



FEDERAL REGISTER

Vol. 80

Thursday,

No. 209

October 29, 2015

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

Office of Inspector General

42 CFR Chapter V

Medicare Program; Final Waivers in Connection With the Shared Savings Program; 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-F]

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: Final rule.

SUMMARY: This final rule finalizes waivers of the application of the physician self-referral law, the Federal anti-kickback statute, and the civil monetary penalties (CMP) law provision relating to beneficiary inducements to specified arrangements involving accountable care organizations (ACOs) under section 1899 of the Social Security Act (the Act) (the “Shared Savings Program”), as set forth in the Interim Final Rule with comment period (IFC) dated November 2, 2011. As explained in greater detail below, in light of legislative changes that occurred after publication of the IFC, this final rule does not finalize waivers of the application of the CMP law provision relating to “gainsharing” arrangements. 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: These regulations are effective on October 29, 2015.

FOR FURTHER INFORMATION CONTACT:

1877CallCenter@cms.hhs.gov, (410) 786-6887, for general issues and issues related to the physician self-referral law. Meredith Williams, (202) 619-0335, or Elizabeth Isbey, (202) 619-0335, for general issues and issues related to the Federal anti-kickback statute or civil monetary penalties.

I. Introduction and Overview

This final rule sets forth waivers of specified fraud and abuse laws necessary to carry out the Shared Savings Program, as previously promulgated in the IFC. As explained in greater detail below, these laws restrict financial arrangements between hospitals, physicians, and other parties

(including, in some cases, beneficiaries) in a position to generate or receive Medicare referrals, and serve, among other things, to prevent and remediate harms often associated with payments connected to referrals. As development of the Shared Savings Program began, stakeholders expressed concerns that these restrictions potentially impede development of innovative integrated-care arrangements envisioned by the Shared Savings Program, including shared savings arrangements and care coordination arrangements. Congress authorized the Secretary to waive these laws as necessary to carry out the Shared Savings Program.

Section I of this final rule gives an introduction and overview of this rule. Section II provides background on the Shared Savings Program. Section III summarizes public comments received in response to the IFC, responds to those comments, and provides additional clarification of several issues identified through experience with the Shared Savings Program. Section IV sets out the final waivers and applicable requirements.

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

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 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 CMS’s first Shared Savings Program final rule published in the **Federal Register** on November 2, 2011 (Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations (76 FR 67802)) (hereinafter referred to as the “2011 Shared Savings Program final rule”), the Shared Savings Program is designed to achieve three goals: Better care for individuals, better health for populations, and lower growth in expenditures. The Shared Savings Program ACOs¹ are a key component of the Medicare delivery system reform initiative designed to reduce fragmented or unnecessary care and excessive costs

for health care services furnished to Medicare fee-for-service beneficiaries.

The physician self-referral law at section 1877 of the Act, the Federal anti-kickback statute at section 1128B(b) of the Act, the CMP law addressing inducements to beneficiaries at section 1128A(a)(5) of the Act (the Beneficiary Inducements CMP), and the CMP law provisions at sections 1128A(b)(1) and (2) of the Act (the Gainsharing CMP), as described in greater detail elsewhere in this final rule, 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. For purposes of the Shared Savings Program, providers must integrate in ways that potentially implicate fraud and abuse laws addressing financial arrangements between sources of Federal health care program referrals and those seeking such referrals. These fraud and abuse laws require financial separation between such parties or regulate relationships between them. The Shared Savings Program focuses on coordinating care between and among providers, including those who are potential referral sources for one another. Stakeholders have expressed concern that the restrictions these laws place on certain coordinated care arrangements may impede some of the innovative integrated-care models envisioned by the Shared Savings Program. Stakeholders believe these laws would inhibit sharing savings and other incentives that they consider key to the success of an ACO, for example, arrangements involving the provision of EHR systems, IT services, or free care management personnel.

Section 1899(f) of the Act authorizes the Secretary to waive the statutes listed above and certain other laws as necessary to carry out the Shared Savings Program. On the basis of stakeholder input, experience with the Shared Savings Program over the past several years, and other factors, the Secretary has found that it is necessary to continue to waive the physician self-referral law, the Federal anti-kickback statute, and the Beneficiary Inducements CMP in certain circumstances in order to carry out the Shared Savings Program. As explained below, the Secretary has determined that it is no longer necessary to waive the Gainsharing CMP. At the time we published the IFC, hospitals were prohibited from knowingly paying physicians to induce them to reduce or limit services, including medically unnecessary services. The statute was recently amended to prohibit hospitals

¹ For purposes of this final rule, the terms “ACO,” “ACO participants,” and “ACO providers/suppliers” have the meanings presently ascribed to them in 42 CFR 425.20.

from knowingly paying physicians to induce them to reduce or limit medically *necessary* services. The amended statute obviates the need to waive this provision to carry out the Shared Savings Program.

In this final rule, we are finalizing the five waivers from the IFC that waived certain provisions of the physician self-referral law, the Federal anti-kickback statute, and the Beneficiary Inducements CMP as necessary to carry out the provisions of section 1899 of the Act. We are waiving 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 the development and operation 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 final rule are promulgated pursuant to the specific authority at section 1899(f) of the Act. This authority applies only to the Shared Savings Program. The Affordable Care Act includes separate authority for the Secretary to waive certain laws, including certain fraud and abuse laws, for some other demonstrations and pilot programs. Guidance regarding such waivers, if any, is issued separately.

B. Medicare Shared Savings Program: Related Regulatory History

On April 7, 2011, CMS published a proposed rule setting forth proposed requirements for ACOs under the Shared Savings Program (Medicare Shared Savings Program: Accountable Care Organizations (76 FR 19528)) and soliciting public comments. As described above, CMS next published the 2011 Shared Savings Program final rule on November 2, 2011. CMS proposed and finalized changes to the ACO quality measurement reporting methodology and quality performance measures in the Calendar Year (CY) 2014 and CY 2015 Physician Fee Schedules. 78 FR 74230 (Dec. 10, 2013); 79 FR 67548 (Nov. 13, 2014). Additionally, on December 8, 2014, CMS published a proposed rule setting forth new proposed requirements for ACOs, and proposed revisions and clarifications to the 2011 Shared Savings Program final rule (Medicare Shared Savings Program: Accountable Care Organizations (79 FR 72760)). CMS finalized certain of these proposed requirements, revisions, and clarifications in the **Federal Register** on June 9, 2015 (Medicare Shared Savings Program: Accountable Care Organizations (80 FR 32692)) (the “2015 Shared Savings Program final rule”). On

July 15, 2015, CMS proposed further changes to the Shared Savings Program (Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (80 FR 41686)).

C. 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)). On November 2, 2011, CMS and OIG jointly published the IFC, which established waivers of the application of certain provisions of the physician self-referral law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP (Medicare Program: Final Waivers in Connection With the Shared Savings Program (76 FR 67992)). Prior to the statutory expiration of the IFC,² CMS and OIG jointly published the “Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule,” extending the effectiveness of the IFC and the timeline for publication of a final rule through November 2, 2015 (79 FR 62356 (Oct. 17, 2014)). We issued this continuation notice because CMS was developing a proposed rule regarding the Shared Savings Program and we wished to ensure the final waiver regulations aligned with the programmatic requirements. On February 12, 2015, CMS and OIG issued additional guidance on the waivers promulgated in the IFC (the “Additional Waiver Guidance”).³ The Additional Waiver Guidance provides guidance on: (1) Public disclosures required under the pre-participation waiver; (2)

² Pursuant to section 1871(a)(3) of the Act, a Medicare interim final rule shall not continue in effect if the final rule is not published before the expiration of the regular timeline. After consultation with the director of the Office of Management and Budget (OMB), the Department of Health and Human Services (HHS or the Department), through CMS, published a notice in the December 30, 2004, **Federal Register** (69 FR 78442) establishing a general 3-year timeline for publishing Medicare final rules after the publication of an interim final rule. Based on this timeline, the IFC, which is a Medicare interim final rule under Title XVIII, would have expired on November 2, 2014.

³ The Additional Waiver Guidance, which may be amended from time to time, is available on CMS’s Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Additional-MSSP-Waiver-Guidance.pdf>, and on OIG’s Web site at: <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>.

notification of failure to submit a timely application by parties who used the pre-participation waiver; and (3) requests for an extension of the pre-participation waiver period.

CMS and OIG are jointly finalizing waivers in this final rule to provide stakeholders with a coordinated approach for the application of certain fraud and abuse laws in connection with the Shared Savings Program. Administration of the physician self-referral law is the responsibility of CMS; 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 Beneficiary Inducements CMP is enforced by OIG.

For reasons elaborated in more detail elsewhere in this final rule, including the consideration of public input, the Department’s own analysis, and CMS’s experience over the last four years with the Shared Savings Program, the Secretary has determined that the waivers in this final rule are necessary to carry out the Shared Savings Program. To date, information available to CMS and OIG suggests that the waivers are adequately protecting beneficiaries and Federal health care programs while promoting innovative structures within the Shared Savings Program. We will continue to monitor the development of ACOs and shared savings arrangements and may consider additional rulemaking, if warranted.

This final rule finalizes the waivers as promulgated in the IFC, with the exception of the following changes:

- The waivers no longer waive the Gainsharing CMP;
- In condition 4 of the pre-participation and participation waivers, we have changed “should” to “must” consistent with our stated intent in the IFC that the ACO governing body’s documentation of its authorization must provide the basis for the determination that an arrangement is reasonably related to the purposes of the Shared Savings Program;
- We are clarifying that, for purposes of this final rule, the term “home health supplier” means a provider, supplier or other entity that is primarily engaged in furnishing home health services; and
- We have corrected certain technical or scrivener’s errors.

