Medicare Shared Savings Program

ACO PARTICIPANT LIST AND PARTICIPANT AGREEMENT

Guidance Document

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

Revision History

VERSION	DATE	REVISION/ CHANGE DESCRIPTION	AFFECTED AREA
1.1	07/05/2016	Last row in Table 2, 2017 ACO Participant List Review Schedule, added back in.	Section 2.3.2
2	06/01/2017	Clarified requirements for providing CCN and NPI information for certain types of ACO participants.	Section 2.1
2	06/01/2017	Added information on requirements for sole proprietor ACO participants.	Section 2.3.3
2	06/01/2017	Added additional information on the process for submitting change requests, the importance of the ACO Participant List, and correctly submitting TIN, CCN, and NPI information. Updated with the 2018 ACO Participant List Review Schedule.	Section 2.3.2
2	06/01/2017	Clarified that the ACO Participant Agreement template must be included when sample ACO Participant Agreement is submitted for review, and that if a sample agreement was previously approved based on initial program requirements but does not meet all current requirements, an updated or new sample agreement that meets all current requirements is required.	Section 5.2
2	06/01/2017	Clarified that ACO participant TIN must be correct, if included in agreement. Added new section to provide additional information on addenda to ACO Participant Agreements.	Section 5.3
2	06/01/2017	Clarified that if an ACO participant changes its TIN mid-year and the ACO submits the new TIN for addition to the ACO Participant List, the new TIN will not become effective until January 1 of the upcoming performance year.	Sections 2.4 and 3.0
2	06/01/2017	Added information on how to notify CMS of a change to an ACO participant's legal business name.	Section 6.0
3	08/01/2017	Updated internal links in the Revision History table.	Revision History
3	08/01/2017	Updated the 2018 ACO Participant List Review Schedule.	Table 2

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Executive Summary

The purpose of this document is to describe the requirements that an Accountable Care Organization (ACO) participating in the Medicare Shared Savings Program (Shared Savings Program), or applying to the Shared Savings Program, must follow with respect to its ACO Participant List, ACO Provider/Supplier List, and ACO Participant Agreements. These requirements are pursuant to policies established by the Shared Savings Program's November 2011 Final Rule (76 FR 67802), as amended by the June 2015 Final Rule (80 FR 32692), June 2016 Final Rule (81 FR 37950), and codified at 42 CFR part 425.

The ACO Participant List is critical to the Shared Savings Program's 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 the 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 your 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 professionals that bill under the taxpayer identification number (TIN) of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year (See Section 2.4).

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.

1 Background

This document replaces previous guidance entitled Changes in ACO Participants and ACO Providers/Suppliers during the Agreement Period and 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 an ACO that improves the quality and cost efficiency of health care. The authority for the Shared Savings Program is Section 1899 of the Social Security Act (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. Section 1899 of the Act states that the Secretary may enter into an agreement with the ACO to participate in the Shared Savings Program for a period of not less than three years. CMS has published three final rules regulating the Shared Savings Program. The first final rule was published in November 2011, the second was published in June 2015, and the third was published in June 2016. Additionally, CMS has addressed certain issues related to the Shared Savings Program in the annual Physician Fee Schedule (PFS) rulemaking. The complete details of the Shared Savings Program's regulations can be found in the Code of Federal Regulations (CFR) at 42 CFR part 425. Additionally, the Electronic Code of Federal Regulations website is a useful resource for viewing the program regulations.

The following terms, all of which are defined in the program regulations, are important in understanding the Shared Savings Program and this guidance document:

Accountable Care Organization (ACO) (42 CFR § 425.20) means a legal entity that is recognized and authorized under applicable state, federal, or tribal law, is identified by a TIN, and is formed by one or more ACO participant(s) that is (are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).[1]

ACO participant (42 CFR § 425.20) means an entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone

