

MEDICARE SHARED SAVINGS PROGRAM

ACO Participant List and Participant Agreement Guidance

April 2025 | Version #13

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REVISION HISTORY – VERSION 13

Revised Section/Description of Revision	Link to Section Affected
Overlap Policy and Precedent Between Models: Updated guidance to detail what occurs in instances of an unresolved overlap between an "Add Participant" and "Renewal Participant" change request.	Section 5.3
Merged or Acquired TIN Documentation: Updated guidance to detail the merged or acquired supporting documentation and attestation requirement.	Section 3.2.3



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1 Executive Summary

The purpose of this document is to describe the requirements that an Accountable Care Organization (ACO) participating in or applying to the Medicare Shared Savings Program (Shared Savings Program) must follow with respect to its ACO Participant List, ACO Provider/Supplier List, and ACO Participant Agreement(s). These requirements are reflected in the regulations for the Shared Savings Program, which are codified at <u>42 CFR part 425</u>.

The ACO Participant List is critical to Shared Savings Program operations. The ACO must submit ACO participants that have agreed to form or partner with the ACO and certify that they are accountable for the quality, cost, and overall care of the ACO's beneficiaries (<u>42 CFR</u> <u>425.100(a)</u>, as well as compliant with the requirements of <u>42 CFR § 425.116(a)</u>. An ACO Participant List identifies all of an ACO's participants by their Medicare-enrolled taxpayer identification numbers (TINs). During Phase 1 of the application submission period, an ACO will create its ACO Participant List.

The Centers for Medicare & Medicaid Services (CMS) uses the list to:

- Screen ACO participants;
- Generate the ACO Provider/Supplier List;
- Determine which Medicare fee-for-service (FFS) beneficiaries will be assigned to an ACO;
- Establish the historical benchmark;
- Perform financial calculations; and
- Coordinate among CMS quality reporting initiatives.

An ACO certifies its ACO Participant List and ACO Provider/Supplier List before the start of an agreement period and before every PY thereafter.

2 ACO Participant List Background

Each ACO is required to have contractual agreements with its ACO participants. An ACO may not include an ACO participant on its ACO Participant List unless individuals with the authority to legally bind the ACO have certified this with a signature to the executed ACO Participant Agreement. This agreement ensures that the ACO participant—and each ACO provider/supplier billing through the TIN of the ACO participant—agrees to the requirements of the Shared Savings Program.

Each year, within its agreement period, the ACO may request changes to their ACO Participant List effective for the next PY. To make changes to the ACO Participant List, ACOs must submit a change request in the ACO Management System (ACO-MS) for CMS approval.



IMPORTANT!

Absent unusual circumstances, CMS does not make adjustments during the PY to the ACO's assignment, historical benchmark, PY financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the PY. CMS has sole discretion to determine if unusual circumstances exist that would warrant such adjustments. Refer to $42 \text{ CFR } \S 425.118(b)(3)(ii)$.

3 ACO Participant List

This section provides detailed information about the process for submitting and updating the ACO participants, which comprise a given ACO Participant List. It also addresses how changes to an ACO Participant List impacts critical program operations.

3.1 INTRODUCTION TO THE ACO PARTICIPANT LIST

An ACO Participant List identifies all ACO participants by their Medicare-enrolled billing TINs. The Shared Savings Program refers to the legal name of the ACO as the "legal entity name" (LEN) and the legal name of an ACO participant as the "legal business name" (LBN). These legal names must be used in the executed ACO Participant Agreement. Each ACO establishes its ACO Participant List during the application process. After multiple feedback cycles that include CMS feedback and ACO responses, an ACO must certify its ACO Participant List as accurate prior to the start of its participation agreement with CMS and annually thereafter before the start of the next PY.

The accuracy of an ACO Participant List is critical to program operations, including but not limited to the following:

- Determining which beneficiaries will be assigned to the ACO (including determining whether the ACO has the required minimum of 5,000 assigned beneficiaries);
- Establishing the historical benchmark;
- Performing financial calculations that contribute to the generation of quarterly and annual program reports and determination of shared savings and losses;
- Determining the providers and suppliers that will be considered part of the ACO;
- Vetting ACO participant and ACO provider/supplier enrollment in Medicare and conducting program integrity screenings, including any history of Medicare program exclusions or other sanctions;
- Coordinating among CMS quality initiatives;
- Determining an ACO's experience with performance-based risk Medicare ACO initiatives;



- Note: CMS monitors for changes to the ACO Participant List of ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives. This would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model (<u>42 CFR § 425.600(h)</u>).
- Overlapping participation in other Medicare initiatives;
- Determining whether an ACO is "low revenue" or "high revenue;"
- Identifying an ACO as "re-entering" based on prior participation of its ACO participants; and
- Determining changes to repayment mechanism amounts that may need to be updated during the ACO's agreement period.

Figure 1 lists the information each ACO must gather and maintain regarding its ACO participants.

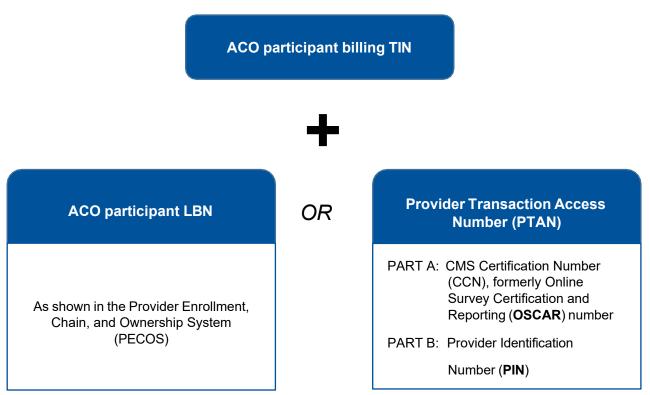


Figure 1. Required ACO Participant Information

The billing TINs submitted in ACO-MS for an ACO Participant List, as well as individuals and entities that have reassigned their billing rights to TINs on the ACO Participant List (i.e., ACO providers/suppliers), will undergo a screening process that may be repeated periodically throughout the agreement period. The purpose for this screening process is to ensure the ACO participants and ACO providers/suppliers continue to meet program requirements (<u>42 CFR § 425.305(a)</u>). The CMS screening process includes, at a minimum, the following:

- Validating active Medicare enrollment status periodically;
- Vetting program integrity history with CMS and law enforcement partners;



- Verifying LBNs;
- Ensuring the ACO participant does not participate in another Medicare shared savings initiative; and
- Determining whether the ACO participant participates in another Shared Savings Program ACO.

