Medicare Shared Savings Program

ACO PARTICIPANT LIST AND PARTICIPANT AGREEMENT

Guidance

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Version #12

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CMS CENTERS FOR MEDICARE & MEDICAID SERVICES | MEDICARE SHARED SAVINGS PROGRAM

Revision History—Version 12

TITLE OF SECTION & REVISIONS/CHANGES DESCRIPTION (since previous version)	LINK TO AFFECTED AREA
Medicare Enrollment Policy: Updated guidance to detail the Medicare enrollment requirements and provide an overview of various enrollment/dis-enrollment scenarios.	Section 3.3.1
Renewal/Early Renewal Application: Updated guidance to outline the process flow for when an ACO withdraws early renewal application and potential implications	Section 3.3.1
Overlap Policy and Precedence Between Models: Updated guidance to detail program requirements regarding overlaps and provided an overview of overlap scenarios and established precedence.	Section 3.3.2
Change Request Process: Updated guidance to provide a link to the *Submitting Change Requests in ACO-MS* tip sheet.	Section 3.3.4

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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. These requirements are reflected in the regulations for the Shared Savings Program, which are codified at 42 CFR part 425.

The ACO Participant List is critical to Shared Savings Program operations. 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 performance year thereafter.

Currently participating ACOs can delete ACO participants from the ACO Participant List at any time during a performance year. The ACO participant is no longer an ACO participant as of the termination effective date of the ACO Participant Agreement; however, absent unusual circumstances, the ACO participant data will continue to be utilized for certain operational purposes.

CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, or the obligation of the ACO to report on behalf of eligible clinicians who bill under the taxpayer identification number (TIN) of an ACO participant for certain CMS quality initiatives to reflect the deletion of entities from the ACO Participant List that became effective during the performance year (refer to Section 3.4.

Through the Shared Savings Program, CMS establishes a participation agreement with each ACO. Each ACO is required to have contractual participant agreements with its ACO participants, which are entities identified by a Medicare-enrolled billing TIN that, alone or together with one or more other ACO participants, compose an ACO. An ACO may not include an ACO participant on its ACO Participant List unless individuals authorized to legally bind the ACO participant and ACO have signed an ACO Participant Agreement. An agreement remains valid as long as it was signed by an authorized official at the time it was executed. 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.

2 Background

The Medicare Shared Savings Program (Shared Savings Program) is a voluntary program that encourages groups of doctors, hospitals, and other health care providers to come together as an Accountable Care Organization (ACO) to give coordinated, high-quality care to their Medicare beneficiaries. The Shared Savings Program rewards ACOs that improve the quality and cost efficiency of health care. The authority for the Shared Savings Program is Section 1899 of the Social Security Act (the Act), which was added by the Patient Protection and

Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010. These public laws are collectively known as the Affordable Care Act. The Shared Savings Program's regulations and definitions of terms can be found in the Code of Federal Regulations at 42 CFR part 425 Additionally, the Electronic Code of Federal Regulations website is a useful resource for viewing the program regulations.

3 ACO Participant List

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

3.1 Introduction to the ACO Participant List

An ACO participant is an entity identified by a Medicare-enrolled TIN through which one or more ACO providers/suppliers bill Medicare that, alone or together with one or more ACO participants, compose an ACO, and is included on the list of ACO participants required under 42 CFR § 425.118.

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" and the legal name of an ACO participant as the "legal business name" (LBN). 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 performance year.

A currently participating ACO may submit change requests to modify its ACO Participant List; however, these changes will become effective only at the start of the next performance year. 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 legal business name (LBN) change). For more information on submitting change requests in the ACO Management System (ACO-MS), please refer to the *Submitting Change Requests in ACO-MS* tip sheet.