[1] Under § 425.102(a), the following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program: (1) ACO professionals in group practice arrangements; (2) Networks of individual practices of ACO professionals; (3) Partnerships or joint venture arrangements between hospitals and ACO professionals; (4) Hospitals employing ACO professionals; (5) Critical Access Hospitals (CAHs) that bill under Method II (as described in 42 CFR § 413.70(b)(3)); (6) Rural Health Clinics (RHCs); (7) Federally Qualified Health Centers (FQHCs); and (8) Teaching hospitals that have elected under 42 CFR § 415.160 to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians. Under § 425.102(b), other ACO participants that are not identified in § 425.102(a) are eligible to participate through an ACO formed by one or more of the ACO participants identified in § 425.102(a).

or together with one or more other ACO participants composes an ACO, and that is included on the list of ACO participants that is required under § 425.118.

ACO Participant Agreement (42 CFR § 425.20) means the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

ACO professional (42 CFR § 425.20) means an individual who is Medicare-enrolled and bills for items and services furnished to Medicare FFS beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant, in accordance with applicable Medicare regulations and who is either of the following:

- A physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action.
- A practitioner who is one of the following:
  - A physician assistant (as defined at § 410.74(a)(2)).
  - A nurse practitioner (as defined at § 410.75(b)).
  - A clinical nurse specialist (as defined at § 410.76(b)).

ACO provider/supplier (42 CFR § 425.20) means an individual or entity that is a provider or supplier (as defined at 42 CFR § 400.202) enrolled in Medicare that bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations, and is included on the list of ACO providers/suppliers that is required under § 425.118.

Agreement period (42 CFR § 425.20) means the term of the participation agreement, which is three performance years unless otherwise specified in the participation agreement.

Assignment (42 CFR § 425.20) means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from ACO professionals so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark or performance year.

Performance year (42 CFR § 425.20) means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise noted in the participation agreement.

Taxpayer Identification Number (TIN) (42 CFR § 425.20) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR § 301.6109-1.

2 ACO Participant List

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

2.1 INTRODUCTION TO THE ACO PARTICIPANT LIST

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. As part of the annual application process (or mid-agreement annual process for currently participating ACOs), an ACO may make changes to its ACO Participant List, but absent unusual circumstances, these changes will become effective only at the start of the next performance year. Specifically, an ACO is able to add new ACO participants, modify existing ACO participants (e.g., TIN legal business name (LBN) change), and/or delete ACO participants from its ACO Participant List (see Section 2.3).

The accuracy of an ACO's 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 (i.e., the "ACO providers/suppliers");
- 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; and
- Coordinating among CMS quality initiatives.

Table 1 lists the information each ACO must include on its ACO Participant List.

Table 1. Required Identifiers for ACO Participants

TYPE	REQUIRED FIELDS
All ACO Participants	▪ ACO participant TIN ▪ ACO participant LBN (as shown in the Provider Enrollment Chain & Ownership System (PECOS)) ▪ Merged or acquired TIN? Y or N

TYPE	REQUIRED FIELDS
Critical Access Hospital (CAH) and Electing Teaching Amendment Hospital ACO Participants	▪ CMS Certification Number (CCN) ▪ CCN LBN (as shown in PECOS) ▪ CCN identification code: C or T
Federally Qualified Health Center (FQHC) and Rural Health Clinic (RHC) ACO Participants	▪ CCN ▪ CCN LBN (as shown in PECOS) ▪ CCN identification code: F or R ▪ Organizational National Provider Identifier (NPI) ▪ Organizational NPI LBN (as shown in PECOS) ▪ Attestation List: ▫ Individual physician NPI (physician specialty verified by PECOS) ▫ Individual NPI first and last name

Entities submitted for an ACO's Participant List and individuals and entities that have reassigned their billing rights to TINs on the ACO Participant List (ACO providers/suppliers) will undergo a screening process, which may be repeated periodically throughout the agreement period to ensure they continue to meet program requirements (§ 425.304(b)). The CMS screening process includes, at a minimum, the following:

- Verifying Medicare enrollment;
- 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;
- Ensuring the ACO participant does not participate with another Shared Savings Program ACO[2]; and
- Ensuring individual NPIs have an M.D. or D.O. specialty.