3.2 ACO PARTICIPANT LIST REQUIREMENTS

Each ACO is responsible for ensuring its ACO Participant List is accurate and includes only those entities that have agreed to participate in the Shared Savings Program as participants of the ACO (<u>42 CFR § 425.118</u>).

Specifically, the ACO must:

- Certify the accuracy of its ACO Participant List prior to the start of an agreement period, before every PY thereafter, and at such other times as specified by CMS in accordance with <u>42 CFR § 425.302(a)(2)</u>;
- Certify the accuracy of its ACO Provider/Supplier List prior to the start of an agreement period, before every PY thereafter, and at such other times as specified by CMS;
- Maintain and update, as necessary, its ACO Participant List within the timeframes specified by CMS;
- Notify CMS of any entities to be added to the ACO Participant List at such time and in the form and manner specified by CMS (refer to <u>42 CFR 425.302</u>) or additional information on added ACO participants; and
- Notify CMS of any entities to be deleted from the ACO Participant List by deleting the ACO participant in ACO-MS no later than 30 days after the ACO Participant Agreement terminates (refer to the <u>ACO Participant Change Requests in ACO-MS</u> tip sheet for additional information for deleting and terminating ACO participants).
 - Failure to comply with the requirement to timely delete an ACO participant from the ACO Participant List may subject the ACO to compliance actions.

3.2.1 Sole Proprietor ACO Participants

If an ACO participant is a sole proprietor that is enrolled in Medicare under its Social Security Number (SSN) and bills Medicare under a separate Employer Identification Number (EIN) that is linked to the SSN's enrollment, both the SSN and the EIN must be included on the ACO Participant List. It is the responsibility of the ACO to communicate with each of its ACO participants to understand how the ACO participant is enrolled in and billing Medicare. ACO participants should contact their respective Medicare Administrative Contractor (MAC) with any questions regarding their Medicare enrollment.

In ACO-MS, an ACO may submit the EIN used for billing to add the sole proprietor to the ACO Participant List, along with the LBN and/or PTAN attached to that EIN, in the change request.



- If the EIN and LBN/PTAN records match a Provider Enrollment, Chain, and Ownership System (PECOS) record for a sole proprietor, the system will complete the change request by linking the sole proprietor's billing TIN to the associated SSN.
- If the EIN and LBN/PTAN records do not match a PECOS record and ACO-MS cannot identify the SSN as a sole proprietor, ACO-MS will not auto-populate a separate linked billing EIN. Thus, for the purpose of the ACO Participant List, the proposed ACO participant associated with this change request will not be identified as a sole proprietor.

Please refer to *Table 1* below for examples.

Information Provided by ACO for ACO Participant Enrolled in Medicare Under SSN and Billing Medicare Under Linked EIN	ACO-MS Response
ACO submits a Medicare-enrolled SSN with the correct LBN or PTAN entered.	ACO-MS will auto-populate the billing EIN. Once the information for the EIN has been auto-populated, the ACO will not be able to delete either identifier from the change request.
ACO submits an EIN with the correct LBN or PTAN entered.	ACO-MS will auto-populate the Medicare enrolled SSN. Once the information for the SSN has been auto-populated, the ACO will not be able to delete either identifier from the change request.
ACO submits an incorrect SSN or EIN. ACO submits an EIN or an SSN without the correct LBN or PTAN entered.	If CMS cannot verify two data points (EIN and LBN/PTAN or SSN and LBN/PTAN) in PECOS, ACO- MS cannot auto-populate information for either the SSN or the EIN. The change request will fail both the PECOS and LBN check and will not be identified as a sole proprietor. In addition, at the time of final disposition, the request to add the entity to the ACO Participant List will be denied if it is not Medicare-enrolled.
ACO submits an SSN with the correct LBN or PTAN entered, but ACO-MS does not auto-populate a billing EIN.	If ACO-MS cannot identify the SSN as a sole proprietor, ACO-MS will not auto-populate a separate linked billing EIN. The ACO participant may not be a sole proprietor but rather a sole owner of a practice (in which case only the billing EIN, not an SSN, is required). It is also possible the SSN is not enrolled in Medicare. ACOs should ensure that they understand how the
	ACOs should ensure that they understand how the ACO participant is enrolled in and billing Medicare, including if the ACO participant is identified as a sole proprietor in PECOS.



3.2.2 Merged or Acquired ACO Participants

Under certain circumstances, per <u>42 CFR § 425.204(g)</u>, CMS may allow the ACO to include a merged or acquired entity's TIN on their ACO participant list. Claims billed by TINs of entities merged or acquired by an ACO participant may be considered by CMS to meet the minimum assigned beneficiary threshold and create a more accurate historical benchmark and beneficiary assignment list for the upcoming PY. If an ACO is submitting a merged or acquired ACO participant must meet the requirements outlined in the checklist below.

		Checklist
		der the following circumstances, an ACO may submit requests to include an quired entity's TIN on its ACO participant list for CMS consideration:
Ċ	Ø	The ACO participant must have subsumed the acquired entity's TIN in its entirety, including all providers and suppliers that reassigned the right to receive Medicare payment to that acquired entity's TIN. All providers and suppliers that previously reassigned the right to receive Medicare payment to the acquired entity's TIN must reassign that right to the TIN of the acquiring ACO participant and be added to the ACO Provider/Supplier List. The acquired entity's TIN must no longer be used to bill Medicare.

Table 2 lists the actions that an ACO can take to add a merged/acquired TIN to its ACO Participant List if the TIN meets specific criteria.

Table 0 ACO	Deuticius euste	:41-	Mana al/A a autima al	TINIA
Table 2. ACO	Participants	with	Merged/Acquired	IIINS

Merged/Acquired Relationship	ACO Actions to Take in ACO-MS				
TIN A acquires TIN B.	ACO submits a change request to add TIN A.				
(Neither is a current ACO	ACO should not mark TIN A as merged/acquired.				
participant.)	 ACO uploads an executed ACO Participant Agreement for TIN A. 				
	ACO submits a separate change request to add TIN B. In the change request, ACO selects "Yes" that TIN B was merged with/acquired by another TIN and enters TIN A's data in the appropriate subfields. ACO uploads the appropriate merged/ acquired supporting documentation (refer to <u>Section 3.2.3</u>) for TIN B.				
TIN C acquires TIN D.	ACO should not make any changes to TIN C.				
(Both TIN C and TIN D are currently approved ACO participants.)	• ACO deletes TIN D from its ACO Participant List (the existing record for the TIN remains on the ACO's Participant List for the remainder of the current PY but will not be included in the next PY).				
	• ACO submits a change request to add TIN D (for the next PY). In the change request, ACO selects "Yes"				

