



# FEDERAL REGISTER

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Vol. 76

Wednesday,

No. 212

November 2, 2011

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## Part III

### Department of Health and Human Services

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Centers for Medicare & Medicaid Services

42 CFR Chapter IV

Office of the Inspector General

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42 CFR Chapter V

Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Chapter IV****Office of Inspector General****42 CFR Chapter V****[CMS-1439-IFC]****RIN 0938-AR30****Medicare Program; Final Waivers in Connection With the Shared Savings Program**

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

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period establishes 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 arrangements involving accountable care organizations (ACOs) under section 1899 of the Social Security Act (the Act) (the Shared Savings Program), including ACOs participating in the Advance Payment Initiative. Section 1899(f) of the Act, as added by the Affordable Care Act, authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act.

**DATES:** *Effective date:* These regulations are effective on November 2, 2011.

*Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2012. 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 here, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**ADDRESSES:** In commenting, please refer to file code CMS-1439-IFC. 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)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *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-1439-IFC, 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.

3. *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-1439-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1813.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

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, call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

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

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

**FOR FURTHER INFORMATION CONTACT:**

Neal Shah (410) 786-1167 or Kristin Bohl (410) 786-8680, 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 Federal 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 be also 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. Introduction and Overview**

Section I. of this interim final rule with comment period (IFC) provides an introduction and overview of this rule. Section II. of this IFC provides background on the Shared Savings Program. Section III. of this IFC summarizes public comments received in response to the Waiver Designs Notice and Shared Savings Program proposed rule (as those terms are defined below). Section IV. of this IFC sets out the waivers and applicable requirements. Section V. of this IFC explains the waivers and solicits comments on specific ways we might modify the waivers to address fraud and abuse or other problems that may arise.

**A. Connection Between Shared Savings Program and Fraud and Abuse Waivers**

Elsewhere in this issue of the **Federal Register**, the Centers for Medicare & Medicaid Services (CMS) published a final rulemaking setting forth the requirements for ACOs under the Shared Savings Program (hereinafter referred to as the "Shared Savings Program final rule"). 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") describes the Shared Savings Program as a Medicare program to promote accountability for a Medicare 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 Shared Savings Program final rule, the Shared Savings Program is designed to achieve three goals: Better health for populations, better care for individuals, and lower growth in expenditures. CMS's expectation is that Shared Savings Program accountable care organizations (ACO)<sup>1</sup> 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 Federal anti-kickback statute, and the civil monetary penalties (CMP) law provisions addressing inducements to beneficiaries and hospital payments to physicians to reduce or limit services, described in greater detail elsewhere in this IFC, are some of the important tools used 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 arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the 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 Shared Savings Program. Based on stakeholder input and other factors, the Secretary has found that it is necessary to waive these fraud and abuse laws in order to carry out the Shared Savings Program.

Accordingly, this IFC sets forth waivers of certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the CMP law prohibiting hospital payments to physicians to reduce or limit services (the Gainsharing CMP), and the CMP law prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP) as necessary to carry out the provisions of section 1899 of the Act. We seek to waive application of these fraud and abuse laws to ACOs formed in connection with the Shared Savings Program 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.

The waivers set forth in this IFC are promulgated pursuant to the specific authority at section 1899(f) of the Act. This authority applies only to the Shared Savings Program and to all ACOs participating in the Shared Savings Program. This includes those Shared Savings Program ACOs that are also participating in the Advance Payment Initiative to be administered by the Center for Medicare & Medicaid Innovation (Innovation Center). The Affordable Care Act includes separate authority for the Secretary to waive fraud and abuse laws for certain other demonstrations and pilot programs. Guidance regarding such waivers will be issued separately.

#### *B. Overview of Final Waivers*

On April 7, 2011, CMS and OIG jointly published a notice with comment period seeking public comment on certain proposed waivers and other waiver design considerations (Waiver Designs in Connection with the Shared Savings Program and the Innovation Center (76 FR 19655)) (hereinafter referred to as the "Waiver Designs Notice"). In that same issue of the **Federal Register**, CMS published a proposed rulemaking setting forth proposed requirements for ACOs under the Shared Savings Program (Shared Savings Program: Accountable Care Organizations (76 FR 19528)) (hereinafter referred to as the "Shared Savings Program proposed rule") and soliciting public comments.

CMS and OIG are jointly establishing waivers under this IFC to provide stakeholders with a coordinated approach to the waivers of fraud and abuse laws in connection with the Shared Savings Program. Administration of the Physician Self-Referral Law is the responsibility of CMS; the OIG is responsible for enforcement of the CMP provisions under the Physician Self-Referral Law. OIG shares responsibility for the Federal anti-kickback statute with the Department of Justice. The Gainsharing CMP and Beneficiary Inducements CMP are administered by the OIG.

For reasons elaborated in more detail elsewhere in this IFC, the Secretary has determined, based on consideration of public input and the Department's own analysis, that it is necessary to waive certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP in some

circumstances to carry out the Shared Savings Program.

Section IV. of this IFC sets out the specific waivers and the conditions pertaining to them. Section V. of this IFC provides commentary explaining the waivers and solicits comments on possible modifications. There are five waivers addressing different circumstances—

- An "ACO pre-participation" waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered;

- An "ACO participation" waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program and for a specified time thereafter;

- A "shared savings distributions" waiver of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing CMP that applies to distributions and uses of shared savings payments earned under the Shared Savings Program;

- A "compliance with the Physician Self-Referral Law" waiver of the Gainsharing CMP and the Federal anti-kickback statute for ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception; and

- A "patient incentive" waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

These waivers include the two waivers proposed in the Waiver Designs Notice (the shared savings distributions waiver and the compliance with the Physician Self-Referral Law waiver), as well as three new waivers developed in response to public comments seeking additional pathways to address a broader array of ACO activities needed to achieve the purposes of the Shared Savings Program. These five waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start-up and operating activities that further the purposes of the Shared Savings Program. These waivers incorporate conditions that, in combination with

<sup>1</sup> For purposes of this IFC, the terms "ACO," "ACO participants," and "ACO providers/suppliers" have the meanings ascribed to them in 42 CFR 425.20.

additional safeguards in the Shared Savings Program final rule, are intended to protect Medicare beneficiaries and the Medicare program from fraud and abuse while furthering the quality, economy, and efficiency goals of the Shared Savings Program.

An arrangement need only fit in one waiver to be protected; parties seeking to ensure that an arrangement is covered by a waiver for a particular law may look to any waiver that applies to that law. In some cases, an arrangement may meet the criteria of more than one waiver.

## II. Shared Savings Program: Background

### A. Section 1899 of the Social Security Act

Section 1899 of the Act establishes the Shared Savings Program to encourage the development of ACOs in Medicare. The Shared Savings Program is one of the first initiatives 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. Redesigned care processes may improve care, increase efficiency, and lower costs for Medicare and other patients served by the ACO.

In accordance with the Shared Savings Program final rule, ACOs will enter into a participation agreement with the Secretary to participate in the Shared Savings Program for no less than a 3-year period under one of two tracks. Under the first track, an ACO will have the opportunity to share in savings generated during the agreement. Under the second track, ACOs will operate under a “two-sided risk” model in which they will be eligible to receive a higher share of savings, but will also be required to repay a portion of the losses sustained by the Medicare program if costs for the ACO’s assigned beneficiaries exceed certain thresholds. 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 Shared Savings Program. ACO participants and ACO

providers/suppliers will continue to receive fee-for-service payments, and, under the Shared Savings Program, the ACO legal entity may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers. ACOs in the Shared Savings Program must also comply with requirements addressing governance, management, and leadership of the ACO, as well as program integrity, transparency, compliance plan, and certification requirements, among others.

### B. 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 Shared Savings Program, and does not apply to 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 accountable care organizations, integrated-care delivery models, or arrangements at a later date. As explained in section V. of this IFC, any waivers for Innovation Center demonstration programs, apart from the Advance Payment Initiative, will be issued separately under the relevant authority.

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. Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Physician Self-Referral Law, the Federal anti-kickback statute, and the CMP laws. Failure to fit in a waiver is not, in and of itself, a violation of the laws. Existing exceptions and safe harbors might apply to ACO arrangements, depending on the circumstances.<sup>2</sup> These include, among others, Physician Self-Referral Law exceptions for employment, personal services arrangements, in-office ancillary services, electronic health records (EHR) arrangements, risk-sharing, and indirect compensation arrangements (to the extent an ACO arrangement is an indirect financial

relationship). Potential Federal anti-kickback statute safe harbors include, among others, those for employment, personal services and management contracts, EHR arrangements, and managed care arrangements.

The waiver authority under section 1899(f) is limited to sections 1128A and 1128B and title XVIII of the Act, and does not extend to any other laws or regulations, including, without limitation, the Internal Revenue Code (IRC) or State laws and regulations. Accordingly, nothing in this IFC affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the IRC or other Federal or State laws and regulations. Moreover, nothing in this IFC changes any Medicare program reimbursement or coverage rule or alters any obligations parties may have under the Shared Savings Program. Although the waivers described in this IFC are necessary to ensure that the fraud and abuse laws do not unduly impede development of ACOs in connection with the Shared Savings Program, the waivers are not intended to suggest that any particular arrangement between particular parties is necessary to implementing the Shared Savings Program.

### C. 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 a designated health service that is furnished pursuant to a prohibited referral. CMPs 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 Physician Self-Referral Law may also result in liability under the False Claims Act (31 U.S.C. 3729–33).

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

Section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b), the “Federal anti-kickback statute”) provides criminal penalties for

<sup>2</sup> 42 CFR 411.355 through 411.357; 42 CFR 1001.952; 42 CFR 1003.110.

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 Federal 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 safe harbor at 42 CFR 1001.952 are not subject to prosecution or sanctions under the Federal anti-kickback statute.

