in kind, to induce them to obtain items or services billable to Medicare or Medicaid that may be

unnecessary, too expensive, or of poor quality. The proposals set forth below aim to ensure that additional protections offered for arrangements that benefit patient care do not lead to such abuses.

Promotes Access/Low Risk of Harm

The first new exception to the definition of "remuneration," added at section 1128A(i)(6)(F) of the Act, 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)."

For purposes of this exception, we propose that the phrase "promotes access to care" mean that the remuneration provided improves a particular beneficiary's ability to obtain medically necessary health care items and services. We solicit comments on whether this phrase should be interpreted more broadly, particularly in light of the movement towards coordinated or integrated care arrangements that depend, in part, on patient engagement. For example, we are considering whether to interpret "promotes access to care" to include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it would otherwise be. We request that any such

comments include specific examples of remuneration that would promote access to care under a broader definition that would not be included within the proposed interpretation above. When providing examples, we request that commenters bear in mind that not all forms of remuneration provided to beneficiaries would be prohibited by the beneficiary inducements CMP. The beneficiary inducements CMP applies only to remuneration that the donor "knows or should know is likely to influence [the recipient] to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made" by Medicare or Medicaid. Thus, remuneration that is not likely to influence a beneficiary to order or receive federally reimbursable items or services from a particular provider, practitioner, or supplier need not meet the conditions of this or any other exception.

We are also considering, and soliciting comments on, whether the test for the exception should be that the remuneration would promote access to care for a particular beneficiary or whether the exception should also apply to remuneration that promotes access to care for a defined beneficiary population generally, such as, by way of example, beneficiaries in a designated care network or

beneficiaries being treated under a designated care protocol. Finally, we are considering, and soliciting comment on, whether we should more broadly interpret "access to care" to include care that is non-clinical but reasonably related to the patient's medical care, such as social services.

We propose to interpret the phrase "low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs" as meaning that the remuneration: (1) is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns.

While some forms of remuneration covered by the prohibition at section 1128A(a)(5) of the Act may promote access to care and some forms may pose a low risk of harm to Medicare and Medicaid beneficiaries and the programs, the amendment to the statute applies only to forms of otherwise prohibited remuneration that meet both of these standards. By way of example, through our advisory opinion process, we have examined and approved arrangements that meet both requirements. In these arrangements, certain hospitals provide lodging assistance to patients and their

families when the assistance was necessary for the patient to obtain appropriate care. Because of the specialized nature of these hospitals, the lodging programs were unlikely to steer patients to those particular hospitals, and the costs were not passed on to Federal programs. Yet, the programs enabled patients to get treatment that they might not otherwise have been able to access because of logistical hurdles. See OIG Advisory Opinion Nos. 11-01 and 11-16. Similarly, we believe that giving items that are necessary for patients to record and report health data, such as blood pressure cuffs or scales, to beneficiaries who could benefit from close monitoring of their blood pressure or weight, promotes access to care, because the recording and reporting of health data increase their ability to obtain medically necessary care and pose a low risk of harm to patients and Federal programs as long as receipt of the items is not conditioned on the patient obtaining other items or services from a particular provider or supplier.

However, not every program that benefits patients would meet the terms of this exception. We continue to believe that offering valuable gifts to beneficiaries in connection with direct or indirect marketing activities is not low risk to beneficiaries or to the Medicare and

Medicaid programs. In addition, we are concerned that rewards offered by providers or suppliers to patients purportedly for compliance with a treatment regimen pose a risk of abuse, in cases when the offerors know or should know that the rewards are likely to influence the recipients to order or receive from a particular source items or services paid for by Medicare or Medicaid. For example, patients might seek or agree to seek unnecessary or poor quality care to obtain the rewards, or providers and suppliers might order or seek orders for additional items or services to recoup the costs of giving the rewards. In either case, such rewards would not be low risk for patients and/or Federal health care programs.