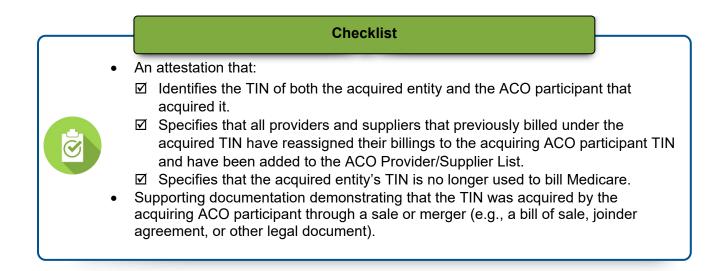


	that TIN D was merged with/acquired by another TIN and enters TIN C's data in the appropriate subfields. ACO submits the appropriate merged/acquired supporting documentation (refer to <u>Section 3.2.3</u>) for TIN D.
TIN E acquires TIN F. (TIN E is a current ACO participant, however, TIN F is not a current ACO participant.)	 ACO submits a change request to add TIN F. In the change request, ACO selects "Yes" that TIN F was merged with/acquired by another TIN and enters TIN E's data in the appropriate subfields. ACO submits the appropriate merged/acquired supporting documentation (refer to <u>Section 3.2.3</u>) for TIN F.
TIN G acquires TIN H. (TIN H is a current ACO participant, however, TIN G is not a current ACO participant.)	 ACO submits a change request to add TIN G. ACO should not mark TIN G as merged/acquired. ACO uploads an executed ACO Participant Agreement for TIN G. ACO deletes TIN H from its ACO Participant List (the existing record for the TIN remains on the ACO's Participant List for the remainder of the current PY but will not be included in the next PY). ACO submits a change request to add TIN H (for the next PY). In the change request, ACO selects "Yes" that TIN H was merged with/acquired by another TIN and enters TIN G's data in the appropriate subfields. ACO submits the appropriate merged/acquired supporting documentation (refer to <u>Section 3.2.3</u> for TIN H).

3.2.3 Merged or Acquired ACO Participant Documentation Requirements

An ACO submitting an entity's TIN that has merged with or been acquired by an ACO participant must submit an attestation and supporting document for CMS' review. The requirements are outlined in $42 \text{ CFR} \S 425.204(g)(2)$ and listed below.





For more information on submitting and tracking the status of submitted change requests, refer to the <u>ACO Participant Change Requests in ACO-MS</u> tip sheet.

4 ACO Participant Agreements

This section provides detailed information on ACO Participant Agreement requirements, including what information is required to be included in submitted executed agreements.

4.1 INTRODUCTION TO ACO PARTICIPANT AGREEMENTS

CMS requires each ACO to execute contractual participant agreements with each of its ACO participants—that has not merged with or been acquired by another ACO participant—to ensure that the requirements and expectations of participation in the Shared Savings Program are clearly articulated, understood, and agreed upon.

An ACO may not include an ACO participant on its ACO Participant List unless an authorized individual of the ACO participant has signed an ACO participant agreement with the ACO. The ACO must submit supporting documentation demonstrating that an agreement is in place between the ACO and each of its ACO participants as part of its change request to add the ACO participant.

Tips for Success

Supporting documentation includes the first page and signature page of the executed ACO Participant Agreement. For a merged/acquired ACO participant, refer to <u>Section 3.2.3</u> for the supporting documentation requirements.

CMS does not provide a boilerplate agreement for the ACO. CMS does not require the submission of sample ACO Participant Agreements as part of the application process. Per <u>42 CFR § 425.204(c)(6)</u>, CMS is authorized to review all ACO Participant Agreements, including executed and sample ACO Participant Agreements.



The ACO is instructed to complete the attestation within the application indicating that the ACO:

- Has addressed all regulatory requirements in the ACO Participant Agreement(s);
- Understands CMS may review all ACO Participant Agreement(s) to determine compliance; and
- Understands that if the ACO's ACO Participant Agreement(s) does not meet regulatory requirements, they must be updated or the ACO may be subject to compliance actions.

The final executed ACO Participant Agreement that the ACO secures with its ACO participants must be consistent with the ACO's sample ACO Participant Agreement. The ACO must provide an executed ACO Participant Agreement when seeking to add a new ACO participant, or when a change to an approved ACO participant occurs—such as an LBN change—if the agreement itself is impacted. Executed ACO Participant Agreements must be uploaded following the same schedule for ACO Participant List change requests.

4.2 ACO PARTICIPANT AGREEMENT REQUIREMENTS

An executed ACO Participant Agreement must comply with the following criteria:

- The only parties to the agreement are the ACO and the ACO participant.
- The agreement is signed on behalf of the ACO and the ACO participant by authorized individuals.
- The agreement identifies the ACO by its LEN and the ACO participant by its LBN as they appear in PECOS.

An ACO can submit documentation of this agreement in the form of a newly executed ACO Participant Agreement that includes either a digital signature (<u>Appendix C</u>) or a "wet signature" and a signature date. A wet signature is a handwritten signature (i.e., not stamped).

4.2.1 Renewal/Early Renewal Applicants Carrying Forward ACO Participants

Renewal/early renewal applicants entering into a new Shared Savings Program agreement period are **not** required to submit a newly executed ACO Participant Agreement for any ACO participants the ACO wishes to carry over into the new agreement period, provided that the current agreement meets the Shared Savings Program requirements under <u>42 CFR § 425.116</u>.

When a renewal/early renewal applicant selects an ACO participant the ACO wishes to carry over into the new agreement period, the ACO will have the option in the change request generated by ACO-MS to either:

- Submit a newly executed ACO Participant Agreement; or
- Have ACO-MS carry forward the previously approved executed ACO Participant Agreement associated with the ACO participant.

All ACO Participant Agreements (for currently participating ACOs, initial applicants, and renewal/early renewal applicants) must meet all Shared Savings Program requirements under the regulations, as described below in Section 5.3.



4.3 EXECUTED ACO PARTICIPANT AGREEMENT REQUIREMENTS

Each executed ACO Participant Agreement must include a signature page that is signed by individuals who have the legal authority to bind the ACO and the ACO participant (e.g., the ACO Executive or Authorized to Sign contacts in <u>ACO-MS</u>). The first page and signature page must reflect correct legal name information for the ACO and the ACO participant.

CMS must receive a copy of each fully executed agreement (first page and signature page) and any amendments (if applicable). A fully executed agreement or amendment is one that includes digital or handwritten signatures for both the ACO and the ACO participant. CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO.

