



Medicare Shared Savings Program
**ACO PARTICIPANT LIST AND
PARTICIPANT AGREEMENT**

Guidance

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MEDICARE
SHARED SAVINGS
PROGRAM

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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.

ACO participants can be terminated and deleted 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. Absent unusual circumstances, however, 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, the quality reporting sample, 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 become effective during the performance year ([Section 3.4](#)).

Through the Shared Savings Program, CMS establishes agreements with each ACO. Each ACO is required to have contractual agreements with 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 an individual authorized to legally bind the ACO participant has signed an ACO Participant Agreement with the ACO. 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

This document is subject to periodic change. Any substantive changes to this document will be noted in the [Revision History table](#).

An ACO is composed of groups of doctors, hospitals, and other health care providers that come together voluntarily to give coordinated, high-quality care to their Medicare FFS 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. CMS has published four final rules regulating the Shared Savings Program. The first final rule was published in November 2011, the second was published in June 2015, the third was published in June 2016, and the fourth was published in December 2018. Additionally, CMS has addressed certain issues related to the Shared Savings Program in the annual Physician Fee Schedule (PFS) rulemaking. The Shared Savings Program's regulations 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.

The definitions of terms that are important to understanding the Shared Savings Program and this guidance document can be found at 42 CFR § 425.20.

3 ACO Participant List

This section provides detailed information about 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 List identifies all of an ACO's participants by their Medicare-enrolled 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 and ACO reviews, 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 and these changes will become effective only at the start of the next performance year. Specifically, at certain times specified by CMS during the performance year, an ACO is able to add new ACO participants and/or update existing ACO participants (e.g., TIN LBN change). An ACO may delete an ACO participant at any time and the TIN is no longer considered an ACO participant as of the agreement termination date. Absent unusual circumstances, however, CMS does not make adjustments during the

performance year to the ACO's assignment, historical benchmark, performance-year financial calculations, the 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 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 ultimately contribute to the generation of quarterly and annual program reports;
- 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;
- 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 ACOs agreement period.

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

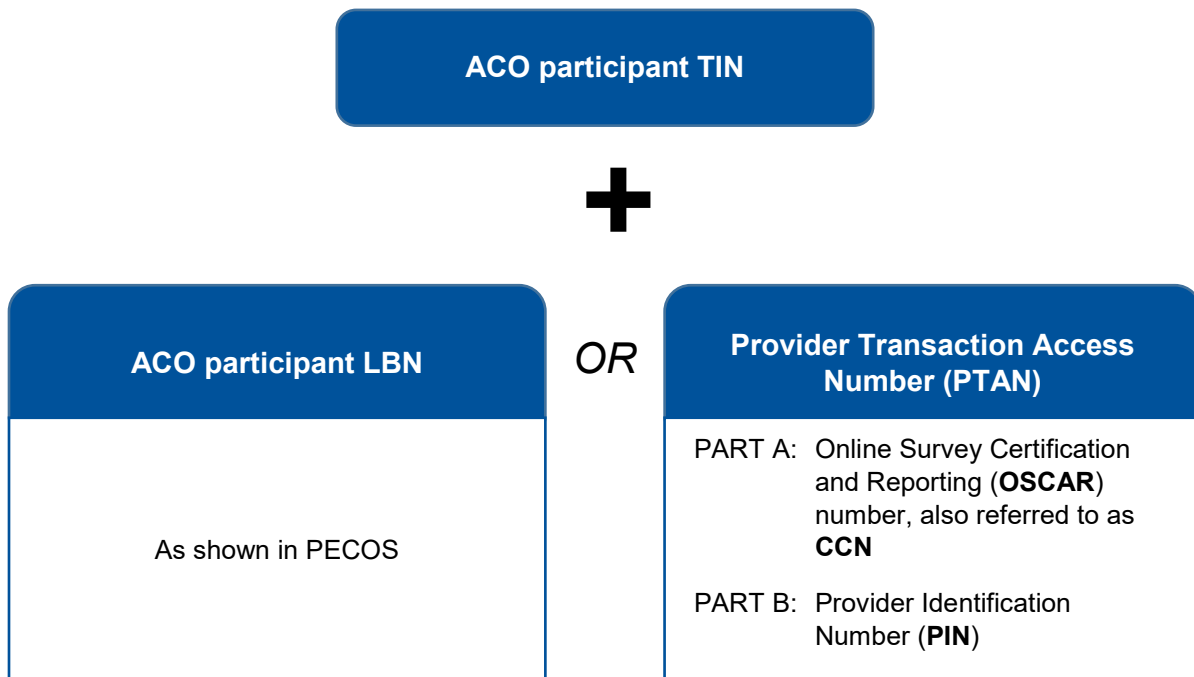


Figure 1. Required ACO Participant Information

The TINs submitted in ACO-MS for an ACO Participant List and 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 to ensure the ACO participants and ACO providers/suppliers continue to meet program requirements (§ 425.304(b)). The CMS screening process includes, at a minimum, the following:

- Updating Medicare-enrollment status periodically;¹
- 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.

¹ Upon entering a TIN and its corresponding LBN (as registered in PECOS) or PTAN in ACO-MS, the ACO will be notified immediately of the TIN's current Medicare enrollment status. Please note the Medicare enrollment status of the TIN may be updated during the change request review cycle. A TIN must be enrolled in Medicare as of the final PECOS check conducted by CMS.

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 (§ 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 § 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 (refer to [Section 3.3](#) for additional information on adding ACO participants); and
 - Notify CMS of any entities to be deleted from the ACO Participant List no later than 30 days after the ACO Participant Agreement terminates, in the form and manner specified by CMS (refer to [Section 3.3](#) for additional information for deleting and terminating ACO participants).

3.2.1 SOLE PROPRIETOR ACO PARTICIPANTS

If an ACO participant is a sole proprietor who is enrolled in Medicare under his or her Social Security number (SSN) and bills Medicare under a separate Employer Identification Number (EIN), 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 with any questions regarding their Medicare enrollment.

Table 1. Sole Proprietor ACO Participants

INFORMATION PROVIDED BY ACO FOR ACO PARTICIPANT ENROLLED IN MEDICARE UNDER SSN AND BILLING MEDICARE UNDER SEPARATE 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. 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.

3.2.2 MERGED OR ACQUIRED ACO PARTICIPANT REQUIREMENTS

Under certain circumstances, per § 425.204(g), CMS may allow the ACO to include ACO participants that come to participate in the ACO as a result of an acquisition or merger. Merged or acquired TINs may be included for purposes of meeting the minimum assigned beneficiary threshold and creating a more accurate historical benchmark and a preliminary prospective assignment list or prospective list of assigned beneficiaries for the upcoming performance year.

Under the following circumstances, CMS may take into account the claims billed under TINs of entities acquired through purchase or merger for purposes of beneficiary assignment and the ACO’s historical benchmark:

- 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; and
- The acquired entity’s TIN must no longer be used to bill Medicare.

Table 2 lists actions an ACO can take to add the 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 are current ACO participants.)	<ul style="list-style-type: none"> ▪ ACO submits a change request to add TIN A. In the change request, ACO selects “Yes” that the TIN merged/acquired another TIN and enters TIN B’s data in the appropriate subfields. ▪ ACO uploads an executed ACO Participant Agreement for TIN A. ACO uploads the appropriate merged/acquired supporting documentation (Section 3.2.3) for TIN B.
TIN C acquires TIN D. (Both TIN C and TIN D are currently approved ACO participants.)	<ul style="list-style-type: none"> ▪ ACO submits a change request to edit TIN C’s merged/acquired indicator to “Yes,” and enters TIN D’s information in the appropriate subfields. ▪ ACO submits the appropriate merged/acquired supporting documentation (Section 3.2.3) for TIN D. ▪ ACO deletes TIN D from its next performance year’s ACO Participant List.
TIN E acquires TIN F. (TIN E is a current ACO participant, however TIN F is not a current ACO participant.)	<ul style="list-style-type: none"> ▪ ACO submits a change request to edit TIN E’s merged/acquired indicator to “Yes,” and enters TIN F’s data in the appropriate subfields. ▪ ACO submits the appropriate merged/acquired supporting documentation (Section 3.2.3) for TIN F.

3.2.3 MERGED OR ACQUIRED TIN DOCUMENTATION

An ACO submitting an ACO participant that has merged with or acquired another TIN—and/or changing the merged/acquired indicator of a TIN as having merged with or acquired another TIN—must also include an attestation stating that all providers and suppliers that previously billed under the acquired TIN have reassigned their billings to an 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, the attestation must identify which ACO participant acquired the TIN.

