DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1345-NC2]

Office of the Inspector General

RIN 0938-ZB05

Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of the Inspector General (OIG), HHS.

ACTION: Notice with comment period.

SUMMARY: Section 1899(f) of the Social Security Act (of the Act), as added by the Affordable Care Act (ACA) authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act (the Medicare Shared Savings Program). This notice with comment period describes and solicits public input regarding possible waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified financial arrangements involving accountable care organizations (ACOs) under the Medicare Shared Savings Program. In addition, section 1115A(d)(1) of the Act, as added by section 3021 the ACA, authorizes the Secretary to waive the same fraud and abuse laws, among others, as necessary solely for the purposes of carrying out the provisions of section 1115A of the Act with respect to the testing of certain innovative payment and service delivery models by the Center for Medicare and

Medicaid Innovation. This notice with comment period also solicits public input regarding that separate waiver authority.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on [insert date 60 days after the date of publication].

ADDRESSES: In commenting, please refer to file code CMS-1345-NC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.
- By regular mail. You may mail written comments to the following address ONLY:

  Centers for Medicare & Medicaid Services,

  Department of Health and Human Services,

  Attention: CMS-1345-NC2,

  P.O. Box 8013,

  Baltimore, MD 21244-8013.

  Please allow sufficient time for mailed comments to be received before the close of the comment period.

- By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1345-NC2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

- By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received by CMS will be shared with OIG.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Neal Shah (410) 786-1167 or Troy Barsky (410) 786-8873, for general issues and issues related to the Physician Self-Referral Law.

James A. Cannatti III (202) 619-0335, for general issues and issues related to the anti-kickback statute or civil monetary penalties.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Medicare Shared Savings Program: Background

A. Introduction

This notice with comment period seeks public comment on proposed waivers of sections 1128A(b)(1) and(2), 1128B(b)(1) and (2), and 1877(a) of the Social Security Act (of the Act) in the specific circumstances described below, as necessary to carry out the provisions of section 1899 of the Act (as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively, the "Affordable Care Act")). We seek to address application of these fraud and abuse laws to accountable care organizations (ACOs[1]) formed in connection with the Medicare Shared Savings Program[2] so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs. Elsewhere in this issue of the **Federal Register**, the Centers for Medicare & Medicaid Services (CMS) published a

[1] For purposes of this notice with comment period, the terms "ACO," "ACO participants," and "ACO providers/suppliers" have the meanings ascribed to them in the Medicare Shared Savings Program proposed rule.

[2] We note that some ACOs may also operate under arrangements with private payers. We address waivers as they might relate to how ACOs distribute payments from private payers in section III. of this notice with comment period.

proposed rulemaking setting forth proposed requirements for ACOs under the Medicare Shared Savings (hereinafter referred to as the Medicare Shared Savings Program proposed rule). Section 3022 of the Affordable Care Act describes the Medicare Shared Savings Program as a program to promote accountability for a patient population, coordinate items and services under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. As described in the Medicare Shared Savings Program proposed rule, the Medicare Shared Savings Program is designed to achieve three goals: better health, better care, and lower cost. CMS's expectation is that ACOs will help foster a new approach to delivering care that reduces fragmented or unnecessary care and excessive costs for Medicare fee-for-service beneficiaries and other patients.

The Physician Self-Referral Law, the anti-kickback statute, and the civil monetary penalty (CMP) provision addressing hospital payments to physicians to reduce or limit services, discussed elsewhere in this notice with comment period, are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms. However, stakeholders have expressed concern that the restrictions these laws place on certain financial arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the Medicare Shared Savings Program. Section 1899(f) of the Act authorizes the Secretary to waive these and certain other laws as necessary to carry out the Medicare Shared Savings Program.

In section II. of this notice with comment period, we set forth proposals for waivers of these fraud and abuse laws that we believe, based on public input and our own analysis, may be necessary to carry out the Medicare Shared Savings Program. We seek public comment on these proposed waivers. In section III. of this notice with comment period, we solicit public input on the possibility of additional or different waivers, as well as input on other related considerations.