While we are concerned about the significant potential for abuse when patients are offered rewards to induce them to receive items or services, we are also aware that, in some circumstances, patients might be offered incentives to encourage them to engage in arrangements that lower health care costs (without compromising quality) or that promote their own wellness and health care, for example, by participating fully in appropriate prescribed treatment, achieving appropriate treatment milestones, or following up with medically necessary appointments. We seek comments on whether otherwise prohibited incentives for compliance with

treatment regimens should be permitted under this exception and if so, what limitations or safeguards should be required. For example, should the incentives be subject to specific dollar value limits? Should providers or suppliers offering the incentives be required to document the milestones reached to earn the incentives? Should the form of the incentive be required to bear a reasonable connection to the medical care? Are there quality or performance metrics or monitoring mechanisms that, if required for safe harbor compliance, would help ensure that protected patient incentives are not used to facilitate abusive arrangements that increase costs or compromise quality? Are there different considerations if the offeror of the incentive is at risk, in whole or in part (or directly or indirectly) for the treatment that the incentive is intended to encourage (e.g., if the offeror is a risk-bearing accountable care organization, medical home, or health plan; a hospital subject to readmissions penalties; or a provider reimbursed under a bundled payment arrangement that includes some or all of the incentivized treatment)?

We recognize that the Department is undertaking a number of initiatives and demonstration programs with the goal of encouraging better care and better health at lower

costs through innovative means, some of which could involve providing incentives to beneficiaries. These programs include, for example, a variety of permanent and demonstration programs testing accountable care organizations, medical homes, bundled payments, coordinated care programs, and other initiatives to improve the quality of care and reduce costs. Some participants in particular CMS models, such as the Bundled Payment for Care Initiative, may have waivers of the CMP for certain arrangements undertaken as part of the applicable CMS model.¹¹ With respect to CMS programs or models to which a waiver does not apply, we are considering whether to make a special provision in this rule for incentives offered by participants to beneficiaries covered by those programs. Many of these programs have safeguards built into their structures. For example, CMS reviews and monitors these programs, beginning with an application process, continuing through the development and implementation phases, and including a final assessment of the overall impact of the program on cost and quality of care. Because incentives offered to beneficiaries to foster patient engagement

¹¹ Nothing in this proposed rule would change the application of existing waivers. It is possible that a final exception, as proposed here, might offer additional protection for participants in programs that have such a waiver.

outside the auspices of such a CMS program are not subject to this oversight, we would not necessarily consider that remuneration (if otherwise prohibited by the beneficiary inducements CMP) to be low risk, unless it met the same safeguards that we finalize in connection with this proposed rule.

We are also soliciting comments on other types of remuneration to beneficiaries not mentioned in this preamble that both promote access to care and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs, to inform our development of regulatory text for this exception. We are not providing regulatory text at this time, but we solicit proposals for language, including specific examples of the types of remuneration to beneficiaries, that would implement the principles described above.

Retailer Rewards Programs

Section 6402(d)(2)(B) of ACA adds the following exception as new section 1128A(i)(6)(G) of the Act:

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)).

This exception concerns retailer rewards programs. We are aware that this genre of program has proliferated in recent years at grocery stores, drug stores, "big-box," and other retailers. Although these retailer rewards programs vary in design, in general most attempt to incentivize and reward customer loyalty by providing benefits to shoppers. Many retailers offering such programs have pharmacies that sell items or services reimbursable by Federal health care programs.

OIG has interpreted the prohibition on offering gifts and other inducements to beneficiaries as permitting Medicare or Medicaid providers generally to offer beneficiaries inexpensive gifts or services (other than cash or cash equivalents) without violating the statute. For enforcement purposes, we have considered inexpensive gifts or services to be those that have a retail value of no more than \$10 individually and no more than \$50 in the aggregate annually per patient.¹² Notwithstanding this interpretation, we understand that many retailer reward

¹² See Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

programs have included a blanket exclusion of Federal health care program beneficiaries. Against this backdrop, we believe this new exception should increase retailers' willingness to include Federal health care program beneficiaries in their reward programs in appropriate circumstances.