[2] In certain special circumstances, a TIN or CCN may participate in more than one Shared Savings Program ACO. In these cases, the TIN or CCN must not bill Medicare for primary care services that are used to determine beneficiary assignment.

2.2 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 a participant 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 (see Section 2.3 for additional information on adding ACO participants); and
    - Notify CMS no later than 30 days after the ACO Participant Agreement terminates of any entities to be deleted from the ACO Participant List, at such time and in the form and manner specified by CMS (see Section 2.3 for additional information for deleting and terminating ACO participants).

2.3 ACO PARTICIPANT LIST CHANGES

Once certified, an ACO Participant List generally remains intact for any given performance year. ACO participants can be terminated and deleted from your ACO Participant List at any time during a performance year. As stated above, 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 professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO Participant List that become effective during the performance year (see Section 2.4).

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 during the performance year in accordance with the CMS-established schedule for submitting change requests (see Section 2.3.2 for more information), and if CMS approves the request, the ACO participant is added to the ACO Participant List effective January 1 of the following performance year. An ACO may request to delete an entity from its ACO Participant List

during the performance year, as well. Section 2.3.1 and Section 2.3.2 outline the form and manner in which an ACO may change its ACO Participant List for the upcoming year. Note the schedule is slightly different for an ACO applying to participate in, or renew its agreement with, the Shared Savings Program from the schedule for an ACO that is currently in an agreement period and not yet eligible to request renewal.

ACO Participant List changes must be electronically submitted, via the Health Plan Management System (HPMS). Instructions for how to make such changes in HPMS are explained in the HPMS SSP ACO Participant List Management Module User Guide. The user guide is located in the "User Manual" section of the SSP ACO Participant List Management module in HPMS.

2.3.1 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) letters. RFI letters will summarize CMS's review of submitted application information, including feedback on ACO participant submissions. An ACO may receive multiple RFI letters 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 Deadlines to Apply and RFI Response Actions tables on the Shared Savings Program How to Apply webpage. Please note that while the Application Cycle deadlines are subject to change, CMS will not accept late submissions.

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

During the performance year, a currently participating ACO in the Shared Savings Program that is in an agreement period and not yet eligible to request renewal, may make changes to its ACO Participant List for the upcoming performance year. Changes requested for an upcoming performance year will be reviewed during an established CMS review cycle; the corresponding dates are presented in Table 2. These review cycles include the provision of CMS feedback and the opportunity for an ACO to correct certain deficiencies CMS may find in advance of the upcoming performance year. Though an ACO may request a change at any time throughout the year for the upcoming performance year, there are deadlines for submitting change requests for consideration for the upcoming performance year according to the ACO Participant List Review Schedule (see Table 2). Feedback on ACO change requests is only provided per the review cycle schedule, as presented in Table 2.

It is important to note that any changes in a digit or digits to a required identifier (TIN, CCN, or NPI) are considered an addition to the ACO Participant List and are not permitted after the deadline for response to change request (CR) Cycle 2 or the deadline for CR Cycle 3.

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 transposed or 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. Please refer to the ACO Participant List Review Schedule in Table 2 for applicable deadlines. All deadline dates are subject to change.