We expect to issue waivers applicable to ACOs participating in the Medicare Shared Savings Program concurrently with CMS's publication of final regulations for the Medicare Shared Savings Program. The requirements of the final regulations will bear on the scope of any waivers granted for the Medicare Shared Savings Program. Because of the close nexus between the final regulations governing the structure and operation of ACOs under the Medicare Shared Savings Program and the development of waivers necessary to carry out the provisions of the Medicare Shared Savings Program, we may consider comments submitted in response to the Medicare Shared Savings Program proposed rule and the provisions of the Medicare Shared Savings Program final rule when crafting waivers applicable to the Medicare Shared Savings Program. CMS may also consider comments received in response to this notice with comment period when finalizing its regulations for the Medicare Shared Savings Program.

B. Section 1899 of the Social Security Act

Section 1899 of the Act establishes the Medicare Shared Savings Program to encourage the development of ACOs in Medicare. The Medicare Shared Savings Program is one of the first initiatives that will be implemented under the Affordable Care Act aimed specifically at improving "value" in the Medicare program—that is, both

higher quality and lower total expenditures for individual Medicare beneficiaries and the Medicare program. Section 1899 of the Act encourages ACOs to promote accountability for individual Medicare beneficiaries and population health management, improve the coordination of patient care under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. The redesigned care processes developed by ACOs should also improve care and lower costs for all patients served by the ACO.

As proposed in the Medicare Shared Savings Program proposed rule, ACOs will enter into an agreement with the Secretary to participate in the Medicare Shared Savings Program for not less than a 3-year period under one of two tracks. Under the first track, an ACO would have the opportunity to share in actual savings during the first 2 years of the agreement. During the third year, the ACOs would be in a "two-sided risk" model in which they would be eligible to receive a higher potential shared savings, but also would be required to repay the Medicare program if costs for the ACO's aligned beneficiaries exceed certain thresholds. Under the second track, ACOs would operate under the two-sided risk model from the beginning of their agreement period. Under either model, in order to share a percentage of achieved savings with the Medicare program, ACOs must successfully meet quality and savings requirements and certain other conditions under the Medicare Shared Savings Program. ACO participants and ACO providers/suppliers will continue to receive fee-for-service payments, and the ACO legal entity may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers.

C. Waiver Authority under Section 1899(f) of the Act

Section 1899(f) of the Act provides that "[t]he Secretary may 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 1899 of the Act]." This waiver authority is specific to the Medicare Shared Savings Program, and does not address other similar integrated-care delivery models. We may consider waivers (where authorized under the Affordable Care Act), exceptions, or safe harbors, as applicable, for other types of ACOs, integrated-care delivery models, or financial arrangements at a later date.

We note that a waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. We note further that many exceptions and safe harbors already exist that might apply to ACO arrangements, depending on the circumstances.

D. Fraud and Abuse Laws—Background

1. Physician Self-Referral Law (Section 1877 of the Act)

Section 1877 of the Act (42 U.S.C. 1395nn, the "Physician Self-Referral Law") is a civil statute that prohibits physicians from making referrals for Medicare "designated health services," including hospital services, to entities with which they or their immediate family members have a financial relationship, unless an exception applies. These entities may not bill Medicare for services rendered as a result of a prohibited referral and section 1877(g)(1) of the Act states that no payment may be made for prohibited designated health service referrals. Civil monetary penalties also apply to any person who presents (or causes to be presented) a bill for services for which he or she

knows or should know payment may not be made under section 1877(g)(1) of the Act. For additional details, see section 1877(g)(3) of the Act. Violations of the statute may also result in liability under the False Claims Act (31 U.S.C. 3729–33).

2. The Anti-Kickback Statute (Section 1128B(b) of the Act)

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 to induce or reward the referral of business reimbursable under any of the 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 of the anti-kickback statute 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). Certain practices that meet all of the conditions of a statutory exception at section 1128B(b)(3) of the Act or regulatory safe harbor at 42 CFR 1001.952 are not subject to prosecution or sanctions under the anti-kickback statute.

3. Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)

Sections 1128A(b)(1) and (2) of the Act (the "Gainsharing CMP") apply to certain payment arrangements between hospitals and physicians, including arrangements commonly referred to as "gainsharing" arrangements. Under section 1128A(b)(1) of the Act, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the

physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (sections 1128A(b)(1) and (2) of the Act).

E. Summary of Public Input Opportunities

Since the passage of the Affordable Care Act, the U.S. Department of Health and Human Services (DHHS) has offered numerous opportunities for the public to provide input into the design and operation of ACOs and waivers necessary to carry out the provisions of the Medicare Shared Savings Program. For example, CMS issued a Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program on November 10, 2010[3], and held multiple listening sessions with stakeholders. CMS, OIG, and the Federal Trade Commission held a joint workshop on October 5, 2010, entitled "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws."[4] We also received and reviewed written public comments in connection with the workshop.[5] Through these means, the DHHS has received public input representing a wide spectrum of views.