Section 6402(d)(2)(B) of ACA excludes from the definition of "remuneration" rewards pursuant to a retailer rewards program that meet three criteria. The first criterion 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 propose to interpret these terms as follows. We interpret a "coupon" as something authorizing a discount on merchandise or services. For instance, if Alpha Store's rewards program mails its customers a flyer offering 20 percent off the purchase price of any item in the store, the flyer would be considered a coupon. Another example of a coupon would be a "buy one get one free" reward. We propose to interpret "rebate" as a return on part of a payment. For example, if Beta Store's retailer reward program consisted of returning to customers a store credit equal to 1 percent of the total money the customer spent out-of-pocket at the retailer during the previous calendar year, it would constitute a

rebate. In no event, however, could a retailer "rebate" an amount that exceeds what the customer spent at the store. We propose to interpret "other rewards" primarily as describing free items or services, such as store merchandise, gasoline, frequent flyer miles, etc. Finally, we interpret "retailer" as having its usual meaning, i.e., an entity that sells items directly to consumers. We note, however, that individuals or entities that primarily provide services (e.g., hospitals or physicians) would not be considered "retailers." We are considering and solicit comments on whether entities that primarily sell items that require a prescription (e.g., medical equipment stores) should be considered "retailers."

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 propose to interpret this requirement consistent with OIG's longstanding concern that providers and suppliers of items or services reimbursable in whole or in part by Federal health care programs not discriminate against ("lemon drop")—or, conversely, "cherry pick"—certain patients on the basis of health insurance status. For example, we do not believe that a retailer that targets its rewards program to Medicare beneficiaries only would meet this

criterion. On the other hand, if a retailer mailed a coupon for \$10 off the next purchase of any item in its store, including prescriptions, to every resident in the surrounding ZIP Code, such a promotion likely would be in compliance with this provision because the coupon would be offered on equal terms to everyone in the ZIP Code, without regard to health insurance status.

The third criterion 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 believe that the objective of this criterion is to attenuate any connection between federally payable items and services and a loyalty program's rewards; this attenuation should be present both in the manner in which a reward is earned and in the manner in which the reward is redeemed, as explained further below. We do not interpret the prohibition on tying the free or below-market items and services to federally reimbursable services as requiring a complete severance of the offer from the medical care of the individual. At the front end of a transaction ("earning" the reward), the reward should 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 non-reimbursable items and services are treated. For instance, a drugstore program that offered a \$20 coupon to customers, including Medicare beneficiaries, who transferred their prescriptions to the drugstore would not meet this criterion because the \$20 coupon would be tied to the drugstore's getting the recipients' Medicare Part D prescription drug business. On the other hand, a program that awarded a \$20 coupon once a customer spent \$1,000 out-of-pocket in the store—even if a portion of that \$1,000 included copayments for prescription drugs—would likely meet the criterion. We also believe that this attenuation must be present on the "redeeming" end of the transaction and therefore interpret it to exclude from protection rewards programs in which the rewards themselves are items or services reimbursed in whole or in part by a Federal health care program. Thus, if Epsilon Store allowed its customers to redeem reward points only for cost-sharing (i.e., the customer's out-of-pocket costs) on DME, prescription drugs, or other federally payable items or services, that program would not meet this criterion. On the other hand, if the \$10 coupon referenced in the first example could be redeemed on anything purchased in the

store, including the customer's out-of-pocket costs for federally reimbursable items, the coupon could meet the terms of the exception.

Financial-Need-Based Exception

A third new statutory provision, added at 1128A(i)(6)(H) of the Act, excepts from the definition of "remuneration" the offer or transfer of items or services for free or at less than fair market value after a determination that the recipient is in financial need and meets certain other criteria.

We begin our consideration of this new provision by noting that it concerns "the offer or transfer of items or services." The term "items or services" does not include cash or instruments convertible to cash. This interpretation is consistent with our interpretation of "permissible incentives for preventive care" under section 1128A(i)(6)(D), as explained in the preamble to that final rule ("we are excluding from the scope of permissible exceptions cash and instruments convertible to cash" (65 FR 24400, 24409 (Apr. 26, 2000))). Other proposed limits on what may be transferred are discussed in the paragraphs below.

The statute provides that protected items or services may not be offered as part of any advertisement or

solicitation. We are including this requirement in our proposed regulation.

The second statutory criterion is that "the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under title XVIII or a State health care program. . . ." To interpret this criterion in a meaningful way, it is necessary to consider it together with the next requirement, which is that there must be a reasonable connection between the items or services and the medical care of the individual. Each requirement is discussed in more detail below.