### 3. Prohibition on Inducements to Beneficiaries (Section 1128A(a)(5) of the Act)

Section 1128A(a)(5) of the Act (42 U.S.C. 1320a–7a(a)(5)), the “Beneficiary Inducements CMP”) prohibits individuals and entities from offering or transferring remuneration to Medicare or Medicaid beneficiaries that the individual or entity knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any Medicare or Medicaid item or service. There are existing exceptions to the Beneficiary Inducements CMP at section 1128A(i)(6) of the Act.

### 4. 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 (42 U.S.C. 1320a–7a(b)(1) and (2)), 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).

### D. Summary of Public Input Opportunities

Since 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 Shared Savings Program, most recently through the Waiver Designs Notice described previously in this IFC. In addition, CMS issued a Request for Information Regarding Accountable Care Organizations and the Shared Saving Program on November 10, 2010,<sup>3</sup> 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.”<sup>4</sup> We also received and reviewed written public comments in connection with the workshop.<sup>5</sup> Finally, we received public comments related to the waivers in response to the Waiver Designs Notice and the Shared Savings Program proposed rule. Through these means, DHHS has received public input representing a wide spectrum of views.

### E. Contents of Waiver Designs Notice

The Waiver Designs Notice proposed several waivers related to ACOs in the Shared Savings Program and also solicited public comments on a range of issues. The proposed waivers included waivers of certain provisions of the Physician Self-Referral Law and the Federal anti-kickback statute 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 Shared Savings Program. We also proposed to waive certain provisions of the Federal anti-kickback statute with respect to 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.

We also proposed to waive certain provisions of the Gainsharing CMP with respect to two scenarios: (1) 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; and (2) 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.

The Waiver Designs Notice recognized that the proposed waivers might not cover all of the possible arrangements involved with setting up and operating an ACO. As such, we solicited comments on waivers, modifications, or additions that would be necessary to carry out the provisions of the Shared Savings Program. We specifically solicited comments on how waivers should address: arrangements related to establishing the ACO; arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals; other arrangements for which a waiver would be necessary; the duration of the waivers; and the scope of the waivers.

### III. Summary of Public Comments to the Waiver Designs Notice and Relevant Sections of the Shared Savings Program Proposed Rule

We received comments related to the proposed waivers and solicitation of comments on other waiver design considerations in response to both the Waiver Designs Notice and the Shared Savings Program proposed rule. We summarize the comments in this section of the IFC. Section V. of this IFC explains the waivers in more detail and responds to comments.

#### A. Threshold Qualifications for Waiver

Commenters requested that we clarify whether we will be issuing waivers that are uniform across all ACOs

<sup>3</sup> 75 FR 70165 (2010).

<sup>4</sup> Information about the workshop is available on CMS’s Web site at <http://www.cms.gov/center/physician.asp>.

<sup>5</sup> The public comments are available on the FTC’s Web site at <http://www.ftc.gov/os/comments/aco/index.shtml>.

participating in the Shared Savings Program. At least one commenter recommended that we retain some provision for individualized review while others requested that waivers apply uniformly to all participants.

#### *B. Scope of Proposed Waivers*

We received numerous comments about the appropriate scope of the waivers. The great majority of commenters supported broader waivers. Many of those commenters indicated that the proposed waivers would be insufficient to foster the innovation and relationships necessary for participation in the Shared Savings Program. However, some commenters expressed concern that the proposed waivers were too broad, or that expanded waivers could lead to program abuses.

##### 1. General Issues

Many commenters stated that the applicable fraud and abuse laws should be waived in their entirety for ACOs participating in the Shared Savings Program because, according to the commenters, the laws are premised on a “fee-for-service” world that has different incentives than those that apply to the Shared Savings Program and because the Shared Savings Program incorporates monitoring, reporting, and other program features that will act as safeguards. These commenters stated that DHHS should waive these laws for entities that successfully enter and participate in the Shared Savings Program, such that the entities would be shielded from penalties for transactions related to ACO business. Many commenters stated that certain elements of the Physician Self-Referral Law exceptions and Federal anti-kickback statute safe harbors cannot sufficiently support the development of innovative ACO structures. For example, these commenters identified the “transaction-by-transaction” structure of the existing exceptions and safe harbors and the “fair market value” or “set in advance” elements of many of them as specific burdens.

Several commenters stated that the fraud and abuse laws should be waived for payments between ACOs enrolled in the Shared Savings Program, their ACO participants, and/or their ACO providers/suppliers, regardless of the source of funding for the payments. Some commenters asserted that the Shared Savings Program’s standards for clinical integration should justify protection for payments other than shared savings distributions, if the payments are made in service of achieving Shared Savings Program goals. Others were concerned that the

continued use of fee-for-service payments in the program created an incentive for overutilization.

The majority of comments generally suggested one of two broad approaches to waiving the laws: First, an “ACO waiver” establishing broad protections for ACO functions, or second, a total waiver of the laws for any ACO participating in the Shared Savings Program. Many commenters called for the agencies to create an “ACO waiver” that would cover ACO activities through the lifespan of an ACO, from arrangements leading up to formation of the ACO, through the end of the ACO’s participation in the program. Other commenters advocated the creation of a “single, comprehensive approach” for compliance, rather than requiring a piecemeal transaction-by-transaction analysis. Some commenters requested “blanket” waivers for certain categories of remuneration, including non-monetary arrangements (such as IT services, EHR systems, and the provision of free care management personnel and/or services) and “systems-level” activities (such as medical directorships or infection prevention/antimicrobial stewardship programs).

In contrast, a minority of commenters favored waivers no broader or narrower than the proposed waivers. Some of these commenters advocated alternate safeguards (discussed later in this IFC), waivers conditioned on certain qualitative limits, and more extensive monitoring (including monitoring of beneficiary access to care and cost-shifting to private insurers). Although some commenters were concerned about an overly broad waiver and cautioned against expanding beyond the proposed waiver designs, the majority of commenters believed the proposed waiver for shared savings distributions would be too narrow, particularly because an ACO, its ACO participants, and its ACO providers/suppliers will not have access to the shared savings distributions until long after the ACO has entered into its participation agreement, thus precluding use of those savings to fund start-up and operating activities.

Some commenters raised issues related to specific scenarios. For example, a commenter requested that ACOs with “commercial motives” be treated differently than ACOs composed of “public health providers” because, according to the commenter, the latter do not give rise to similar fraud and abuse concerns. Other commenters stated that the fraud and abuse laws presented a particular challenge for

prospective ACOs in States with “corporate practice of medicine” laws because providers and suppliers could not satisfy certain important exceptions and safe harbors (including the employment exception and safe harbor) in those States.

We also received requests for clarification about the proposed waivers. Several commenters requested clarification about how the fraud and abuse laws would interact with specific Shared Savings Program rules. For example, one commenter expressed concern about the phrase “distributions of shared savings,” and asked the agencies to clarify whether a payment from an ACO to its ACO participants or its ACO providers/suppliers must be conditioned on the same quality and cost terms that govern the ACO’s participation agreement (or whether it would be sufficient that the payment initially comes from shared savings). We also received a number of comments on the proposed “necessary for and directly related to” standard. Commenters overwhelmingly requested that we clarify this phrase, arguing it was too restrictive and thus did not provide sufficient assurance that ACOs could participate in the Shared Savings Program. Some commenters believed the standard was overly broad, with one expressing concern that the standard could allow arrangements that would eliminate competition. Some commenters requested concrete examples of relationships that would meet this standard, while others requested that the agencies allow greater flexibility. Commenters also suggested a range of different standards, including, for example, mandating that relationships simply be “related” or “directly related” to the ACO, making the standard subjective, or requiring payments to entities outside the ACO to be linked to quality improvement goals. Finally, some commenters stated that it would be difficult to isolate arrangements that are “necessary for and directly related to” the ACO because many arrangements will only be feasible if applied to all payers and/or patients.

Some commenters also raised questions about how the waivers would function practically. For example, one commenter asked whether all ACO participants or ACO providers/suppliers would endanger their Medicare fee-for-service payments if the ACO (or one of its ACO participants or ACO providers/suppliers) fails to satisfy one of the qualifications of the waiver. We also received many requests for clarification of the scope of the waiver for shared savings distributions. For example,

some commenters asked us to confirm that downstream distributions would be covered by the waiver, while others asked us to clarify whether repayment of start-up costs out of shared savings would be considered “necessary for and directly related to” the ACO’s participation in the program.

## 2. Compliance With the Physician Self-Referral Law Waiver

We received several comments asking for clarification of the proposed waiver of the Federal anti-kickback statute and Gainsharing CMP for financial relationships 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 Shared Savings Program that implicate the Physician Self-Referral Law and fully comply with an existing exception at 42 CFR 411.355 through 411.357. Several commenters requested expansion of this waiver to cover relationships that would not implicate the Physician Self-Referral Law either because the relationship would not involve designated health services or would not involve referring physicians covered by the Physician Self-Referral Law. While commenters on this topic generally welcomed the alignment of the Federal anti-kickback statute, the Gainsharing CMP, and the Physician Self-Referral Law for ACO arrangements, some expressed concern that the proposed waiver design was too limited to promote many innovative ACO arrangements.

## 3. Gainsharing CMP

Some commenters requested clarification of the application of the waiver of the Gainsharing CMP. For example, some commenters asked us to confirm that distributions of shared savings made from the ACO to a physician would be protected, even if the ACO is owned in part by a hospital. Some commenters urged us to adopt a narrow waiver of the Gainsharing CMP and to carefully monitor ACOs to ensure that the waiver does not lead to a reduction or limitation of medically necessary services. Many commenters requested additional clarification of the “medically necessary” standard that limited application of the proposed waiver of the Gainsharing CMP to arrangements that do not reduce medically necessary care. Several commenters asked us to clarify or confirm whether reliance on evidence-based protocols would be sufficient to meet the “medically necessary” standard. Several commenters noted that successful ACOs may reduce some

types of medically necessary services by encouraging the use or ordering of alternative medically necessary services, for example, arrangements that incentivize reductions in emergency room visits by encouraging management of conditions on a non-emergency basis or arrangements that reduce inpatient admissions in favor of coordinated outpatient care. A commenter urged us to permit financial rewards that incent implementation of evidence-based treatment protocols, even though such payments may be intended to encourage clinicians to select one type of medically necessary service over another.