Please review example introductory paragraphs and signature pages for ACO Participant Agreements and amendments in <u>Appendix B</u>. CMS strongly encourages each ACO to include the information indicated in the format referenced in these examples.

Note that the ACO participant LBN must appear on either the first page or signature page of the ACO Participant Agreement.

4.3.1 ACO Participant Legal Business Name Changes

If an ACO participant changes its LBN for any reason, a currently participating ACO must update the relevant ACO Participant Agreement to reflect the new LBN. This document should be maintained internally and available for CMS review upon request. The updated ACO Participant Agreement should be submitted at the time of renewal if the ACO plans to carry the ACO participant forward into the next PY.

5 ACO Participant List Changes

This section provides information on the changes that ACOs may make to its ACO Participant List. This section also details when during the application submission period ACOs may submit change requests to make these changes.

5.1 ADDING AND DELETING ACO PARTICIPANTS

An ACO is required to maintain and update, as necessary, its ACO Participant List. ACO Participant List changes must be submitted electronically in ACO-MS. An ACO may request to add an entity to its ACO Participant List during Phase 1 of the application submission period in accordance with the CMS-established schedule for submitting change requests.

During Phase 1 of the Shared Savings Program application submission period, both new applicants and currently participating ACOs may add new ACO participants and/or update existing ACO participants (e.g., TIN LBN change). A currently participating ACO may submit change requests to modify its ACO Participant List outside of the application cycle; however, these changes will become effective only at the start of the next PY. For more information on submitting change requests, refer to the <u>ACO Participant Change Requests in ACO-MS</u> tip sheet.



When adding new ACO participants and/or updating existing ACO participants, applicants and currently participating ACOs must confirm if their ACO participant TINs are participating in a joint venture. A "joint venture" is when two or more persons or entities engage in a defined project in which all of the following exist:

- An express agreement;
- A common purpose that the parties intend to carry out;
- Shared profits and losses related to the project; and
- Each party has a voice in controlling the project.

An ACO may also delete entities from its ACO Participant List for the upcoming PY during Phase 1 of the application submission period.

IMPORTANT!

The final opportunity for ACOs to **add** ACO participants is the **Phase 1 RFI-1** deadline.

The final opportunity for ACOs to **delete** ACO participants is the **Phase 1 RFI-2** deadline.

For more information on submitting and tracking the status of submitted change requests, refer to the <u>ACO Participant Change Requests in ACO-MS</u> tip sheet.

Additionally, ACO participants can be terminated and deleted from your ACO Participant List at any time during a PY, but all ACO participants deleted after the final deadline to delete ACO participants for the current PY will appear on the ACO's Participant List for the next PY. The ACO participant is no longer an ACO participant as of the termination effective date of the ACO Participant Agreement; however, as indicated in the background section above, the ACO participant data will continue to be utilized for certain operational purposes. Information regarding the program deadlines, including the final deadline to add and delete ACO participants for the current PY, can be found at the <u>Application Types and Timeline webpage</u>.

Published Resources Available

- 0.
 - ACO Participant Change Requests in ACO-MS
 - Application Types & Timeline webpage



IMPORTANT!

If an ACO submits a change request to its ACO Participant List and a required identifier is submitted incorrectly (e.g., the digits of the TIN are typed incorrectly), the error can only be corrected by submitting a new change request to add the correct ACO participant. This new change request must be submitted on/before the final deadline established by CMS to add ACO participants.

ACOs should ensure that all information submitted for ACO Participant List changes is correct.

5.1.1 Initial and Renewal/Early Renewal Applicants

CMS reviews all ACO change requests adding ACO participants to an ACO's Participant List. As part of this review, CMS may require an ACO to correct or update the information submitted as part of its application. CMS will provide the ACO with request for information (RFI) notifications in the deficiencies released at Phase 1 RFI-1 and Phase 1 RFI-2. The RFIs will summarize CMS' review of submitted application information and include feedback on ACO participant submissions. An ACO may receive multiple RFIs during the application process. It is important that the ACO carefully review any RFIs, as there are limited opportunities to correct CMS-identified deficiencies. For additional information on responding to RFI notifications, refer to the <u>Application Reference Manual</u>.

When a renewal or early renewal applicant submits an application to renew its participation agreement in the Shared Savings Program for a new agreement period, all currently approved TINs participating in that ACO for the current PY are placed in pending status and are subject to review by the Shared Savings Program.



IMPORTANT!

No renewing applicant ACO receives precedence for, or automatically retains, any currently approved TIN on its renewing applicant ACOs participant list.

CMS will provide the ACO with overlap information when the RFI deficiencies are released at Phase 1 RFI-1 and Phase 1 RFI-2.

Figure 2 defines the notifications ACOs receive following CMS review of submitted change requests.



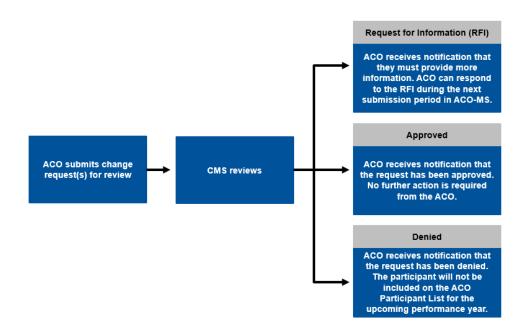
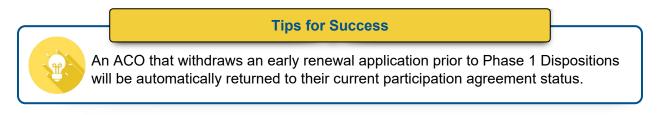


Figure 2. Workflow of ACO Submitting Change Request(s) for CMS review

Whether an ACO is an initial or a renewal/early renewal applicant, the applicant must adhere to the deadlines listed in the Application Timeline on the Shared Savings Program <u>Application</u> <u>Types & Timeline webpage</u>. Please note that while application deadlines are subject to change, CMS will not accept late submissions.



When an ACO withdraws an early renewal application prior to Phase 1 Dispositions, the following actions will occur:

- Any change requests to renew a current ACO participant will be withdrawn and the ACO participant will be reverted to an approved status.
 - If an overlap had existed on the renewal change request, the ACO for which the TIN was previously approved will retain the ACO participant and the overlap will be resolved.
- Any change requests submitted to add ACO participants will be carried forward applicable to the next PY. These will receive a disposition in accordance with the CMS application and change request cycle timeline.