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

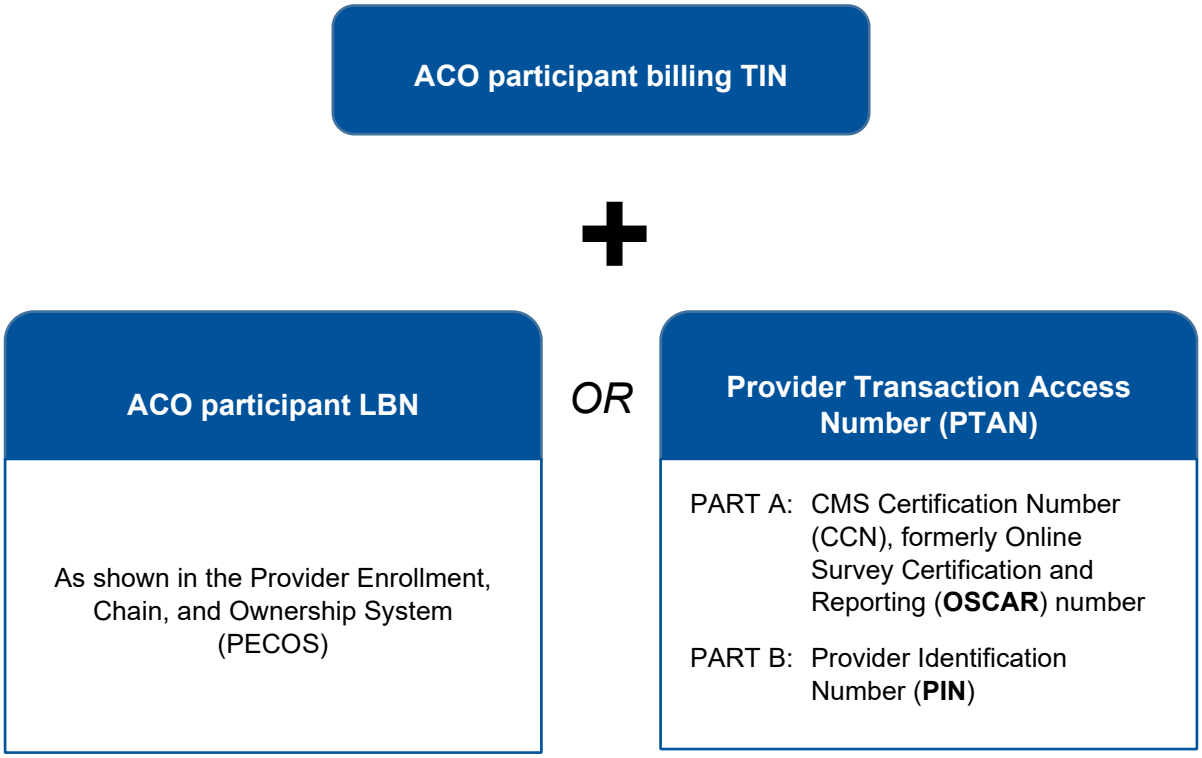
During the performance year, CMS will not adjust an ACO's assignment, historical benchmark or performance year financial calculations. CMS will also not make adjustments to the obligation of an ACO to report on behalf of eligible clinicians who bill under the taxpayer identification number (TIN) of an ACO participant for certain CMS quality initiatives to reflect the deletion of entities from the ACO Participant List that become effective during the performance year.

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 that would cause the ACO to be considered experienced with performance-based risk Medicare ACO initiatives and ineligible for participation in a one-sided model (42 CFR § 425.600(h)).
- 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 (42 CFR § 425.305(a)). 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 (42 CFR § 425.118).

Specifically, the ACO must:

- Certify the accuracy of its ACO Participant List prior to the start of an agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with 42 CFR § 425.302(a)(2)
- Certify the accuracy of its ACO Provider/Supplier List prior to the start of an agreement period, before every performance year thereafter, and at such other times as specified by CMS.
- Maintain and update, as necessary, its ACO Participant List within the time frames 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 (n 3.3) or additional information on adding ACO participants); and
    - Notify CMS of any entities to be deleted from the ACO Participant List by deleting the ACO participant from the ACO Participant List in ACO-MS no later than 30 days after the ACO Participant Agreement terminates (refer to 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. Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance-year financial calculations, 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 to reflect the deletion of entities from the ACO Participant List that become effective during the performance year. Refer to 42 CFR §§ 425.118(b)(3)(ii) and 425.216.

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 Contractors (MACs) 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 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 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.

Table 1. Sole Proprietor ACO Participants

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 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 Participant Requirements

Under certain circumstances, per 42 CFR § 425.204(g) CMS may allow the ACO to include on their ACO participant list a merged or acquired entity's TIN. Claims billed by TINs of entities merged or acquired by an ACO participant may be considered by CMS for purposes of meeting the minimum assigned beneficiary threshold and creating a more accurate historical benchmark as well as the beneficiary assignment list for the upcoming performance year.

Under the following circumstances, and ACO may submit requests to include an acquired entity's TIN on its ACO participant list for CMS' consideration:

- The ACO participant must have subsumed the acquired entity's TIN in its entirety, including all the providers and suppliers that reassigned the right to receive Medicare payment to that acquired entity's TIN.