## C. Duration of Waivers

Commenters generally objected to the proposed requirement that the waivers would apply only so long as an ACO, its ACO participants, and its ACO providers/suppliers remained in compliance with Shared Savings Program requirements. Some commenters requested that this requirement be eliminated and replaced by a simpler threshold for waiver qualification, asserting that the auditing and oversight functions at the outset of and during the Shared Savings Program are sufficient to protect against fraud and abuse.

Many commenters requested that the waivers cover periods prior to an ACO’s acceptance into the Shared Savings Program. Some of these commenters also expressed a desire that the waivers cover time periods after the ACO, its ACO participants, and its ACO providers/suppliers have left the Shared Savings Program, for purposes of winding down the arrangement or otherwise ensuring continued compliance with the laws. One commenter suggested that the waivers cover a period of at least 24 months prior to the start of any agreement with CMS, with no possibility of retroactive enforcement, in order to avoid a chilling effect on innovation. Other commenters suggested that the agencies apply the waivers to payments whenever made, if the payments relate to activities leading up to or occurring within the agreement period.

## D. Additional Waiver Design Considerations

### 1. Start-Up Costs

Many commenters stated that the fraud and abuse laws should be waived in a manner that allows participants to finance others’ start-up costs. As examples, commenters identified: Infrastructure creation and provision prior to acceptance in the Shared

Savings Program (for example, care coordination mechanisms; EHR systems; data reporting systems; new staff; and systems to make operational performance measurements and allocate performance results and payments accordingly); market analysis for antitrust purposes; potential novel arrangements created to facilitate integration across multiple organizations; organizational and training costs; incentives to attract primary care physicians; and any loans, capital contributions, grants and withholdings.

Some commenters suggested that waivers covering start-up costs should be limited to providers that have a financial stake in the success of the ACO, or, absent this requirement, that any waiver should be limited to distributions of shared savings only.

## 2. Other Arrangements Among the ACO, Its ACO Participants, and Its ACO Providers/Suppliers

Most commenters on this topic stated that waivers should cover arrangements (in addition to those arising out of shared savings) among the ACO, its ACO participants, and its ACO providers/suppliers. One commenter recommended that the waivers not apply to additional arrangements unless the arrangements are necessary for or directly related to the ACO’s operations under the Shared Savings Program. But the majority of commenters, supporting a broader approach to waivers, explained that waivers for other arrangements are necessary to allow for start-up, operating, and maintenance costs in the context of innovative arrangements. These commenters had various suggestions about how the laws should be waived. As noted previously, many commenters suggested that the fraud and abuse laws should be waived broadly for ACOs in the Shared Savings Program. Others suggested that the laws should be waived for compensation that is expressly conditioned on quality improvements, cost savings, or adherence to objective clinical measures, care coordination guidelines, and/or treatment models. Others suggested that waivers should cover payments that are made in connection with the operations and goals of the ACO and are commercially reasonable. Some commenters asked us to consider situations in which ACOs do not generate shared savings immediately, if at all, and pointed to the Medicare Physician Group Practice demonstration project as an example. One commenter proposed that the waiver should cover hospitals that share the proceeds of system-wide savings they achieve

outside the context of the Shared Savings Program or some other formal payer-organized shared savings program.

### 3. Other Arrangements With Parties Outside the ACO

Some commenters asked us to clarify the term “outside individuals and entities” as that term was used in the solicitation of comments on this issue. For example, commenters asked whether the waivers would cover arrangements with physicians and other providers who are not ACO participants or ACO providers/suppliers but who treat ACO patients and voluntarily comply with the ACO’s policies and procedures.

Many commenters appreciated the proposed waiver for arrangements with parties outside the ACO that are funded with distributions of shared savings. However, many commenters requested that we expand the waiver to cover arrangements with individuals or entities outside the ACO even if the payments are not derived from shared savings. Some commenters suggested that covered arrangements be restricted to those that meet articulated standards (for example, only arrangements arising out of the distribution of shared savings should be waived) and that CMS monitor referrals to ensure that non-ACO participants and non-ACO providers/suppliers are not being unfairly marginalized.

### 4. Relationships With Private Payers/ Other Payers

Many commenters stated that the agencies should waive the fraud and abuse laws for arrangements involving payments from private payers to ACOs, including “downstream” arrangements between or among the ACO, ACO participants, and ACO providers/suppliers. These commenters generally believed that limiting the waiver to arrangements involving Medicare shared savings would limit economies of scale and introduce significant complexity from the perspective of governance and management. One commenter argued that the involvement of private health plans in ACO relationships would reduce fraud and abuse concerns. Some commenters expressed concern that failure to address private payer arrangements would perpetuate uncertainty for ACOs enrolling in the Shared Savings Program that were also contemplating similar arrangements with private payers. These commenters observed that arrangements downstream of private payer incentive payment programs can be sensitive to the volume or value of “other business

generated” for providers and suppliers and thus might not fit in existing exceptions to the Physician Self-Referral Law. One commenter representing health plans expressed concern about ACO arrangements under the Shared Savings Program that might result in cost-shifting to private plans or steering of patients to or from Medicare managed care plans based on the services required by the patient. Some commenters stated that we should not create waivers for private payer arrangements.

Some commenters suggested that, if the final waivers do not cover relationships with private payers, the agencies should clarify how elements of existing exceptions and safe harbors may be applied to such arrangements involving ACOs. For example, commenters requested further clarification on the following: whether hospital distribution of a private payer’s shared savings payments would constitute “indirect compensation” under the Physician Self-Referral Law; how to calculate “fair market value” of downstream distributions of private payer shared savings for purposes of applicable exceptions; and whether the Physician Self-Referral Law risk-sharing exception could be used. Finally, one commenter requested that the agencies integrate guidance for private payers with guidance for other non-Medicare payers, including Medicaid.

### 5. Appropriate Safeguards

Some commenters stated that safeguards beyond the transparency, accountability, and oversight protections built into the Shared Savings Program proposed rule are unnecessary because such safeguards adequately address patient and program abuse. A commenter stated that providing opportunities for creativity without waiver-specific, restrictive safeguards will not increase the likelihood that individuals or organizations will place their own financial interests above those of their patients; instead, it will allow them to focus on furnishing appropriate and necessary care coordination. A commenter suggested that safeguards be based on prior OIG advisory opinions or the CMS proposed incentive payment and shared savings exception.

Other commenters believed that additional safeguards are necessary and suggested, for example, requiring arrangements to meet a fair market value or commercial reasonableness standard; requiring additional disclosures to CMS and to patients; or imposing more specific requirements related to methods for distributing shared savings

to address the commenters’ concerns about distributions inappropriately influencing physician ordering patterns or possible stinting on care.

A commenter stated that the waiver for shared savings distributions should not protect distributions of shared savings from an ACO to an ACO participant on the basis of that ACO participant’s generation of other business for another ACO participant. Some commenters suggested monitoring of referrals outside the ACO to detect improper referral patterns. One commenter requested that CMS create a system to continually assess the compliance of an ACO, its ACO participants, and its ACO providers/suppliers with the fraud and abuse laws.

### 6. Two-Sided Risk

We received several comments in response to our solicitation on waiver considerations related to two-sided risk. One commenter noted that a waiver should apply equally to both one- and two-sided risk models. Other commenters recommended that CMS either extend the proposed waiver to cover hospitals’ disproportionate assumption of risk or change the Shared Savings Program proposed rule to make the two-sided option voluntary or make it clear that such assumption of risk is not remuneration under the Physician Self-Referral Law. Commenters asked that we protect the means or allocation of shared savings and losses, and that we define the “proper” allocation of such savings or losses.

### 7. Existing Exception and Safe Harbor for Electronic Health Records

We sought comments in the Waiver Designs Notice addressing whether, in connection with the Shared Savings Program, we should use the authority at section 1899(f) of the Act to waive the Physician Self-Referral Law and the Federal anti-kickback statute for ACO arrangements that satisfy the existing exception and safe harbor<sup>6</sup> for EHR arrangements but that are expected to occur after the sunset date of 2013. Some commenters requested that the agencies waive the current sunset date of 2013 that applies to the existing EHR exception and safe harbor, and suggested that the agencies protect the EHR arrangements of ACOs in the Medicare Shared Savings Program after 2013 on the same terms as the existing exception and safe harbor. Some commenters particularly argued that the Shared Savings Program proposed rule’s standard of 50 percent meaningful use

<sup>6</sup> 42 CFR 411.357(w) and 42 CFR 1001.952(y), respectively.



of EHRs demonstrated the need to extend the waiver to relationships intended to reach that standard.

One commenter disagreed with waiving the EHR exception and safe harbor and suggested rescinding the exception and safe harbor or specifically excluding these types of arrangements from the waiver, because the EHR incentive in American Recovery and Reinvestment Act of 2009 was sufficient to achieve the exception's and safe harbor's original purpose of promoting adoption of technology. However, most commenters addressing this topic requested that we make the exception and safe harbor permanent, extend them for several years, or protect ACOs at any time after the sunset on the same terms as the exception and safe harbor.

#### 8. Beneficiary Inducements

Most commenters addressing this topic supported a waiver of the Beneficiary Inducements CMP, section 1128A(a)(5) of the Act, although some of them expressed opposition. Among commenters supporting a waiver, many cited the need for a waiver to promote greater preventive care, to incentivize patients to follow treatment or follow-up care regimes, and to increase participation in ACOs in order to achieve the goals of the Shared Savings Program. Several supporters of a waiver suggested that the waiver cover reduced or eliminated beneficiary cost-sharing, or other financial incentives, such as allowing beneficiaries to share in ACO cost savings. Commenters opposing a Beneficiary Inducements CMP waiver stated it could negatively impact patient choice by promoting incentives that might induce beneficiaries to seek care only within a particular ACO.