- The ACO may withdraw individual ACO participant change requests before the Phase 1 RFI-2 submission deadline. If that deadline has elapsed, the ACO will not be able to make the withdrawal.
- Any ACO participants that were not carried forward with the ACO's early renewal application and were put into deleted status by the ACO when the ACO's application was submitted will remain in deleted status after the withdrawal of the early renewal application.
 - Previously deleted ACO participants can be submitted for CMS review by new change requests before the Phase 1 RFI-1 submission deadline. If that deadline has elapsed, the ACO will not be able to make the addition.

5.1.2 Currently Participating ACOs (Mid-Agreement Period)

An ACO that is not in the last PY of its agreement period and is not applying to renew or early renew may make changes to its ACO Participant List during Phase 1 of the Application and change request cycle. CMS reviews change requests during an established review cycle in advance of the upcoming PY that includes CMS feedback and the opportunity for the ACO to correct deficiencies. More information on how change request submissions can impact participation can be found in the <u>Managing Program Participation Guidance</u>.

5.2 MEDICARE ENROLLMENT STATUS

Upon entering a TIN and its corresponding LBN (as enrolled in PECOS) or PTAN in ACO-MS, the ACO will be notified immediately of the TIN's current Medicare enrollment status.

Tips for Success



ACOs may submit a change request that does not initially pass the ACO-MS PECOS checks; however, the proposed ACO participant must be enrolled in Medicare and pass all enrollment checks by the final PECOS check, which occurs prior to the issuance of the Phase 1 Final Dispositions, conducted by CMS.

5.3 OVERLAP POLICY AND PRECEDENT BETWEEN MODELS

Per <u>42 CFR § 425.114(a)</u>, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

If an ACO submits a change request to add a proposed ACO participant TIN that is already participating in a program as defined by 42 CFR 425.114(a), then the "Add Participant" change request would receive an overlap deficiency. Current ACO-MS functionality allows for a check of any applicable overlap deficiencies during the submission of an "Add Participant" change request.



IMPORTANT!



The Shared Savings Program checks for ACO participant overlaps periodically during the application cycle. It is neither an automatic check nor a check updated daily. Thus, the successful termination of a TIN from a qualifying program or initiative will not automatically remove the overlap deficiency. However, if the termination occurs prior to the next overlap check, then the overlap deficiency will be removed when the overlap check occurs.

To resolve the overlap, the overlapping participant must determine which ACO they wish to participate with. The overlapping participant should then contact the ACO with whom they do not wish to participate and request the change request the ACO submitted to add the participant to its ACO Participant List be withdrawn immediately.

- If the overlap is with another currently participating Shared Savings Program ACO, the ACO can also find information about the overlapping ACO in the <u>Accountable Care Organizations</u> <u>data file</u>.
- If the overlap is with an initial applicant within the Shared Savings Program, the ACO should contact the Shared Savings Program helpdesk to request the public contact information for the overlapping ACO.
- If the overlap is with an ACO participating in the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, the ACO can find information about the overlapping ACO in the <u>ACO REACH data file</u>.
- In the event of an unresolved overlap between a ACO REACH ACO and a Shared Savings Program ACO, the overlapping participant TIN and affiliated Participant Providers (as identified by their National Provider Identifier (NPI)) will be removed from the ACO REACH model's participant list.
- If the overlap is with an ACO participating in the Kidney Care Choices (KCC) Model, the ACO can find information about the overlapping Kidney Contracting Entity (KCE) on the model website.
- If the overlap is with an ACO participating in the Vermont Medicare ACO Initiative: Vermont OneCare, the ACO can find more information on the <u>Vermont model website</u>.

ACO participants participating in a Shared Savings Program ACO are allowed to participate in the models listed below as long as the ACO is **not** also participating in the ACO Primary Care (PC) Flex Model.

- Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model
- Kidney Care First (KCF) Model

The ACO participants or practices of these models may not participate in an ACO that joins the ACO PC Flex Model. ACO PC Flex participation is at the ACO level, therefore any ACO participant or practice that wishes to remain in any of these models must withdraw from their ACO PC Flex Model participating ACO. ACO participants participating in a Shared Savings Program ACO are allowed to participate in the previously listed models; however, if the ACO is also participating in the ACO PC Flex Model, no overlaps are allowed. Information about the



overlapping ACO PC Flex Model ACO participant can be found in the Accountable Care Organizations data file.

In the event of an **unresolved** overlap between two Shared Savings Program ACOs who both submitted "Add Participant" change requests, the following situations may occur:

- If one ACO withdraws their "Add Participant" change request for an overlapping ACO
 participant or terminates the ACO participant from their ACO Participant List by the Phase 1
 Request for Information 2 (RFI-2) final deadline, then the deficiency will be removed from
 the other ACO's "Add Participant" change request.
- If one "Add Participant" change request has an ACO Participant Agreement deficiency in addition to the overlap, while another "Add Participant" change request only has an overlap, the change request with both deficiencies may be denied. This may allow for the ACO with the "Add Participant" change request with the submitted executed ACO Participant Agreement meeting Shared Savings Program requirements to retain the ACO participant.
- If the overlap remains past the RFI-2 final deadline and both the "Add Participant" change requests were submitted with executed ACO Participant Agreements that meet Shared Savings Program requirements, they may be denied for both ACOs.

In the event of an **unresolved** overlap between two Shared Savings Program ACOs where one ACO submitted a "Renewal Participant" change request and the other ACO submitted an "Add Participant" change request, the following situations may occur:

- If one ACO withdraws their "Renewal Participant" or "Add Participant" change request for an
 overlapping ACO participant or terminates the ACO participant from their ACO Participant
 List by the Phase 1 Request for Information 2 (RFI-2) final deadline, then the deficiency will
 be removed from the other ACO's "Add Participant" change request.
- If the overlap remains past this final deadline, the "Add Participant" change request may be denied for both ACOs.
- If CMS approves the change request, the ACO participant is added to the ACO Participant List effective January 1st of the upcoming PY. Unresolved overlaps are only resolved if there are no other deficiencies remaining on the change request.

Tips for Success

A currently participating ACO may delete an entity from its ACO Participant List anytime during the PY. However, all ACO participants deleted after the final Phase 1 application deadline to delete ACO participants for the upcoming PY will remain on the ACO's Participant List for the entirety of the upcoming PY for purposes related to ACO's assignment, historical benchmark, PY financial calculations, quality reporting, or the obligation of the ACO to report on behalf of eligible clinicians who bill under the TIN of an ACO participant for certain CMS quality initiatives.