- All the 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 certain criteria.

Table 2. ACO Participants with Merged/Acquired TINs

MERGED/ACQUIRED RELATIONSHIP	ACO ACTIONS TO TAKE IN ACO-MS
TIN A acquires TIN B. (Neither is a current ACO participant.)	• ACO submits a change request to add TIN A. • ACO should not mark TIN A as merged/acquired. • 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 Section 3.2.3) for TIN B.
TIN C acquires TIN D. (Both TIN C and TIN D are currently approved ACO participants.)	• ACO should not make any changes to TIN C. • 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 performance year but will not be included in the next performance year). • ACO submits a change request to add TIN D (for the next performance year). 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 Section 3.2.3) 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 Section 3.2.3) for TIN F.

MERGED/ACQUIRED RELATIONSHIP	ACO ACTIONS TO TAKE IN ACO-MS
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 performance year but will not be included in the next performance year). • ACO submits a change request to add TIN H (for the next performance year). 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 Section 3.2.3 for TIN H.

3.2.3 Merged Or Acquired TIN Documentation

An ACO submitting an entity's TIN that has merged with or been acquired by an ACO participant must identify which ACO participant acquired the TIN. Additionally, the attestation must state that all providers and suppliers that previously billed under the acquired TIN have reassigned their billings to the acquiring ACO participant TIN and have been added to the ACO Provider/Supplier List, and that the acquired entity's TIN is no longer used to bill Medicare.

In addition to submitting the acquired TIN and the required attestation, an ACO must also submit supporting documentation via ACO-MS demonstrating that the TIN was acquired by the acquiring ACO participant through a sale or merger (e.g., a bill of sale, joinder agreement, or other legal document). For more information on submitting and tracking the status of submitted change requests, refer to the *Adding ACO Participants & SNF Affiliates in ACO-MS* tip sheet.

3.3 ACO Participant List Changes

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.

An ACO may also delete entities from its ACO Participant List for the upcoming performance year during Phase 1 of the application submission period. 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 *Adding ACO Participants & SNF Affiliates in ACO-MS* tip sheet.

3.3.1 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. 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.

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 CR 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.

3.3.2 Overlap Policy and Precedent Between Models

Per 42 CFR § 425.114(a), 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.

Note: Organizati**on**s will only be able to concurrently participate in the Shared Savings Program and the Making Care Primary (MCP) Model from July 1, 2024- December 31, 2024.

- 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.
- 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 ACO and/or the proposed ACO participant should contact the ACO identified in the overlap deficiency. The ACO should communicate with the ACO participant identified in the overlap to confirm the Shared Savings Program ACO or entity from another shared savings initiative with which the ACO participant wants to participate and whether the ACO participant has a valid, signed agreement with the overlapping ACO/entity.
    - If the overlap is with another currently participating Shared Savings Program ACO, the ACO can also find information about overlapping ACO in the Accountable Care Organizations data file.

  - If the overlap is with an initial applicant within the Shared Savings Program, the ACO should contact the Shared Savings Program help desk.
  - 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 ACO REACH data file.
  - 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.

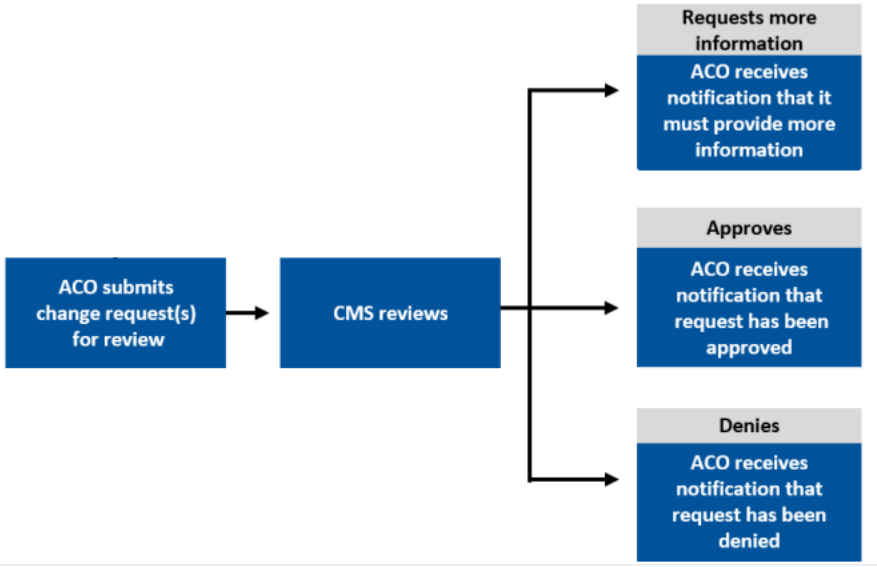
- In the event of an **unresolved** overlap between an MCP Model participant and a Shared Savings Program ACO participant, the overlapping ACO participant TIN and affiliated Participant providers (as identified by their National Provider Identifier (NPI) may be removed from the Shared Savings Program's ACO Participant List.
- In the event of an **unresolved** overlap between two Shared Savings Program ACOs, 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 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 performance year. As stated previously, a currently participating ACO may delete an entity from its ACO Participant List anytime during the performance year. However, all ACO participants deleted after the final Phase 1 application deadline to delete ACO participants for the upcoming performance year will remain on the ACO's Participant List for the entirety of the upcoming performance year for purposes related to ACO's assignment, historical benchmark, performance year financial calculations, quality reporting sample, 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.