To be protected under the statute, the item or service being offered or transferred must not be tied to the provision of other reimbursed services. Consistent with our interpretation of the same criterion described in connection with the exception for retailer rewards programs described above, we do not interpret the prohibition on tying the free or below-market items and services to services reimbursable by Medicare or Medicaid as requiring a complete severance of the offer from the medical care of the individual. However, a provider's conditioning the offer or transfer of items or services on the patient's use of other services from the provider that would be reimbursed by Medicare or Medicaid would violate this

requirement. For example, we interpret this criterion to exclude from protection offers by providers of lodging or transportation to receive a particular service from the provider.¹³ We solicit comments on this interpretation.

The third statutory requirement is that there "is a reasonable connection between the items or services and the medical care of the individual." We must interpret this requirement in the context of this particular exception. This exception is designed to help financially needy individuals access items or services related to their medical care; unlike the preventive care exception referenced above, this exception is not designed to induce the patient to seek additional care.

For purposes of this requirement, we interpret "medical care" to refer to 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. Consistent with the statutory language, our proposed regulation would require a "reasonable connection" between the remuneration and the

¹³ As explained above, we have approved lodging and transportation assistance programs through our advisory opinion process. However, we found that the programs were consistent with the exception to the definition of "remuneration" for programs that promote access to care and pose a low risk of harm to patients and Federal health care program beneficiaries.

patient's medical care. Whether a "reasonable connection" exists depends on a situation's specific facts and circumstances. In particular, this requirement warrants a dual consideration: whether a reasonable connection exists from a medical perspective and whether a reasonable connection exists from a financial perspective. A reasonable connection exists from a medical perspective when the items or services would benefit or advance identifiable medical care or treatment that the individual patient is receiving. From a financial perspective, remuneration disproportionately large compared with the medical benefits conferred on the individual patient would not have a reasonable connection to the patient's medical care. Such remuneration gives rise to an inference that at least part of the transfer is being provided to induce beneficiaries to obtain additional services, and such remuneration would not be covered by the Financial-Need-Based Exception.

Examples of transfers of items or services that, in context, might qualify as reasonably connected to medical care include:

- distribution of protective helmets and safety gear to hemophiliac children;

- distribution of pagers to alert patients with chronic medical conditions to take their drugs;
- provision of free blood pressure checks to hypertensive patients;
- distribution of free nutritional supplements to malnourished patients with end-stage renal disease (ESRD); and
- provision of air conditioners to asthmatic patients.

However, in another context, these same items and services would not likely qualify as reasonably connected to an individual patient's medical care. Most obviously, these would include transfers of items or services to an individual for whom they were not medically indicated. We are considering and seek comments, however, on the boundaries of the concept of "medically indicated." For example, should a hospital be permitted to provide free bicycle helmets or other child safety devices to financially needy families when children are treated for injuries in the emergency department? We use this example, which arguably is not related to "care," in order to inform comments on the limits of the "reasonable connection to care" requirement.

From a financial perspective, transfers of items or services of disproportionately large value compared with their medical benefit for the individual patient would not qualify. For example, transfer to a diabetic patient of a smartphone preloaded with an "app" relating to management of blood sugar levels would not likely qualify, while an offer to the diabetic patient of only a complimentary download of the app onto his or her own smartphone might.

We are considering whether we can (and, if so, whether we should) identify specific conditions under which remuneration would be deemed to be "reasonably connected" to the patient's medical care, and we solicit suggestions for possible conditions. For example, one condition we are considering is whether the patient's physician or other health care professional has concluded that the items or services would benefit the individual patient's treatment. Another possible condition is whether, absent the transfer of needed health care items or services, the patient would otherwise be expected to lack access to them for reasons including lack of payment resources; lack of appropriate health care facilities in the patient's community or the surrounding areas; and unique physical, behavioral, or mental health issues that might interfere with the patient's ability to otherwise obtain access. Such

circumstances in a patient's case would support the argument for a reasonable connection. We solicit comments about what additional or alternative factors should be considered, if any, in the determination of a reasonable connection between items or services offered or transferred and the medical care of the individual.