Table 2. 2018 ACO Participant List Review Schedule

	ACTOR	ACTIVITY	COMPLETION DATE	NOTES
2018 CHANGE REQUEST CYCLE 1	ACO	Add, delete, or modify data on ACO Participant List for the 2018 performance year, and upload executed ACO Participant Agreements.	March 31, 2017	▪ Any changes in a digit or digits to a TIN, CCN, or NPI are considered an addition to the ACO Participant List and require a new change request. ▪ CMS processes delete change requests the business day after each cycle deadline, and at various other times, between March 31 and July 2017. CMS will approve delete change requests during each cycle. Once a delete change request has been approved, it cannot be withdrawn or reversed.
	CMS	Review and provide feedback to ACOs on deficient change requests.	Mid-May 2017	
	ACO	Correct deficiencies identified by CMS when applicable, and resubmit ACO Participant List change requests and executed ACO Participant Agreements.	May 23, 2017	
	CMS	Approve or deny ACO Participant List changes for the 2018 performance year via email to ACOs, per submitted change request by the March 31, 2017, deadline.	Early July 2017	
2018 CHANGE REQUEST CYCLE 2	ACO	Add, delete, or modify data on ACO Participant List for the 2018 performance year, and upload executed ACO Participants Agreements.	July 31, 2017, at 12:00 p.m. (noon) ET	▪ CMS processes delete change requests the business day after each cycle deadline, and at various other times between July 31 and December 2017. CMS will approve delete change requests during each cycle. Once a delete change request has been approved, it cannot be withdrawn or reversed. ▪ Any changes in a digit or digits to a TIN, CCN, or NPI are considered an addition to the ACO Participant List and require a new change request.
	CMS	Review and provide feedback to ACOs on deficient change requests.	Late August 2017	
	ACO	Correct deficiencies identified by CMS when applicable, and resubmit ACO Participant List change requests and executed ACO Participant Agreements.	September 6, 2017, at 12:00 p.m. (noon) ET	
	CMS	ACOs receive approval or denial of add or modify change requests submitted as part of Cycle 2 at the end of change request Cycle 3, except for the approval of delete change requests as noted.		

	ACTOR	ACTIVITY	COMPLETION DATE	NOTES
2018 CHANGE REQUEST CYCLE 3	ACO	Add, delete, or modify data on ACO Participant List for the 2018 performance year, and upload executed ACO Participant Agreements.	September 6, 2017, at 12:00 p.m. (noon) ET	▪ This is the **last opportunity** to add ACO participants to the ACO Participant List or modify ACO participant information for the 2018 performance year. This is the **last opportunity** to add ACO participants from any ACO applicants that wish to combine with currently participating ACOs. ▪ CMS processes delete change requests the business day after each cycle deadline, and at various other times between September 6 and December 2017. CMS will approve delete change requests during each cycle. Once a delete change request has been approved, it cannot be withdrawn or reversed.
	CMS	Review and provide feedback to ACOs on deficient change requests.	Late September 2017	
	ACO	Correct deficiencies identified by CMS when applicable, and resubmit ACO Participant List change requests and executed ACO Participant Agreements.	October 2, 2017, at 12:00 p.m. (noon) ET	▪ Any changes in a digit or digits to a TIN, CCN or NPI are considered an addition to the ACO Participant List and require a new change request. ▪ **You cannot correct any errors with a digit or digits for a TIN, CCN, or NPI at this point, as this is considered an ACO Participant List addition.**
2018 CHANGE REQUEST CYCLE 4 (DELETES ONLY)	ACO	Delete ACO participants for the 2018 performance year, and modify and upload executed ACO Participant Agreements based on CMS-identified deficiencies from Cycles 2 and 3.	October 26, 2017, at 12:00 p.m. (noon) ET	▪ This is the **last opportunity** to remove ACO participants from the ACO Participant List by submitting delete change requests, and/or withdraw pending change requests before the start of the 2018 performance year. ACOs must submit delete change requests to remove ACO participants from the ACO Participant List, and withdraw pending change requests for any ACO participants they do not wish to add for the 2018 performance year. ACOs may no longer add ACO participants for the 2018 performance year.
	CMS	CMS processes delete change requests the business day after each cycle deadline, and at various other times between October 26 and December 2017. CMS will approve delete change requests during each cycle. Once a delete change request has been approved, it cannot be withdrawn or reversed.	October 2017	
2018 CHANGE REQUEST CYCLES 2, 3	CMS	Approve or deny ACO Participant List changes for the 2018 performance year submitted during Cycles 2 and 3.	Late fall 2017	▪ CMS processes delete change requests the business day after each cycle deadline, and at various other times needed during each cycle. CMS will approve delete change requests during each cycle. Once a delete change request has been approved, it cannot be withdrawn or reversed.