Therefore, we are finalizing five waivers as follows:

- An “ACO pre-participation” waiver of the physician self-referral law and the Federal anti-kickback statute 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 and the Federal anti-kickback statute 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 and the Federal anti-kickback statute 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 Federal anti-kickback statute for ACO arrangements that implicate the physician self-referral law and satisfy the requirements of 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, ACO participants, or ACO providers/suppliers under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

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 additional safeguards in the Shared Savings Program regulations at 42 CFR part 425, subpart D, 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.

In order to receive waiver protection, an arrangement need only fit in one waiver, although in some cases an arrangement may meet the criteria of more than one waiver. 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.

II. Shared Savings Program: Background

A. Section 1899 of the Social Security Act

Section 1899 of the Act establishes the Shared Savings Program to foster the development of ACOs in Medicare. 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 stimulate investment in infrastructure and redesigned care processes for high quality and efficient service delivery. CMS’s analysis of ACOs has shown improved patient care and savings for the Program.⁴

Under section 1899(b)(2)(B) of the Act and 42 CFR 425.200, ACOs must enter into an agreement with the Secretary to participate in the Shared Savings Program for no less than a three-year period. ACOs in the Shared Savings Program must comply with requirements addressing governance, management, and leadership of the ACO, as well as program integrity, transparency, compliance plan, and certification requirements, among others. Pursuant to 42 CFR 425.204(e), an ACO must select one of three tracks, which allows an ACO to choose whether to assume one- or two-sided performance-based risk as well as the degree of such performance risk. Under Track 1, described at 42 CFR 425.600(a)(1), an ACO has the opportunity to share in savings generated during the term of the participation agreement. A Track 1 ACO has one-sided risk (*i.e.*, no liability for shared losses). As set forth in 42 CFR 425.600(a)(2), an ACO that selects Track 2 operates under a two-sided performance-based risk model in which it is eligible to receive a higher share of savings than a Track 1 ACO, but is required to repay a portion of the losses sustained by the Medicare program if costs for the ACO’s assigned beneficiaries exceed certain thresholds. An ACO that selects Track 3, described in 42 CFR 425.600(a)(3), also operates under a two-sided performance-based risk model, but can receive a higher share of savings than a Track 2 ACO, in exchange for accepting accountability for repaying a greater share of losses. For any of the three tracks, in order to share a percentage of achieved savings with the Medicare program, an ACO must successfully meet quality and savings requirements and certain other conditions under the Shared Savings Program. ACO participants and ACO providers/suppliers continue to receive fee-for-service payments, and the ACO may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers.

⁴ A press release describing the improved patient care and savings resulting from ACOs can be found at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-08-25.html>.

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. As further described elsewhere in this final rule, the waivers are intended to foster innovative ACO arrangements—including care coordination arrangements—that further the quality and efficiency goals of the Shared Savings Program, while also protecting beneficiaries and the Shared Savings Program from fraud and abuse.

A waiver of a 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. Where a waiver of a fraud and abuse law exists, failure to fit in the waiver is not, in and of itself, a violation of 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 Beneficiary Inducements CMP. Existing exceptions and safe harbors might apply to ACO arrangements, depending on the circumstances.⁵ These include exceptions to the physician self-referral law for *bona fide* employment relationships, personal service arrangements, in-office ancillary services, electronic health records (EHR) arrangements, risk-sharing, and indirect compensation arrangements. Potential Federal anti-kickback statute safe harbors include 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 final rule 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

⁵ Section 1128A(i)(6) of the Act; 42 CFR 411.355 through 411.357; 42 CFR 1001.952.

final rule changes any Medicare program payment or coverage rule or alters any obligations parties may have under the Shared Savings Program. Although the waivers described in this final rule are necessary to ensure that the fraud and abuse laws do not unduly impede development and operation of ACOs in connection with the Shared Savings Program, the waivers are not intended to suggest that any particular arrangement between specific parties is necessary to participate in 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 a physician from making referrals for Medicare “designated health services,” including hospital services, to an entity with which the physician or an immediate family member of the physician has a financial relationship, unless an exception applies. An entity may not bill Medicare for designated health services furnished 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. Violations of the physician self-referral law may also result in liability under the False Claims Act (31 U.S.C. 3729–33). An ACO arrangement involving a physician who makes referrals for designated health services to an entity with which he or she or an immediate family member has a financial relationship is prohibited under the physician self-referral law, unless an exception applies.

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 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. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. 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). 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. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. For example, the distribution of shared savings by ACOs to or among its 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 could implicate the Federal anti-kickback statute and might not comply with an existing safe harbor. Arrangements for the provision of EHR technology or to engage specialists in care coordination might also potentially implicate the Federal anti-kickback statute and might not comply with an existing safe harbor.

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 an individual or entity from offering or transferring remuneration to a Medicare or Medicaid beneficiary 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 item or service payable by Medicare or a State health care program (including Medicaid). Existing exceptions to the Beneficiary Inducements CMP are found at section 1128A(i)(6) of the Act. The CMP defines “remuneration” as including transfers of items or services for free or for other than fair market value. OIG has previously taken the position that incentives that are only nominal in value are not prohibited by the statute and has interpreted nominal in value to mean no more than \$10 per item, or \$50 in the aggregate on an annual basis. See 65 FR 24400.

Stakeholders have indicated that a waiver of this law is needed to promote greater preventive care, to incentivize patients to follow treatment or follow-

up care regimes, and to increase participation in ACOs. Without this waiver, the Beneficiary Inducements CMP could prohibit ACOs, ACO providers/suppliers, and ACO participants from using appropriate incentives to help achieve better health and better care for their Medicare patients, two of the goals of the Shared Savings Program. For example, the provision of a blood pressure cuff for a hypertensive patient participating in an ACO’s chronic disease management program may, depending on the circumstances, implicate the Beneficiary Inducements CMP.

4. Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Medically Necessary 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. Hospitals that make (and physicians who receive) payments prohibited by the Gainsharing CMP are liable for CMPs of up to \$2,000 per patient covered by the payments (sections 1128A(b)(1) and (2) of the Act). When the IFC was published on November 2, 2011, under section 1128A(b)(1) of the Act, a hospital was prohibited from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or State health care program beneficiaries under the physician’s direct care, including medically unnecessary services. In the IFC, we included a waiver of the Gainsharing CMP in the pre-participation, participation, shared savings distribution, and compliance with the physician self-referral law waivers. See 76 FR 68000–68001.

Section 512(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, revised the Gainsharing CMP so that it prohibits hospitals from knowingly making payments, directly or indirectly, to induce physicians to reduce or limit “medically necessary” services provided to Medicare or State health care program beneficiaries under the physician’s direct care. In light of the statutory change, payments by hospitals to induce physicians to reduce or limit medically unnecessary services no longer implicate the Gainsharing CMP. In other words, arrangements between hospitals and physicians that incentivize greater efficiency and reduction of waste, which previously

may have run afoul of the Gainsharing CMP, would no longer implicate the provision, provided those arrangements do not involve reductions or limitations in medically necessary care. Thus, a waiver of the Gainsharing CMP is no longer necessary to carry out the Shared Savings Program, which, by its terms, promotes quality and patient care goals like fostering efficient medically necessary care, but not stinting on medically necessary care. Accordingly, we are not finalizing the waivers of the Gainsharing CMP that were promulgated in the IFC. See 76 FR 68000–68001. This decision will not affect the ability of parties to enter into arrangements that previously fit into a waiver of the Gainsharing CMP in the IFC.

Both the amended Gainsharing CMP and the waivers of the Gainsharing CMP in the IFC permit payments from hospitals to physicians to reduce or limit *medically unnecessary* (e.g., wasteful, inefficient) services. Payments from hospitals to physicians to reduce or limit medically necessary services are not, and never have been, consistent with the purposes of the Shared Savings Program, were not protected by the waivers in the IFC, are not permitted by the amended Gainsharing CMP, and are not protected by the waivers in this final rule. CMS stated in the 2015 Shared Savings Program final rule that it has and will continue to use, among other tools, its monitoring authorities (set forth in 42 CFR 425.316(b)) to ensure that ACOs, ACO participants, and ACO providers/suppliers do not stint on medically necessary care. 80 FR 32781.

By way of example, we explained in the IFC that knowing payments by a hospital to induce a physician 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 protection under the shared savings distribution waiver. In contrast, we explained in the IFC that we would protect payments from shared savings designed to “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).” 76 FR 68006 (emphasis in original).

For clarity and consistency with the amended Gainsharing CMP, and for the reasons noted above, we are modifying the pre-participation waiver, participation waiver, shared savings distribution waiver, and compliance

with the physician self-referral law waiver to remove the waiver of the Gainsharing CMP. In the IFC, we excluded from the shared savings distribution 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.” 76 FR 68006 (emphasis in original). Because we are removing the waiver of the Gainsharing CMP, we are also removing this condition from the shared savings distribution waiver.

We emphasize that this modification does not alter the scope of permissible arrangements under the Gainsharing CMP and will not affect the ability of parties to enter into arrangements that qualified for protection under the waivers of the Gainsharing CMP in the IFC. Going forward, ACO arrangements involving payments from hospitals to physicians to reduce or limit services must comply with the Gainsharing CMP, as amended. For purposes of this final rule, we will continue to interpret “medical necessity” consistent with Medicare program rules and accepted standards of practice, including the IFC guidance regarding alternate and appropriate medical care.

III. Explanation of Waiver Requirements, Clarifications of Certain Provisions, Summaries of Comments, and Responses to Comments

A. Overview

The entire set of waivers and applicable requirements are set forth in section IV of this final rule, pursuant to the authority granted under section 1899(f) of the Act. The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier participating in the Shared Savings Program. The waivers are self-implementing. Apart from meeting applicable waiver conditions (which include some required actions), no special procedures (such as the submission of a separate application for a waiver) are required by parties in order to be covered by a waiver. Parties need not apply for an individualized waiver. As stated below, we will also make the waiver text available via both the CMS and OIG Web sites.

