

Additional Guidance for Medicare Shared Savings Program Accountable Care Organization (ACO) Applicants

In response to questions from industry stakeholders, we write to provide additional guidance to all Medicare Shared Savings Program applicants and future applicants about the requirements under 42 CFR part 425 related to the Medicare Shared Savings Program Accountable Care Organization (ACO) applicants. This memo summarizes some of the requirements you have attested to or will attest to in your application, and the requirements you will be agreeing to if you are selected and choose to sign a participation agreement with the Centers for Medicare & Medicaid Services (CMS).

An ACO participant is identified at the billing TIN level. An ACO provider/supplier is a practitioner billing through the ACO participant's TIN.

We want to ensure that each applicant understands the definition of an **ACO participant** and **ACO provider/supplier**. According to the regulations at 42 CFR 425.20, an ACO participant means an individual or a group of ACO providers/suppliers that is identified by a Medicare-enrolled TIN that alone or together with one or more other ACO participants comprises the ACO. For example, an ACO participant may be a solo practice, a group practice, a hospital, an FQHC, among others. An ACO participant may be composed of one or many ACO providers/suppliers that use, or have reassigned their billings to, the ACO participant TIN. An ACO provider/supplier means a provider or supplier enrolled in Medicare that bills for items and services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant. The key point is that an ACO participant is identified by its Medicare-enrolled TIN.

All ACO providers/suppliers billing through an ACO participant TIN are included in the ACO by virtue of their relationship to the ACO participant and the ACO participant's relationship with the ACO.

The Medicare Shared Savings Program is a program designed for ACO participants, as described above, that come together to form an ACO. Many important program operations use claims and other information submitted to CMS by the ACO participant through its billing TIN, including calculation of shared savings, assignment, and benchmarking. Therefore, an ACO cannot apply to participate in the Medicare Shared Savings Program unless the ACO participants have agreed to participate in the Medicare Shared Savings Program and to comply with the program regulations. The ACO applicant also must ensure that all ACO providers/suppliers associated with each ACO participant TIN have agreed and will comply with the program regulations. Consequently, an ACO may not include an entity as an ACO participant unless all Medicare enrolled providers and suppliers billing under that entity's billing TIN have agreed to participate.

Agreements or contracts between or among the ACO, ACO participant, and ACO providers/suppliers related to participation in the Medicare Shared Savings Program must be executed before the ACO submits its application.

As part of the application process, we ask that you submit the list of ACO participants, who, along with all the ACO participants' associated ACO providers/suppliers, have agreed to participate in the program. This means that the ACO participants you submitted or will submit, in addition to all their associated ACO providers/suppliers, signed agreements or contracts before the application was or is submitted.

It is important that agreements between and among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities comply with our regulations.

Content of agreements or contracts between the ACO and ACO participant.

As part of the application process, we ask that you submit a sample agreement you have with each of your ACO participants. This sample agreement and the associated executed agreements with ACO participants, at minimum, MUST contain the following:

- 1) An explicit requirement that the ACO participant agrees to participate in and comply with the requirements of the Medicare Shared Savings Program under 42 CFR part 425. General references to compliance with Federal law are not sufficient. General references to compliance with Medicare regulations are not sufficient.
- 2) A description of the ACO participants' rights and obligations in, and representation by, the ACO, including how the opportunity to share in savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines and should include language giving the ACO the authority to terminate an ACO participant for its non-compliance with the ACO's participation agreement with us or any of the requirements of 42 CFR part 425.

Additionally, ACOs must not require that beneficiaries be referred to ACO participants or ACO providers/suppliers or to any other provider or supplier (42 CFR 425.304(c)(2)), except under the specific and limited circumstances expressly permitted by the regulations.

The ACO may or may not need a separate legal entity, however the ACO governing body must have a specific fiduciary duty to the ACO.

We want to ensure each applicant understands the eligibility requirement related to the **ACO's governing body**. According to the regulations at 42 CFR 425.106, the ACO must maintain an identifiable governing body with authority to execute the functions of the ACO. The governing body must have responsibility for oversight and strategic direction, holding the ACO management accountable for the ACO's activities. The governing body members must have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.

- The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants. The governing body members cannot meet this fiduciary duty requirement if the governing body is also responsible for governing the activities of individuals or entities that are not part of the ACO.

- If an already existing entity applies to the program as an ACO, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies the other requirements for a governing body, including the fiduciary duty requirement.

These regulations mean that if your ACO is comprised of two or more otherwise independent ACO participants, your ACO must have a legal entity and governing body that is distinct and separate from each of them (the governing body must be the governing body of the legal entity that is the ACO, and not the governing body of a parent or subsidiary entity). For example, if several separate group practices decide to come together for purposes of participating in the Medicare Shared Savings Program (but will otherwise maintain separate practices), they must form a separate legal entity to be the ACO. This legal entity must have a legal structure with a governing body that has a fiduciary responsibility to the ACO alone and not to any other individual or entity. If an existing entity, such as an IPA representing many group practices wants to apply as an ACO using its existing legal structure and governing body, each group practice represented by the IPA must agree to be an ACO participant and each Medicare enrolled provider and supplier within each group practice must agree to be ACO providers/suppliers as discussed above. If only some of the represented group practices want to become ACO participants, the IPA cannot use its existing legal structure and governing body for the ACO, because it cannot meet the regulatory requirements, including the fiduciary duty requirement. If only some of a group practice's Medicare enrolled providers and suppliers agree to be ACO providers and suppliers, then that group practice may not become an ACO participant. In summary, the ACO's governing body decisions must be independent from influence of interests that may conflict with the ACO's interests, including the interests of group practices that are not participating in the ACO but continue to be represented by the IPA for other purposes, such as commercial contracting.

Assess your application for the Medicare Shared Savings Program.

Please review this memo carefully and consider your current ACO organization, agreements, and application attestations in light of it. If you have already submitted your application but do not believe your organization meets the requirements of the Shared Savings Program, you should consider what changes you need to make.

If you wish to apply during a future application cycle or modify your existing application, you must submit a written request. Please do not submit a new NOI. The following information must be included:

- Your organization's legal entity name
- ACO ID
- Request to change your program start date Or
- Request to modify your existing application

If you have any questions, or to send your request, please contact us via email at: SSPACO_Applications@cms.hhs.gov.