2.3.3 SOLE PROPRIETOR ACO PARTICIPANTS

If an ACO participant is a sole proprietor that 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 Medicare Administrative Contractor (MAC) with any questions with regard to their Medicare enrollment. We expect ACOs to provide CMS with both the SSN and corresponding EIN. In the event an ACO does not provide CMS both the SSN and EIN, CMS will respond in accordance with Table 3 below.

Table 3. Sole Proprietor ACO Participants

INFORMATION PROVIDED BY ACO FOR ACO PARTICIPANT ENROLLED IN MEDICARE UNDER SSN AND BILLING MEDICARE UNDER SEPARATE EIN	CMS RESPONSE
ACO submits an EIN without a corresponding SSN for an ACO Participant who is a sole proprietor.	CMS will attempt to assist the ACO in identifying and rectifying this situation, as the CMS schedule for review of ACO Participant List changes allows.
ACO submits an SSN without an EIN for an ACO Participant that is a sole proprietor before the change request Cycle 2 deadline (see Table 2) for application submission deadline.	CMS will identify this error and the ACO will have an opportunity to submit the EIN prior to the final deadline to add or modify data on the ACO Participant List.
ACO submits an SSN without an EIN for an ACO participant that is a sole proprietor after the change request Cycle 2 deadline (see Table 2) or application submission deadline.	CMS will inform the ACO there are no opportunities to add the participant to the ACO Participant List for the upcoming performance year. The change request to add the SSN would be denied without the accompanying EIN, unless CMS verifies through its own data that there is no EIN associated with the sole proprietor.

2.4 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 professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO Participant List that become effective during the 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.

2.4.1 HOW CHANGES IN ACO PARTICIPANTS AFFECT DATA SHARING

CMS provides beneficiary identifiable claims data through Claims and Claim Line Feed (CCLF) files. CMS does not share these data for any beneficiaries who have declined sharing of their claims data. For each Track 3 ACO, the CCLF files contain claims data for beneficiaries who appear on the prospective assignment list. For each Track 1 and 2 ACO, the CCLF files contain data for assignable beneficiaries, as defined below.

Assignable beneficiaries are those who either appear on the ACO's preliminary prospective assignment list or 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.[3] Each month, CMS will use the ACO's certified ACO Participant List to determine which assignable beneficiaries will be included in the CCLFs. Each time an ACO Participant List is recertified, CMS will determine the list of assignable beneficiaries and, in turn, the beneficiaries that are included in future CCLF files. For example, if an ACO certifies an ACO Participant List for Performance Year 1 with three ACO participants, and submits an approved change request to terminate an ACO participant with a termination effective date at the end of Performance Year 1, that ACO participant will not be present on the ACO's Performance Year 2 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 will be excluded from that ACO's performance year 2 CCLF files.

2.4.2 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 (QPP). For 2017 and subsequent reporting years, ACOs, on behalf of eligible clinicians who bill under the TIN of an ACO participant, must completely report all of the CMS Web Interface measures on behalf of their eligible clinicians for purposes of the quality performance category of the QPP. For purposes of determining which eligible clinicians on whose behalf the ACO is responsible for reporting, CMS uses the ACO's certified ACO

[3] Please refer to the Shared Savings and Losses and Assignment Methodology Specifications for additional information on assignable beneficiaries.

Participant List that the ACO certified before the start of the applicable performance year. The Shared Savings Program and QPP have made resources available on the QPP website that describe the interactions between the programs.

As noted previously, ACO Participant List changes submitted during a given performance year generally do not change the eligible clinicians on whose behalf the ACO is responsible for reporting. For example, absent unusual circumstances, if an ACO notifies CMS of an ACO participant termination in July 2017, the ACO will remain responsible for quality reporting on behalf of the eligible clinicians who bill under the terminated ACO participant TIN for the 2017 performance year.

2.4.3 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, please see the Shared Savings and Losses and Assignment Methodology Specifications on the CMS website.

CMS will adjust an ACO's historical benchmark at the start of a performance year if the ACO makes changes to the ACO Participant List it certified at the start of the previous performance year (42 CFR § 425.118(b)(3)(i)). The ACO's updated certified ACO Participant List will then be 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.

