

CMS's Proposed Changes to the MSSP Aim to Grow Two-Sided Risk Models and Modify Processes for Evaluating and Facilitating Care Coordination

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The [Centers for Medicare & Medicaid Services](#) (CMS) has published long-awaited changes to the [Medicare Shared Savings Program](#) (MSSP). The [official version](#) of the proposed rule (the Proposed Rule), released December 8th, 2014, makes numerous technical changes, but also provides more insight into CMS's policy vision. The Proposed Rule is CMS's most comprehensive effort to reinvigorate a seminal part of the Obama Administration's vision to transform the health care delivery system and contain costs.

Initial stakeholder reaction has been mixed, with providers cautiously supportive of CMS's proposal to recognize services from non-physician providers in the assignment process, to update benchmarking processes for ACOs, and to establish a new ACO two-sided risk arrangement model (Track 3) with fully prospective beneficiary assignment. However, most ACOs have been critical of CMS's lack of significant changes to the one-sided risk model (Track 1). Although the Proposed Rule provides relief from a requirement that Track 1 ACOs must convert to a two-sided risk model (Track 2) by their second agreement period (2015 for the first cohort), it does little to increase the savings potential for Track 1 participants. As a result, ACOs and prospective ACOs may be wary of Track 1 participation. Some ACO coalitions have responded with cautious skepticism, stating that Track 1 participants lack the necessary incentives to convert to Track 2, including only retrospective assignment during Track 1.

In the coming weeks, we will provide more in-depth analysis and summaries of the Proposed Rule and evolving stakeholder reaction on our blog, [Health Law & Policy Matters](#). Here is our initial analysis of some key provisions of the Proposed Rule and its anticipated effects for MSSP ACOs:

1. New and Amended Definitions

CMS proposes to create three new defined terms — ACO participant agreement, assignment window, and participant agreement — and to amend the definitions of nine other terms, including ACO participant, ACO provider, ACO supplier, and hospital. CMS expects that these changes will eliminate stakeholder confusion that became apparent in the first few years of operation of the MSSP Program. The Proposed Rule also expands the definition of primary care services to include transitional care management (TCM) Current Procedural Terminology (CPT) codes 99495 and 99496, and chronic care management (CCM) HCPCS code GXXX1.

2. Narrower Structural Flexibility

Section II.B of the preamble to the Proposed Rule outlines the planned changes to the technical processes and prerequisites of becoming an MSSP ACO. Overall, CMS purports to use the Proposed Rule to (1) codify current CMS sub-regulatory guidance currently available in documents such as the [Frequently Asked Questions](#); (2) clarify and supplement certain participation requirements; (3) provide CMS with greater flexibility in overseeing ACOs; and (4) create ACO structural requirements that would promote better care coordination. CMS's proposal to codify previously published sub-regulatory guidance is noteworthy because, over the past few years, stakeholders and advocates have expressed concern that CMS used "guidance" documents posted to its website to circumvent the regulatory comment process, effectively promulgating regulations without public input.



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The Proposed Rule eliminates many aspects of flexibility for MSSP ACOs. For example, CMS proposes the deletion of 42 C.F.R. § 425.108(e), which gives MSSP ACOs the ability to request an exception to the leadership and management provisions of 42 C.F.R. § 425.108(b) that require that the ACO's operations "must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body." Also, CMS wants to revise 42 C.F.R. § 108(c)(5) to remove the ability of ACOs to have less than 75% control of the governing body be held by ACO participants, because no ACOs to date have needed this flexibility. But most importantly, CMS is remaining adamant that all ACO participation agreements among ACOs and CMS and ACO participants evidence "direct legal relationships," so that no third parties are involved in any agreement. This requirement has been very hard for organizations like Independent Practice Associations and other entities that do not operate under a single TIN to handle, but the Proposed Rule provides a formal opportunity for these entities to air their grievances about it. The Proposed Rule, however, does not address whether structures that were already approved for participation in the MSSP would remain grandfathered in – as the Proposed Rule reads, all currently participating MSSP ACOs would be subject to these regulatory requirements upon adoption, even in the middle of a 3-year MSSP agreement period (because they do not relate to beneficiary assignment). However, in a nod to some measure of flexibility, CMS proposes to allow an individual who is not a participating provider or supplier in the ACO to serve as a medical director of the ACO.

3. Expanded Beneficiary Assignment Flexibility

CMS's Proposed Rule attempts to clarify the limitations governing the beneficiary assignment process relating to eligible beneficiaries, eligible primary care services, and eligible primary care service suppliers. The overall effect of these proposed modifications would likely be to make it easier for MSSP ACOs to meet the 5,000 assigned beneficiary threshold and more accurately reflect the scope and source of primary care services provided to Medicare beneficiaries.

As mentioned above, CMS proposes to include as eligible primary care services TCM CPT codes 99495 and 99496 and CCM HCPCS code GXXX1. In addition, CMS proposes that all future changes to the set of primary care services to be considered in the beneficiary assignment process be made in the Physician Fee Schedule update released annually.