In addition to the required attestation, an ACO must submit supporting documentation demonstrating that the TIN was acquired by an ACO participant through a sale or merger (e.g., a bill of sale, joinder agreement, or other legal document).

3.3 ACO PARTICIPANT LIST CHANGES

ACO participants can be terminated and deleted 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. Absent unusual circumstances, however, 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, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible clinicians that 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 [Section 3.4](#)).

An ACO is required to maintain and update, as necessary, its ACO Participant List. An ACO may request to add an entity to its ACO Participant List in accordance with the CMS-established schedule for submitting change requests, and if CMS approves the request, the ACO participant is added to the ACO Participant List effective January 1 of the upcoming performance year. An ACO may delete an entity from its ACO Participant List during the performance year. ACO Participant List changes must be submitted electronically in ACO-MS.

3.3.1 SHARED SAVINGS PROGRAM ACO APPLICANTS (INCLUDING APPLICANTS FOR RENEWAL)

Part of the process for an ACO applying to either begin or renew its participation in the Shared Savings Program requires CMS to review its ACO participants. As part of this review, CMS may require an ACO to correct or update the information on the ACO Participant List 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, including 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.

Whether an ACO is an initial or a renewing applicant, it 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.

3.3.2 CURRENTLY PARTICIPATING ACOs IN THE SHARED SAVINGS PROGRAM (MID-AGREEMENT PERIOD)

An ACO that is not in the last performance year of its agreement period may make changes to its ACO Participant List for the upcoming performance year. 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. The review cycle includes three opportunities for ACOs to submit change requests for CMS review, feedback, and disposition.

It is important to note that any change to the digit(s) of a required identifier TIN is considered a request to add a new entity to the ACO Participant List and is not permitted after the final deadline to submit change requests to add ACO participants. For example, 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. ACOs should ensure that all information submitted for ACO Participant List changes is correct.

3.3.3 ACO PARTICIPANT LEGAL BUSINESS NAME CHANGES

It is important that all of the information on the ACO Participant List be correct and current, including the ACO participant LBN. If an ACO participant changes its LBN for any reason, the ACO must promptly notify CMS of the LBN change and update the relevant ACO Participant Agreement to reflect the new LBN. This procedure is necessary to ensure the accuracy of the ACO Participant List and the relevant ACO Participant Agreement.

If the LBN of an ACO participant changes, the ACO must take the following steps to notify CMS and request an update to the ACO participant's LBN in ACO-MS:

- Send an email to the Shared Savings Program mailbox (SharedSavingsProgram@cms.hhs.gov) to notify CMS of the ACO participant LBN change. Include the following information in the email: ACO participant LBN currently in ACO-MS and the redacted ACO participant TIN (e.g., xxx-xx-1234).
- Once this email has been received and the change has been confirmed in PECOS, the Shared Savings Program will contact you via your CMS coordinator to set up a time for you to submit a change request in ACO-MS to update the ACO Participant Agreement so that it reflects the correct ACO participant LBN.

CMS will review the request to update the ACO participant's LBN in ACO-MS and respond to the ACO.

3.4 IMPACT OF ACO PARTICIPANT LIST CHANGES ON PROGRAM OPERATIONS

As mentioned above, absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance-year financial calculations, the 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 to reflect the deletion of entities from the ACO Participant List that become effective during the performance year. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments. CMS does not intend to define every potential unusual circumstance in

which it may use its discretion to make changes; however, examples may include evidence that an ACO or its ACO participants engaged in activities related to avoidance of at-risk beneficiaries or identification of a program integrity issue. This section describes how changes in an ACO Participant List impact critical downstream program operations.

3.4.1 HOW CHANGES IN ACO PARTICIPANTS AFFECT DATA SHARING

CMS provides beneficiary identifiable claims data through Claim and Claim Line Feed (CCLF) files. CMS does not share this data for any beneficiaries who have declined sharing of their claims data. For ACOs that have selected the prospective assignment methodology, the CCLF files contain claims data for beneficiaries who appear on the prospective assignment list. For ACOs that have selected the preliminary prospective with retrospective reconciliation assignment methodology, the CCLF files contain data for assignable beneficiaries, as defined below.