3.3.3 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. 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 *Requests for Information in ACO-MS* tip sheet and the *Application Reference Manual*.

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



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 Application Types & Timeline webpage. Please note that while application deadlines are subject to change, CMS will not accept late submissions.

An ACO that withdraws an early renewal application prior to Phase 1 Dispositions will be automatically returned to their current participation agreement status.

- Any change requests to renew a current ACO participant will be withdrawn and instead 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 performance year. These will receive a disposition in accordance with the CMS application and change request cycle timeline.
    - The ACO may withdrawal individual ACO participant change requests before 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 Phase 1 RFI-1 submission deadline. If that deadline has elapsed, the ACO will not be able to make the addition.

3.3.4 Currently Participating ACOs (Mid-Agreement Period)

An ACO that is not in the last performance year of its agreement period and not applying to renew or early renew may make changes to its ACO Participant List during Phase 1 of the

application submission period. CMS reviews change requests during an established review cycle in advance of the upcoming performance year that includes CMS feedback and the opportunity for the ACO to correct deficiencies. For more information on how change request submissions can impact participation can be found in the *Managing Program Participation Guidance*.

3.3.5 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 procedure is necessary to ensure the accuracy of the relevant ACO Participant Agreement. This document should be maintained internally and available for CMS review upon request. The updated ACO Participant Agreement should be submitted when the ACOs submits its renewal application if the ACO plans to carry the ACO participant forward into the next performance year. If the submission of the change request to carry forward the ACO participant generates a TIN-LBN-mismatch deficiency due to the ACO participant LBN entered in the change request not matching the LBN of the TIN as it appears in PECOS, the ACO will have the opportunity to update the LBN in the change request during the Phase 1 RFI response periods.

3.4 Impact Of ACO Participant List Changes on Program Operations

This section describes how changes to an ACO Participant List impact critical downstream program operations. Absent unusual circumstances, CMS does not make adjustments during the performance year to the certified ACO Participant List and will continue to utilize the data for certain operational purposes.

3.4.1 How Changes in ACO Participants Affect Data Sharing

At the start of the agreement period and routinely during the performance year, 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, performance year expenditures used in financial reconciliation, and the ACO's quality sample.

ACOs will also receive beneficiary identifiable claims data in the Claim and Claim Line Feed (CCLF) files. Refer to the Program Guidance & Specifications webpage 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 performance year, including deletion of ACO participants from the certified ACO Participant List for the current performance year, additions or deletions of ACO providers/suppliers for the current performance year, and proposed changes to the ACO Participant List for the upcoming performance year that are made during the annual application and change request cycle.

For example, if a currently participating ACO certifies an ACO Participant List for Performance Year (PY) 1 with three ACO participants and during the course of the performance year deletes

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 performance year is the last opportunity for ACOs to delete an existing ACO participant from the certified ACO Participant List before the next performance year begins. ACO participants that are deleted after the deadline will remain on the ACO Participant List for the upcoming performance year and will be used for purposes related to ACO's assignment, historical benchmark, performance year financial calculations, quality reporting sample, 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 is deleted after the above referenced deadline, it will remain on the 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 all program operations for PY 2.

3.4.2 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 performance year. Resources are available on the Quality Payment Program (QPP) website that describe the interactions between the Shared Savings Program and the QPP.

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

3.4.3 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 Program Guidance & Specifications webpage.

CMS will adjust an ACO's historical benchmark at the start of a performance year to reflect changes to the ACO's certified Participant List made since the start of the previous performance year (42 CFR § 425.118(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.