There appears to be a general consensus among public stakeholders that ACOs have the potential to change health care delivery in a manner that improves patient care, and that some waivers of the fraud and abuse laws may be necessary to facilitate their operations. However, in general, no clear consensus has emerged on the scope of the waivers necessary to carry out the Medicare Shared Savings Program, perhaps because

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[3] 75 FR 70165 (2010)
[4] Information about the workshop is available on CMS's website at http://www.cms.gov/center/physician.asp.
[5] The public comments are available on the FTC's website at http://www.ftc.gov/os/comments/aco/index.shtm.

the relevant regulations have not yet been published. Moreover, it is possible that the Medicare Shared Savings Program final regulations will include additional modifications in response to public comments to the proposed regulations. Therefore, our approach is to propose and solicit comments on possible waivers in section II. of this notice with comment period, and to solicit comments on different, potentially broader waivers, as well as additional waiver design considerations, in section III. of this notice with comment period. This approach will facilitate full and informed stakeholder input on, and government consideration of, these important, inter-connected issues.

II. Medicare Shared Savings Program: Proposed Waivers

We currently contemplate that, pursuant to the authority granted under section 1899(f) of the Act, the Secretary would waive sections 1128A(b)(1) and (2), 1128B(b)(1) and (2), and 1877(a) of the Act in the specific circumstances described below. The waivers would not apply to any other provisions of Federal or State law. All financial arrangements not covered by a waiver would be required to comply with existing laws. We invite the public to comment on the proposed waivers described in this section.

To promote efficiency and ease of use, it is our intent to promulgate waivers that will be consistent across the fraud and abuse laws to the extent possible given the different scope and structure of the laws. We also intend to apply these waivers uniformly to all qualified ACOs, ACO participants, and ACO providers/suppliers participating in the Medicare Shared Savings Program.

A. Threshold Qualification for Proposed Waivers

In order to qualify for any of the proposed waivers described in section II.B. of this notice with comment period--

● ACOs would be required to enter into an agreement with CMS to participate in the Medicare Shared Savings Program; and

● ACOs, ACO participants, and ACO providers/suppliers would be required to comply with the agreement, section 1899 of the Act, and its implementing regulations (including, without limitation, all transparency, reporting, and monitoring requirements).

B. Scope of the Proposed Waivers

1. Physician Self-Referral Law (Section 1877(a) of the Act)

Under this proposal, the Secretary would waive application of the provisions of section 1877(a) of the Act (42 U.S.C. 1395nn(a)) to distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO′s participation in and operations under the Medicare Shared Savings Program. Our intent with this proposal would be to protect financial relationships created by the distribution of shared savings within the ACO, as well as financial relationships created by a distribution of shared savings outside the ACO, but only if the distribution outside the ACO relates closely to the requirements for an ACO under section 1899 of the Act, including achieving the quality and savings goals of the Medicare Shared Savings Program. We do not intend to protect distributions of shared savings dollars to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. Other

financial relationships with referring physicians outside the ACO would need to meet an existing exception under the Physician Self-Referral Law (for example, the fair market value, personal services, or indirect compensation exceptions).

This proposed waiver would be limited to distributions of shared savings; all other financial relationships involving physicians (or their immediate family members) or entities participating in the Medicare Shared Savings Program that implicate the Physician Self-Referral Law would still need to satisfy an existing exception.

2. The Anti-Kickback Statute (Sections 1128B(b)(1) and (2) of the Act)

Under this proposal, the Secretary would waive application of the provisions of sections 1128B(b)(1) and (2) of the Act (42 U.S.C. 1320a-7b(b)(1)–(2)) with respect to the following two scenarios:

- Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.

- Any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

As with the proposed waiver of the Physician Self-Referral Law described previously, our intent with the proposal under the first bulleted paragraph would be to protect financial arrangements created by the distribution of shared savings within the ACO, as well as financial arrangements created by a distribution of shared savings outside the ACO, but only if the distribution outside the ACO is for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. We do not intend to protect distributions of shared savings dollars to referral sources outside the ACO, unless those referral sources are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. Other financial arrangements outside the ACO would need to fit in a safe harbor or otherwise comply with the anti-kickback statute.