#### 9. Timing of Waivers

Generally, commenters supported issuance of the waivers prior to or at the same time as the Shared Savings Program final rule in order to afford prospective ACOs, their ACO participants, and ACO providers/suppliers as much time as possible to prepare for application to the Shared Savings Program with known waiver protection.

#### 10. Other Issues Related to Shared Savings Program Waivers

Commenters raised a number of other issues related to the waivers. Some commenters requested that the waivers apply to clinically integrated organizations that do not participate in the Shared Savings Program. Others raised the issue that waivers of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing

CMP laws do not offer protection with respect to State laws. Several commenters asked the agencies to clarify how the proposed waivers would affect programs outside the Shared Savings Program. Commenters proposed that CMS should extend uniform waivers for all Medicare projects involving coordinated care, including the Independence at Home project, Bundled Payment project, and demonstrations sponsored by the Innovation Center. One commenter requested that the waiver apply to healthcare providers other than ACO participants or ACO providers/suppliers, while others requested that waivers apply to all arrangements between ACO participants and/or ACO providers/suppliers, and individuals or entities outside the Shared Savings Program.

We also received a number of comments that are outside the scope of this rulemaking. Those comments are not summarized here.

### IV. Provisions of the Interim Final Rule With Comment Period: Waiver Requirements

#### A. Overview

Section IV.B. of this IFC sets forth the specific waivers and waiver requirements, pursuant to the authority granted under section 1899(f) of the Act. The waivers apply only to the specific provisions of the laws enumerated in the waivers and do not apply to any other provisions of Federal or State law, including, without limitation, any provisions of the IRC. We invite the public to comment on the waivers set forth in section IV.B. of this IFC.

To promote efficiency and ease of use, we crafted the waivers to apply consistently across the waived fraud and abuse laws to the extent possible. The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier (as those terms are defined in section IV.B. of this IFC pursuant to the Shared Savings Program) participating in the Shared Savings Program. The waivers are intended to be self-implementing. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required by parties in order to be covered by a waiver. Parties need not apply for an individualized waiver.

This IFC includes five waivers. The multiplicity of waivers is intended to afford flexibility to ACOs in varying circumstances and to be responsive to public comments outlining a wide variety of arrangements that ACOs of

various types might need to undertake in order to be successful at carrying out the Shared Savings Program. While the waivers contain many common elements, there are distinctions among them tailored to address particular circumstances, including particular fraud and abuse risks. The first two waivers are an ACO pre-participation waiver and an ACO participation waiver that should, collectively, address the majority of ACO-related start-up and operating arrangements identified by public comments and the DHHS's own analysis as necessary to carry out the Shared Savings Program. Two additional waivers—for shared savings distributions and arrangements that are in compliance with the Physician Self-Referral Law—were described in the Waiver Designs Notice and are being established in this IFC with minor modifications. Many arrangements covered by these waivers could also be protected under the ACO pre-participation and ACO participation waivers. However, some parties may find these two additional waivers more suitable to their particular needs, and we have elected to make them available. The remaining waiver addresses incentives offered to beneficiaries to foster preventive health care and patient compliance with treatment regimes in order to engage patients in quality and care improvement. For ease of reference, the entire set of waivers and applicable requirements is set forth in section IV.B. of this IFC. We will also make the waiver text available on both the CMS and OIG Web sites. Because the waivers cover multiple legal authorities and to ensure that the waivers, if modified, remain consistent over time and across relevant laws, we are not codifying the waivers in the Code of Federal Regulations. We solicit comments about this approach.

Additional explanation appears in section V. of this IFC, as well as additional solicitations of comments on possible modifications to the waiver designs.

#### B. The Waivers and Applicable Requirements

As used in these waivers, *ACO*, *ACO participant*, and *ACO provider/supplier* have the meanings set forth in 42 CFR 425.20. In the context of the ACO pre-participation waiver, these terms refer to individuals or entities that would meet the definitions of the terms set forth in 42 CFR 425.20, if the ACO had a participation agreement, but for the fact that the ACO has not yet submitted the list required under 42 CFR 425.204(c)(5) to be provided with the application for the Shared Savings Program.

As used in these waivers, *participation agreement* refers to the agreement between an ACO and CMS for the ACO's participation in the Shared Savings Program that is described in 42 CFR 425.208.

As used in these waivers, *purposes of the Shared Savings Program* means one or more of the following purposes consistent with section 1899(a) and (b) of the Act: promoting accountability for the quality, cost, and overall care for a Medicare patient population as described in the Shared Savings Program, managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO, or encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.

As used in these waivers, *start-up arrangements* means any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by such ACO, ACO participants, or ACO providers/suppliers.

*ACO Pre-participation Waiver.* Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to start-up arrangements that pre-date an ACO's participation agreement, provided all of the following conditions are met:

1. The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the "target year") and to submit a completed application to participate in the Shared Savings Program for that year. The parties to the arrangement must include, at a minimum, the ACO or at least one ACO participant of the type eligible to form an ACO (as set forth at 42 CFR 425.102(a)). The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers.

2. The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet the requirements of 42 CFR 425.106 and 425.108 concerning the ACO's

governance, leadership, and management.

3. The ACO's governing body has made and duly authorized a *bona fide* determination, consistent with a duty to the ACO that is equivalent to the duty owed by ACO governing body members under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.

4. The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, the documentation of the authorization must be contemporaneous with the authorization, and the documentation of the diligent steps must be contemporaneous with the diligent steps. All such documentation must be retained for at least 10 years following completion of the arrangement (or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application, as described in item 6) and promptly made available to the Secretary upon request. The documentation must identify at least the following:

a. A description of the arrangement, including all parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.

b. The date and manner of the governing body's authorization of the arrangement. The documentation of the authorization should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.

c. A description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an ACO that would be eligible for a participation agreement.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

6. If an ACO does not submit an application for a participation agreement by the last available application due date for the target year,

the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.

For arrangements that meet all of the preceding conditions, the pre-participation waiver applies as follows:

- The waiver period would start on—
  - ++ The date of publication of this IFC for target year 2012; or

- ++ One year preceding an application due date (the "selected application date") for a target year of 2013 or later.

- The waiver period would end—
  - ++ For ACOs that submit an application by the selected application date and enter into a participation agreement for the target year, on the start date for that agreement;

- ++ For ACOs that submit an application by the selected application date for the target year, but whose application is denied, on the date of the denial notice, except with respect to any arrangement that qualified for the waiver before the date of the denial notice, in which case the waiver period would end on the date that is 6 months after the date of the denial notice; and

- ++ For ACOs that fail to submit an application by the selected application due date for the target year, on the earlier of the selected application due date or the date the ACO submits a statement of reasons for failing to submit an application, except that an ACO that has been unable to submit an application, but can demonstrate a likelihood of successfully developing an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date, may apply for an extension of the waiver, pursuant to procedures to be established by the Secretary in guidance. The determination whether to grant a waiver will be in the sole discretion of the Secretary and will not be reviewable.

- ++ An ACO may use the pre-participation waiver (including any extensions granted) only one time.

*ACO Participation Waiver.* Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. The ACO meets the requirements of 42 CFR 425.106 and 425.108 concerning its governance, leadership, and management.

3. The ACO's governing body has made and duly authorized a *bona fide* determination, consistent with the governing body members' duty under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.

4. Both the arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:

a. A description of the arrangement, including all parties to the arrangement; date of the arrangement; the purpose of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.

b. The date and manner of the governing body's authorization of the arrangement. The documentation should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end 6 months following the earlier of the expiration of the participation agreement, including any renewals thereof, or the date on which the ACO has voluntarily terminated the participation agreement. However, if CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

### 3. Shared Savings Distribution Waiver

Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to distributions or use of shared savings earned by an ACO, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement;

2. The shared savings are earned by the ACO pursuant to the Shared Savings Program;

3. The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.

4. The shared savings are—

a. Distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or

b. Used for activities that are reasonably related to the purposes of the Shared Savings Program.

5. With respect to the waiver of sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services to patients under the direct care of the physician.

### 4. Compliance With the Physician Self-Referral Law Waiver

Pursuant to section 1899(f) of the Act, sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Physician Self-Referral Law, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. The financial relationship is reasonably related to the purposes of the Shared Savings Program.

3. The financial relationship fully complies with an exception at 42 CFR 411.355 through 411.357.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated.

### 5. Waiver for Patient Incentives

Pursuant to section 1899(f) of the Act, section 1128A(a)(5) of the Act (relating to the beneficiary inducements CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair-market-value if all four of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. There is a reasonable connection between the items or services and the medical care of the beneficiary.

3. The items or services are in-kind.

4. The items or services—

a. Are preventive care items or services; or

b. Advance one or more of the following clinical goals:

i. Adherence to a treatment regime.

ii. Adherence to a drug regime.

iii. Adherence to a follow-up care plan.

iv. Management of a chronic disease or condition.

For arrangements that meet all of the preceding conditions, this waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated, provided that a beneficiary may keep items received before the participation agreement expired or terminated, and receive the remainder of any service initiated before the participation agreement expired or terminated.

## V. Provisions of the Interim Final Rule With Comment Period: Explanation of Waiver Requirements

This section explains the waivers set forth in section IV.B. of this IFC and responds to public comments. We are providing guidance in this section V. of this IFC to help stakeholders interpret

the waiver requirements. We remind readers that the waivers should be interpreted in a reasonable manner. We are soliciting comments about our approach, whether we should provide greater specificity, and, if so, how and for which waivers and waiver conditions.

#### *A. Reasonably Related to the Purposes of the Shared Savings Program*

Several waivers described in section IV.B. of this IFC require that arrangements be “reasonably related to the purposes of the Shared Savings Program.” We have defined “purposes of the Shared Savings Program” consistent with the purposes set forth in Section 1899(a) and (b) of the Act. We are using the statutory purposes of the Shared Savings Program in the waiver context because the waiver authority speaks to carrying out the Shared Savings Program. As used in these waivers, the purposes of the Shared Savings Program consist of promoting accountability for the quality, cost, and overall care for a Medicare population as described in the Shared Savings Program; managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries. As further explained in the statute and regulations, these purposes can involve, for example, promoting evidence-based medicine and patient engagement; meeting requirements for reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing clinical and administrative systems for the ACO; meeting the clinical integration requirements of the Shared Savings Program; or meeting the quality performance standards of the Shared Savings Program. Additional purposes consistent with the statute and regulations include, for example, evaluating health needs of the ACO’s assigned population; communicating clinical knowledge and evidence based medicine to beneficiaries; and developing standards for beneficiary access and communication, including beneficiary access to medical records.