3.4.4 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 42 CFR part 425, subpart B. 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.
- **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 participate at Level A of the basic track.

  Additions to or deletions from the ACO Participant List may affect an ACO's AIP eligibility. As specified in 42 CFR § 425.316(e), if the ACO makes additions to or deletions from the ACO Participant List and CMS determines that the ACO has become experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high revenue ACO during any performance year 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 42 CFR §§ 425.216 and 425.218.

  More information can be found in the *Advance Investment Payments Guidance*.

- **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 performance year 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 performance year 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 42 CFR § 425.112 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 performance year 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.

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.

4 Managing Changes to the ACO Provider/Supplier List

CMS uses the ACO Participant List to generate the ACO's Provider/Supplier List. Annually, CMS will provide each ACO with all of the providers/suppliers that have reassigned their billing rights to the TINs on their ACO Participant List. As with its ACO Participant List, each ACO must certify its CMS-generated ACO Provider/Supplier List prior to the start of every performance year 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, ACO-MS provides ACOs the functionality to electronically add or delete providers/suppliers from the initial list provided by CMS prior to the beginning of the performance year.

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.

REMINDER

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. 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.

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 performance year 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 performance year, which ACOs are not required to certify.

Periodically during the performance year, 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 (42 CFR § 425.402(f)(3)(i)). Such providers will not be included in the ACO Provider/Supplier List that CMS generates prior to the start of every performance year, 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 performance year, 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 Opt-Out Affidavits webpage.

5 ACO Participant Agreements

This section provides information on ACO Participant Agreement requirements.

5.1 Introduction to ACO Participant Agreements

CMS requires each ACO to execute contractual participant agreements with each of its ACO participants—that have 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. Supporting documentation includes the first page and signature page of the

executed ACO Participant Agreement or, for a merged/acquired ACO participant, refer to Section 3.2.3 for the requirements for supporting documentation. 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 42 CFR § 425.204(c)(6), CMS is authorized to review all ACO Participant Agreements, including executed and sample ACO Participant Agreements, as a part of any compliance monitoring activities.

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) do 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.

5.2 ACO Participant Agreement Requirements

In addition to the requirements detailed in Section 5.1 each ACO must submit with its application an executed ACO Participant Agreement (first page and signature page) for each of its ACO participants that complies with the requirements of 42 CFR § 425.116(a). An ACO can submit documentation of this agreement in the form of a newly executed ACO Participant Agreement that includes either a digital signature (Appendix C) or a "wet signature," and a signature date. A wet signature is a handwritten signature (i.e., not stamped).

5.2.1 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 42 CFR § 425.116.

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 submitted 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.

5.3 Sample ACO Participant Agreement Requirements

CMS recommends that ACO Participant Agreements explicitly address how participation in the ACO may impact the ACO participants. The ACO is also expected to confirm the accuracy of the following information with respect to its ACO Participant Agreements:

- The ACO legal entity name matches the name in ACO-MS;
- The ACO participant LBN matches the LBN in PECOS;
- The ACO participant TIN matches the TIN listed for the entity in PECOS; and
- The ACO participant TIN is correctly entered into the change request, and it is correctly presented on the Participant Agreement, if included.

CMS does not require that ACOs upload and submit sample ACO Participant Agreements as part of an initial or renewal application. Please review example introductory paragraphs and signature pages for ACO Participant Agreements and amendments in and Appendix B. CMS strongly encourages each ACO to include the information indicated in the format referenced in these examples.

5.3.1 Executed ACO Participant Agreement Requirements

Each executed ACO Participant Agreement must be consistent with the sample ACO Participant Agreement and 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 ACO-MS). 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 complete, original, and wet signature executed agreements.

5.3.2 ACO Participant Legal Business Name Changes

If an ACO participant changes its Legal Business Name (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 performance year.

Appendix A: Example ACO Participant Agreement Language

Sample Introductory Paragraph:

This ACO Participant Agreement ("**Agreement**") is by and between Accountable Care Organization of ABC, LLC D/B/A ABC ACO ("**ACO**"), and XYZ Group Practice P.C. ("**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:

This Amendment to ACO Participant Agreement ("**Amendment**") by and between Accountable Care Organization of ABC, LLC D/B/A ABC ACO ("**ACO**"), and XYZ Group Practice P.C. ("**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	DBA Name
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 Electronic Signatures in Global and National Commerce Act (E-Sign Act), 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 re-executed 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.