The fourth and final statutory requirement is that the items or services may be provided only "after determining in good faith that the individual is in financial need." We propose to interpret this provision as requiring an individualized assessment of the patient's financial need on a case-by-case basis. Moreover, the assessment must be conducted in good faith. We believe, among other things, that a good faith assessment requires the use of a reasonable set of income guidelines, uniformly applied. This reasonable set of financial need guidelines should be based on objective criteria and be appropriate for the applicable locality. Under our proposal, "financial need" would not be limited to "indigence," but could include any reasonable measure of financial hardship. What constitutes a good faith determination of "financial need" may vary depending on the individual patient's circumstances; the individual or entity offering the items or services should have flexibility to consider relevant variables. We are

considering whether we have authority to require documentation of the financial need assessment as a condition of the exception. Regardless, it would be prudent for those seeking protection under the proposed exception to maintain accurate and contemporaneous documentation of the need assessment and the criteria applied.

Waivers of Cost-Sharing for the First Fill of a Generic Drug

The fourth new provision added at section 1128A(i)(6)(I) of the Act excepts from the definition of "remuneration" waivers 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. Section 6402(d)(2)(B) of ACA does not define the term "generic drug," so we propose to rely on the definition in the Part D regulations at 42 CFR 423.4.

The type of waiver described in the statute is designed to minimize drug costs by encouraging the use of lower cost generic drugs. To implement this waiver, we propose interpreting this statutory provision consistently with current CMS guidance. Thus, 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 propose to include this requirement both to ensure consistency with current CMS practice and to ensure transparency to beneficiaries when they select Part D or MA plans. We propose to make this exception effective for coverage years beginning after publication of the final rule. We note, however, that CMS already permits these waivers as part of Part D and MA plan benefit designs. Although this proposed regulation will not be effective until a future date, we will not exercise our enforcement authority against plans complying with CMS requirements for these waivers in the interim.

2. Gainsharing

The Gainsharing CMP is a self-implementing law that prohibits hospitals and critical access hospitals 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. We proposed regulations in 1994 to interpret the Gainsharing CMP (59 FR 61571 (Dec. 1, 1994)), but the proposed rule was not finalized. In July 1999, we published a Special Advisory Bulletin titled "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (the

Gainsharing SAB), available at:

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>

m. In the Gainsharing SAB, we explained that the Gainsharing CMP is broad and prohibits any hospital incentive plan that involves payments to physicians to encourage reductions or limitations in items or services provided to patients under the physicians' clinical care. We observed that the statute does not limit this prohibition to reductions or limitations of *medically necessary* items or services.

We have previously observed that not all changes in practice necessarily constitute a reduction of services. Health care payment and delivery systems are changing, with greater emphasis on accountability for providing high quality care at lower costs. We propose to codify the Gainsharing CMP in our regulations and interpret certain provisions in a manner that reflects today's health care landscape.

OIG has recognized that gainsharing can be beneficial. In fact, we have approved 16 gainsharing arrangements through our advisory opinion process.¹⁴ We found that the particular facts presented to us in those arrangements

¹⁴ OIG Advisory Opinion Nos.: 00-02, 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21, 07-22, 08-09, 08-15, 08-21, 09-06, 12-22.

presented few risks relative to those of other gainsharing arrangements. The gainsharing programs in the advisory opinions set out specific actions to be taken and tied remuneration to the actual cost savings attributable to the arrangements. They included specific safeguards against patient and program abuse.

Citing to many of these advisory opinions, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress authorize the Secretary to allow gainsharing arrangements and to regulate those arrangements to protect the quality of care and minimize financial incentives that could influence physician referrals. See MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* (March 2005) (MedPAC Report). The MedPAC Report provided examples of safeguards included in OIG advisory opinions and posited that gainsharing programs could lead to program savings over time. See id. at p. 46.

Later that year, the Chief Counsel to the Inspector General testified to the House Committee on Ways and Means about gainsharing. The testimony highlighted three types of safeguards that the OIG looked for when evaluating the risks posed by a gainsharing program: measures that promote accountability, adequate quality controls, and controls on payments that may change referral patterns.