Assignable beneficiaries are those who have received at least one primary care service billed by an ACO participant during the assignment window or who have received at least one primary care service billed by an ACO participant upon whom assignment is based during the most recent 12-month period.² Each month, CMS will use the ACO's certified ACO Participant List to determine which assignable beneficiaries will be included in the CCLF files. Each time an ACO Participant List is recertified, CMS will determine the list of assignable beneficiaries and, in turn, the beneficiaries who will be included in future CCLF files. For example, if an ACO certifies an ACO Participant List for Performance Year 1 (PY1) with three ACO participants and submits a change request to terminate an ACO participant with a termination effective date at the end of PY1, that ACO participant will not appear on the PY2 ACO Participant List. In this example, any beneficiary who does not appear on the preliminary prospective assignment list for the ACO and did not receive a primary care service from one of the remaining two ACO participants during the assignment window will be excluded from that ACO's PY2 CCLF files.

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](#)

² Refer to the current version of the Shared Savings and Losses and Assignment Methodology Specifications, available on the [CMS website](#), for additional information on assignable beneficiaries.

[website](#) that describe the interactions between the Shared Savings Program and the Quality Payment Program.

As noted previously, 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 [CMS website](#).

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 3 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 identify a new medical director who meets requirements or the current medical director would

have to be physically present on a regular basis at the location of another current ACO participant.

- **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.³
- **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 CMS coordinator.⁴ The ACO may be 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 an 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.⁵ 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 add or delete electronically providers/suppliers from the initial list provided by CMS prior to the beginning of the performance year.

³ 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 § 425.112 and is held accountable for meeting the ACO's performance standards for each required process.

⁴ Each ACO is assigned a CMS coordinator who works with the ACO as a liaison in the Shared Savings Program and to assist the ACO in ensuring compliance with program requirements.

⁵ CMS uses PECOS to generate each ACO's Provider/Supplier List, based on the certified ACO Participant List.

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. 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.

 **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.

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.

CMS is aware that there are certain types of practitioners who complete the Opt-Out Affidavit.⁶ 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.

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 agreements with each of its ACO participants—that have not merged with or been acquired by another ACO

⁶ For more information on opting out, please refer to the [Opt-Out Affidavits webpage](#) on the CMS website.

participant⁷—to ensure that 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. As part of the application process, CMS requires that each ACO submit a sample or form ACO Participant Agreement (sample ACO Participant Agreement) for CMS approval. This sample agreement must comply with the ACO Participant Agreement requirements specified in the regulations at § 425.116 and described below (refer to [Section 5.3](#)). CMS does not provide a boilerplate agreement for the ACO but instead reviews the sample ACO Participant Agreements to ensure that they comply with the agreement requirements as established in the regulations. If the ACO does not use the same sample agreement for all ACO participants, it must submit for CMS review and approval all sample ACO Participant Agreements that it uses.

The ACO is instructed to identify where in its sample ACO Participant Agreement certain regulatory requirements are addressed when submitting them for CMS review. ACO-MS will display a table similar to the one included in [Appendix C](#), which the ACO must use to identify the location of these requirements.

The final executed ACO Participant Agreement that the ACO secures with all of its ACO participants must be consistent with the ACO's CMS-approved 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

All ACOs applying to participate (both initial and renewal) or currently participating in the Shared Savings Program must submit their sample ACO Participant Agreements and complete the ACO Participant Agreement tables in ACO-MS.

In addition to submitting a sample ACO Participant Agreement and completing the ACO Participant Agreement table in ACO-MS, each ACO applying to renew its agreement with CMS must submit with its application an executed ACO Participant Agreement for each of its ACO participants. It is important that each ACO participant is aware that the ACO is pursuing another agreement period (applying to renew) with CMS and that each ACO participant agrees to continue its participation with the ACO in the Shared Savings

⁷ Merged/acquired TINs are not considered ACO participants and therefore do not need an executed ACO Participant Agreement.

Program for an additional term of no less than one performance year. An ACO can submit documentation of this agreement in the form of a newly executed ACO Participant Agreement or an amendment to the initial ACO Participant Agreement that includes either a digital signature ([Appendix D](#)) or a “wet signature”⁸, and a signature date.

All ACO Participant Agreements (for currently participating ACOs, initial applicants, and renewal applicants) must meet all Shared Savings Program requirements under the regulations, as described in [Section 5.3](#). If an ACO’s sample ACO Participant Agreement was previously approved based on initial program requirements but does not meet all current requirements, the ACO will need to update the sample agreement to meet all current requirements, or develop a new sample agreement. The ACO must submit the new or updated sample agreement and agreement table to its CMS coordinator for review and approval. The ACO must use the approved sample agreement that meets all current requirements when executing agreements with ACO participants.