2.4.4 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:

- **If an ACO consists of a single ACO participant** and is not set up such that the governing body of the ACO and that of the ACO participant are separate and unique, the ACO may not add ACO participants to its ACO Participant List. If such an ACO elects to become an ACO with multiple ACO participants, it must reapply to the Shared Savings Program as a new entity.
- **ACO participants must hold at least 75 percent control of the ACO's governing body;** additions to or deletions from the ACO's 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's 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 that 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 the ACO's likely success.[4]

If any changes to an ACO's 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.[5] The ACO will be asked to submit a narrative for review describing why it seeks to deviate from these requirements and how it will continue to meet the goals and objectives of the Shared Savings Program.

3 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 benchmark and preliminary prospective assignment list or prospective list of assigned beneficiaries for the upcoming performance year.

Under the following circumstances, CMS may take the claims billed under TINs of entities acquired through purchase or merger into account 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;

[4] 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.

[5] 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.

- 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.

The ACO may electronically submit a request to add a merged or acquired TIN, or to change the Merged or Acquired Flag to "Yes" for an ACO participant that is on its current ACO Participant List, as long as all program requirements, described in this section, are met. Instructions for how to make such changes in HPMS are explained in the HPMS SSP ACO Participant List Management Module User Guide. The user guide is located in the "User Manual" section of the SSP ACO Participant List Management module in HPMS.

If the ACO participant TIN change was the result of a purchase or merger, the ACO may request to keep the ACO participant's old TIN on the ACO Participant List as a merged or acquired TIN if the old TIN meets the requirements for merged or acquired ACO participants, and the ACO submits a change request in HPMS to change the Merged or Acquired Flag to "Yes."

3.1 MERGED OR ACQUIRED TIN DOCUMENTATION

The submission of a merged or acquired TIN, and/or the flagging of a TIN as being merged or acquired, must also include an attestation stating that all ACO providers/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. Refer to the HPMS SSP ACO Participant List Management Module User Guide to learn how to submit supporting documentation with change requests.

4 Managing Changes to the ACO Provider/Supplier List

CMS uses an ACO's 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.[6] 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 Provider/Supplier List provided by CMS reflects PECOS reassignments

[6] CMS uses PECOS to generate each ACO's Provider/Supplier List, based off the certified ACO Participant List.

from a single point in time; therefore, CMS provides ACOs an opportunity to electronically add or delete providers/suppliers from the initial list provided by CMS, via HPMS. For instructions on how to make ACO Provider/Supplier List changes in HPMS, please see Annual Certification: The HPMS Electronic Signature Management (ESM) Module User Guide under "ESM User Manuals" in the SSP ACO Electronic Signature Management module in HPMS. It is also available on the SSP ACO Portal under Program Announcements.

During the performance year, 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. An ACO may need to add a provider or supplier that has reassigned its billing to the ACO after the ACO had certified its ACO Provider/Supplier List. An ACO that needs to make a change to its certified ACO Provider/Supplier List during the performance year must notify CMS by making changes to the Provider/Supplier List directly in HPMS. For instructions on how to upload changes in HPMS, please see Annual Certification: The HPMS Electronic Signature Management (ESM) Module User Guide under "ESM User Manuals" in the SSP ACO Electronic Signature Management module in HPMS. It is also available on the SSP ACO Portal under Program Announcements. Please refer to Sections 5.2 and 5.3 of the user guide for instructions. You will not have to recertify your ACO Provider/Supplier List for updates made outside of the Annual Certification cycle.

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.

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 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 person 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 the

application process, CMS requires that each ACO submit a sample ACO Participant Agreement for CMS approval. This sample agreement must comply with the ACO Participant Agreement requirements specified in regulation at § 425.116 and described below (see 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 agreements it uses.

CMS also provides an agreement template that the ACO must complete and submit with its application to identify for CMS reviewers where in its sample ACO Participant Agreement the regulatory requirements are addressed.[7] 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, as provided in Sections 2.3.1 and Section 2.3.2 above.

