



Track 1 New ACO Application Memo

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MEMORANDUM

To: NAACOs
From: Dentons US LLP
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Date: May 25, 2018
Subject: Application as a New Track 1 ACO

I. Question Presented

May an existing Medicare Shared Savings Program (MSSP) Track 1 ACO apply for participation as a new Track 1 ACO? To what extent would CMS be likely to approve an application that otherwise complies with all requirements, but consists largely of a group of ACO participants that were previously participants in a Track 1 ACO that has already operated for the two agreement periods permitted for Track 1?

II. Brief Answer

We found no specific prohibition on the approval of such an application. As discussed below, we reviewed the statute, regulations, limited samples of regulation preamble discussion, and certain application materials and their related guidance (*i.e.*, the Notice of Intent to Apply and the Initial Application for a new ACO).

For purposes of this analysis, we assumed, consistent with the Question Presented, that the application would otherwise fully comply with requirements in regulations and in the required application documents, including the requirement to disclose the past participation of the ACO participants, and of the ACO (if applicable).¹

Based on our understanding, CMS has approved the application to be a new Track 1 ACO submitted by participants in an existing Track 1 ACO in instances where there were changes in the composition of participants or investors in the existing Track 1 ACOs. (Such instances include the addition or deletion of physician groups, hospitals or health systems.) In those cases, a new legal entity typically has been formed. Given these precedents, we recommend that participants in an existing Track 1 ACO applying to be a new Track 1 ACO create a new legal entity in order to more clearly distinguish the new ACO from the prior ACO. In addition, as discussed below, we recommend that a substantial purpose for the formation of and application to be a new Track 1 ACO be articulated and documented.

¹ For example, the Initial Application form asks, "Does your ACO or any of your ACO participants, under the same or different name, currently participate in any Medicare initiative involving a shared savings arrangement?" It would be necessary to fully disclose all past participation in the Track 1 ACO program. See: CMS. Initial Application - Performance Year 2018 (Sample), at 7 (question 19). Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP_Application_Initial.pdf.

There is a viable argument that the Secretary must approve ACOs that meet all the requirements articulated in the MSSP statute and regulations. (And we see no reason why an applicant to be a new Track 1 ACO of the type described in the Question Presented would not be able to meet the statutory and regulatory requirements, as well as all the requirements articulated in the application forms.)

On the other hand, approval is not a certain outcome. An argument could be made that CMS could make a determination that such an applicant fails to meet the requirement in 42 C.F.R. § 425.600(b), that "ACOs may operate under the one-sided model for a maximum of two agreement periods." Also, CMS could potentially determine that the applicant ACO, while otherwise meeting requirements in regulations, is not "qualified to participate in the Shared Savings Program," pursuant to 42 C.F.R. § 425.206(a)(1). The likely outcome would depend on the policy direction of CMS.

III. Discussion

A. Statute

As noted above, there is an argument that CMS does not have discretion to deny ACOs that meet all criteria articulated in regulations. Specifically, Section 1899 of the Social Security Act states that, "as determined appropriate by the Secretary, the following groups...are eligible to participate as ACOs ..."² The provisions of the statutory subsection are relatively robust in enumerating requirements, which typically indicates that the Secretary's discretion (and therefore, CMS' discretion) is relatively limited. We would argue that CMS, acting for the Secretary, only has discretion to determine whether the ACOs meet the criteria in the statute, as further defined in regulations, but not to deny ACOs that "are eligible" by those standards. See excerpt below.

Social Security Act, Section 1899(a)(1)

In general.—Subject to the succeeding provisions of this subsection, as determined appropriate by the Secretary, the following groups of providers of services and suppliers which have established a mechanism for shared governance are eligible to participate as ACOs under the program under this section...³

B. Regulations

Similar to the statutory language, nothing in the regulations directly states that the determination of ACO status is discretionary; at the same time, nothing directly indicates that CMS must approve every application that meets the requirements articulated in the regulations.

The regulation governing approval of applications (42 C.F.R. § 425.206) states that CMS approves or disapproves in accord with whether the applicant satisfies the regulations "and is qualified to participate" in MSSP.

² 42 U.S.C. § 1395jjj(a)(1)

³ *Id.*

§425.206 Evaluation procedures for applications

(a) Basis for evaluation and determination.

(1) CMS evaluates an ACO's application to determine whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program, and approves or denies applications accordingly.⁴

Furthermore, CMS may rely on a variety of sources of information in order to make the following determination.

42 C.F.R. § 425.206(a) (con'td)

Applications are approved or denied on the basis of the following:

- (i) Information contained in and submitted with the application by an application deadline specified by CMS.
- (ii) Supplemental information that was submitted in response to a CMS request and by a deadline specified by CMS.
- (iii) Other information available to CMS.