The Proposed Rule also provides a comprehensive list of physician specialties that would not count in the second step of the beneficiary assignment process, which relies on the specialty codes paired with the primary care service (e.g., the Proposed Rule would exclude general surgery, dermatology, pathology, urology, etc.). The proposed changes to beneficiary assignment and eligible primary care services would create additional flexibility for certain specialty practitioners to participate in multiple ACOs. MSSP ACOs seeking to involve specialists should not count this as a full victory, however, because CMS strongly emphasized that "an ACO participant that submits claims to Medicare for primary care services must be exclusive to a single ACO" and does not condition this requirement on whether the beneficiary to whom those services are delivered is ultimately assigned to the MSSP ACO.

The Proposed Rule seeks to also give CMS greater flexibility to allow MSSP ACO applicants to submit additional TINs to CMS if, during the application process, CMS determines that the prospective ACO will not meet the requisite minimum of 5,000 assigned beneficiaries. In addition, CMS proposes more flexibility to issue a Corrective Action Plan (CAP) to MSSP ACOs if the assigned beneficiary population falls below the minimum threshold and regarding the timing for the MSSP ACO to become compliant with the beneficiary threshold requirement under a CAP. On a related note, CMS is soliciting comments on whether it would be useful to allow prospective MSSP ACO beneficiaries to attest in writing that a physician is their "main doctor," which is already being tested in the [Pioneer ACO Model](#) operating through the [CMS Innovation Center](#). These changes to the beneficiary assignment methodology are intended to help MSSP ACOs predict their assigned population's behavior with more certainty.

Although CMS proposes to continue to use the two-step beneficiary assignment process generally, it is also seeking comment on whether a one-step beneficiary assignment process would be more effective.

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4. Pushing Transitions With Changes to Two-Sided Risk Models

Much of CMS's [fanfare and press](#) surrounding the Proposed Rule focuses on proposed modifications to the various MSSP ACO "tracks" for which MSSP ACOs may apply and CMS's attempts to push more beneficiaries from the one-sided risk, shared-savings only model (Track 1) ACOs to two-sided risk model ACOs (Track 2 or Track 3). We provide some of the highlights of these proposed modifications here.

First, the Proposed Rule explores providing Track 1 ACOs a longer lead time to transition to a two-sided performance risk model, rather than forcing them to withdraw from the MSSP if they do not move to Track 2 after the first three-year performance period. CMS is leaning toward giving the over 300 Track 1 ACOs one additional MSSP ACO agreement period to make the switch, and creates a new MSSP renewal process under 42 C.F.R. § 425.224 to facilitate this transition without requiring participating MSSP ACOs to go through the full application process. Track 1 ACOs that enter a second MSSP ACO agreement period at the same status would see their potential sharing rate decrease by 10%, making their maximum sharing rate 40%. CMS is seeking comment on whether Track 1 ACOs should be able to continue in the one-sided risk model for third and subsequent MSSP ACO agreement periods subject to a 10% reduction in the shared savings for each agreement period beyond the first, which signifies CMS's seriousness about moving ACOs out of Track 1 as quickly as possible. In addition, CMS is seeking comment on other MSSP ACO agreement extension proposals for Track 1 ACOs.

The five remaining existing Track 2 ACOs would also be able to renew under the new procedures, but would not be able to step down to Track 1 status. But rather than all being subject to a flat 2% Minimum Savings Rate (MSR) and Minimum Loss Rate (MLR), the MSR and MLR rates for Track 2 ACOs would vary based on the ACO's size. Thus, smaller ACOs must incur more losses before having to make shared losses payments to CMS than larger ACOs and, conversely, larger ACOs have a smaller cushion of losses they can incur before they must make shared losses payments. The MSR/MLR ranges between 2% to almost 4%. This increased downside risk protection will supposedly make it more attractive for smaller ACOs to transition to Track 2. CMS is also developing regulations to allow Pioneer ACOs to easily transition to the MSSP, which is to the agency's benefit because CMS wants these experienced Pioneer ACOs to bolster the number of Track 2 ACOs participating in the MSSP.

In addition, CMS is proposing to create a Track 3 two-sided risk model, which would integrate some elements from the Pioneer ACO model. For instance, Track 3 ACOs would stand to obtain up to 75% of the shared savings earned during an MSSP agreement period and would only be accountable for beneficiaries prospectively assigned to the ACO. Although the Track 3 ACO could actually lose beneficiaries based on the assignment criteria at the end of a performance year, they would not run the risk of being assigned new beneficiaries. In contrast, Track 1 and 2 ACOs would remain accountable for beneficiaries both prospectively assigned to the ACO and added to the ACO during the performance year, regardless of whether the beneficiary ultimately receives a plurality of primary care service from non-ACO participants. Another key difference for Track 3 ACOs is that their beneficiary assignment window and risk adjustment methodology would be based on a 12-month assignment window offset from the calendar year prior to the start of each performance year, but Part A and Part B expenditures would still be determined based on the calendar year. In other respects, the Track 3 model would adopt the features of the current Track 2 model, such as a flat MSR/MLR of 2%.