The Department has taken several opportunities to solicit and reply to public comments on the Shared Savings Program.⁶ The Department received a

total of 15 timely filed comments in response to the IFC from entities and individuals, and section III summarizes and responds to these public comments. Overall, commenters supported the waivers and generally agreed that they provide the flexibility needed to permit innovation in the Shared Savings Program. However, we received some specific comments about various aspects of the waivers. In addition, we received comments that are outside the scope of this rulemaking; those comments are not summarized or responded to here.

In section III, we are adopting, in large part, the guidance from section V of the IFC in order to provide the public with a comprehensive document regarding the Shared Savings Program fraud and abuse waivers. In addition, section III explains the minor clarifications made to the waivers found in section IV of this final rule as well as our position with respect to several of the waiver requirements.

B. Reasonably Related to the Purposes of the Shared Savings Program

Several waivers contain language specifying that an arrangement be “reasonably related to the purposes of the Shared Savings Program.” As we stated in the IFC, under this standard, an arrangement “need only be reasonably related to one enumerated purpose, although we would expect that many arrangements would relate to multiple purposes.” 76 FR 68002. In the IFC, we defined “purposes of the Shared Savings Program” consistent with the purposes set forth in sections 1899(a) and (b) of the Act. In this final rule, we continue to define the purposes of the Shared Savings Program in accordance with the statutory purposes, namely, 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. In addition, we continue to interpret the purpose of “efficient service delivery” 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.

⁶ See Request for Information Regarding Accountable Care Organizations and the Shared Savings Program, 75 FR 70165 (Nov. 10, 2010), and “Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback,

and Civil Monetary Penalty (CMP) Laws” at <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>.

In the IFC, we gave the following examples of activities that would be reasonably related to the purposes of the Shared Savings Program, which remain applicable in this final rule: (1) Promoting evidence-based medicine and patient engagement; (2) meeting requirements for reporting on quality and cost measures; (3) coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; (4) establishing clinical and administrative systems for the ACO; (5) meeting the clinical integration requirements of the Shared Savings Program; (6) meeting the quality performance standards of the Shared Savings Program; (7) evaluating health needs of the ACO's assigned population; (8) communicating clinical knowledge and evidence-based medicine to beneficiaries; and (9) developing standards for beneficiary access and communication, including beneficiary access to medical records. 76 FR 68002.

Arrangements that are unrelated to the Shared Savings Program, but that may have similar underlying purposes, are not covered by the term "purposes of the Shared Savings Program." 76 FR 68002. We continue to believe that arrangements involving care for ACO beneficiaries, but that also encompass care for non-ACO beneficiaries, may be eligible for waiver protection; such arrangements can further the purposes of the Shared Savings Program. The definition of "purposes of the Shared Savings Program" applies uniformly to all waivers in which it appears.

Comment: Some commenters objected to the "reasonably related" standard as overly broad, vague, or ambiguous. One commenter suggested that our "reasonably related" standard was not sufficiently narrow so as to waive only such requirements of sections 1128A and 1128B and Title XVIII of the Act as may be "necessary" to carry out the purposes of the Shared Savings Program.

Response: We disagree with the commenters. We believe the "reasonably related" standard best achieves our goal of providing flexibility to ACOs to develop the innovative arrangements envisioned by CMS, while still requiring a verifiable connection with the Shared Savings Program so as to minimize the risk of allowing fraudulent or abusive arrangements.

We underscore that not every arrangement connected to an ACO will be reasonably related to the purposes of the Shared Savings Program. We believe there are a range of arrangements that ACOs, ACO participants, and/or ACO providers/suppliers might enter into

that have no connection to the purposes of the Shared Savings Program. In the IFC, we gave the example, which we are adopting here, of a per-referral payment (e.g., 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) as not being reasonably related to the purposes of the Shared Savings Program. 76 FR 68004. Other examples of arrangements that are not reasonably related to the purposes of the Shared Savings Program include the following: (1) An arrangement whereby a physician, a physician practice, or other provider is required to pay a sum to receive ACO-related referrals (e.g., "pay-to-play" arrangements); (2) medical directorships or personal service arrangements where referring physicians or other providers receive payments for no actual services performed; (3) payments to induce a physician or other provider to stint on medically necessary care for beneficiaries; or (4) free gifts, such as sporting event tickets, to referring ACO providers/suppliers or ACO participants. These arrangements are suspect and subject to ordinary case-by-case review under all applicable fraud and abuse laws.

Unlike the examples provided above, and as we pointed out in the IFC, arrangements with specialists or other practitioners, such as 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 resulted in a greater likelihood that the patient might be referred to or within an ACO. 76 FR 68004. Similarly, compensation to a physician for achieving certain quality metrics for patient care set by the ACO could be reasonably related to the purposes of the Shared Savings Program, although this arrangement may result in that physician being more likely to refer to or within the ACO. We remind parties that they must comply with the programmatic safeguard at 42 CFR 425.304(c), which prohibits certain required referrals and cost-shifting.

C. Eligibility for the Waivers

This final rule finalizes four waivers that are available to protect certain 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. As noted below, some waivers include certain ACO-related arrangements with

other parties if all waiver conditions are met. (A fifth waiver, described below, addresses incentives offered to beneficiaries.)

The first of the five waivers that we finalize in this final rule, the ACO pre-participation waiver, is available for start-up arrangements, 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. As we stated in the IFC:

[T]o 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 [42 CFR 425.102]). 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.

76 FR 68002. Further, in that rulemaking we stated that the pre-participation waiver does not cover arrangements involving drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers. As we explained in the IFC, drug and device manufacturers and distributors are not Medicare enrolled suppliers and providers. We also explained that DME suppliers and home health suppliers have historically posed a heightened risk of program abuse,⁷ and therefore we excluded these entities from the pre-participation waiver.

Comment: Several commenters requested clarification of the term "home health supplier." One commenter asked that we confirm that the pre-participation waiver protects arrangements with Medicare-certified home health agencies or providers. Another commenter questioned whether the exclusion applied to those who furnish home health supplies outside

⁷ In addition to the government's enforcement and oversight experience with these suppliers, we note that CMS has designated these entities as high or moderate risk for purposes of provider enrollment screening. See e.g., "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers", 76 FR 5862 (Feb. 2, 2011) at <http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf>.

the Medicare program. A commenter also noted that the term “home health supplier” is not defined in the Medicare program.

Additionally, we received several comments objecting to the exclusion of all home health agencies from the pre-participation waiver. These commenters asked that CMS and OIG clarify whether all home health agencies were excluded intentionally from the pre-participation waiver, regardless of whether they are certified by Medicare. In general, these commenters urged us to consider that home health agencies are in a position to generate savings for the Shared Savings Program through quality, efficient care in a less costly setting. One commenter noted that a *per se* exclusion of home health agencies from the pre-participation waiver unfairly punishes good actors because of isolated issues of program abuse, and other commenters asserted that categorical exclusion of these providers may be detrimental to the purposes of the Shared Savings Program and may have anti-competitive effects. Several commenters requested that we clarify that home health agencies may be parties to arrangements protected by the participation, shared savings distributions, compliance with the physician self-referral law, and patient incentives waivers even if excluded from the pre-participation waiver, and may participate in the Shared Savings Program as post-acute care providers.

One commenter suggested that home health agencies should be permitted to participate in start-up arrangements protected by the pre-participation waiver if they have a compliance program in place that is consistent with OIG’s Compliance Program Guidance for Home Health Agencies. Another commenter suggested that CMS and OIG adopt an approach that would exclude a provider from any sector, including home health care, from the pre-participation waiver if it is currently subject to a corporate integrity agreement, does not maintain a compliance program reasonably consistent with OIG guidelines, or is subject to a payment suspension.

Response: This final rule continues to recognize that home health plays an important role in care coordination. Under this final rule, “home health suppliers” are permitted to use all waivers offered in this final rule, if the applicable waiver conditions are met, except the pre-participation waiver. Moreover, certain start-up arrangements involving entities that furnish home health services may fit in existing safe harbors to the Federal anti-kickback

statute or exceptions to the physician self-referral law.

We continue to be concerned that the pre-participation waiver could be more prone to abuse than other waivers because, among other things, it applies in circumstances that pre-date a prospective ACO’s actual commitment to the Shared Savings Program and the attendant regulation and oversight. We remain concerned about potential misuse of the waiver by those who are not acting in good faith to create an ACO for the Shared Savings Program. Because of this risk, we have incorporated a number of targeted safeguards into the pre-participation waiver. For instance, we are requiring notification of failure to submit a timely application, and we are prohibiting use of the waiver by certain types of entities that are not central to forming a Shared Savings Program ACO and have historically posed an elevated risk of fraud, as described above.

One type of entity we excluded from the pre-participation waiver in the IFC was “home health supplier,” and we agree that we should clarify the intended meaning of this term in the final rule. As a commenter points out, the term does not have a specific meaning in the Medicare program. We are clarifying that, for purposes of this final rule, the term “home health supplier” means a provider, supplier, or other entity that is *primarily engaged* in furnishing “home health services,” as that term is defined in section 1861(m) of the Act. The term “home health supplier” would include freestanding home health agencies (as that term is commonly used by CMS and industry stakeholders) and their parent entities, which may own one or more freestanding home health agencies, if the parent entity is primarily engaged in the delivery of home health services.

