

**Medicare Shared Savings Program Waivers:  
Special ACO Pre-Participation Waiver Guidance for the 2021 Application Cycle**

**(Issued: May 8, 2020)**

This document provides guidance on the start date of the ACO Pre-Participation Waiver for parties acting with good faith intent to develop an ACO to participate in the Shared Savings Program in 2021 and to submit a completed application to participate in 2021. It also provides guidance on the procedure for extension of the ACO Pre-Participation Waiver period for such parties. This guidance is effective as of the issuance date of this document.

**BACKGROUND**

The final rule entitled “Final Waivers in Connection With the Shared Savings Program” sets forth the conditions for the ACO Pre-Participation Waiver. See 80 FR 66726, 66742-43 (Oct. 15, 2015). The ACO Pre-Participation Waiver protects “start-up arrangements” that pre-date an ACO’s participation agreement provided all of the conditions of the waiver are met. For arrangements that meet all such conditions, the ACO Pre-Participation Waiver period starts one year preceding an application due date (the “selected application date”)<sup>1</sup> for a target year of 2013 or later. See 80 FR 66742. ACOs<sup>2</sup> that claim protection under the ACO Pre-Participation Waiver but that are unable to submit an application to participate in the 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. See 80 FR 66742-43.

Generally, the application due date for participation in the Shared Savings Program occurs in late July or early August of the year preceding the relevant performance year. For the 2021 application cycle,<sup>3</sup> CMS originally specified an application date of June 11, 2020. However, CMS has since announced that it is forgoing the 2021 application cycle due to the COVID-19 public health emergency.<sup>4</sup>

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<sup>1</sup> For ease of reference throughout this document, we use the term “selected application date,” but we intend for that term to also encompass “selected application due date.” See 80 FR 66742.

<sup>2</sup> 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.

<sup>3</sup> For purposes of this guidance, the term “2021 application cycle” means the process for obtaining a Shared Savings Program Participation Agreement that would have become effective in 2021.

<sup>4</sup> See 85 FR 27550 (<https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory>)

## **START DATE**

In light of the original application due date established for the 2021 application cycle, we recognize that parties preparing to participate in the 2021 application cycle could have reasonably relied on a selected application date of June 11, 2020. Pre-Participation Waiver protection for arrangements that meet all required waiver conditions could have therefore begun as early as June 11, 2019. Accordingly, for parties that were preparing to participate in the 2021 application cycle, CMS and OIG will recognize June 11, 2019, as the earliest potential start date for ACO Pre-Participation Waiver protection. Of course, waiver protection would not begin until the arrangement at issue complies with all conditions of the waiver.

## **EXTENSION OF WAIVER PROTECTION**

As noted previously, ACOs that claim protection under the ACO Pre-Participation Waiver but that are unable to submit an application to participate in the 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. See 80 FR 66742-43.

We recognize that because CMS is forgoing the 2021 application cycle, any ACO that intended to submit an application for the 2021 performance year is now unable to do so. Therefore, CMS and the OIG are deeming all such ACOs that are in compliance with all waiver conditions to have applied for and been granted an extension of the ACO Pre-Participation Waiver period that began on June 11, 2019. Accordingly, for such ACOs, the next available application due date for a participation agreement starting in 2022 will become the selected application date for purposes of the ACO Pre-Participation Waiver. The new waiver period will end in accordance with the terms of the ACO Pre-Participation Waiver, as applied to performance year 2022. See 80 FR 66736.

The following example illustrates the effect of this guidance.

An ACO that in good faith intended to submit an application for a Shared Savings Program participation agreement starting in 2021, entered into start-up arrangements with a hospital on September 1, 2019 and July 1, 2020. Both arrangements implicate the physician self-referral law and the Federal anti-kickback statute. The ACO and hospital relied upon, and met all conditions of, the ACO Pre-Participation Waiver in establishing and operating under these start-up arrangements. Both start-up arrangements will fall within the ACO Pre-Participation Waiver period. The waiver period will end as follows:

- If the ACO submits an application by the next available application due date and enters into a participation agreement that starts in 2022, the waiver period will start on June 11, 2019 and end on the start date for that participation agreement.
- If the ACO submits an application by the next available application due date for a participation agreement starting in 2022, but its application is denied, the waiver

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period will start on June 11, 2019 and end 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 will end on the date that is six months after the date of the denial notice.

- If the ACO fails to submit an application by the next available application due date for a participation agreement starting in 2022, the waiver period will start on June 11, 2019 and end on the earlier of the next available application due date or the date the ACO submits a statement of reasons for failing to submit an application, unless the ACO applies for and receives an extension of waiver protection pursuant to the terms of the ACO Pre-Participation Waiver.