5.4 ACO PARTICIPANT LEGAL BUSINESS NAME CHANGES

If an ACO participant changes its LBN, then the ACO must update the relevant ACO Participant Agreement to reflect the new LBN.

If the ACO submits its renewal application, then the updated ACO Participant Agreement can be submitted if the ACO plans to carry the participant forward into the next PY.

If the change request generates a TIN-LBN-mismatch deficiency (due to a discrepancy between the LBN entered and the LBN listed in PECOS), the ACO has an opportunity to update the LBN during the Phase 1 RFI response period.

The updated ACO Participant Agreements should be maintained internally and made available for CMS review upon request.

5.5 IMPACT OF ACO PARTICIPANT LIST CHANGES ON PROGRAM OPERATIONS

This section describes how changes to an ACO Participant List impact critical downstream program operations.

5.5.1 How Changes in ACO Participants Affect Data Sharing

At the start of the agreement period and routinely during the PY, CMS will use the ACO's certified ACO Participant List to provide ACOs with information on their assigned beneficiary population and financial performance. CMS will provide ACOs with reports that reflect information including, but not limited to, the ACO's historical benchmark, PY expenditures used in financial reconciliation, and quality reporting.

ACOs will also receive beneficiary identifiable claims data in the Claim and Claim Line Feed (CCLF) files. Refer to the <u>Program Guidance & Specifications webpage</u> for additional information—specifically, the documents available under Data and Report Sharing and the current version of the Shared Savings and Losses and Assignment Methodology and Quality Performance Standard Specifications.

Information in the reports and CCLF files referenced above will not be impacted by changes made to the ACO Participant List during the PY, including deletion of ACO participants from the certified ACO Participant List for the current PY, additions or deletions of ACO providers/suppliers for the current PY, and proposed changes to the ACO Participant List for the upcoming PY that are made during the annual application and change request cycle.

For example, if a currently participating ACO certifies an ACO Participant List for PY 1 with three ACO participants and during the course of the PY delete an ACO participant with a termination effective date at the end of PY 1, that ACO participant will not appear on the PY 2 ACO Participant List.

However, the deletion of the ACO participant will not impact program operations for PY 1. Furthermore, proposed ACO Participant List additions that are made during the application and change request cycle for PY 2 (which occurs during the course of PY 1) will not impact PY 1 program operations, as those changes do not take effect until January 1st of PY 2.



Additionally, the final deadline to delete ACO participants during the annual application and change request cycle for the upcoming PY is the last opportunity for ACOs to delete an existing ACO participant from the certified ACO Participant List before the next PY begins.

ACO participants that are deleted after the deadline will remain on the ACO Participant List for the upcoming PY and will be used for purposes related to the ACO's assignment, historical benchmark, PY financial calculations, quality reporting, or the obligation of the ACO to report on behalf of eligible clinicians who bill under the TIN of an ACO participant for certain CMS quality initiatives. Continuing the example above, if the ACO participant from the PY 1 ACO Participant List for not only the remainder of PY 1, but also for all of PY 2. The effective termination date will be set to December 31st of PY 2, and the ACO participant will be included in all program operations for PY 2.

5.5.2 How Changes in ACO Participants Affect Quality Reporting

The Shared Savings Program has aligned quality measures and quality reporting with other CMS quality initiatives, including the Quality Payment Program. For purposes of determining the eligible clinicians on whose behalf the ACO is responsible for reporting, CMS uses the ACO Participant List that the ACO certified before the start of the applicable PY.

Resources on quality reporting are available in the <u>Program Guidance &</u> <u>Specifications webpage</u>.

ACO Participant List changes submitted during a given PY do not change the eligible clinicians on whose behalf the ACO is responsible for reporting.

5.5.3 How Changes in ACO Participants Affect Merit-based Incentive Payment System (MIPS) Promoting Interoperability Reporting for Purposes of Satisfying the Shared Savings Program Certified Electronic Health Record Technology (CEHRT) Requirement

For purposes of determining the eligible clinicians on whose behalf the ACO is responsible for reporting the MIPS Promoting Interoperability performance category, CMS uses the ACO Participant List that the ACO certified before the start of the applicable PY. More information can be found in the <u>Frequently Asked Questions on the Shared Savings Program Requirement to</u> <u>Report Objectives and Measures for the MIPS Promoting Interoperability Performance</u> <u>Category</u>. ACO Participant List changes submitted during a given PY do not change the eligible clinicians on whose behalf the ACO is responsible for reporting the MIPS Promoting Interoperability performance Interoperability performance category.

5.5.4 How Changes in ACO Participants Affect Public Reporting

ACOs participating in the Shared Savings Program are required to publicly report certain ACO information on a designated webpage in a standardized format specified by CMS, in accordance with <u>42 CFR § 425.308</u>. ACOs are required to report the following for ACO participants:

• If your ACO would also like to include the ACO participant's doing business as (DBA) name, enter the DBA name in parentheses next to the ACO participant's LBN.



- If an ACO participant has merged with or been acquired by another ACO participant, only include the acquiring ACO participant on the public reporting webpage.
- Do not include the ACO participant's TIN.
- In addition, identify participants in joint ventures between ACO professionals and hospitals.

5.5.5 How Changes in ACO Participants Affect Benchmarking

Historical benchmarks are established at the start of an ACO's agreement period using the ACO's certified ACO Participant List to derive the assigned beneficiary population. For more information on the historical benchmark, refer to the current version of the *Shared Savings and Losses and Assignment Methodology Specifications* available on the <u>Program Guidance & Specifications webpage</u>.

CMS will adjust an ACO's historical benchmark at the start of a PY to reflect changes to the ACO's certified Participant List made since the start of the previous PY ($\frac{42 \text{ CFR}}{\frac{5425.118(b)(3)(i)}}$). The ACO's updated certified ACO Participant List is used to assign beneficiaries to the ACO for the benchmark period (the three years prior to the start of the ACO's agreement period) in order to determine the ACO's adjusted historical benchmark.

The historical benchmark may be adjusted upward or downward since it is a function of the assigned beneficiary population derived from the ACO's newly constructed ACO Participant List.

