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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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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 ACOs [1] 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) 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

[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.*

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