5.3 SAMPLE ACO PARTICIPANT AGREEMENT REQUIREMENTS

Each ACO must complete the ACO Participant Agreement table when it submits a sample ACO Participant Agreement for CMS approval. An ACO applicant to the Shared Savings Program (whether initial or renewing) must submit these documents through ACO-MS during either the Notice of Intent to Apply (NOIA) submission period and/or the application submission period. A currently participating ACO in the middle of an agreement period may submit these documents directly in ACO-MS. The ACO Participant Agreement must, as specified in § 425.116 and § 425.305(b) of the Shared Savings Program regulations, require the ACO participant to comply with the requirements of the Shared Savings Program, including those set forth in [Appendix C](#).

CMS also recommends that ACO Participant Agreements explicitly address how participation in the ACO may impact the ACO participants. If this information is not included in the ACO Participant Agreement, CMS expects the ACO to discuss the impacts of participation in the ACO before the ACO participant signs the agreement. The ACO is also expected to confirm the accuracy of the following information with respect to its ACO Participant Agreements:

- The ACO’s start date in the Shared Savings Program is correct (e.g., if the ACO’s start date is July 1, 2019, the agreement should refer to a July 1, 2019 ACO start date **or** if the ACO’s start date is January 1, 2020, the agreement should refer to a January 1, 2020 ACO start date);
- The ACO legal entity name matches the name in ACO-MS;

⁸ Wet signatures are handwritten signatures (i.e., not stamped).

- 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.

Please review example introductory paragraphs and signature pages for ACO Participant Agreements and amendments in [Appendix A](#) 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 approved sample agreement and include a signature page that is signed by individuals who have the legal authority to bind the ACO and the ACO participant. The person signing on behalf of the ACO must be currently listed as the ACO Executive or Authorized to Sign contact role. The signature page must reflect information (such as contact information) for both the ACO and the ACO participant and should be consistent with the legal names listed on the first page of the ACO Participant Agreement.

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, wet signature executed agreements.

5.3.2 AMENDMENTS TO ACO PARTICIPANT AGREEMENTS

If an ACO chooses to amend its ACO Participant Agreement (for example, to update the agreement to incorporate new Shared Savings Program requirements or to correct a deficiency), the amendment must clearly identify the specific executed agreement that it amends and the terms of the executed agreement that it is adding or amending. If any changes are marked on the executed agreement, each change must be initialed by both parties and typed (or clearly legible if handwritten). For sample amendment language, refer to [Appendix B](#).

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.

<u>For the ACO</u>	<u>For the ACO Participant</u>
_____	_____
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.

<u>For the ACO</u>	<u>For the ACO Participant</u>
_____	_____
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: ACO Participant Agreement Table

ACOs must identify where the following requirements are in their sample agreements when submitting for CMS review. ACO-MS will display a table similar to the one below that the ACO must use to identify the location of each requirement.

a) The only parties to the agreement are the ACO and the ACO participant. § 425.116	Agreement Section	Page Number
b) The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively. § 425.116	Agreement Section	Page Number
c) The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b) (federal criminal law, False Claims Act, anti-kickback statute, civil monetary penalties law, and physician self-referral law)). § 425.116	Agreement Section	Page Number
d) The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F (§ 425.500-425.508), the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings. § 425.116	Agreement Section	Page Number
e) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO. § 425.116	Agreement Section	Page Number

f) The agreement must require the ACO participant to update its enrollment information, including the addition and deletion of ACO professionals and ACO provider/suppliers billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements and to notify the ACO of any such changes within 30 days after the change. § 425.116

Agreement Section

Page Number

g) The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS. § 425.116

Agreement Section

Page Number

h) The agreement must be for a term of at least 1 performance year and must articulate potential consequences for early termination from the ACO. § 425.116

Agreement Section

Page Number

i) The agreement must require completion of a close-out process upon termination or expiration of the agreement that requires the ACO participant to furnish all data necessary to complete the annual assessment of the ACO's quality of care and addresses other relevant matters. § 425.116

Agreement Section

Page Number

Appendix D: 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 a request for information (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

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.

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

No. So 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.

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.

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.