5.5.6 How Changes in ACO Participants Affect Program Eligibility

ACO Participant List changes may impact an ACO's compliance with Shared Savings Program eligibility requirements in <u>42 CFR part 425, subpart B</u>. These include, but are not limited to, the following examples:

- ACO participants must hold at least 75 percent control of the ACO's governing body; additions to or deletions from the ACO Participant List may affect compliance with this requirement.
 - Note: Merged or acquired (M/A) ACO participant Tax Identification Numbers (TINs) cannot be included as an "ACO Participant Representative" on your governing body and will not be counted towards the 75 percent ACO participant control requirement.
- An ACO's clinical management and oversight must be managed by a senior level Medical Director who is a board-certified physician licensed in a state in which the ACO operates and is physically present on a regular basis at a clinic, office, or other location of the ACO, an ACO participant, or an ACO provider/supplier. Additions to or deletions from the ACO Participant List may affect compliance with this requirement.
 - For example, if the ACO's Medical Director is physically present on a regular basis at the location of a single ACO participant and that ACO participant is removed from the ACO Participant List, the ACO would need to either identify a new Medical Director who meets requirements, or the current Medical Director would have to be physically present on a regular basis at another location that meets the requirements.
- Advance Investment Payments (AIP) (42 CFR § 425.630(b)) eligibility is determined, in part, from the ACO Participant List. To be eligible to receive advance investment payments,



an ACO must be a new ACO, inexperienced with risk, low revenue, and applying to participate at Level A of the BASIC track.

- Changes to an ACO's Participant List may affect an ACO's experience with risk determination and/or revenue status and therefore impact AIP eligibility. As specified in <u>42 CFR § 425.316(e)</u>, if an ACO makes changes to its ACO Participant List and CMS determines that the ACO has become experienced with performance-based risk Medicare ACO initiatives during its first or second PY of its agreement period or that the ACO became a high revenue ACO during any PY of its agreement period, CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO. CMS may also take compliance action as specified in <u>42 CFR § 425.216</u> and <u>425.218</u>.
- o More information can be found in the <u>Advance Investment Payments Guidance</u>.
- Eligibility for continued participation in the BASIC track's glide path requires the ACO to be remain inexperienced with performance-based risk Medicare ACO initiatives (42 CFR § 425.600). CMS monitors ACOs identified as inexperienced with performance-based risk Medicare ACO initiatives for changes to the ACO Participant List that would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for continued participation on the glide path (42 CFR § 425.600(h)). Pursuant to 42 CFR § 425.600(h)(2)(i), the ACO is permitted to complete the PY for which it met the definition of experienced with performance-based risk Medicare ACO initiatives in a one-sided model of the BASIC track, but is ineligible to continue participation in the glide path after the end of that PY if it continues to meet the definition of experienced with performance-based risk Medicare ACO initiatives.
- When the ACO adds ACO participants, these new ACO participants and their affiliated providers and suppliers must demonstrate a meaningful commitment to the mission of the ACO to ensure its likely success.
 - For example, a meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by <u>42 CFR § 425.112</u> and is held accountable for meeting the ACO's performance standards for each required process.
- When the ACO removes ACO participants, the ACO may fall below the requirement to maintain at least 5,000 assigned beneficiaries during the PY and be subject to compliance action.
- An ACO's repayment mechanism amount may need to be updated to reflect the addition or deletion of ACO participants during an agreement period.



Following each Phase 1 submission period, CMS reviews ACO participant change requests and issues requests for information (RFIs) to any ACO participant change request with deficiencies.

Tips for Success

Information on how deficiencies impact ACO participant TIN and ACO level beneficiary assignment estimates can be found in the Beneficiary Assignment Estimate tab of the Participation Options Report and within Participation Options Report Data Dictionary in ACO-MS.

If any changes to an ACO Participant List are determined to cause the ACO to become noncompliant with program eligibility requirements regarding the composition and control of the governing body, the ACO should contact its ACO Coordinator. The ACO may be issued a compliance action and asked to submit a narrative for review describing why it seeks to deviate from certain requirements and how it will continue to meet the goals and objectives of the Shared Savings Program.

6 Managing Changes to the ACO Provider/Supplier List

ACOs must certify the list of ACO participants who will be participating in the ACO during the upcoming PY. CMS uses the ACO Participant List to generate the ACO's Provider/Supplier List. ACOs must also review and certify the list of ACO providers/suppliers that will be participating in the ACO during the upcoming PY.

As with its ACO Participant List, each ACO must certify its CMS-generated ACO Provider/Supplier List prior to the start of every PY and at such other times as specified by CMS. The initial ACO Provider/Supplier List provided by CMS reflects PECOS reassignments from a single point in time; therefore, <u>ACO-MS</u> provides ACOs the functionality to electronically add or delete provider/suppliers from the initial list provided by CMS prior to the beginning of the PY. CMS provides the initial Provider/Supplier List annually to all ACOs prior to the ACO Signing Event which is in accordance with the CMS-established schedule.

Published Resource Available

General information on how to review and certify your ACO Participant List and ACO Provider/Supplier List in ACO-MS during the ACO Signing Event can be found in the <u>How to Review and Certify the ACO Participant List and ACO</u> <u>Provider/Supplier List in ACO-MS</u> tip sheet.

Thereafter, each ACO is required to notify CMS within 30 days of a change to its ACO Provider/Supplier List. An example of a change would be if a provider or supplier is no longer Medicare-enrolled. The ACO must notify CMS no later than 30 days after the provider or supplier ceases to be Medicare-enrolled.



Tips for Success

Updates to the ACO Provider/ Supplier List in ACO-MS will not be reflected in PECOS. If the ACO participant wishes to update PECOS information, it must follow PECOS instructions.

An ACO may need to add a provider or supplier that has reassigned its billing to the TIN of an ACO participant after the ACO certified its ACO Provider/Supplier List. The ACO must notify CMS within 30 days after the provider or supplier reassigns its billing to the TIN of an ACO participant.

IMPORTANT!

An ACO that needs to make a change to its certified ACO Provider/Supplier List must notify CMS by making changes to the ACO Provider/Supplier List directly in ACO-MS. ACO entries in ACO-MS do not modify PECOS.

Modifying ACO providers/suppliers in ACO-MS does not impact beneficiary assignment or Medicare FFS billing rules. For key points on adding and/or deleting ACO providers and suppliers in ACO-MS, please review the <u>Managing the ACO Provider/Supplier List in ACO-MS</u> <u>Tip Sheet</u>. ACOs have the opportunity to add and/or delete multiple ACO providers and suppliers by utilizing the bulk upload functionality and uploading a file into ACO-MS. For detailed instructions, review the <u>ACO Provider/Supplier Bulk Upload in ACO-MS Tip Sheet</u>. Note that after an ACO certifies its ACO Provider/Supplier List, an ACO cannot make any additional changes until January 1st of the upcoming PY.