Arrangements with similar purposes but that are unrelated to the Shared Savings Program are not covered by the term “purposes of the Shared Savings Program.” Arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waiver. We interpret the purpose of

“efficient service delivery” in section 1899 of the Act to include, among other things, appropriate reduction of costs to, or growth in expenditures of, the Medicare program, consistent with quality of care, physician medical judgment, and patient freedom of choice. The definition of “purposes of the Shared Savings Program” applies uniformly to all waivers in which it appears.

When a waiver requires that the terms of the arrangement be “reasonably related to the purposes of the Shared Savings Program,” the arrangement need only be reasonably related to one enumerated purpose, although we would expect that many arrangements would relate to multiple purposes. Where a reasonable relationship exists, it should not be difficult for parties to articulate clearly the nexus between their arrangement and the purposes of the Shared Savings Program. Consistent with our goal to foster flexibility, adaptability, and innovation, we are not further describing in the waiver text the specific arrangements that will be considered reasonably related to the purposes of the Shared Savings Program or providing in the waiver text a list of acceptable arrangements. To provide additional assurance to ACOs, we have provided in this section V of this IFC an illustrative, non-exhaustive list of arrangements that constitute start-up arrangements for purposes of the pre-participation waiver.

As described previously in this IFC, public comments reflected significant variation and scope of anticipated ACO arrangements. We expect parties to apply a reasonable interpretation of the waiver terms. We are, however, soliciting comments on whether we should further define the “reasonably related to purposes of the Shared Savings Program” standard and, if so, how. We note that we are not using the proposed language from our Waiver Designs Notice requiring arrangements to be “necessary for and directly related to ACO purposes.” Several public commenters expressed concern that this language was not clear. We believe the language that we are using in the waivers is simpler and addresses public comments. We note that arrangements that are necessary for and directly related to the purposes of the Shared Savings Program would be among those that meet the “reasonably related” standard.

#### *B. Eligibility for Waiver*

In general, four of the five waivers set forth in this IFC are available to protect arrangements involving an ACO, its ACO participants, and/or its ACO

providers/suppliers, if the ACO has a participation agreement and remains in good standing under that agreement. We are considering whether to require expressly that an ACO that is under a corrective action plan (CAP) be in compliance with the CAP as a condition of a waiver. We solicit comments on these requirements.

The fifth waiver, the ACO pre-participation waiver, is available for start-up arrangements (as defined in the waiver) provided that the ACO is making good faith efforts to form an ACO and to submit an application to participate in the Shared Savings Program, and all other conditions of the waiver are satisfied. To qualify for the pre-participation waiver, the parties to the arrangement must include, at a minimum, the ACO or at least one individual or entity that is eligible to form an ACO (as defined in the Shared Savings Program final rule). In the context of the ACO pre-participation waiver, the terms ACO, ACO participant, and ACO provider/supplier refer to individuals or entities that would meet the definitions of those terms set forth in the Shared Savings Program regulations at 42 CFR 425.20, if the ACO had a participation agreement (but for the fact that the required list under the regulations has not yet been submitted to CMS). Individuals or entities that are prospective ACO participants or ACO providers/suppliers should be those that would be on the list if it were to be submitted. The pre-participation waiver does not cover arrangements involving drug and device manufacturers, distributors, DME suppliers, or home health suppliers. Drug and device manufacturers and distributors are not Medicare enrolled suppliers and providers; DME and home health suppliers have historically posed a heightened risk of program abuse.

#### *C. Pre-Participation and Participation Waivers*

##### *1. Scope*

The intent of the pre-participation and participation waivers in this IFC is to establish pathways to protect *bona fide* ACO investment, start-up, operating, and other arrangements that carry out the Shared Savings Program, subject to certain safeguards. We do not believe it is feasible at this time to enumerate in the waiver text specific protected arrangements given the anticipated wide variation in ACO composition, size, resources, and ACO readiness, as well as the goal of the program to foster innovation, adaptability, and variation in furtherance of quality, efficiency, and

economy. We are concerned that, given the limitations of foresight in the context of a new program, a fixed list might be under-inclusive and omit arrangements that are necessary for *bona fide* ACO activities.

The pre-participation waiver covers a broad array of start-up arrangements, as defined in the waiver text and discussed in this section, subject to certain conditions. The participation waiver covers any arrangement that meets its conditions, including start-up arrangements. Many commenters observed that arrangements necessary to develop an ACO may occur both before and after the ACO enrolls in the Shared Savings Program.

Consistent with views expressed by many commenters, both the pre-participation and participation waivers rely, as a threshold matter, on the programmatic requirements of the Shared Savings Program to safeguard Medicare beneficiaries and the Medicare program. The design of the waivers is premised on our expectation that risks of fraud and abuse, such as overutilization, inappropriate utilization, and underutilization, will be mitigated, in the first instance, by the Shared Savings Program design, including, for example, the eligibility requirements, the quality of care and accountability provisions, and the program integrity provisions. In these waivers, we are adding additional safeguards in the form of governance responsibility, transparency, and a documented audit trail. These points are explained in more detail later in this IFC. We are aiming for an approach that will provide ACOs with flexibility, certainty, and latitude for beneficial innovation and variation in connection with the new Shared Savings Program, while also protecting Medicare beneficiaries and the Medicare program from fraud and abuse.

## 2. Start-Up Arrangements for the Pre-Participation Waiver

We are limiting the pre-participation waiver so that it applies to “start-up arrangements.” We define the term start-up arrangements to mean any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by such ACO, ACO participants, or ACO providers or suppliers. We also consider the provision of a subsidy for these items, services, facilities, or goods to be a start-up arrangement. Even though the definition of start-up arrangements is specifically included in the pre-participation waiver, we anticipate that many start-up arrangements will also

take place during the participation phase of an ACO’s existence; those arrangements can qualify for the participation waiver.

Based on comments received, we recognize that ACOs may have a difficult time anticipating all necessary start-up arrangements that will need waiver protection. While we are not providing a specific list of ACO start-up arrangements in the waiver text, in order to provide additional assurance to developing ACOs, we offer additional guidance in this section. By way of example only, we consider the provision of the following items, services, facilities, and goods to be start-up arrangements:

- (1) Infrastructure creation and provision;
- (2) Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care;
- (3) Care coordination mechanisms, including care coordination processes across multiple organizations;
- (4) Clinical management systems;
- (5) Quality improvement mechanisms including a mechanism to improve patient experience of care;
- (6) Creation of governance and management structure;
- (7) Care utilization management, including chronic disease management, limiting hospital readmissions, creation of care protocols, and patient education;
- (8) Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses;
- (9) Hiring of new staff, including:
  - a. Care coordinators including nurses, technicians, physicians, and/or non-physician practitioners;
  - b. Umbrella organization management;
  - c. Quality leadership;
  - d. Analytical team;
  - e. Liaison team;
  - f. IT support;
  - g. Financial management;
  - h. Contracting;
  - i. Risk management;
- (10) Information Technology, including:
  - a. EHR systems;
  - b. Electronic health information exchanges that allow for electronic data exchange across multiple platforms;
  - c. Data reporting systems, including all payer claims data reporting systems;
  - d. Data analytics, including staff and systems, such as software tools, to perform such analytic functions;
- (11) Consultant and other professional support, including:

- a. Market analysis for antitrust review;
- b. Legal services;
- c. Financial and accounting services;
- (12) Organization and staff training costs;

(13) Incentives to attract primary care physicians;

(14) Capital investments including loans, capital contributions, grants and withholds.

In order to foster innovation and creativity within ACOs, we recognize that it is impossible to create an exhaustive list of *bona fide* start-up arrangements. We solicit comments on our definition of start-up arrangements and specifically seek input as to whether this definition allows for sufficient innovation in the creation and development of ACOs.

## 3. Additional Safeguards

The pre-participation waiver and the participation waiver require that the governing body of the ACO make a *bona fide* determination that the arrangement for which waiver protection is sought is reasonably related to the purposes of the Shared Savings Program (as described previously in this IFC) and that the governing body duly authorize the arrangement. (For the ACO participation waiver, the governance, as well as the leadership and management of the ACO, must additionally be in compliance with the applicable rules under the Shared Savings Program final rule at 42 CFR 425.106 and 425.108.) The intent of this requirement is to ensure that any arrangement for which waiver protection is sought falls under the auspices of the ACO; is transparent within the ACO to ACO participants and members of the governing body; and is integral to the ACO’s mission and plans to effectuate its role in the Shared Savings Program. This approach interposes the ACO’s governing body as an intermediary responsible, in the first instance, for ensuring that all protected arrangements are in furtherance of ACO purposes and are not isolated arrangements furthering the individual financial or business interests of ACO participants or ACO providers/suppliers.

We are not specifying in the waivers how the ACO governing body makes the *bona fide* determination or duly authorizes it. The determination and authorization must be contemporaneously documented. Documentation must include the basis for the determination that the arrangement is reasonably related to the purposes of the Shared Savings Program. We note that the governing body under the Shared Savings Program final rule must have a meaningful

conflicts of interest policy for its members (42 CFR 425.106(d)). We are considering, and soliciting comments on, whether we should specify particular methods by which governing bodies make determinations and authorize arrangements to ensure that ACOs are making *bona fide*, meaningful determinations and authorizations, such that arrangements covered by these waivers are truly furthering the interests of the ACO as a whole in meeting the objectives of the Shared Savings Program. We note that the pre-participation and participation waivers are intended to cover arrangements, among others, in which an ACO might receive funding or in-kind items or services from ACO participants or ACO providers/suppliers and, subject to an independent ACO governing body determination, redistribute them to other ACO participants or ACO providers/suppliers.