A Medicare-enrolled provider or supplier, such as a hospital, skilled nursing facility, physician practice, or other provider or supplier could be a party to an arrangement protected by the pre-participation waiver, even if such provider or supplier furnishes home health services, so long as the hospital, skilled nursing facility, physician practice, or other provider or supplier is not primarily engaged in providing home health services.

This clarification is consistent with our intent in the IFC. We did not intend there, and do not intend in this final rule, to exclude from the pre-participation waiver hospitals, skilled nursing facilities, physician practices, or other providers and suppliers that may furnish some home health services. To do otherwise would have precluded

from the waiver the very types of providers and suppliers the pre-participation waiver was meant to protect to enable them to form ACOs for the Shared Savings Program. To this end, a provider or supplier that furnishes home health services could be a party to an arrangement covered by the pre-participation waiver, so long as that entity is *not* primarily engaged in the furnishing of home health services.

Whether a provider, supplier or other entity is excluded as a home health supplier under this final rule does not turn on whether the supplier is Medicare-certified. Medicare-certified home health agencies are excluded if they meet the definition of a home health supplier, set forth in this final rule. Finally, we appreciate another commenter’s suggestions for additional restrictions in the pre-participation waiver. We did not propose these restrictions and believe they would require further study. We plan to continue to monitor the use and impacts of the pre-participation waiver and may consider these suggestions in future rulemaking, if warranted. We are not adopting the suggestion to permit home health agencies that have compliance plans to use the pre-participation waiver.

In summary, we are finalizing the pre-participation waiver to exclude home health suppliers, as defined above, DME suppliers, and pharmaceutical and device manufacturers, because of continuing program integrity risks, the heightened risks inherent in the pre-participation waiver, and an assessment based on four years of program experience that the pre-participation waiver is sufficiently broad for purposes of the Shared Savings Program. We believe this policy is consistent with the goals of the Shared Savings Program and has not created barriers to the participation or development of ACOs.

D. Pre-Participation and Participation Waivers

1. Scope

The pre-participation waiver covers a broad array of start-up arrangements, subject to certain conditions. The participation waiver covers any arrangement that meets its conditions, including start-up arrangements. Because these two waivers may serve to protect a wide variety of arrangements entered into by and among ACOs, ACO participants, and ACO providers/suppliers, and are necessary to carry out the purposes of the Shared Savings Program, we are finalizing these waivers (minus the Gainsharing CMP waiver)

with some clarification, as described in more detail below.

When we developed the pre-participation and participation waivers in the IFC, our intent was 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. The pre-participation and participation waivers rely on the programmatic requirements of the Shared Savings Program to safeguard Medicare beneficiaries and the Medicare program. 76 FR 68003. As explained in the IFC, the waivers reflect our position that risks of fraud and abuse, such as overutilization and inappropriate utilization, are mitigated, in the first instance, by the Shared Savings Program design, the eligibility requirements, the quality of care and accountability provisions, and the program integrity provisions. As described in more detail below, the waivers include additional safeguards in the form of governance responsibility, transparency, and a documented audit trail. *Id.*

2. Start-Up Arrangements Under the Pre-Participation Waiver

Consistent with the IFC, the pre-participation waiver is limited to “start-up arrangements.” We are making a technical correction to the waiver text so that the term “start-up arrangements” applies to *arrangements for items, services, facilities, or goods* (including non-medical items, services, facilities, or goods) that are used to create or develop an ACO and that are provided by such an ACO, ACO participants, or ACO providers/suppliers. We continue to believe that the provision of a subsidy for these items, services, facilities, or goods can constitute a start-up arrangement. We note that arrangements meeting the definition of a “start-up arrangement” can also qualify for the participation waiver if they occur after the ACO’s start date in the Shared Savings Program, provided all other waiver conditions are met.

We believe that the following list, taken from the IFC, remains representative of the types of start-up arrangements that ACOs enter into, and that may qualify under the pre-participation waiver:

(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.

76 FR 68003.

We have included the list in this final rule so that ACOs may continue to use these examples as guideposts in determining whether a particular arrangement may qualify for protection under this waiver.

3. Additional Safeguards

One of the key safeguards to mitigate the risk of fraud or abuse from arrangements protected under these waivers is the involvement of the ACO’s governing body in the authorization of each arrangement. In the IFC, the pre-

participation and the participation waivers require the governing body of the ACO to 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 and to 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 42 CFR 425.106 and 425.108, as recently amended, and the governing body must have a meaningful conflicts of interest policy for its members. 76 FR 68003.) As we observed in the IFC:

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.

Id. We are finalizing this policy regarding the ACO governing body determination and authorization, with the additional clarification provided below.

Comment: Some commenters supported our requirement in the pre-participation and participation waivers that an ACO governing body document its *bona fide* determination that an arrangement reasonably relates to the purposes of the Shared Savings Program. Commenters suggested that we provide additional examples of particular methods by which governing bodies may make a *bona fide* determination regarding an arrangement. The commenters also advocated for requiring governing bodies to make information regarding the authorization of arrangements publicly available. Another commenter suggested that proof that the governing body made a meaningful determination should be reflected in the minutes of the ACO governing body’s meeting when the arrangement requiring a waiver is being considered. Others suggested that we provide examples of arrangements that *cannot* be authorized by a governing body as reasonably related to the purposes of the Shared Savings Program.

Response: We appreciate the commenters’ support for our

requirement that an ACO governing body make a *bona fide* determination that an arrangement reasonably relates to the purposes of the Shared Savings Program. We note that this determination is only one of several requirements that an ACO must meet in order for an arrangement to be protected by these waivers. We refer the commenters to the guidance in the IFC (76 FR 68004), and we are providing additional clarification on three safeguards for these waivers: (1) Methods of the ACO governing body's authorization; (2) documentation requirements; and (3) transparency requirements.

Methods of the ACO Governing Body's Authorization

As we explained above, the pre-participation and participation waivers require the ACO governing body to make a *bona fide* determination that an arrangement is reasonably related to the purposes of the Shared Savings Program. We reiterate that a key role of the ACO governing body is to evaluate and identify clearly whether arrangements are reasonably related to one or more purposes of the Shared Savings Program. We do not believe that an ACO governing body can make and authorize a *bona fide* determination that an arrangement is reasonably related to the purposes of the Shared Savings Program by "rubber stamping" its approval of an arrangement. We are not prescribing particular methods for this determination. ACO governing bodies have available to them a variety of methods for making such a determination, provided they meet all of the requirements in this condition of the waiver. We believe and expect that members of the ACO governing body will employ a thoughtful, deliberative process for making a determination that an arrangement is reasonably related to the purposes of the Shared Savings Program, and will articulate clearly the basis for their determinations and authorizations. As we stated in the IFC, a meaningful determination and authorization by the ACO's governing body is essential because it serves to ensure "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." 76 FR 68004.

These waivers do not protect sham governing body determinations for arrangements that are not connected to the Shared Savings Program. One factor we would consider when evaluating whether the ACO governing body's determination is *bona fide* would be the proximity in time between the

establishment of the arrangement (and any material amendments and modifications to the arrangement) and the ACO governing body's corresponding determination and authorization. For example, a significant passage of time between the establishment of the arrangement and the ACO governing body's determination might indicate that the ACO governing body did not make a *bona fide* determination and was acting for other purposes.

In response to the commenters' request for examples of arrangements that cannot be reasonably related to the purposes of the Shared Savings Program, we provide several examples in section III.B above of arrangements that are not reasonably related to the purposes of the Shared Savings Program.

We reiterate that, in all instances, no waiver protection applies until all requirements of the waiver are met.

Documentation Requirements

As we emphasized in the IFC, the determination and authorization must be contemporaneously documented by the ACO governing body. 76 FR 68003. Among their requirements, the pre-participation and participation waivers mandate that the documentation must identify at least a description of the arrangement and the date and manner of the ACO governing body's authorization of the arrangement; we specified that documentation should include the basis for the ACO governing body's determination that the arrangement is reasonably related to the purposes of the Shared Savings Program. *Id.* at 68000, 68001. In section V of the IFC, we explained that "documentation *must* include the basis for the determination that the arrangement is reasonably related to the purposes of the Shared Savings Program." *Id.* at 68003 (emphasis added). In this final rule, we are correcting the waiver text in condition 4.b. of the pre-participation and participation waivers by replacing "should" with "must" so that the waivers align with our stated intent for this documentation requirement in section V of the IFC. We stated that the documentation requirement was mandatory, not discretionary, because we believed (and continue to believe) that the determination by the ACO governing body is necessary to trigger protection of the waiver. *Id.* at 68004. The ability to ascertain the ACO governing body's rationale for its determination, as reflected in its documentation, is essential in being able to distinguish between arrangements for which the ACO

governing body has made a *bona fide* determination that the arrangement is reasonably related to the purposes of the Shared Savings Program, and those for which the ACO governing body has not made such a determination. Particularly in this decision-making capacity, the ACO governing body serves as a gatekeeper to ensure only arrangements that are integral to the ACO's mission and role in the Shared Savings Program are protected, and that isolated arrangements furthering the individual financial or business interests of ACO participants or ACO providers/suppliers are not. The existence of documentation that corresponds with the actions of the ACO governing body is critical to the functionality of this safeguard.

It is essential that an ACO have sufficient documentation to identify clearly the arrangement its governing body is considering, and to be able to point to the basis or bases for the decision that an arrangement is "reasonably related" to the purposes of the Shared Savings Program. We stated in the IFC that the documentation should allow "the government or another third party reviewing the documentation [to be] able to ascertain the material terms of the arrangement, including the information listed in item 4 of the pre-participation and participation waivers." 76 FR 68004. We are more concerned with the level of specificity included in the ACO governing body's records about the arrangement (and any material amendments and modifications to the arrangement), and the corresponding basis or bases for the ACO governing body's determination, than the particular format of that documentation. For example, while it would be a best practice to have a written resolution duly authorized by the ACO governing body evidencing the basis or bases for its determination that a particular arrangement is reasonably related to the purposes of the Shared Savings Program, such a resolution is not required, and the documentation requirements of the waivers can be met in other ways. In addition, we note that the waivers do not require an agreement signed by the parties in order for an arrangement to be protected, although such an agreement is a best documentation practice (and is one way to satisfy the writing requirement included in relevant exceptions to the physician self-referral law if a waiver does not apply).