Our intent with the proposal under the second bulleted paragraph would be to protect under the anti-kickback statute those financial relationships between and among the ACO, its ACO participants, and its ACO providers/suppliers that relate closely to the ACO's operations under section 1899 of the Act, but only if the relationship implicates the Physician Self-Referral Law and fits squarely in an exception. Ordinarily, compliance with an exception to the Physician Self-Referral Law does not operate to immunize conduct under the anti-kickback statute, and arrangements that comply with the Physician Self-Referral Law are still subject to scrutiny under the anti-kickback statute. Here, however, in light of the specific safeguards proposed to be incorporated in the Medicare Shared Savings Program, the authority under section 1899(f) of the Act for the Secretary to waive the anti-kickback statute as necessary to carry out section 1899 of

the Act, and our desire to minimize burdens on entities establishing ACOs under section 1899 of the Act, we are proposing a limited exception to the general rule.

Failure to qualify for one of the proposed waivers under the anti-kickback statute would not mean that an arrangement is automatically illegal under the anti-kickback statute. To the extent that the anti-kickback statute is implicated by a financial arrangement that is not subject to a waiver, the financial arrangement would need to comply with the law. We note that the same financial arrangement might violate the Physician Self-Referral Law and would need to be analyzed for compliance with that law.

3. Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)

Under this proposal, the Secretary would waive application of the provisions of sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a-7a(b)(1) and (2)) with respect to the following two scenarios:

● Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that--

++ The payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and

++ The hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

● Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's

participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

C. Duration of Waivers

1. Shared Savings Waivers

The waivers related to the distribution of shared savings would apply to the distributions of shared savings earned by the ACO during the term of agreement with CMS to participate in the Medicare Shared Savings Program, even if the actual distributions occur after the expiration of the agreement.

2. Anti-Kickback Statute and Gainsharing CMP Waivers for Arrangements In Compliance with a Physician Self-Referral Law Exception

The anti-kickback statute and Gainsharing CMP waivers described above in sections II.B.2. of this notice with comment period (related to the anti-kickback statute) and II.B.3. of this notice with comment period (relating to the Gainsharing CMP) for arrangements that comply with an existing Physician Self-Referral Law exception would apply during the term of the ACO's agreement with CMS to participate in the Medicare Shared Savings Program.

III. Medicare Shared Savings Program: Solicitation of Public Comments on Additional Waiver Design Considerations

We have proposed waivers in this notice with comment period that address stakeholder input with respect to shared savings distributions and treatment under the anti-kickback statute and Gainsharing CMP for certain arrangements that comply with a Physician Self-Referral Law exception. We recognize that the proposed waivers

described in section II. of this notice with comment period do not cover all of the possible financial arrangements involved with setting up and operating an ACO. Some of those arrangements may not need additional protection under the fraud and abuse laws (for example, they might fit in existing exceptions and safe harbors or might not implicate the laws), while others may need additional protection. Accordingly, we are soliciting comments regarding waivers for financial arrangements that would be necessary to carry out the provisions of the Medicare Shared Savings Program. When commenting in response to this notice with comment period, please explain how any favored waivers, modifications, or additions would be necessary to carry out the provisions of the Medicare Shared Savings Program and why the financial arrangements at issue would not qualify for existing safe harbors or exceptions.

We have received significant public input suggesting that we consider promulgating waivers for ACOs in the Medicare Shared Savings Program that would apply more broadly than our proposals in section II. of this notice with comment period. Accordingly, we are soliciting comments on the topics that follow. Our current view is that we would grant waivers that would apply uniformly to all ACOs, ACO participants, and ACO providers/suppliers participating in the Medicare Shared Savings Program.

Our goal is ultimately to use our waiver authority to support beneficial ACO development under the Medicare Shared Savings Program, while still protecting patients and programs from harms caused by fraud and abuse. Striking this balance is both critically important and particularly challenging in the context of the Medicare Shared Savings Program. This is because providers and suppliers will continue to be paid on a fee-for-service basis, even under the two-sided risk model. We welcome comments on

how best to balance these interests.