An ACO governing body must make a *bona fide* determination that an arrangement is reasonably related to the purposes of the Shared Savings Program. Depending on the waiver, the ACO governing body can make this determination for a wide range of arrangements, including, without limitation, start-up arrangements and ACO operating activities, as well as performance-based compensation ("results-based" compensation) that is dependent upon achieving quality thresholds or efficiency measures of the Shared Savings Program. Members of the ACO governing body would be well-advised to exercise diligence in ensuring that arrangements are reasonably related to one or more purposes of the Shared Savings Program and to articulate clearly the bases for their determinations and authorizations. Arrangements should be scrutinized with care to ensure that the reasonable relationship between an arrangement and the purposes of the Shared Savings Program can be clearly identified. Not every arrangement will be reasonably related to the purposes of the Shared Savings Program. For example, we do not believe that a per-referral payment (such as, expressly paying a specialist \$500 for every referral generated by the specialist or paying a nursing facility staff member \$100 for every patient transported to the ACO's hospital) would be reasonably related to the purposes of the Shared Savings Program. However, by way of example only, arrangements with specialists or nursing facility staff members to engage in care coordination for ACO beneficiaries or implement evidence-based protocols could be reasonably

related to the purposes of the Shared Savings Program even if the arrangement were to reflect a likelihood that the patient might be referred to or within an ACO. (Importantly, parties remain obligated to comply with the provisions at 42 CFR 425.304(c) that prohibit certain required referrals and cost-shifting.)

Next, the ACO pre-participation and ACO participation waivers require an audit trail of contemporaneous documentation that identifies core characteristics of the arrangement (as listed in the waiver text), is maintained for 10 years, and is available to the Secretary, upon request. We are not specifying in the waivers any particular form of documentation, which can be in paper or electronic form. Notably, the waivers do not require an agreement signed by the parties, although such an agreement is a best documentation practice (and would typically be required for compliance with the Physician Self-Referral Law if a waiver does not apply). The core characteristics of the arrangement should be evident from the documentation with sufficient clarity that the government or another third party reviewing the documentation would be able to ascertain the material terms of the arrangement, including the information listed in item 4 of the pre-participation and participation waivers. Material amendments and modifications to the arrangement should be similarly documented and subject to governing body approval and disclosure. The pre-participation waiver also requires contemporaneous documentation of the diligent steps the parties are taking to develop the ACO. Documentation of the diligent steps must be retained for at least 10 years following that date that the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application, as described later in this IFC. As set forth in more detail in the Shared Savings Program final rule, ACOs will be monitored, and we will make periodic requests for documentation of arrangements protected by waivers.

The third main safeguard included in these waivers is a transparency requirement that requires arrangements for which waiver protection is desired to be publicly disclosed. The public disclosure will include the description of the arrangement, but shall not include the financial or economic terms of the arrangement. Our decision to shield financial or economic terms from the public transparency requirement is premised, among other considerations, on potential antitrust implications. (We

note that, while not subject to the public transparency requirement, the financial or economic terms of the arrangement are among the matters that must be documented pursuant to the documentation requirements of the waivers and made available to the Secretary upon request.)

The goals of this transparency requirement are three-fold. First, the requirement recognizes that secrecy is necessary for most criminal or fraudulent conduct, and we are declining to protect hidden arrangements. Second, the requirement makes information about waived arrangements more readily available to parties involved with the ACO, regulators, and the public.<sup>7</sup> Third, transparency creates an incentive for ACOs to exercise due diligence when arrangements are being established to ensure that they are waiver compliant and otherwise consistent with the ACO's mission and the duty each member of the governing body owes to make decisions in the interests of the ACO. We do not expect that the disclosure requirements, to be determined by the Secretary in additional guidance, will be onerous.

We expect that ACOs will be able to use the same disclosure process that will apply to disclosure of organizational, quality, and performance information under the Shared Savings Program final rule at 42 CFR 425.308. ACOs using the pre-participation waiver will be able to use a similar disclosure process. We are soliciting comments on additional methods for public disclosure that would be minimally burdensome, as well as the timing for disclosures. In the latter regard, we are considering whether to require disclosures on a rolling basis or on a fixed interval basis. We are also interested in comments addressing whether, in lieu of additional guidance, the disclosure requirements should be set out with greater specificity in the waiver text. Until such time as additional guidance is issued, parties seeking to use the ACO pre-participation or participation waivers should meet the disclosure requirement by posting information identifying the parties to the arrangement and the type of item, service, good, or facility provided under the arrangement on a public Web site belonging to the ACO or an individual or entity forming the ACO, clearly labeled as an arrangement for which waiver protection is sought, within 60 days of the date of the

<sup>7</sup> For example, currently, the government has limited information regarding actual usage of existing safe harbors and exceptions.

arrangement. The Web site must include the name of the ACO (or, if the name of the ACO is not known, the parties forming the ACO) and other identifying information sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the Web site.

The current design of these waivers applies to arrangements within the ACO (that is, between or among the ACO, its ACO participants, and/or its ACO providers/suppliers), as well as ACO-related arrangements with outside providers and suppliers, such as hospitals, specialists, or post-acute care facilities that might not be part of the ACO but have a role in coordinating and managing care for ACO patients. (The pre-participation waiver excludes drug and device manufacturers, distributors, DME suppliers, and home health suppliers.) All such arrangements must be reasonably related to the purposes of the Shared Savings Program. We are soliciting comments on whether we should modify the waivers to exclude outside party arrangements. We are also seeking comments on whether we should add additional conditions to the participation waiver—such as conditions requiring commercial reasonableness or fair market value or prohibiting exclusivity—that would apply to ACO relationships with outside parties, such as laboratories, equipment or supply companies, drug and device manufacturers, or distributors or purchasing organizations.

The waiver text sets forth specific duration periods for the pre-participation waiver to account for the varying circumstances of ACOs that submit applications that are accepted, submit applications that are rejected, or are unable to submit an application. These specifications are necessary to ensure that the waiver covers only pre-participation arrangements that are closely linked to the Shared Savings Program. The ACO pre-participation waiver covers arrangements undertaken by parties acting with good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the “target year”). For ACOs pursuing target year 2012, the waiver period starts on the date of publication of this IFC. For ACOs pursuing later target years, the waiver period would begin one year preceding an application due date for the target year (the “selected application date”). Application due dates for these years will be established in later guidance by CMS but, by way of illustration only, if an application due date for target year 2014 were September 1, 2013, the ACO

pre-participation waiver period would begin on September 1, 2012.

For an ACO that submits an application and enters into a participation agreement, the pre-participation waiver lasts until the start date of the participation agreement, at which point waiver protection merges seamlessly into the participation waiver, and no further governing body approval is required for arrangements that had been protected by the pre-participation waiver. If the application is denied, the waiver lasts until the date of the denial notice, except that waiver protection extends for 6 months after the date of the denial notice for arrangements that qualified for the waiver before the date of the denial notice. However, no newly created arrangements would be protected during the 6-month period. The waiver period will end for ACOs that fail to submit an application on the final application due date for the target year. ACOs that fail to submit an application by the final application due date must instead submit a statement describing the reasons the ACO failed to submit a timely application.

ACOs that do not submit an application for the selected application date, may apply for an extension of the waiver period. The ACO must submit documentation of its diligent steps, as required under the waiver, and make a showing that it is likely to successfully develop an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date. The Secretary will establish procedures in guidance for the extension process. The determination whether to grant a waiver will be in the sole discretion of the Secretary and will not be reviewable. If an extension is granted, the next available application due date will become the selected application date and the new waiver period will end in accordance with the terms of the pre-participation waiver. An ACO may only use the pre-participation waiver one time. If an extension is not granted, the ACO may no longer rely on the pre-participation waiver.

We are considering whether to further limit the pre-participation waiver by, for example, requiring that parties submit a notice of intent to form an ACO; limiting the waiver for target years after 2013 to ACOs that file applications to enroll in the Shared Savings Program; or curtailing the availability or scope of the pre-participation waiver in future years once ACO structures have become better established.

As described previously in this IFC, for some circumstances, the pre-participation and participation waivers

include a 6-month “tail” period applicable to protected arrangements in existence at the time the waiver expires or terminates; this “tail” period responds to public comments urging that waivers allow for the orderly unwinding or restructuring of arrangements as necessary to ensure continued compliance with the law. The “tail” periods protect only arrangements that were in place and otherwise qualified for the waiver at the time the waiver expires or terminates. No “tail” period applies to ACOs that CMS terminates. We considered both shorter and longer periods for the “tail” period and are soliciting comments on whether we should modify the “tail” periods of the waivers.

#### *D. Waiver for Shared Savings Distributions*

The intent behind the waiver for shared savings distributions is to protect arrangements created by the distribution of shared savings within an ACO that qualifies for the waiver, as well as arrangements created by the use of shared savings to pay parties outside such an ACO if those payments are reasonably related to the purposes of the Shared Savings Program. This waiver permits shared savings to be distributed or used within the ACO in any form or manner, including “downstream” distributions or uses of shared savings funds between or among the ACO, its ACO participants, and its ACO providers/suppliers. This less restrictive waiver for shared savings distributions within the ACO is premised, in part, on recognition that an award of shared savings necessarily reflects the collective achievement by the ACO and its constituent parts of the quality, efficiency, and cost reduction goals of the Shared Savings Program. These goals are consistent with interests protected by the fraud and abuse laws. This waiver also affords ACOs latitude to use shared savings in arrangements with outside parties, provided that the arrangements are reasonably related to the purposes of the Shared Savings Program.

Because the payment of shared savings by CMS to an ACO under the Shared Savings Program may not occur until after expiration of the ACO’s 3-year agreement, the waiver applies to distributions and uses of shared savings earned during the term of the agreement, even if distributed subsequently. Similarly, the waiver applies to distributions of shared savings to individuals or entities that were ACO participants and ACO providers/suppliers at the time the shared savings were earned, even if they



are not part of the ACO at the time of the actual distribution.