While we have not specified the form of documentation that will be sufficient, as that will vary depending on the circumstances, the documentation must clearly evidence the nexus between the

arrangement and the purposes of the Shared Savings Program. Documentation that lacks an adequate description of the arrangement or of the ACO governing body's basis for its determination will not meet the requirements of condition 4 of the pre-participation and participation waivers in this final rule. Finally, we reiterate that the documentation may be in paper or electronic form.

In this final rule, we are finalizing the document retention policies from the IFC. Specifically, the ACO must have an audit trail of contemporaneous documentation that identifies core characteristics of the arrangement (as listed in the waiver text), maintain such documentation for 10 years, and make the documentation available to the Secretary, upon request. For the pre-participation waiver, documentation of the diligent steps must be retained for at least 10 years following the date that the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application.

We decline to adopt the commenters' recommendations to require the ACO to make information about the authorization publicly available. We believe the combination of the documentation requirements in the final waivers, the existing public disclosure requirements for these arrangements, and the Secretary's monitoring authorities appropriately mitigate the risk of fraud or abuse.

Transparency Requirements

We are finalizing the IFC requirement for public disclosure—at a time and in a place and manner established in guidance issued by the Secretary—of arrangements for which waiver protection under the pre-participation or participation waiver is invoked. As we explained in the IFC, the public disclosure must include the description of the arrangement, but shall not include the financial or economic terms of the arrangement because of potential antitrust implications, among other considerations. We reiterate, however, that the financial and economic terms of the arrangement must be documented pursuant to the documentation requirements described in condition 4.a. of the pre-participation and participation waivers and must be made available to the Secretary upon request. 76 FR 68004.

Comment: Most of the commenters supported the public disclosure criterion, and some commenters wanted to impose additional requirements on ACOs. One commenter suggested that we promulgate regulations that set out

these additional requirements in greater specificity. According to several commenters, we should require public posting of the use of the waivers on a rolling basis, and one commenter recommended that we require parties to publicize a notice of intent to form an ACO. Another commenter advocated for disclosure of the use of a waiver to CMS, as well as to the public via the media serving the community in which ACO participants are located.

Response: In the IFC, we set out three reasons for developing the transparency requirement:

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. 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.

76 FR 68004 (footnote omitted).

In the IFC, we stated that, until such time as additional guidance was issued, parties seeking to use the ACO pre-participation or participation waiver would meet the disclosure requirement by posting information identifying the parties to the agreement 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 was sought, within 60 days of the date of the arrangement. We subsequently provided further guidance on the method and content of required public disclosures in the Additional Waiver Guidance. Parties seeking to use the pre-participation or participation waiver meet the disclosure requirements only if they post information in accordance with the instructions in the Additional Waiver Guidance, as it may be updated by the Secretary from time to time. (Prior to the Additional Waiver Guidance, parties could meet the disclosure requirement by following the guidance in the IFC cited above.)

We believe the disclosure process detailed in the Additional Waiver Guidance, which was issued after the comment period for the IFC closed, addresses the commenters' suggestion that we set out additional requirements with greater specificity and that we provide for rolling disclosures. The waivers provide that the time, place,

and manner of the public disclosure shall be set by the Secretary; we do not believe separate regulations are necessary. Further, requiring publication of a notice of intent to form an ACO for purposes of these waivers would be overly burdensome. With respect to one commenters' suggestions regarding public disclosure of waivers, including to CMS or local media, we believe the public disclosure requirements in the Additional Waiver Guidance are sufficient because they provide for public transparency regarding arrangements for which waiver protection is sought while minimizing the burden on ACOs.

4. Outside Party Arrangements

The IFC included certain ACO-related arrangements with outside providers and suppliers, such as hospitals, specialists, or post-acute care facilities, within the scope of the pre-participation and participation waivers. An outside party arrangement is an arrangement with an individual or entity that does not meet the definition of an ACO, an ACO participant, or an ACO provider/supplier, as those terms are defined in section IV of this final rule, but has a role in coordinating and managing care for ACO patients.

Comment: Some commenters supported our approach to protect certain ACO-related arrangements with outside providers and suppliers. One commenter stated that the arrangements protected by the pre-participation and participation waivers serve a significant role in ensuring patient access to care. Other commenters urged CMS and OIG to limit the waivers to ACOs, ACO participants, and ACO providers/suppliers. One commenter advocated requiring arrangements with outside parties to be fair market value and commercially reasonable, while another commenter believed we should require outside party arrangements to be necessary or directly related to the ACO's operations under the Shared Savings Program. Finally, a commenter suggested that, if the waivers are extended to outside party arrangements, those outside parties should be subject to certification requirements and other similar safeguards.

Response: As we observed in the IFC:

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.

76 FR 68005.

We agree with the commenters who advocated that arrangements with outside parties should be protected under these waivers so long as all requirements for the applicable waiver are met. We believe that these arrangements are important in furthering the quality and patient care goals of the Shared Savings Program. We recognize that, for example, some individuals and entities furnishing care to beneficiaries in an ACO will not be an ACO participant or ACO provider/supplier. ACOs may want to enter into arrangements with these outside individuals or entities, however, to promote care coordination for their patients or to encourage quality improvement.

While we understand the benefits of arrangements with outside parties, we recognize the concerns of those commenters who recommended additional safeguards, such as fair market value or commercial reasonableness requirements. We have reviewed the comments and considered the types of arrangements that may be necessary to meet the goals of the Shared Savings Program, the wide variation of arrangements ACOs are undertaking to redesign care, and the challenges of funding ACO infrastructure and operations. Based on these considerations and experience with the Shared Savings Program to date, we are not imposing additional conditions on outside party arrangements at this time. Similarly, we are not adopting the commenter's suggestion that arrangements with outside parties be subject to certification requirements or similar safeguards at this time.

5. Duration of the Pre-Participation and Participation Waivers

For the participation waiver, the waiver period starts on the start date of the participation agreement and ends 6 months following the earlier of the expiration of the participation agreement (including any renewals) or the date on which the ACO has voluntarily terminated the participation agreement. If CMS terminates the participation agreement, the waiver period will end on the date of the termination notice. 76 FR 68001.

As we explained in the IFC, 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. Our intent behind these specific duration periods was, and

continues to be, to ensure that the pre-participation waiver covers only start-up arrangements that are closely linked to the Shared Savings Program. 76 FR 68005.

Under condition 1 of the pre-participation waiver in the IFC, which we adopt in this final rule, we specify that the waiver covers only arrangements 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"). For target year 2013 or later, the waiver period starts one year preceding an application due date (the "selected application date"). For example, for ACOs pursuing target year 2016, the application due date was August 7, 2015, which means the ACO pre-participation waiver period would have begun on August 7, 2014. Application due dates for future years will be announced by CMS.

In the IFC, we provided three scenarios that clarify the end of coverage of the pre-participation waiver, which we are finalizing in this final rule. First, for an ACO that submits an application that is ultimately accepted and enters into a Shared Savings Program 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. 76 FR 68005. No further governing body approval is required for arrangements that were protected by the pre-participation waiver. Second, for an ACO that submits an application that is ultimately denied by CMS (for any reason), the pre-participation waiver 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. No newly created arrangements established on or after the date of the denial notice would be protected during the 6-month period immediately following the denial notice. Third, if an ACO fails to submit an application on the final application due date for the target year, the pre-participation waiver ends on the earlier of the application due date for the target year 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 application due date, may apply for an extension of the waiver. If an ACO seeks protection for an arrangement under the pre-

participation waiver but fails to submit a Shared Savings Program application by the final application due date, this final rule requires that the ACO submit a statement describing the reasons it failed to submit a timely application, in a form and manner to be determined by the Secretary. *Id.* The Additional Waiver Guidance,⁸ provides instructions on the form and manner of the statement explaining why the ACO failed to submit an application.

ACOs falling under the third scenario provided above may apply for an extension of the waiver period using procedures established by the Secretary. We are continuing to require that an ACO seeking an extension submit documentation of its diligent steps to develop an ACO and show 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. 76 FR 68000. The Additional Waiver Guidance lays out in detail the procedures for submitting a request for an extension of the pre-participation waiver period. The determination whether to grant an extension of the waiver will be at the sole discretion of the Secretary and will not be reviewable. As we stated in the IFC, 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 use the pre-participation waiver only once. If an extension is not granted, the ACO may no longer rely on the pre-participation waiver. *Id.* at 68005.

As we discussed in the IFC and above, under certain 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. We reiterate in this final rule that the "tail" periods protect only arrangements that were in place and otherwise qualified for the waiver at the time the waiver expires or terminates.

Comment: One commenter supported our decision to include a 6-month tail period for the pre-participation and participation waivers, but requested that we extend this tail period for the participation waiver in situations where CMS terminates the ACO. The commenter stated that these entities

⁸ The Additional Waiver Guidance, which may be amended from time to time, is available on CMS's Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/sharedsavingsprogram/Downloads/Additional-MSSP-Waiver-Guidance.pdf>, and on OIG's Web site at: <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>.

should have an “unwinding period” to discontinue activities previously protected under this waiver.