The topics on which we seek comment are described in the paragraphs that follow. We note that certain comments will be relevant to multiple topics; we will consider comments even when they combine several of the following topics:

● Arrangements related to establishing the ACO. We are interested in comments addressing whether it is necessary to waive the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP for remuneration, directly related to: (1) forming the ACO; (2) implementing the governance and administrative requirements applicable to the ACO under the final regulations for the Medicare Shared Savings Program; or (3) building technological or administrative capacity (including providing training) needed to achieve the Medicare Shared Savings Program cost and quality goals. For purposes of this paragraph, we are interested in comments addressing remuneration in the form of payments used to finance actual investment or startup expenses, as well as nonmonetary benefits transferred for the purpose of establishing the ACO. We also seek public comment on the exact type of expenses and corresponding financial arrangements that might be covered by a waiver for arrangements involving initial investments or startup expenses, and the period of time during which an investment or payment would be considered an "initial" investment or "startup" expenditure. We also seek comments on any safeguards that could be incorporated to protect patients or Federal health care programs from fraud and abuse. For example, we seek comments on whether protected remuneration should be required to be commercially reasonable.

● Arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals.

We are interested in comments addressing whether the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should be waived for financial arrangements (other than those created by distributions of shared savings, as described in section II. of this notice with comment period) between or among ACO participants and/or ACO providers/suppliers that are: (1) necessary for and directly related to operating the ACO; or (2) necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the Medicare Shared Savings Program. If such a waiver is favored, we request public comments on the types of financial arrangements that should be covered by a waiver and whether these financial arrangements should be required to be commercially reasonable and reflect fair market value.

- Arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities. We are interested in comments addressing whether the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should be waived for financial arrangements (other than those created by distributions of shared savings, as described in section II. of this notice with comment period) between the ACO, its ACO participants, and/or its ACO providers/suppliers and entities or individuals outside the ACO, where the financial arrangements are: (1) necessary for and directly related to establishing the ACO; or (2) necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the Medicare Shared Savings Program. We seek particular input on how this could be done while minimizing the potential for fraud and abuse (including whether these financial arrangements should be required to be commercially reasonable and reflect fair market value).

- Distributions of shared savings or similar payments received from private payers. We are interested in comments addressing whether a waiver is necessary to address distributions of shared savings payments received by the ACO from a private payer. We are seeking comments on this topic because ACOs under the Medicare Shared Savings Program may also operate under private payer contracts. Some stakeholders have expressed concern that payments under private payer contracts might implicate the fraud and abuse laws where the payments flow between parties that also have referral relationships with respect to Federal health care program patients. We solicit comments on the advisability of a waiver in this context, the scope and design of such a waiver, and whether any specific conditions are needed or should be imposed to prevent fraud and abuse.

- Other financial arrangements for which a waiver would be necessary. We are interested in comments addressing whether there are financial arrangements not addressed in the above topics for which waivers of the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should apply. Specifically, we seek comments describing specific financial arrangements (or combinations of arrangements), why they would be necessary for and directly related to the operations of ACOs under the Medicare Shared Savings Program, why no current exception or safe harbor would apply, and any applicable conditions or safeguards that should apply if a waiver were to be granted.

- Duration of waivers. We are interested in views on the duration of any waivers. Except as noted in section II. of this notice with comment period with respect to shared savings distributions, we currently expect that waivers would apply during the

term of an ACO's agreement with CMS under the Medicare Shared Savings Program, and that waivers would cease to apply if the agreement is terminated before the end of the term. We solicit comments on this or other approaches.

- Additional safeguards. We seek comments addressing any additional safeguards that might be necessary for and effective to protect patients and the Federal health care programs. We have premised our proposed waivers on the fact that ACOs, ACO participants, and ACO providers/suppliers under the Medicare Shared Savings Program will be required to comply with all applicable rules and regulations governing the program, including, for example, all monitoring, transparency, marketing, and quality requirements. We are interested in public comments addressing the sufficiency of these protections for purposes of fraud and abuse law waivers.

- Scope of proposed waivers in section II. of this notice with comment period. We seek comments addressing the scope of the waivers described in section II. of this notice with comment period. In particular, we are interested in comments as to whether the proposed waivers are too broad or too narrow, and, if so, how such over- or under-breadth might best be addressed. In addition, in section II.B. of this notice with comment period, we propose that the Physician Self-Referral Law, anti-kickback statute, and Gainsharing CMP be waived in circumstances where certain activities are "necessary for and directly related to" the ACO's participation in and operations under the Medicare Shared Savings Program. We seek comments on this standard, as well as comments recommending other standards that might be used to ensure that a waiver of the fraud and abuse laws is limited to ACO purposes. We are interested in examples of how this standard might apply to specific arrangements contemplated by ACOs, either to include

or exclude the arrangements from the protection of a waiver. For example, we do not intend to extend waiver protections to ACO participants or ACO providers/suppliers that have independent financial arrangements with potential referral sources that are unrelated to the ACO, its operations, or the Medicare Shared Savings Program.

