

Medicare Shared Savings Program Waivers: Additional Guidance

(Issued: February 12, 2015)

The interim final rule with comment period (IFC), entitled “Final Waivers in Connection with the Shared Savings Program,” set forth the conditions for the ACO Pre-Participation and ACO Participation Waivers. 76 FR 67992; see also 79 FR 62356 (extending effectiveness of the IFC). This document sets forth additional guidance related to certain conditions of the waivers. Specifically, this document provides additional guidance concerning three areas: (1) public disclosures required under the ACO Pre-Participation and ACO Participation Waivers, (2) notification of failure to submit a timely application by parties who used the ACO Pre-Participation Waiver, and (3) requests for an extension of the ACO Pre-Participation Waiver period. This guidance is effective as of the issuance date of this document.

I. Public Disclosure of Arrangements under the ACO Pre-Participation and ACO Participation Waivers

The ACO Pre-Participation and ACO Participation Waivers require that the description of an arrangement for which waiver protection is sought be publicly disclosed “at a time and in a place and manner established in guidance issued by the Secretary.” 76 FR at 68000–01. Section V of the IFC included temporary guidance concerning the method and content of the public disclosures. 76 FR at 68004–5. We are finalizing that temporary guidance with slight modifications. Thus, parties¹ seeking to use the ACO Pre-Participation Waiver meet the disclosure requirement by posting a description of the arrangement for which waiver protection is sought on a public website belonging to the ACO or an individual or entity forming the ACO within 60 days of the date of the arrangement. Parties seeking to use the ACO Participation Waiver meet the disclosure requirement by posting a description of the arrangement for which waiver protection is sought on a public website belonging to the ACO within 60 days of the date of the arrangement.

The posted arrangement should be clearly labeled as an arrangement for which waiver protection is sought. The description of the arrangement must include information identifying the parties to the arrangement, the date of the arrangement, and the type of item, service, good, or facility provided under the arrangement. See 76 FR 68004. The website must also include the name of the ACO (or, if the name of the ACO is not known, the parties forming the ACO) and other identifying information sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the website. If the ACO makes a material amendment or modification to a previously disclosed arrangement, the amendment or modification

¹ For ease of reference throughout this document, we use the term “ACO,” but we intend for that term to encompass a party or parties developing an ACO, as applicable in the context of the ACO Pre-Participation Waiver.

should be disclosed in the same manner described above and identified as an amendment or modification.

NOTE: Public disclosure for purposes of both the ACO Pre-Participation and the ACO Participation Waivers shall not include the financial or economic terms of the arrangement.

II. Notification of Failure to Submit a Timely Application

ACOs that claim protection under the Pre-Participation Waiver but that do not submit an application for a participation agreement in the Medicare Shared Savings Program by the last available application due date for the target year must submit a statement to the Centers for Medicare & Medicaid Services ("CMS") describing the reasons the ACO was unable to submit an application. 76 FR at 68000, see also 76 FR at 68005. Such statements must be submitted by the date and in the form and manner described below.

1. **What information must be submitted?** A statement that includes at least the following:
 - a description of the reasons the ACO was unable to submit an application; and
 - a certification by an individual with the authority legally to bind the ACO that the information contained in the statement is true, correct, and accurate to the best knowledge of the signatory.
2. **Where should the statement be submitted?** The statement must be submitted to CMS, Division of Technical Payment Policy. All submissions will be shared with the Department of Health and Human Services Office of Inspector General ("OIG").
3. **How should the statement be submitted?** Statements must be submitted electronically (in PDF format) to the following email address: SSP_Preparticipation@cms.hhs.gov. An automatic response will be generated indicating that the statement was successfully submitted to CMS. It is a best practice to maintain documentation of the automatic response as evidence of receipt by CMS.
4. **When should the statement be submitted?** Statements must be submitted on or before the last available application due date for the target year.

III. Request for Extension of the ACO Pre-Participation Waiver

Parties that claim protection under the ACO Pre-Participation Waiver but that are unable submit an application to participate in the Medicare Shared Savings Program by a selected application due date for a target year may apply for an extension of the ACO

Pre-Participation Waiver period pursuant to procedures established by the Secretary. 76 FR at 68000; see also 76 FR at 68005. This process is separate from the Notification of Failure to Submit a Timely Application process described above.

The ACO requesting an extension must demonstrate a likelihood of successfully developing an ACO that would be eligible to participate in the Medicare Shared Savings Program by the next available application due date. 76 FR at 68000. The determination whether to grant an extension of the ACO Pre-Participation Waiver will be in the sole discretion of the Secretary and will not be reviewable. 76 FR at 68000. ACOs seeking an extension must submit a request pursuant to the procedures described below.

1. **What information must be submitted?** A request for an extension of the ACO Pre-Participation Waiver that includes at least the following:
 - 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 Medicare Shared Savings Program participation agreement;
 - any additional evidence demonstrating a likelihood of successfully developing an ACO eligible to participate in the Medicare Shared Savings Program by the next available application due date. Such evidence could include, for example, descriptions of activities underway and expected time frames for obtaining needed agreements or commitments; and
 - a certification by an individual with the authority legally to bind the ACO that the information contained in the request is true, correct, and accurate to the best knowledge of the signatory.
2. **Where should the request for extension be submitted?** The request for extension should be submitted to the CMS, Division of Technical Payment Policy. All requests will be shared with the OIG.
3. **How should the request for extension be submitted?** Requests must be submitted electronically (in PDF format) to the following email address: SSP_Preparticipation@cms.hhs.gov. An automatic response will be generated indicating that the request was successfully submitted to CMS. It is a best practice to maintain documentation of the automatic response as evidence of receipt by CMS.
4. **When should the request for extension be submitted?** The completed request for an extension must be submitted no later than 60 days prior to the selected application due date.