Response: We are not adopting the commenter’s recommendation to apply the 6-month tail period to the participation waiver for an ACO that CMS terminates. In such circumstances, the Government has determined that an ACO is not acceptable for participation in the Shared Savings Program, and we believe that it is appropriate to terminate waiver protection as well. As such, consistent with the waiver period in the IFC, following the date of the notice of termination of the ACO by CMS, no protection under the applicable waiver would extend to arrangements involving the ACO, its ACO participants, or its ACO providers/suppliers. To the extent the arrangements continued following the date of the notice of termination of the ACO by CMS, such arrangements would be subject to review for compliance with all applicable fraud and abuse laws.

E. Waiver for Shared Savings Distributions

As we explained in the IFC, the purpose of the waiver for shared savings distributions is two-fold. First, the waiver protects arrangements created by the distribution of shared savings within an ACO that qualify for the waiver. As we noted in the IFC, “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.” 76 FR 68005. This statement was and continues to be true so long as all waiver conditions are met. We recognize 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. *Id.* We continue to believe that these goals are consistent with interests protected by the fraud and abuse laws.

Second, the waiver protects arrangements that involve the use of shared savings to pay parties outside an ACO, provided all applicable waiver conditions are met. 76 FR 68005. As discussed above, we believe that arrangements with outside parties are important in furthering the quality and patient care goals of the Shared Savings Program. We underscore, however, that to qualify for protection under this waiver, the payments to outside individuals or entities must be used for activities that are reasonably related to the purposes of the Shared Savings

Program. *Id.* Although not required by the terms of the waiver, an ACO would be well advised to maintain documentation that explains how payments would be and are being used for activities that are reasonably related to the purposes of the Shared Savings Program. We discuss the meaning of “reasonably related to the purposes of the Shared Savings Program” above.

This waiver is limited to distributions of shared savings generated by the ACO through its participation in the Shared Savings Program. As we stated in the IFC:

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 [participation] 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 [or] 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.

76 FR 68005–68006.

If the arrangement does not exclusively involve the distribution of shared savings generated through participation in the Shared Savings Program, the arrangement would need to qualify for another waiver outlined in section IV of this final rule, fit in an existing exception or safe harbor, or otherwise comply with the laws. 76 FR 68006. This waiver does not protect, for example, distributions to physicians, providers, or other parties outside the ACO in return for referring patients to the ACO. The only shared savings distributions to parties outside the ACO that are protected under this waiver would be compensation (using shared savings) for activities that are reasonably related to the purposes of the Shared Savings Program. *Id.* Examples of arrangements that are not reasonably related to the purposes of the Shared Savings Program are addressed above.

Comment: Two commenters requested that we incorporate additional safeguards to prevent stinting of care for Medicare beneficiaries, cherry picking only the healthiest patients, or reducing or limiting medically necessary items or services. One commenter suggested that CMS and OIG incorporate into the final waivers additional safeguards previously identified by the agencies, for example, providing assurance that physicians can still use the same items and services that were available before the establishment of the shared savings arrangements.

Response: We agree with commenters that it is critical to protect patients from cherry picking, stinting on care, and the withholding of medically necessary items or services. As explained above, we are no longer waiving the Gainsharing CMP. As recently amended, the Gainsharing CMP prohibits a hospital from knowingly making payments to physicians to reduce or limit medically necessary services. There is no need to waive the amended Gainsharing CMP in order to carry out the Shared Savings Program and waiving the statute, as amended, would potentially eliminate protection from stinting on care. Our approach in this final rule preserves the protections contained in the Gainsharing CMP and reflects our commitment to the quality and safety of patient care. We also note that the program rules contain extensive quality requirements and CMS has monitoring authorities under 42 CFR 425.316(b) to prevent ACOs from engaging in these prohibited activities. Further, shared savings payments are conditioned on meeting certain quality metrics, which should reduce the risk of ACOs stinting on care. Finally, ACOs annually report on a core set of quality measures that spans prevention, chronic disease, care coordination, patient outcomes, and patient experience of care. These measures are used by CMS in conjunction with other program results and compliance activities to monitor for avoidance of at-risk beneficiaries. As a result, we are not adopting the commenter’s suggestion at this time that we incorporate additional safeguards into the waivers, such as ensuring the availability of the same range of items and services.

Commercial Plans

In the IFC, we requested comments on whether we should develop a specific waiver to apply to shared savings derived from programs comparable to the Shared Savings Program that are sponsored by commercial health plans (and, if so, how we should define a comparable program with sufficient precision).

Comment: Several commenters opposed extending the waivers in the IFC to arrangements that involve the distribution of shared savings earned by an ACO under a comparable program sponsored by a commercial plan, noting generally that this may lead to an increase in fraud and abuse concerns. One commenter pointed to OIG’s longstanding concern with parties providing favorable terms in non-Federal health care program arrangements in return for Federal health care program business. In

addition, the commenter noted that extending the waiver to ACO-type arrangements with commercial plans is not necessary in order to meet the purposes of the Shared Savings Program. Similarly, another commenter stated that the waivers should not apply to activities by an ACO, ACO participants, or ACO providers/suppliers outside of their ACO participation agreement, as these activities do not provide a benefit to the Medicare program or Medicare beneficiaries.

Response: We appreciate the comments on this issue. We will continue to monitor the development of ACOs and shared savings arrangements and may consider addressing shared savings derived from commercial plans in future rulemaking.

As we stated in the IFC:

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 concerns 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.

76 FR 68006.

In the IFC, we laid out four examples of ways in which private payer arrangements might not need a specific waiver, and we believe these examples remain applicable to commercial plan ACO arrangements. First, an arrangement “downstream” of commercial plans (for example, arrangements between hospitals and physician groups) might qualify for the participation waiver if there is a sufficient nexus with the Shared Savings Program. Unlike the shared savings distribution waiver, the participation waiver does not turn on the source of the funds for the arrangement. Second, we continue to believe that 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). Third, some private payer arrangements may fit in existing Federal anti-kickback statute safe harbors, such as the managed care safe harbors. Finally, as noted previously in this final rule, no waiver or other protection is needed for arrangements that do not implicate the fraud and abuse laws. This

statement is equally true for private payer arrangements.

F. Compliance With the Physician Self-Referral Law Waiver

This waiver, as finalized here, waives the Federal anti-kickback statute for arrangements that qualify under an existing physician self-referral law exception. As we explained in the IFC, we seek to avoid requiring parties to “undertake a separate legal review under the Federal anti-kickback statute” for these arrangements. 76 FR 68006.

Comment: Most commenters who provided comments on this waiver strongly supported it. A supporting commenter approved of our decision not to require parties to undertake a separate legal review if an arrangement qualifies for an exception under the physician self-referral law. Another commenter supported this waiver because, in the commenter’s view, it is narrowly tailored. One commenter stated that the waiver creates a high risk of abusive relationships, and urged us to eliminate the waiver or, in the alternative, subject ACOs, ACO participants, and ACO providers/suppliers to auditing and monitoring when they use the waiver.

Response: We reiterate our position, first stated in the IFC, that the purposes of this waiver being granted to those arrangements that qualify under an existing physician self-referral law exception are to “ease the compliance burden on providers” and to minimize the obligations on entities establishing or operating ACOs under the Shared Savings Program. 76 FR 68006. We appreciate the commenter that supported this waiver. We continue to believe that this waiver offers an efficient means for providers to protect *bona fide* arrangements without having to conduct an exhaustive legal review, while also presenting a low risk of raising fraud and abuse concerns under the Federal anti-kickback statute. Apart from removing the waiver for the Gainsharing CMP, we are not making any changes to the waiver in this final rule.

As we explained in the IFC, this waiver covers arrangements that otherwise implicate the physician self-referral law, meaning arrangements involving entities that furnish designated health services and referring physicians. See 42 CFR 411.351. Some arrangements need not (and, thus, do not) qualify for an exception to the physician self-referral law simply because they are not within the ambit of that law. 76 FR 68006. In the IFC, we gave the example, which we adopt here, of arrangements between facilities that

do not involve referring physicians and noted that these arrangements might qualify for the other waivers.

Arrangements covered by this waiver remain subject to scrutiny—including monitoring, auditing, or other means—for compliance with the physician self-referral law. Importantly, we remind stakeholders that compliance with an exception to the physician self-referral law does not ordinarily operate to immunize conduct under the Federal anti-kickback statute, and arrangements that comply with the physician self-referral law are still subject to scrutiny under the Federal anti-kickback statute. 76 FR 68006. As we made clear in the IFC, we are departing from this general rule because we believe there are specific safeguards in the Shared Savings Program that minimize some typical fraud and abuse concerns and we desire to reduce the burden on ACOs. Further, section 1899(f) of the Act grants the Secretary the authority to waive the Federal anti-kickback statute, as necessary, to carry out the Shared Savings Program. We believe that exercising our discretion to waive the Federal anti-kickback statute for those arrangements that comply with an existing exception to the physician self-referral law will continue to facilitate the development of arrangements that present a low risk of fraud and abuse through continuing compliance with the requirements of the applicable physician self-referral law exception.

This waiver applies until the participation agreement, including any renewals thereof, expires or terminates. 76 FR 68006. In the IFC, we solicited comments on whether it might be necessary for this waiver to continue for some period of time, such as 3 to 12 months, after expiration or termination of an ACO’s participation agreement.

Comment: Certain commenters recommended that we establish a 6-month tail period of protection for arrangements after expiration or termination of an ACO’s participation agreement. One commenter stated that this tail period should align with the period established for other waivers. Other commenters urged us not to extend protection to arrangements protected under the compliance with the physician self-referral law waiver after expiration or termination of the ACO’s participation agreement, or to provide a shorter window of protection, such as three months.