- Two-sided risk model. The Medicare Shared Savings Program proposed rule contemplates that all ACOs will eventually participate in a two-sided risk model pursuant to which the ACO would assume financial risk if costs for its aligned beneficiaries exceed certain thresholds. As currently proposed, CMS would not require the ACO to put its ACO participants or ACO providers/suppliers at risk for cost overages. However, CMS would permit ACOs to place some or all ACO participants and/or ACO providers/suppliers at risk. We are interested in comments addressing whether additional or different fraud and abuse waivers might be appropriate for ACOs participating in the two-sided risk model. We are particularly interested in comments on the relative risk of overutilization or increased program costs (and, conversely, the risk of underutilization or stinting) arising from the downside risk feature of the two tracks being proposed for the Medicare Shared Savings Program and whether the relative risk should impact the scope of the waiver. In addition, we seek comments on whether different waivers would be necessary for and appropriate in circumstances where ACO participants and/or ACO providers/suppliers may individually bear risk for the cost of items and services furnished to ACO beneficiaries. For example, we are interested in whether such waivers should extend only to compensation that places referring parties at risk for achieving the quality and performance metrics under the Medicare Shared Savings Program. Similarly, we are interested in comments addressing whether any additional financial arrangements arising

in connection with the downside risk (for example, escrow accounts, surety bonds, and letters of credit) necessitate waiver protection and, if so, under what circumstances.

- Use of existing exception and safe harbor for electronic health records arrangements. We are interested in comments addressing whether we should waive the Physician Self-Referral Law and anti-kickback statute for ACO arrangements that satisfy the existing exception and safe harbor for electronic health records arrangements (42 CFR 411.357(w) and 42 CFR 1001.952(y)), but that are expected to occur after the sunset date of 2013 currently applicable to that exception and safe harbor.

- Beneficiary inducements. We seek comments addressing whether and under what circumstances it would be necessary for the Secretary to waive, in whole or in part, the provisions of section 1128A(a)(5) of the Act (the prohibition on inducements offered to Medicare and Medicaid beneficiaries) in connection with the Medicare Shared Savings Program. Specifically, we seek comments describing arrangements (or combinations of arrangements) that would require protection, why those arrangements would be necessary to carry out the provisions of the Medicare Shared Savings Program, and any applicable conditions or safeguards that should apply if a waiver were to be granted to ensure that beneficiaries are not inappropriately induced to obtain services from ACO participants or ACO providers/suppliers.

- Timing of waivers. We seek comments addressing whether final waivers should be published contemporaneously with, in advance of, or soon after final rule regarding the Medicare Shared Savings Program.

IV. Center for Medicare and Medicaid Innovation: Solicitation of Public Comments on Waiver Design Considerations

Section 1115A of the Act establishes within CMS the Center for Medicare and Medicaid Innovation (Innovation Center) “to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles.” In selecting models, the Secretary is directed to prefer models that also improve coordination, quality, and efficiency of health care services furnished to Medicare, Medicaid, and dually eligible individuals. In relevant part for purposes of this notice, section 1115A(d)(1) of the Act provides that the Secretary “may waive such requirements of Title XI and XVIII . . . as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).” This waiver authority is specific to activities carried out under section 1115A of the Act and, like the waiver authority under section 1899(f) of the Act, does not address other arrangements. At this time, we are interested in public comments on the separate waiver authority at section 1115A(d)(1) of the Act and how we might best exercise it to address demonstrations and pilot programs under section 1115A of the Act.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this document.

CMS-1345-NC2

Authority: Sections 1899 and 1115A of the Act.

Dated: <u>**March 24, 2011**</u>

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Donald M. Berwick,

<u>Administrator,</u>

<u>Centers for Medicare & Medicaid</u>

<u>Services</u>

Dated: **<u>March 28, 2011</u>**

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Daniel R. Levinson,

<u>Inspector General</u>

BILLING CODE: 4120-01-P and 4152-01

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