This waiver is limited to distributions of shared savings; all other arrangements would still need to qualify for one of the other waivers outlined in section IV. of this IFC, fit in an existing exception or safe harbor, or otherwise comply with the laws. This waiver does not protect distributions of shared savings to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities that are reasonably related to the purposes of the Shared Savings Program or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

Some commenters to the Waiver Designs Notice inquired about our proposal, which we are adopting here, to exclude from the shared savings distributions waiver of the Gainsharing CMP situations in which a payment is made knowingly to reduce or limit *medically necessary* services to patients under the physician's direct care. This limitation is consistent with the quality and patient care goals of the Shared Savings Program and must be interpreted in that context. In the context of waivers designed to carry out the Shared Savings Program, distributions of shared savings by an ACO, including downstream arrangements, that incentivize the provision of *alternate and appropriate* medically necessary care consistent with the purposes of the Shared Savings Program (such as the provision of coordinated outpatient care rather than inpatient services or the use of evidence-based protocols for medically necessary care) are protected by this waiver. Knowing payments by a hospital to induce a physician to reduce or limit medically necessary care without providing acceptable alternative medically necessary care (for example, payments to discharge patients without regard to appropriate care transitions or payments to use a drug or device known to be clinically less effective) would not qualify for the waiver. We will interpret "medical necessity" consistent with Medicare program rules and accepted standards of practice. We also note that distributions of shared savings payments also may be structured to fit in the other waivers.

Finally, we have not included in this IFC specific waiver protection for the distribution of shared savings earned by an ACO enrolled in the Shared Savings Program under a comparable program sponsored by a commercial health plan. We recognize that ACOs participating in the Shared Savings Program may also

receive similar performance-based payments from commercial plans and that those payments may reflect care coordination, quality improvement, and cost-effectiveness activities similar to those promoted by the Shared Savings Program. However, at this time, we are not persuaded that a specific waiver for such payments is necessary to carry out the Shared Savings Program. In addition, we lack an adequate basis for identifying comparable private payer arrangements of ACOs that would be subject to the waiver.

Shared savings or similar performance-based payments received from a commercial plan do not necessarily implicate the fraud and abuse laws; however, in some circumstances, funds are calculated or used in downstream arrangements in ways that influence the referring of, or ordering for, Medicare or other Federal health care program patients. Moreover, we are mindful of the concerns expressed by commenters that some private payer arrangements may be sensitive to the volume of business generated for downstream providers or suppliers and that this characteristic may have implications for the application of the Physician Self-Referral Law.

Although we are not providing a specific waiver for private payer arrangements at this time, we believe avenues exist to provide flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements "downstream" of commercial plans (for example, arrangements between hospitals and physician groups) from qualifying for the participation waiver described in section IV. of this IFC. The participation waiver does not turn on the source of the funds for the arrangement. Second, many commercial shared savings arrangements are, or can be, structured to fit within the Physician Self-Referral Law exception for risk-sharing arrangements at 42 CFR 411.357(n) and some may be structured to fit in other exceptions. Some private payer arrangements may also fit in existing Federal anti-kickback statute safe harbors, such as the managed care safe harbors. Finally, as noted previously in this IFC, no waiver or other protection is needed for private payer arrangements that do not implicate the fraud and abuse laws.

We are soliciting comments on our approach to shared savings arrangements with commercial plans, whether our approach is consistent with the needs of ACOs participating in the Shared Savings Program, and whether a specific waiver should apply to shared

savings derived from commercial plans comparable to the Shared Savings Program (and, if so, how we should define a comparable program with sufficient precision).

#### *E. Compliance With the Physician Self-Referral Law Waiver*

This waiver is intended to ease the compliance burden on providers that might elect to use existing Physician Self-Referral Law exceptions for their ACO arrangements and to reassure those with existing arrangements that already fit in such an exception that they need not undertake a separate legal review under the Federal anti-kickback statute or Gainsharing CMP. This waiver covers arrangements that otherwise implicate the Physician Self-Referral Law, meaning, for example, arrangements involving designated health services entities, as defined at 42 CFR 411.351, and referring physicians, as defined at 42 CFR 411.351. Arrangements that cannot qualify for a Physician Self-Referral Law exception because they are not within the ambit of the law, such as arrangements between facilities that do not involve referring physicians, can qualify for the other waivers described in this IFC. Ordinarily, compliance with an exception to the Physician Self-Referral Law does not operate to immunize conduct under the Federal anti-kickback statute or Gainsharing CMP, and arrangements that comply with the Physician Self-Referral Law are still subject to scrutiny under the Federal anti-kickback statute and Gainsharing CMP. Here, however, we are deviating from this general rule in view of the specific safeguards in the Shared Savings Program, the authority under section 1899(f) of the Act for the Secretary to waive the Federal anti-kickback statute and Gainsharing CMP as necessary to carry out the Shared Savings Program, and our desire to minimize burdens on entities establishing or operating ACOs under the Shared Savings Program.

This waiver is structured to apply until the participation agreement, including any renewals thereof, expires or terminates. We are considering whether it might be necessary for this particular waiver to continue for some period of time, perhaps in the range of 3 to 12 months, after expiration or termination of an ACO's participation agreement. We are soliciting comments on this consideration.

#### *F. Waiver for Patient Incentives*

As described in section III of this IFC, several public commenters indicated that, in carrying out the quality and cost reduction goals of the Shared Savings



Program, ACOs would need to engage patients in better managing their own health care, including obtaining preventive care and complying with treatment plans for chronic conditions. Therefore, in light of this need, this IFC promulgates a waiver of the Federal anti-kickback statute and Beneficiary Inducements CMP to address arrangements pursuant to which ACOs, ACO participants, and ACO providers/suppliers provide beneficiaries with free or below-fair market value items and services that advance the goals of preventive care, adherence to treatment, drug, or follow-up care regimes, or management of a chronic disease or condition. This waiver will help ACOs foster patient engagement in improving quality and lowering costs for Medicare and beneficiaries by removing any perceived obstacles presented by the Beneficiary Inducements CMP or Federal anti-kickback statute. Beneficiary compliance with care management programs is critical to the success of ACOs, and ACOs should have the flexibility to develop incentives to that end, with certain safeguards. In the interest of promoting broad improvement in care coordination and quality for all beneficiaries and in light of the mechanisms for assigning beneficiaries under the Shared Savings Program final rule, at this time we are not limiting this waiver to beneficiaries assigned to the ACO. However, we are soliciting comments on whether the waiver could and should be limited to beneficiaries assigned to the ACO.

In order to balance the goal of beneficiary compliance with care management programs against the risk that ACOs could use extravagant incentives to steer beneficiaries, we are requiring that there be a reasonable connection between the incentives and the medical care of the individual. By way of example, the waiver would cover blood pressure cuffs for hypertensive patients, but not beauty products or theatre tickets. The waiver will protect incentives that are in-kind items or services, but not financial incentives, such as waiving or reducing patient cost sharing amounts (that is, copayment or deductible), which we believe are prone to greater abuse. We note that the Shared Savings Program at 42 CFR 425.304(a)(1) itself prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from, or remaining in, an ACO or with providers

in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers; clearly then, such incentives are not covered by this waiver. As further provided in the Shared Savings Program final rule, 42 CFR 425.304(a)(2) permits certain incentives that are consistent with the requirements of 42 CFR 425.304(a)(1) and the terms of this waiver. This waiver applies only to the application of the Federal anti-kickback statute and Gainsharing CMP; nothing in this waiver supplants any applicable requirement in the Shared Savings Program final rule or other Medicare payment or coverage rules. We are not defining preventive care for purposes of this waiver in order to provide some flexibility as care models develop in the Shared Savings Program and evidence-based care programs are adopted by ACOs. However, we are soliciting comments on whether we should provide a specific definition.

This waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO participants, or ACO providers/suppliers. The patient incentives waiver would cover ACOs, ACO participants, and ACO provider/suppliers that give beneficiaries items or services that they have received from manufacturers at discounted rates. However, the waiver would not cover the discount arrangement (or any arrangement for free items and services) between the manufacturer and the ACO, ACO participant, or ACO provider/supplier.

This waiver applies during the term of the ACO's participation agreement. However, to ensure continuity of care for beneficiaries if an ACO's agreement terminates or is not renewed, we are providing that a beneficiary may keep any items received during the term of the ACO's participation agreement pursuant to the waiver and may continue to receive any service initiated during the term of the ACO's participation agreement pursuant to the waiver, if the service was in progress when the participation agreement terminated. Illustrative examples could include, but would not be limited to, a post-surgical patient receiving free home visits to coordinate in-home care during the recovery period, a hypertensive patient using home telehealth monitoring of blood pressure, or a beneficiary halfway through a normal course of smoking cessation treatment. Nothing precludes ACOs, ACO participants, or ACO providers/suppliers from offering patient incentives to promote their clinical care

if the incentives fit in an applicable safe harbor or exception or do not otherwise violate the Federal anti-kickback statute and Beneficiary Inducements CMP. For example, many such arrangements may fit in the exception to the Beneficiary Inducements CMP for incentives given to individuals to promote the delivery of preventive care at section 1128A(i)(6)(D) of the Act; 42 CFR 1003.101.

#### *G. Application of Waivers to Innovation Center Demonstrations*

Several commenters inquired about the application of these waivers to ACO demonstration programs sponsored by the Innovation Center, including application to the Pioneer ACOs. The waivers in this IFC are promulgated under section 1899(f) of the Act and, as set forth in the statute, are limited to the Shared Savings Program. Section 3021 of the Affordable Care Act includes a similar waiver authority that may be exercised for Innovation Center demonstration programs, including the Pioneer ACOs. We will address the exercise of that waiver authority in guidance relevant to those programs. As noted previously in this IFC, the waivers in this IFC will apply to ACOs participating in the Advance Payment Initiative because those ACOs also participate in the Shared Savings Program.