See Testimony of Lewis Morris, Chief Counsel to the Inspector General, House Committee on Ways and Means, Subcommittee on Health (October 7, 2005), available at <https://oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf>. Although the testimony focused largely on specific risks in gainsharing programs, and safeguards to counteract those risks, the testimony also explained that if properly structured, "gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of Federal health care program patients." Id. at p. 1. In fact, OIG would be unlikely to bring a case against a hospital or physician for a gainsharing arrangement that included patient and program safeguards such as those identified in our advisory opinions.¹⁵

In addition, since 2005, Congress has authorized, and the Secretary has approved, a number of projects involving gainsharing. For example, the Deficit Reduction Act of 2005¹⁶ required the Secretary to establish a gainsharing

¹⁵ OIG has never pursued any gainsharing CMP case. OIG always has been, and remains, open to pursuing a gainsharing CMP case under appropriate facts. Prior to initiating any such case, we would consider the factors set out in the advisory opinions and considerations discussed in this preamble. Pending further notice from OIG, gainsharing arrangements are not an enforcement priority for OIG unless the arrangement lacks sufficient patient and program safeguards.

¹⁶ Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007, 120 Stat. 4, 34-36 (2006).

program to test and evaluate arrangements between hospitals and physicians designed to govern utilization of certain inpatient services to improve the quality and efficiency of care. Section 3022 of ACA required the Secretary to establish a Medicare shared savings program (Shared Savings program) and allowed the Secretary to waive such requirements of sections 1128A and 1128B and Title XVIII of the Act as may be necessary to carry out the provisions of section 3022. In the Interim Final Rule implementing the Shared Savings program waivers, the Secretary waived the Gainsharing CMP with respect to certain aspects of the Shared Savings program, subject to applicable conditions. See 76 FR 67992 (Nov. 2, 2011).

Both government and private insurers have increased efforts to lower costs and improve the quality of care. Better ways of measuring quality and outcomes exist now than in the past. The growth of health information technology, developments in data analytics and quality metrics, and broader use of evidence-based medicine all facilitate such measurements and accountability for performance. For example, the Shared Savings program, as enacted, promotes an evidence-based medicine approach for accountable care organizations participating in the Shared Savings program (ACOs): "[t]he ACO shall define processes

to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Section 1899(b)(2)(G) of the Act.

Notwithstanding these and similar developments, the Gainsharing CMP has not been amended by Congress. It prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician. The statute does not prohibit only payments to reduce medically necessary services; it prohibits payments to reduce or limit "services." Without a change in the statute, we continue to believe that we cannot read a "medically necessary" element into the prohibition. However, given the changes in the practice of medicine over the years, including collaborative efforts among providers and practitioners and the rise of widely accepted clinical metrics, we are considering a narrower interpretation of the term "reduce or limit services" than we have previously held.

Since issuing the Gainsharing SAB, we have had the opportunity to examine a number of different gainsharing

arrangements through our advisory opinion process. In each favorable opinion we issued, we found that the cost-saving measures proposed by the hospitals implicated the statute. For example, in OIG Advisory Opinion No. 05-01, we stated: "the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital." We went on to state that "[w]e recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP." OIG Advisory Opinion No. 05-01 (issued Jan. 28, 2005, at pp. 7-8).¹⁷ This language implies that any change to current medical practice that a hospital might initiate is potentially a reduction in care that could trigger CMP liability. However, as hospitals move towards using objective quality metrics, we recognize that a change in practice does not necessarily constitute a limitation or reduction of

¹⁷ Under section 1862 of the Act, no payment may be made under Part A or Part B for any expenses incurred for items or services that (with certain exceptions) are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under the Part A prospective payment system (PPS) for hospital inpatient stays, payments are made for hospital stays that are reasonable and necessary; however, additional payment is not made if a patient receives individual items or services in excess of, or more expensive than, those factored into the PPS payment for covered care.

services, but may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality.