If an ACO submits timely notice to CMS, the addition of an individual or entity to the ACO Provider/Supplier List is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the ACO fails to submit timely notice to CMS, the addition of an individual or entity to the ACO Provider/Supplier List is effective on the date of the notice. The deletion of an individual or entity from the ACO Provider/Supplier List is effective on the date the individual or entity ceased to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare FFS beneficiaries under a billing number assigned to the TIN of an ACO participant.

Providers identified by CMS Certification Numbers (CCNs) that CMS identifies prior to the start of the PY as enrolled under the TIN of an ACO participant but with a deactivated enrollment status in Medicare (42 CFR 425.402(f)(1)) are not included on the ACO Provider/Supplier List. Such providers are included in the assignment list reports that ACOs receive prior to and during the PY, which ACOs are not required to certify.

Periodically during the PY, CMS identifies providers (identified by CCNs) with no prior Medicare claims experience that enroll under the TIN of an ACO participant after the ACO certifies its ACO Participant List (<u>42 CFR § 425.402(f)(3)(i)</u>). Such providers will not be included in the ACO



Provider/Supplier List that CMS generates prior to the start of every PY, but ACOs are required to add such providers to the ACO Provider/Supplier List as described above. These providers will be included in the assignment list reports that ACOs receive during the PY, which ACOs are not required to certify.

CMS is aware that there are certain types of practitioners who complete the Opt-Out Affidavit. Physicians and practitioners who have opted out of Medicare do not enroll in Medicare, and neither the physician/practitioner nor the beneficiary submits the bill to Medicare for services rendered. Therefore, a physician or practitioner who has opted out of Medicare would not meet the definition of an ACO professional or ACO provider/supplier. If such a physician or practitioner opts out of Medicare after he or she had been identified on an ACO Provider/Supplier List, the ACO must remove the individual from the list. For more information on opting out, please refer to the <u>Opt-Out Affidavits webpage</u>.



Appendix A: Example ACO Participant Agreement Language

Sample Introductory Paragraph:

This ACO Participant Agreement ("**Agreement**") is by and between <u>Accountable Care</u> <u>Organization of ABC, LLC D/B/A ABC ACO</u> ("**ACO**"), and <u>XYZ Group Practice P.C.</u> ("**ACO Participant**") and is effective [Month, Day, Year] ("Effective Date").

<Body of Agreement>

Sample Signature Page:

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the dates below.

For the ACO	For the ACO Participant
Legal Entity Name	Legal Business Name
DBA Name (if applicable)	DBA Name (if applicable)
Authorized Signatory	Authorized Signatory
Name	Name
Title	Title
Date	Date
Address	Address
City, State ZIP Code	City, State ZIP Code
Business Phone	Business Phone



Appendix B: Example ACO Participant Agreement Amendment Language

Sample Introductory Paragraph:

Amendment to ACO Participant Agreement ("**Amendment**") by and between <u>Accountable Care</u> <u>Organization of ABC</u>, <u>LLC D/B/A ABC ACO</u> ("**ACO**"), and <u>XYZ Group Practice P.C.</u> ("**ACO Participant**") is effective [Month, Day, Year] ("Effective Date").

WHEREAS, the **ACO** and **ACO** participant entered into an ACO Participant Agreement on or about [Month, Day, Year] (the "Agreement"); and both parties wish to amend the Agreement to [insert purpose of amendment].

NOW, THEREFORE, in reliance on the mutual agreements contained herein, the parties agree as follows:

[Enumerate and describe the various amendments]

Sample Signature Page:

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the dates below.

For the ACO	For the ACO Participant
Legal Entity Name	Legal Business Name
DBA Name (if applicable)	DBA Name (if applicable)
Authorized Signatory	Authorized Signatory
Name	Name
Title	Title
Date	Date
Address	Address
City, State ZIP Code	City, State ZIP Code
Business Phone	Business Phone



Appendix C: Information on Digital Signature Requirements

General Overview of Digital Signatures

If an ACO and ACO participant both consent to the use of digital signatures to execute an ACO Participant Agreement, they must use industry-accepted software to verify that the digital signatures represent the signers' consent to the terms of the agreement. Generally, a digital signature requires two components: the signature generation process (i.e., when a signer embeds a unique signature in the electronic document, thus legally executing the document), and the signature verification process (i.e., the mechanism by which an auditing party is able to verify the signature's authenticity).

ACOs should maintain all physical and/or electronic records necessary to verify each digital signature that they submit for CMS review and provide these records to the Shared Savings Program upon request.

Digital Signature Programs

The Shared Savings Program does not require the use of any particular software product to execute an ACO Participant Agreement, and any software that employs digital signature algorithms and that fulfills the two requirements—signature generation and signature verification—may be employed. Should CMS question the integrity of the software used, it may send the ACO an RFI. Should an ACO receive an RFI, it should provide CMS with documented evidence of the verification process for the signature in question.

Regulation of Digital Signatures

The <u>Electronic Signatures in Global and National Commerce Act (E-Sign Act)</u>, which was enacted on June 30, 2000, promotes the use of electronic contract formation, signatures, and recordkeeping in private commerce by establishing legal equivalence between paper and electronic contracts; pen and ink signatures and electronic signatures; and other legally required written documents (termed "records") and their electronic equivalents.

Additional Questions

Q1. What is the difference between a digital signature and an electronic signature?

Per Section 106 of the E-Sign Act, an electronic signature is defined as "an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record." A digital signature consists of both the electronic signature itself and the verification process used to authenticate it. Digital signatures require the signer to use a digital certificate that links the signer with the document being signed, and a unique digital "fingerprint" is embedded in the document once signed. An electronic signature that lacks an authentication verification process will not be accepted. Any non-handwritten signature must be verifiable according to industry standards.



Q2. Do both parties to the Agreement have to use digital signatures to sign the ACO Participant Agreement?

No. As long as both parties agree that a digital signature has the full force and effect of a handwritten signature, one party may use a digital signature while the other uses a handwritten signature.

However, if only one party will be executing the document by a handwritten signature, then that party must sign the document first. The remaining party should then scan in the signed document and embed their digital signature upon that scanned document. Printing out a document that contains a digital signature hinders validation of the encryption required for authentication in this format.

Q3. What if a party needs to amend or change an agreement that was executed with digital signatures?

Should an agreement containing a digital signature need to be amended, it must be reexecuted with a new digital signature to indicate consent to the changes.

Q4. Can CMS recommend any digital signature programs for ACOs to use in executing agreements with ACO participants?

The E-Sign Act does not permit agencies to require the use of specific products and/or manufacturers. Therefore, CMS cannot recommend any specific products or companies. However, in choosing a digital signature program, an ACO should review the E-Sign Act requirements and focus on the particular product's signature generation and verification capabilities.