Response: We appreciate the comments received. We are finalizing our decision not to provide a tail period for the compliance with the physician self-referral law waiver. We are aware of no information suggesting that, in the

circumstances of an arrangement that is compliant with the physician self-referral law, a waiver of the Federal anti-kickback statute following termination or expiration of an ACO's participation agreement would be necessary or appropriate. We believe it is more appropriate to subject such arrangements to case-by-case review under the Federal anti-kickback statute.

G. Waiver for Patient Incentives

Like the IFC, this final rule includes 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.

One example of an appropriate incentive that could be protected under this waiver is a blood pressure cuff for a hypertensive patient participating in an ACO's chronic disease management program. Depending on the facts and circumstances, such an arrangement potentially implicates the Federal anti-kickback statute and the Beneficiary Inducements CMP, and, again depending on the facts and circumstances, no safe harbor or exception may be available. The waiver would not cover inducements in the form of items such as beauty products or theatre tickets not reasonably related to a beneficiary's medical care. We are finalizing the patient incentives waiver as set forth in the IFC.

Comment: Many commenters supported the waiver for patient incentives, stating that it encourages preventive care and compliance with treatment regimes through patient engagement, which are key to successful patient outcomes. However, several commenters opposed the scope of the waiver, suggesting that it is too broad and will encourage behaviors that the commenters viewed as fraudulent and abusive, such as the provision of free gym memberships, personal training sessions, massages, or skin creams. One commenter advocated that ACOs should have the same flexibility to offer inducements that is permitted under current law, which the commenter believes will allow health care professionals not in an ACO to be on a level playing field with those in ACOs. Finally, some commenters urged us to limit the waiver to incentives provided to beneficiaries assigned to an ACO, while others encouraged us to apply the waiver more broadly.

Response: We continue to believe this waiver helps ACOs foster patient engagement in improving quality and lowering costs for the Medicare program and its beneficiaries by removing any perceived obstacles presented by the Beneficiary Inducements CMP or Federal anti-kickback statute while at the same time protecting beneficiaries from abusive arrangements. 76 FR 68007. Because beneficiary compliance with care management programs is critical to the success of ACOs, we believe ACOs should have more flexibility than what may be allowed under current law to develop incentives to that end, so long as the safeguards in this waiver are in place (e.g., a reasonable connection between the items or services and the medical care of the beneficiary). *Id.* We note that incentives of the type described by the commenter (gym memberships, personal training services, massages, and skin creams) should be carefully scrutinized by the ACO on a case-by-case basis for compliance with waiver conditions.

As we indicated in the IFC, we are interested in promoting broad improvement in care coordination and quality for all beneficiaries, and therefore are not limiting the waiver to incentives provided to beneficiaries assigned to an ACO. We are mindful of the commenters' concerns that this waiver could encourage fraudulent and abusive behavior, and we will continue to monitor ACOs to ensure that the waiver does not lead to fraudulent and abusive arrangements that may harm beneficiaries or the Medicare program. As such, we are finalizing the patient incentives waiver without modification.

Reasonable Connection Between Incentives and Medical Care

Comment: One commenter supported the standard in the IFC that requires a "reasonable connection" between the items or services provided to a beneficiary and his or her medical care, while another commenter requested we more specifically define this term and limit its applicability to items and services for preventive care only.

Response: When we established the patient incentives waiver in the IFC, we required that there be a reasonable connection between the incentives and the medical care of the individual "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" 76 FR 68007. We believe that the "reasonable connection" standard is appropriate, and we do not agree with the commenter who suggested we limit its

applicability. The patient incentives waiver protects in-kind items or services, but does not cover financial incentives, such as waiving or reducing patient cost sharing amounts (e.g., copayment or deductible). 76 FR 68007. In addition, we note that 42 CFR 425.304(a)(1) 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/suppliers in a particular ACO. The same prohibition applies to gifts or other remuneration to beneficiaries as inducements for receiving items or services from ACO participants or ACO providers/suppliers. To be clear, such incentives are not covered by this waiver. Further, 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 the Beneficiary Inducements CMP; nothing in this waiver supplants or amends any requirement in the Shared Savings Program final rule or other Medicare payment or coverage rules. 76 FR 68007.

Preventive Care

We solicited comments on whether we should define the term "preventive care" for purposes of this waiver. 76 FR 68007.

Comment: Some commenters requested that the agencies refrain from defining the term "preventive care," because a clarification of this term could unnecessarily narrow the scope of the waiver. Several other commenters expressed concern that leaving this term undefined would lead to increased risks of fraud and abuse because it would allow ACOs, ACO participants, and ACO providers/suppliers to contend that any activity qualifies as "preventive care." One commenter advocated that we define the term consistent with other statutory provisions.

Response: We did not define preventive care in the IFC "in order to provide some flexibility as care models develop in the Shared Savings Program and evidence-based care programs are adopted by ACOs." 76 FR 68007. We are mindful of the evolving nature of clinical practice guidelines and recommendations for practices that are categorized as "preventive care." Accordingly, we are finalizing the policy not to define preventive care in order to maintain this flexibility for ACOs that are seeking to develop *bona*

fide patient engagement programs to maintain effective treatment regimes. That said, we advise parties seeking to use the waiver to exercise caution in ensuring that activities for which they desire waiver protection are reasonably considered preventive care.

Pharmaceutical Manufacturers

Comment: A commenter opposed the exclusion of pharmaceutical manufacturers from protection under the patient incentives waiver, highlighting that these entities are particularly well situated to develop effective programs to educate and support patients.

Response: The patient incentives waiver applies to incentives furnished by an ACO, its ACO participants, or its ACO providers/suppliers. Pharmaceutical manufacturers do not meet the definitions of these terms under the Shared Savings Program regulations at 42 CFR 425.20. We are not extending protection under this waiver to incentives provided by any other parties, including pharmaceutical manufacturers. We reiterate in this final rule our position in the IFC that no waiver protection is offered for “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” or “the discount arrangement (or any arrangement for free items and services) between the manufacturer and the ACO, ACO participant, or ACO provider/supplier.” 76 FR 68007. Based on CMS’s program experience to date, we continue to believe that such waivers are not necessary to carry out the Shared Savings Program. However, the patient incentives waiver would cover ACOs, ACO participants, and ACO providers/suppliers that give beneficiaries items or services that they have received from manufacturers at discounted rates.

Duration of the Waiver

We explained in the IFC that the waiver applies until the earlier of the expiration or termination of the ACO’s participation agreement. We recognized that to ensure continuity of care for beneficiaries if an ACO’s participation agreement terminates or is not renewed, we needed to allow a beneficiary to keep any items received during the term of the ACO’s participation agreement pursuant to the waiver, and to 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. 76

FR 68007. In the IFC, we gave three representative examples of situations in which it would be appropriate for a beneficiary to continue to receive a service: (1) A post-surgical patient receiving free home visits to coordinate in-home care during the recovery period; (2) a hypertensive patient using home telehealth monitoring of blood pressure; and (3) a beneficiary halfway through a normal course of smoking cessation treatment. We are maintaining this interpretation of the waiver in this final rule. Specifically, the waiver will protect any items or services received by a beneficiary during the term of the ACO’s participation agreement pursuant to the waiver, and will allow a beneficiary to keep any items provided and continue to receive any service initiated during the term of the ACO’s participation agreement pursuant to the waiver, if the item was received before, or the service was in progress when, the participation agreement terminated. We did not receive any comments regarding the duration of the patient incentives waiver.

As we made clear previously in the IFC, nothing precludes ACOs, ACO participants, or ACO providers/suppliers from offering a patient an incentive to promote his or her clinical care if the incentive fits in an applicable safe harbor or exception or does 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. *See* Section 1128A(j)(6)(D) of the Act; 42 CFR 1003.101.

General Information

In our experience interacting with stakeholders, we have received questions regarding whether local transportation arrangements can qualify as an in-kind item or service under the patient incentives waiver. We did not receive public comments on this issue, but we are taking this opportunity to clarify that nothing would preclude local transportation from being an in-kind item or service under the patient incentives waiver set forth in the IFC and this final rule. Accordingly, transportation provided by an ACO, ACO provider/supplier, or ACO participant to a beneficiary may be protected like other in-kind items and services, provided that all waiver conditions are met. We note that, under the terms of the waiver, transportation provided to a patient for purposes of getting to a medical appointment or to

pick up prescriptions could be protected, but transportation to attend entertainment or recreational events, or to run errands unrelated to the medical care of the beneficiary, would not be protected. Moreover, because the waiver protects only in-kind incentives, patients may not be given cash reimbursement for transportation costs (e.g., bus or taxi fare or reimbursement for gasoline). Patients may be given prepaid vouchers redeemable solely for transportation services pursuant to a contractual arrangement between the ACO, the ACO participant, or the ACO provider/supplier and the transportation provider.

H. Additional Policy Considerations

We are finalizing the waivers in this final rule under section 1899(f) of the Act to foster the success of the Shared Savings Program, the purpose of which is 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. As we stated in the IFC:

The waivers adopted in [the 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.

76 FR 68007.

The waivers in this final rule emanate from our continued expectation that “ACOs and their constituent parts will [continue to] act in compliance with program rules and in the best interests of patients and the Medicare program, including the Shared Savings Program.” 76 FR 68007. Further, it is our expectation that the waivers promulgated in this final rule have been and will continue to be used for their intended purposes to carry out the Shared Savings Program. *Id.* at 68008. As we have made clear in the IFC and this final rule, the waivers are designed to promote a high degree of certainty, innovation, and variation in the continuing development and operation of ACOs to improve quality of care, as

well as economy and efficiency in the Medicare program.