The regulatory text we are proposing largely tracks the statute and is similar to the text proposed in 1994. Besides codifying the gainsharing prohibition itself, we propose to add a definition of "hospital" to proposed section 42 CFR 1003.110 (current § 1003.101). This definition would refer to the definitions of "hospital" and "critical access hospital" in the Act. In addition, however, we are considering and solicit comments on whether we should include a definition of the term "reduce or limit services" to address the considerations we express above. If so, we solicit specific proposals and safeguards that we should include in this definition to ensure that the goal of the statute is met: to prevent hospitals from paying physicians to discharge patients too soon or take other action that inappropriately limits a beneficiary's care. We are not proposing text of a definition at this time. We specifically solicit comments on the following areas of concern, but we welcome any other comments relating to the topic:

- We have interpreted the prohibition on payments to reduce or limit *services* as including payments to

limit *items* used in providing services, which is consistent with the definition of "services" found at 42 CFR 400.202. Is this interpretation appropriate or necessary in the context of the Gainsharing CMP?

- Should a hospital's decision to standardize certain items (e.g., surgical instruments, medical devices, or drugs) be deemed to constitute reducing or limiting care? Would the answer be the same if the physicians were simply encouraged to choose from the standardized items, but other items remained available for use when deemed appropriate for any particular patient?
- Should a hospital's decision to rely on protocols based on objective quality metrics for certain procedures ever be deemed to constitute reducing or limiting care (e.g., protocols calling for the discontinuance of a prophylactic antibiotic after a specific period of time)? Should hospitals deciding to compensate physicians in connection with the use of such protocols be required to maintain quality-monitoring procedures to ensure that these protocols do not, even inadvertently, involve reductions in care? What types of monitoring and documentation would be reasonable and appropriate?

- Should a hospital desiring to standardize items or processes as part of a gainsharing program be required to establish certain thresholds based on historical experience or clinical protocols, beyond which participating physicians could not share in cost savings (i.e., change beyond the relevant threshold would be deemed to constitute reducing or limiting services)? For example, in OIG Advisory Opinion 05-01, the hospital had a policy of performing blood cross-matching (in addition to typing and screening) in all cases and proposed to perform cross-matching only when a patient required a transfusion. The facts in that opinion were that less than 30 percent of cases actually required transfusions, so 30 percent was used as the threshold. Therefore, the surgeon group would not receive any share of savings resulting from performing cross-matching in fewer than 30 percent of cases.
- If we define "reduce or limit services," should the regulation include a requirement that the hospital and/or physician participating in a gainsharing program notify potentially affected patients about the program? Would such a requirement help ensure that

gainsharing payments were for legitimate purposes and not for the purpose of reducing or limiting care?

Our proposal to define the term "reduce or limit services" and our solicitation of comments related to that definition reflect our recognition that the delivery of health care, and the potential safeguards to protect patients and promote accountability for outcomes, has been changing. We seek to interpret the statutory prohibition broadly enough to protect beneficiaries and Federal health care programs, but narrowly enough to allow low risk programs that further the goal of delivering high quality health care at a lower cost. We emphasize that this proposed regulation would interpret the Gainsharing CMP. We have no authority to create an exception to the statute.

III. 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 authorities and 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, if at all, by these proposed revisions.

The changes to the safe harbors and CMP authorities and 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 agreements would not subject them to liability under the anti-kickback statute and the beneficiary inducement or gainsharing CMPs. 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 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, non-profit 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 provisions would be minimal, and the changes to the anti-kickback statute safe harbors would not significantly affect small providers as these would not impose any requirement on any party.

In summary, we have concluded that this proposed 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 (42 U.S.C. 1302) 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 proposed 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 proposed 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 proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

IV. Paperwork Reduction Act

This document does not impose 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.

42 CFR Part 1003

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

For the reasons set forth in the preamble, the Office of Inspector General, Department of Health and Human Services, proposes to amend 42 CFR chapter V as follows:

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), (k) introductory text, and by adding paragraphs (k)(3), (k)(4), (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 coinsurance and deductible amounts. As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.

* * * * *

(3) If the copayment, coinsurance, or deductible 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 part D of Title XVIII provided that—

(i) The waiver 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 copayment, coinsurance, or deductible amounts and

(B) The pharmacy waives the copayment, coinsurance, or deductible amounts only after determining in good faith that the individual is in financial need or fails to collect the copayment, coinsurance, or deductible after making reasonable collection efforts.