Lastly, although CMS is not making any formal proposals at this time, CMS is interested in comments regarding what we can term "split-level" ACOs. This option would be available to Track 1 ACOs that may have some ACO participants that are ready to transition to two-sided risk models and some that desire to remain in Track 1.

5. Payment Policy Waivers

The Proposed Rule shows that CMS realizes that ACOs are experiencing barriers to providing innovative care models because of certain Medicare conditions of payment requirements. Thus, CMS is seeking comment on whether specific payment waivers would help ACOs to transition more easily into two-sided risk models. For instance, CMS is proposing that, as part of the application process, ACOs must discuss use of enabling technology, including telehealth, to promote care coordination. As a complement to this proposal, CMS is also

considering possible waivers of certain conditions of payment requirements related to telehealth services. CMS is also proposing to transition the waiver of the rule that patients must have a minimum 3-day inpatient hospital stay before being admitted to a SNF (the SNF 3-day rule) that is already in place for Pioneer ACOs into the MSSP. Other areas where CMS has expressed interest in providing payment policy waivers involve the homebound requirement for the home health benefit and referrals to post-acute care settings.

6. Increased Public Reporting and Transparency Requirements

The Proposed Rule also imposes additional requirements on MSSP ACOs to post information about their “key clinical and administrative leaders,” in addition to identifying members of their governing bodies, associated committees, and committee leadership. However, CMS is allowing the ACO to update changes to its ACO participant list without submitting such materials to the agency for marketing review, even though CMS still considers the MSSP ACO’s website to qualify as a marketing material or activity. CMS is seeking to prescribe a standardized template for MSSP ACOs to use for submitting information subject to the public reporting requirements in 42 C.F.R. § 425.308 and would like to post this ACO-specific information to the CMS and [Physician Compare](#) websites.

7. Application Requirements, MSSP ACO Agreement Terminations, and Reconsideration Reviews

The Proposed Rule is tightening CMS’s hold on the MSSP application process. Although CMS is providing applicants with more opportunities to supplement information in the MSSP application (particularly with respect to beneficiary assignment issues), it is taking a hard line on timing. Thus, MSSP applicants who fail to meet deadlines during the application process will not receive any leniency from CMS. By becoming stricter during the application process, CMS hopes to streamline the consideration of MSSP applications. However, MSSP ACOs and other stakeholders have experienced numerous issues with ensuring that CMS and its regional offices reviewing applications have completely understood and appropriately considered all information provided. Although the MSSP application consideration period may be “condensed” by these changes, the risk for stakeholders is that these modifications may actually result in more determinations that the MSSP applicants view as inconsistent with the information provided.

CMS also proposes to modify its processes with regard to terminating MSSP ACOs and allowing aggrieved ACOs to seek review of CMS determinations. CMS is increasing the reasons why it may terminate MSSP ACOs while reducing reconsideration requests to “on-the-record” reviews, which do not allow for MSSP ACOs to seek oral argument in an administrative hearing if they disagree with CMS’s determinations. In addition, CMS proposes more explicit criteria for winding down the terminated MSSP ACO’s activities, and clarifies that terminating an MSSP ACO agreement before the end of a performance period (e.g., December 31st of that year) would result in the MSSP ACO forfeiting any shared savings that it may have earned, while failing to complete the close-out process as CMS requires would forfeit those savings as well.

8. Miscellaneous Areas for Stakeholder Input

CMS is seeking comment, without proposing formal proposed regulatory changes, regarding the following:

- how ACOs may show that they have the ability to repay potential losses and repayment mechanisms;
- how the benchmark setting process can be made more adaptable to potential addition and removal of ACO participants, local and regional geographic variation in health care costs, and other factors;
- whether CMS should continue to rebase the benchmarks for MSSP ACOs to meet at the start of each three-year agreement period, which would lower the risk threshold and likely subject the ACOs to less shared savings and to more risk for losses; and
- whether CMS should reward ACOs for achieving shared savings through the benchmark setting process.

The overall purpose of seeking stakeholder input on these issues appears to be to find ways to further encourage the transition of ACOs into two-sided risk models. However, CMS is likely already anticipating serious pushback from health care providers who believe that the only way to gain successful two-sided risk participation will be through a more generous one-sided risk program. Providers will argue that only through a positive experience in Track 1 will ACOs have enough experience and financial support to move into Track 2.

As stakeholders and advocates rush to evaluate and respond to the Proposed Rule, CMS should carefully evaluate how it will measure success for the MSSP, be it by increasing the total number of ACOs, regardless of their experience level and ability to improve quality, or by focusing on fewer ACOs to prove a theory of policy that would inform future Medicare payment changes for the health care system at-large.

If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.

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