#### *H. Additional Policy Considerations and Solicitation of Comments*

The waivers adopted in this IFC take into account the specific redesigned care delivery incentives and processes of the Shared Savings Program, as well as the obligation of ACOs, ACO participants, and ACO providers/suppliers to comply with the Shared Savings Program rules, including requirements addressing governance, management, leadership, transparency, data, quality, performance, compliance, patient freedom of choice, and others. Moreover, the Shared Savings Program requires ACOs and their constituent parts to demonstrate a meaningful commitment to the Shared Savings Program. The waivers emanate from the expectation that ACOs and their constituent parts will act in compliance with program rules and in the best interests of patients and the Medicare program, including the Shared Savings Program. The waivers are an attempt to promote a high degree of certainty, innovation, and variation in the development of ACOs to improve quality of care, as well as economy and efficiency in the Medicare program.

The government's enforcement experience reflects that, to varying degrees, all Federal health care

programs are susceptible to fraud and abuse. These waivers should not be read to reflect any diminution of our commitment to protect programs and beneficiaries from harms associated with kickbacks and referral payments, including overutilization, increased costs, and substandard or poor quality care. DHHS will monitor ACOs and the Shared Savings Program as a whole for fraud or abuse, such as billing for medically unnecessary or upcoded services, submitting false or fraudulent data, or providing worthless or substandard care. If these or other problematic practices are found, the government has a number of tools to address the problem. In appropriate cases, we will use these tools to protect the interests of beneficiaries and the Medicare program.

We intend to closely monitor ACOs entering the program in 2012 through June 2013. We plan to narrow the waivers established in this IFC unless the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements.<sup>8</sup> In particular, if we find that undesirable effects (for example, aberrant patterns of utilization) have occurred because of the waivers, we will revise this IFC to address those problems by narrowing the waivers. Modifications to the waivers would apply to future ACO applicants beyond July 2013 and to ACOs that renew their participation agreements. There are several options for modifying the waivers to address problems that may arise. Should we identify specific areas of fraud and abuse resulting from arrangements covered by the waivers, we could modify the waivers to add or substitute conditions tailored to address specific abusive conduct. We could also limit ACO arrangements involving referral sources to those that are fair market value or commercially reasonable or involve services performed by the referral source. This approach could include exceptions for specified arrangements, including, for example, a limited amount of start-up costs, information technology, medical training, care coordination, or goods or services provided to referral sources' patients. In addition, we could preclude waiver protection for arrangements that involve individuals or entities that are not part of the ACO or we could include

a requirement that ACOs submit reports to the Secretary regarding their arrangements. We solicit comments in this rulemaking regarding these narrow waivers. We also seek comments on additional categories of arrangements that would require protection through a waiver and how the categories should be defined and what limits, if any, should be imposed.

We are establishing waivers under section 1899(f) of the Act to foster the success of the Shared Savings Program, the purposes of which are to promote accountability for a Medicare patient population, manage and coordinate care for Medicare fee-for-service beneficiaries, and encourage redesigned care processes to improve quality. Our goal is to balance effectively the need for ACO certainty, innovation, and flexibility in the Shared Savings Program with protections for beneficiaries and the Medicare program. It is our expectation that the waivers promulgated in this IFC will be used for their intended purposes to carry out the Shared Savings Program. We will closely monitor the program and ACO conduct. We plan to narrow the waivers in this IFC unless information gathered through monitoring or other means suggests that the waivers in this IFC are adequately protecting the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services. We are soliciting comment on the specific narrowed waivers described above.

## VI. Procedural Rulemaking Matters

### A. Waiver of Proposed Rulemaking

Under the Administrative Procedures Act (5 U.S.C. 553(b)), an agency may waive publication of a notice of proposed rulemaking if the agency finds good cause that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and the agency incorporates into the rule a statement of, and the reasons for, such a finding. For the reasons discussed later in this IFC, we find that it would be unnecessary, impracticable, and contrary to the public interest to delay the issuance of the waivers granted in this IFC until after a public notice and comment process is completed.

In section 1899(a)(1) of the Act, Congress expressly required the Secretary to establish the Shared Savings Program no later than January 1, 2012. As noted earlier in this document, Congress authorized the Secretary to waive the requirements of sections 1128A and 1128B and title XVIII of the

Act as may be necessary to carry out the Shared Savings Program. The Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP, discussed elsewhere in this IFC, are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms.

We recognize, however, that these laws may prohibit or significantly restrict certain arrangements necessary for the formation of ACOs under the Shared Savings Program. Moreover, the significant financial consequences of noncompliance with these laws (and the potential False Claims Act liability) will likely have a chilling effect on the willingness of health care providers to participate in the Shared Savings Program at its inception if these provisions are not waived. Delaying the issuance of final waivers would effectively delay the program's establishment well beyond the statutory deadline and delay the savings that the program is expected to achieve at a time when reducing the Federal budget is a critical priority. For this reason, it is impracticable and contrary to the public interest to issue the waivers of these laws only after additional months of notice and comment rulemaking. In addition, the failure to simultaneously issue the Shared Savings Program final rule and the waivers promulgated in this IFC would impede development of the innovative integrated-care models envisioned by the Shared Savings Program and deny Medicare beneficiaries the opportunity to benefit from a new approach to the delivery of health care that is designed to result in better care for individuals, and better health for populations, as well as lower growth in expenditures. Neither result is in the public interest.

We also believe it is unnecessary to offer what would essentially be a second opportunity to comment on these waivers and thereby delay finalizing waivers that will permit arrangements that are essential to the implementation success of the Shared Savings Program. On April 7, 2011, we published the Waiver Designs Notice. That notice solicited public comment regarding possible waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties law provisions to specified arrangements involving ACOs under the Shared Savings Program. This IFC responds to public comments received on that notice. Moreover, the public will nonetheless receive an opportunity to

<sup>8</sup> As described in section III of this IFC, several commenters suggested that we establish either narrow waivers or none at all; some commenters suggested specific additional conditions for waivers that we have not adopted.

comment on the specific policy choices made in this rule because we are publishing it as an IFC. In accordance with section 1871(a)(3) of the Act, we are obligated to consider comments and publish a final rule addressing those comments within 3 years.

Finally, we note that in the absence of final program rules, it would have been impracticable, if not impossible, to issue a comprehensive notice of proposed rulemaking on fraud and abuse waivers that would adequately support the Shared Savings Program. As we stated in the Waiver Designs Notice, the requirements of the final program rules regarding the structure and operations of ACOs under the Shared Savings Program would affect the scope of the waivers. For this reason, we indicated in the Waiver Designs Notice that, in drafting the final waivers, we would consider comments received on the Shared Savings Program proposed rule and the terms of the final rule. We have, in fact, done so in creating the waivers set forth in this IFC. Simply put, the proposal of definitive waivers was not possible until now.

For the reasons noted previously in this IFC, we believe that it would be impracticable and contrary to the public interest to delay the issuance of final waivers until after the receipt and analysis of additional public comments. Therefore, we find good cause to waive prior notice and comment procedure and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

#### *B. Waiver of Delayed Effective Date*

Section 1871(e)(1) of the Act generally requires that a final rule become effective at least 30 days after the issuance or publication of the rule. This requirement for a 30-day delayed effective date can be waived, however, if the Secretary finds that waiver of the 30-day period is necessary to comply with statutory requirements or that the requirement for a delayed effective date is contrary to the public interest.

As indicated previously in this IFC, section 1899 of the Act expressly requires the Secretary to establish the Shared Savings Program no later than January 1, 2012. Prospective ACOs that wish to participate in the Medicare Shared Savings Program in 2012 must submit an application and enter into a participation agreement with CMS that commences on April 1, 2012 or July 1, 2012. We expect that the application deadline for participation agreements with an April 1, 2012 start date will be no later than January 1, 2012. Based on the comments submitted in response to the Waiver Designs Notice, we believe

that a significant number of ACO applicants for the Shared Savings Program would forego applying to participate in the Shared Savings Program until final waivers have become effective and sufficient time has elapsed to allow the applicants to use the waivers in a manner that would support their applications and the purposes of the program. We believe that a 30-day delay in the effective date for the final waivers could jeopardize an ACO's ability to submit timely an application for a participation agreement commencing in 2012. For this reason, we find that waiver of the requirement for a delayed effective date is necessary to comply with a statutory requirement.

We also find that a delayed effective date would be contrary to the public interest. The success of the Shared Savings Program depends in no small part on allowing prospective ACOs sufficient time to prepare for application to the program and to build the innovative, cost effective, integrated healthcare delivery models envisioned by the Shared Savings Program. Delaying the effective date of this rule would be contrary to the public interest because it would effectively delay the timely implementation of the Shared Savings Program, thereby denying the public the benefits of a new approach to health care delivery that is designed to result in better care for individuals, and better health for populations, as well as lower growth in expenditures.

In addition, we find that it is not in the public interest to delay the effective date of a rule that does not impose a burden upon anyone. This IFC waives the aforementioned authorities, provided certain conditions are met. In short, the rule rescinds, rather than adds, restrictions with which prospective ACOs, their prospective ACO participants, and their prospective ACO providers/suppliers must comply. Accordingly, a delay in the effective date of this IFC is unnecessary and contrary to the public interest.

#### **VII. Collection of Information Requirements**

While this IFC does include information collection and record keeping requirements, section 3022 of the Affordable Care Act provides that Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this IFC need not be reviewed by the Office of Management and Budget.

#### **VIII. Regulatory Impact Statement**

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is 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 (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this IFC will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this IFC will not have a significant impact on the

operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services and the Office of the Inspector General are implementing this interim final rule under the authority of section 1899 of the Act.

**Authority:** Section 1899(f) of the Act.

Dated: October 6, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: October 19, 2011.

**Daniel R. Levinson,**

*Inspector General, Department of Health and Human Services.*

Approved: October 19, 2011.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2011-27460 Filed 10-20-11; 11:15 am]

**BILLING CODE 4120-01-P; 4152-01-P**