We recognize that, to varying degrees, all Federal health care programs are susceptible to fraud and abuse. 76 FR 68007–68008. To be clear, the waivers in this final rule “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.” *Id.* at 68008. As we made clear in the IFC, we will continue to monitor ACOs and the Shared Savings Program for fraud and abuse, including but not limited to: (1) Billing for medically unnecessary or upcoded services; (2) stinting on medically necessary services; (3) submitting false or fraudulent data; or (4) providing worthless or substandard care. If these or other problematic practices are found, we have a number of tools to address the problem and, where necessary, we will use these tools to protect the interests of beneficiaries and the Medicare program. CMS and OIG are monitoring the Shared Savings Program and will continue to do so. To date, information available to us suggests that the waivers are adequately protecting beneficiaries and Federal health care programs while enabling care coordination arrangements under the Shared Savings Program. In this final rule, we are not narrowing the waivers. We will continue to monitor the development of ACOs and shared savings arrangements and may consider additional rulemaking if warranted.

Comment: Some commenters supported the statement in the IFC that we would narrow the waivers. One commenter requested that CMS, OIG, and other agencies vigilantly monitor ACOs to ensure compliance with all waiver provisions and the objectives of the Shared Savings Program. Some commenters requested that we narrow the waivers if monitoring reveals any undesirable result or makes clear that the waivers are shielding fraudulent or abusive arrangements. One commenter requested that CMS and OIG narrow the waivers to prevent specific abusive conduct, such as arrangements with physician-owned distributorships.

Other commenters strongly opposed any narrowing of the waivers by the agencies, advocating that the waivers in the IFC appropriately recognize the benefits of shared savings arrangements while minimizing fraud and abuse risks. Many of these commenters expressed concern that CMS and OIG called into question the permanency of these waivers by suggesting the waivers could

be narrowed, and argued that narrowing the waivers would not align with the agencies’ goals to provide flexibility, certainty, and latitude to ACOs, and to allow for innovation in the Shared Savings Program. Many of the commenters who opposed narrowing the waivers urged that any material change to the waivers in the IFC would require formal notice-and-comment rulemaking. If the agencies elect to pursue this notice-and-comment rulemaking, one commenter requested that the narrowed waivers apply only to arrangements that become effective after any final rulemaking.

Response: In the IFC, we stated that “[w]e plan to narrow the waivers . . . unless information gathered through monitoring or other means suggests that the waivers . . . are adequately protecting the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services.” 76 FR 68008. As we explained above and in the IFC, we will continue to gather information through monitoring and other means to assess whether the waivers are having unintended effects, such as shielding abusive arrangements.

It remains our priority to ensure that waivers necessary to carry out the Shared Savings Program protect the Medicare program and beneficiaries from the harms caused by fraudulent or abusive conduct. Should we identify specific areas of fraud or abuse resulting from arrangements covered by the waivers, or if we determine that the risks of fraud and abuse associated with waiving our laws for certain arrangements outweigh the benefits associated with the Shared Savings Program, we may propose to revise these waivers or take other appropriate action to address our concerns. We will continue to monitor whether certain arrangements that may be protected under the waivers raise concerns, such as overutilization, increased costs to Federal health care programs and beneficiaries, and substandard or poor quality of care. Any needed modifications of the waivers in this final rule would be implemented through notice-and-comment rulemaking.

Although we are not narrowing the waivers in this final rule, we underscore that the waivers have never been intended to, and will not, cover arrangements unless all criteria for the applicable waiver are met. By way of example only, an ACO that fails to have its governing body properly make and authorize a *bona fide* determination that an arrangement is reasonably related to the purposes of the Shared Savings Program, which is required for the pre-

participation and participation waivers, would not have the protection of the waiver unless and until the ACO meets the requirements in this final rule. The waiver protects an arrangement only when all criteria have been met; there is no retroactive protection. The arrangement described above would be subject to ordinary review for compliance with fraud and abuse laws up until the point of having documentation of the authorization by the ACO’s governing body, provided that all other waiver conditions are also met.

Comment: Several commenters suggested that our waivers conflict with existing state laws that would prohibit certain entities from participating in ACOs. These commenters asked us to modify the waivers to preempt conflicting state laws and promote participation in ACOs.

Response: We do not have the authority to preempt state law.

Comment: One commenter requested that we codify the waivers issued in this final rule in the Code of Federal Regulations in order to ensure prospective participants of their permanency and provide a degree of certainty for ACOs developing innovative arrangements.

Response: We intend the waivers in this final rule, as with the waivers in the IFC, to have binding legal effect notwithstanding the absence of codified regulation text. We note that binding waivers are generally not promulgated through rulemaking (e.g., waivers of Medicare and Medicaid program requirements promulgated pursuant to section 402(b), 1115, and 1115A of the Act). Although these fraud and abuse waivers have been promulgated through rulemaking, we are not codifying them in the Code of Federal Regulations (CFR). First, waivers published in the **Federal Register** are typically not codified in the CFR. The Office of the Federal Register recognizes that waivers of agency rules that are generally applicable need not have regulatory text or amend the CFR. Second, we believe that the waivers are more easily accessible to the public when published in a single **Federal Register** document made available online through the Government Printing Office, OIG, and CMS Web sites. Because these waivers cover multiple legal authorities administered by two different agencies, they might be codified in several different places in the CFR. For ease of reference, the entire set of waivers and applicable requirements are set forth in section IV of this final rule, and we will continue to make the waivers available on the CMS and OIG Web sites.

Moreover, publication in a single uncodified document ensures that the waivers, if modified, remain consistent over time and across relevant laws.

Finally, we are making a technical correction to the waiver text from section IV of the IFC by replacing “Physician Self-Referral Law” with “physician self-referral law.”

IV. Provisions of the Final Rule: 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 the pre-participation waiver, *home health supplier* means a provider, supplier, or other entity that is primarily engaged in furnishing “home health services,” as that term is defined in section 1861(m) of the Act.

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 arrangements for 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.

1. 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) 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 must 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 the 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 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.

2. ACO Participation Waiver

Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the physician self-referral law) 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 must

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) 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.

4. Compliance With the Physician Self-Referral Law Waiver

Pursuant to section 1899(f) of the Act, 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. 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.

We find that a delayed effective date for this final rule would be contrary to the public interest. The waivers published in the IFC have been in place for approximately four years, and we understand that there may be arrangements in place or under development for which an ACO may be seeking to use these waivers. Delaying the effective date of this final rule would be contrary to the public interest because it would cause a lapse in the waivers between the expiration date of the IFC and the effective date of this final rule, and ACOs have relied, and continue to rely, on these waivers to develop and maintain arrangements that further the quality, economy, and efficiency goals of the Shared Savings Program.

VI. Collection of Information Requirements

While this final rule does include information collection requirements as defined in the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35 *et seq.*, 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 final rule need not be reviewed by OMB.

VII. 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 (January 18, 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).

We believe that this final rule does not reach the economic threshold for being considered economically significant and, thus, is not considered a major rule. This final rule would allow ACOs, ACO participants, and ACO providers/suppliers to enter into certain beneficial arrangements. These waivers of certain fraud and abuse laws are critical to providing stakeholders with flexibility necessary for innovative care redesign. ACOs, ACO participants, and ACO providers/suppliers would be allowed to seek to comply with one or more of the five waivers so that they would have assurance that participating in certain arrangements would not subject them to liability under the physician self-referral law, Federal anti-kickback statute, or the Beneficiary Inducements CMP.

CMS reports that there are over 400 ACOs currently participating in the Shared Savings Program. CMS anticipates that the majority of ACOs will renew their participation and the number of ACOs will continue to grow as new organizations apply every year. From the comments received on the IFC, we understand the waivers have numerous important benefits to the operation and success of the Shared Savings Program. Namely, they remove legal and regulatory barriers that can impede care coordination in furtherance of the Shared Savings Program, and they reduce burden on ACOs, ACO participants, and ACO providers/suppliers.

Although these waivers are critical, we cannot quantify the number of arrangements among participants and others, making assessing the costs and benefits of these waivers difficult. First, ACOs, ACO participants, and ACO providers/suppliers are not required to apply to CMS or OIG for an individualized waiver, which impedes an accurate calculation of the number of ACOs, ACO participants, and ACO providers/suppliers that use these waivers. In addition, the Department does not routinely collect data regarding the number of arrangements that may qualify for waiver protection. For this reason, we cannot calculate the number of arrangements that are entered into or will be entered into by those ACOs, ACO participants, and ACO providers/suppliers that use these waivers.

Further, we did not receive comments from stakeholders regarding the costs associated with using these waivers. Although there could be some burden associated with the conduct covered by these waivers, such as record keeping and other documentation needs, we believe the time, effort, and financial resources necessary to implement and comply with the conditions of the waivers would typically be incurred by ACOs, ACO participants, and ACO providers/suppliers during the normal course of participation in the Shared Savings Program. Moreover, compliance with many of the conditions of the waivers can be achieved by activities ACOs, ACO participants, and ACO providers/suppliers undertake to comply with the Shared Savings Program rules. We therefore believe any incidental costs that may be attributable solely to the waivers would be minimal. Finally, waivers may be used in a variety of contexts for a wide range of arrangements, so we cannot accurately predict the economic impact of any individual waiver or the use of the waivers as a whole. For the above reasons, we cannot monetize the costs of using these waivers.

For all these reasons, we believe that the aggregate economic impact of the waivers would be minimal and we do not expect an effect on the economy or on Federal or State expenditures greater than \$100 million.

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 \$7.5 million to \$38.5 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 final rule 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 final rule 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 2015, that threshold is approximately \$144 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 OMB.

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

Authority: Section 1899(f) of the Act.

Dated: October 7, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 7, 2015.

Daniel R. Levinson,

Inspector General, Department of Health and Human Services.

Approved: October 22, 2015.

Sylvia Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-27599 Filed 10-28-15; 8:45 am]

BILLING CODE P