Therefore, based on the authority in subsection (ii) above, CMS may inquire as to the purpose of the new ACO. We recommend that there be a robust answer readily available and documented prior to the inquiry. For example, this purpose would ideally be documented in a the new ACO's Articles of Incorporation, By-Laws or any Mission Statement. In addition, it may be appropriate to address this as part of the required Initial Application's request for a narrative overview "of your ACO's history, mission, and organization."⁵ Finally, we recommend that the purpose clearly articulate the relationship between the transition to a new ACO entity and the goals of the MSSP program.

If the application is denied, the applicant may appeal that decision through the reconsideration process.⁶ The burden of proof is on the applicant "to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the requirements of this part or applicable statutory authority."⁷

C. Case Law

No applicable administrative case law was identified.

⁴ 42 C.F.R. § 425.206

⁵ CMS. Initial Application - Performance Year 2018 (Sample), at 4. Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP_Application_Initial.pdf

⁶ 42 C.F.R. § 425.800 (The list of MSSP issues precluded from judicial review does not include the denial of an application for ACO status); 42 C.F.R. § 425.802(a) ("An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.")

⁷ 42 C.F.R. § 425.804(b)

D. Application Materials and Guidance

No application materials or guidance would clearly allow or prohibit the proposed activity. However, in looking at this guidance, we also identified some operational concerns for an ACO that decides to pursue this course. Also included are some questions about factors not addressed in the Question Presented, and suggestions for increasing the probability that CMS would accept the applicant as a new ACO.

1. Did the applicant form a new legal entity?

This is an important factor in support of demonstrating the organization's status as a new ACO. This appears to be a basis on which the application-related forms distinguish one ACO from another. We note that it would be best if the creation of the legal entity were accomplished in advance of submitting the Notice of Intent to Apply (NOIA). More information on the NOIA and corresponding deadlines is available on this CMS [webpage](#). However, the legal entity would not need to have a fully completed set of governance documents and related agreements for purposes of the Notice of Intent to Apply.⁸

More extensive documentation regarding the governing body is required for the Initial Application. (The Initial Application requires, for example, CMS's "Governing Body Template," which identifies the members of the governing body and their roles.⁹ We note that the governing body structure and related documents used for the prior ACO could serve as the basis for the governing body for the new ACO, to the extent that these are appropriate for the new ACO's participants and purposes of the new ACO.

2. Could the applicant change its form with respect to the number of participants and TIN?

Application guidance, as quoted below, indicates that the applicant will be a new ACO if the ACO transitions from one participant (with same tax ID as ACO) to multiple participants:

Note, if the ACO's current approved legal entity status has changed, the ACO may not be able to apply as a renewing Shared Savings Program ACO. For example, if the ACO is transitioning from a single taxpayer identification number (TIN) ACO (comprised of one ACO participant with the same tax ID as the ACO) to an ACO that is comprised of multiple ACO participants, the ACO must apply as a new applicant. In this instance, CMS would consider the ACO a new entity, which requires the ACO to apply as an initial applicant.¹⁰

⁸ CMS. Notice of Intent to Apply - Guidance Document (May 2017), at 13 *et seq.*(Appendix B). Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-NOI-Memo.pdf> (Appendix B lists Initial Application sample questions, which include questions regarding the ACO TIN, the date of formation, the type of legal entity (partnership, limited liability company, etc.) and tax status.

⁹ CMS. Initial Application - Performance Year 2018 (Sample), at 5-6 (Section 5). Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP_Application_Initial.pdf . (Question 14 requests the "Governing Body Template.")

¹⁰ CMS. Notice of Intent to Apply - Guidance Document (May 2017), at 4 (Section 2.3). Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-NOI-Memo.pdf>

If accepted, the ACO would begin a new agreement period at the start of the upcoming performance year. We recognize that making the kind of transition described above may be operationally infeasible or inappropriate, but it is an option under which an organization would clearly be a new ACO

IV. Conclusion

In conclusion, this is new and uncertain territory, and CMS has significant freedom to interpret the regulations in accord with its policy objectives, but there is a reasonable possibility that such an activity could be approved under current regulations. While there is a supportable argument that CMS is obligated to approve such an application, the argument has never been tested, and the applicant would bear a significant burden of proof when appealing a denial. We recommend that, if possible, a new legal entity be formed, that the record of historical ACO participants and new ACO participants be accurately presented, and the purpose for the formation of the new ACO be documented (e.g., in the governing body's documents), and provided to CMS.