(4) If the coinsurance or deductible amounts are owed to an ambulance provider or supplier for emergency ambulance services for which Medicare 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 federally recognized Indian tribe;

(ii) The ambulance provider or supplier is the Medicare Part B provider or supplier of the emergency ambulance services;

(iii) The ambulance provider's or supplier's reduction or waiver of coinsurance or deductible amounts is not

considered to be the furnishing of free services paid for directly or indirectly by a government entity;

(iv) The ambulance supplier offers the reduction or waiver on a uniform basis, without regard to patient-specific factors; and

(v) The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

* * * * *

(z) 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, so 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 full compliance with all 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)) to established patients who are Federal health care program beneficiaries for the purpose of obtaining medically necessary items or services if all the following conditions are met:

(1) The availability of the free or discounted local transportation services is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

(2) The free or discounted local transportation services do not take the form of air, luxury, or ambulance-level transportation;

(3) The free or discounted local transportation services are not marketed or advertised, 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;

(4) The Eligible Entity that makes the free or discounted transportation available furnishes the services only:

(i) To the established patient (and, if needed, a person to assist the patient) to obtain medically necessary items or services, and

(ii) Within the local area of the health care provider or supplier to which the patient would be transported;

(5) The Eligible Entity that makes the transportation available bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto Medicare, a State 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; and if the distance from the patient's location to the provider or supplier to which the patient would be transported is no more than 25 miles, the transportation is deemed to be local.

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. Section 1003.101 as proposed to be redesignated as 1003.110 and amended at 79 FR 27080 (May 12, 2014) is further amended by adding the definition of "Hospital" and by amending the definition of "Remuneration" by revising the introductory text and adding paragraphs (5) through (9) to read as follows:

1003.101 Definitions

* * * * *

Hospital means a hospital as defined in section 1861(e) of the Act or critical access hospital as defined in section 1861(mm)(1) of the Act.

* * * * *

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 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—

* * * * *

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

(6) [Reserved];

(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;

(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 sponsor of a Prescription Drug Plan under part D of Title XVIII or a Medicare Advantage organization offering an MA-PD Plan under part C of such title 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) for individuals enrolled in the Prescription Drug Plan or MA-PD Plan, respectively, as long as such waivers are included in the benefit design package submitted to CMS. This exception is effective for coverage years beginning after publication of the final rule.

* * * * *

5. Part 1003, as proposed to be amended at 79 FR 27080, (May 12, 2014) is further amended by adding subpart G to read as follows:

Subpart G--CMPs for Gainsharing Violations

Secs.

1003.700 Basis for civil money penalties.

1003.710 Amount of penalties.

1003.720 Determinations regarding the amount of penalties.

§ 1003.700 Basis for civil money penalties.

OIG may impose a penalty against any person who it determines in accordance with this part-

(a) Is a hospital that knowingly makes a payment, directly or indirectly, overtly or covertly, in cash or in kind, to a physician as an inducement to reduce or limit services provided to an individual who is eligible for Medicare or Medicaid benefits and who is under the direct care of the physician;

(b) Is a physician who knowingly receives a payment described in paragraph (a) of this section.

§ 1003.710 Amount of penalties.

(a) OIG may impose a penalty against a hospital of not more than \$2,000 for each individual for whom payment was made to a physician in violation of §1003.700.

(b) OIG may impose a penalty against a physician of not more than \$2,000 for each individual for whom the

physician received payment from a hospital in violation of §1003.700.

§ 1003.720 Determinations regarding the amount of penalties.

In determining the amount of any penalty or assessment, OIG will consider the factors listed in § 1003.140, as well as the following:

- (a) The nature of the payment designed to reduce or limit services and the circumstances under which it was made,
- (b) The extent to which the payment encouraged the limiting of medical care or the premature discharge of the patient,
- (c) The extent to which the payment caused actual or potential harm to program beneficiaries, and
- (d) The financial condition of the hospital (or physician) involved in the offering (or acceptance) of the payment.

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Daniel R. Levinson
Inspector General

APPROVED: September 18, 2014

Sylvia M. Burwell
Secretary

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