5.2 ACO PARTICIPANT AGREEMENT REQUIREMENTS

Applicants to the Shared Savings Program (both initial and renewal) must submit their sample ACO Participant Agreement and completed ACO Participant Agreement template with their application.

In addition to submitting its sample ACO Participant Agreement and completed ACO Participant Agreement template, 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 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 a "wet signature" and a signature date.[8]

If an ACO is updating its sample ACO Participant Agreement in the middle of an agreement period, it must submit the updated sample agreement and agreement template to its CMS coordinator for review and approval. It must also inform its CMS coordinator of whether the new agreement replaces the old sample agreement, or if the

[7] Detailed instructions on how to complete the ACO Participant Agreement template are available on the Shared Savings Program website through the Application Toolkit.
[8] CMS considers wet signatures to be original handwritten signatures (i.e., not stamped and not an electronic signature).

new agreement will be in use only for ACO participants newly joining the ACO. All ACO Participant Agreements (for currently participating ACOs, initial applicants and renewal applicants) must meet all Shared Savings Program requirements 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 template 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 include a completed ACO Participant Agreement template when it submits a sample ACO Participant Agreement for CMS approval. An ACO applicant to the Shared Savings Program (both initial and renewing) must submit these documents through HPMS. A currently participating ACO in the middle of an agreement period may submit these documents to its CMS coordinator. The ACO Participant Agreement must, as specified in § 425.116 of the Shared Savings Program regulations, comply with the following:

- The only parties to the agreement are the ACO and the ACO participant;
- 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;
- 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, federal criminal law, False Claims Act, anti-kickback statute, civil monetary penalties law, and physician self-referral law);
- 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 42 CFR part 425, subpart F, the beneficiary notification requirements in § 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;
- 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/clinical guidelines established by the ACO;

- The agreement must require the ACO participant to update its Medicare enrollment information, including the addition and deletion of ACO professionals and ACO providers/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;
- 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;
- The agreement must be for a term of at least one performance year and must articulate potential consequences for early termination from the ACO; and
- 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.

CMS also recommends that ACO Participant Agreements explicitly address how participation in the ACO may impact the ACO participants, for example, the responsibility of the ACO to quality report on behalf of its ACO participants (and, by extension, the providers and suppliers that bill through the ACO participant). If this information is not included in the ACO Participant Agreement, the ACO should discuss the impacts of participation in the ACO before the ACO participant signs the agreement. The ACO should also 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 January 1, 2017, the agreement should refer to a January 1, 2017, ACO start date);
- The ACO legal entity name matches the name in the Basic Agreement Data page in HPMS;
- 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 HPMS SSP ACO Participant List Management module 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 in HPMS 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 entity names listed on the first page of the ACO Participant Agreement. Electronic signatures are not permitted.

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 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 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. For sample amendment language, see Appendix B.

6 ACO Participant Legal Business Name Changes

It is important that all of the information on the ACO Participant List be correct and current, including ACO participant LBN. If an ACO participant changes its LBN for any reason, the ACO must promptly notify CMS of the LBN change and modify 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 HPMS:

- Follow the instructions in the HPMS SSP ACO Participant List Management Module User Guide for making a change to the LBN of an approved ACO participant. The user guide is located in the "User Manual" section of the SSP ACO Participant List Management module in HPMS.

- After taking steps to update the ACO participant LBN in HPMS, the ACO should send an email to the Shared Savings Program mailbox (sharedsavingsprogram@cms.hhs.gov) and request the ACO participant LBN change. Include the following information in the email: ACO participant LBN currently in HPMS, redacted ACO participant TIN, the change request number the ACO submitted in HPMS to update the ACO Participant Agreement, and a screen shot of the ACO participant's updated LBN in PECOS.

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

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 the 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** previously entered into an ACO Participant Agreement on or about [Month, Day, Year] (the "Agreement"); and both parties mutually agree to continue the Agreement by way of this Addendum.

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

<Body of Agreement>

Sample Signature Page:

IN WITNESS WHEREOF, the parties have caused this Addendum to be executed by the 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