

Medicare Shared Savings Program Proposed Rule: Enough Incentive to Encourage More ACO Risk?

Stakeholder Comments Will Help Shape the Future Direction of the Program

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On December 1, 2014, the Centers for Medicare & Medicaid Services ("CMS") released a proposed rule ("Proposed Rule")¹ setting forth long-anticipated changes to the Medicare Shared Savings Program ("MSSP"), including payments made under the program to accountable care organizations ("ACOs"). The Proposed Rule contains extensive polices impacting current and prospective ACOs.

Through the Proposed Rule, CMS is clearly making a concerted effort to keep ACOs in the MSSP through enhanced flexibility, evidenced by a new two-sided shared savings and loss model and by seeking guidance from stakeholders regarding the most appropriate benchmarking methodology. However, there is more that CMS can do to achieve its objective, and the agency has made clear that the policies in the final MSSP rule will be driven by stakeholder comments.

Comments on the Proposed Rule are due by 5 p.m. ET on February 6, 2015.² If you would like to discuss submitting comments, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.

I. Updates to MSSP Performance Models

Track 1 Performance Model – CMS acknowledges in the Proposed Rule that ACOs in the one-sided shared savings only ("Track 1") performance model may need more time

¹ The text of the Proposed Rule is available at <u>http://www.ofr.gov/OFRUpload/OFRData/2014-</u> <u>28388_PI.pdf</u>.

² Interested parties can submit comments to CMS through <u>http://www.regulations.gov</u>.

to gain the experience or level of program participation necessary to transition to the two-sided shared savings and losses ("Track 2") performance model as required under current regulations. Also Track 2, as currently designed, may not provide an adequate financial risk/reward model to attract ACOs to transition from Track 1. As such, many ACOs may be left with the choice of taking on more risk than they can manage or otherwise simply dropping out of the MSSP altogether.

Therefore, CMS proposes to remove the requirement that Track 1 ACOs transition to Track 2 after the initial three-year agreement period. Specifically, a current Track 1 ACO will be allowed to renew for one additional three-year Track 1 agreement period, if it has not had significant losses in at least one of its initial two years. CMS is seeking comment on whether this proposal will help keep ACOs in the program and whether additional performance requirements should be satisfied in order to be approved for a second three-year period. To keep the one-sided risk model from becoming too attractive to ACOs after the first agreement period, CMS also proposes to decrease the maximum shared savings rate by 10 points to 40 percent for the second three-year period.

CMS is considering allowing additional or indefinite Track 1 extensions, albeit at diminishing shared savings rates.

Track 2 Performance Model – CMS also proposes to modify the financial thresholds for the Track 2 performance model to reduce the level of risk faced by ACOs and "smooth the on-ramp to performance-based risk." Specifically, CMS would allow the minimum savings rate ("MSR") and minimum loss rate ("MLR") under Track 2 to vary based on the number of assigned beneficiaries, instead of using the present fixed MSR and MLR. This is intended to provide greater protection to ACOs against losses from normal variation, particularly variation associated with smaller assigned populations. CMS seeks comments on whether this proposal will successfully make Track 2 more attractive to ACOs.

Track 3 Performance Model – CMS proposes the option of an additional two-sided shared savings and losses model ("Track 3") that requires greater performance risk in exchange for greater potential savings. This new Track 3 would utilize the Track 2 payment methodology but with the following adjustments:

- Despite historical concerns with prospective assignment extensively articulated in the Proposed Rule, CMS proposes to prospectively assign beneficiaries in Track 3 ACOs and will be performing only a very narrow reconciliation at the end of the performance year that would remove only beneficiaries determined ineligible for assignment at the time of reconciliation.
- CMS proposes the shared savings rate for Track 3 ACOs as up to 75 percent of savings under the updated benchmark in exchange for accepting risk for up to 75 percent of all losses, provided an ACO meets the quality performance requirements. The shared savings payment limit would be set at 20 percent of

the ACO's updated benchmark and shared losses could not exceed 15 percent of the updated benchmark.

 CMS proposes to apply to Track 3 ACOs a fixed 2 percent MSR and MLR as a means to offer greater predictability to attract ACOs to bear more risk.

II. CMS Declines to Propose, but Seeks Comments on, Changes to Benchmarking Methodology

Per the authorizing statute, estimated ACO benchmarks for each agreement period are set using the most recently available three years of per beneficiary expenditure data for Parts A and B services for Medicare beneficiaries assigned to the ACO. The benchmarks are adjusted by beneficiary characteristics and other factors determined appropriate by the Secretary of the Department of Health and Human Services ("HHS") and updated by the absolute amount of growth in national per capita expenditures for Parts A and B services, thereby accounting for national Medicare fee-for-service ("FFS") trends.

It is noteworthy that CMS declines at this time to propose a specific change to its benchmarking methodology. CMS clearly is interested in an updated methodology for establishing, updating, and resetting benchmarks as evidenced by the extensive discussion of the various methodologies available to it. CMS seeks comment on a range of alternative methods, including: (1) equally weighting the three benchmark years; (2) accounting for shared savings payments in benchmarks; (3) using regional, as opposed to national, FFS expenditures to determine trends; (4) resetting benchmarks that would hold an ACO's historical costs constant relative to costs in its region for periods after the initial agreement period; and (5) resetting benchmarks based only on regional FFS costs as opposed to the ACO's own costs, over multiple agreement periods.

The statute grants the Secretary authority to use other payment models that may include alternate benchmarking methodologies. CMS seeks comments on any alternative methodologies in addition to those it describes in the Proposed Rule.

III. Additional Flexibility Provided Through Waivers

CMS plans to exercise its statutory waiver authority under Section 1899(f) of the Social Security Act to further promote participation in the two-sided performance-based risk models. The proposed waivers are designed to give risk-bearing ACOs—which already have an incentive to reduce wasteful spending and over-utilization—additional flexibility with respect to certain Medicare payment and program requirements. Specifically, CMS proposes to apply this waiver authority to inpatient skilled nursing facility ("SNF") care, telehealth services, home health care, and hospital discharge planning for Track 3 ACOs as follows:

- SNF 3-Day Rule To promote cost savings and care coordination, CMS proposes to waive the "SNF 3-day rule," under which beneficiaries must have a prior inpatient hospital stay of at least three consecutive days to become eligible for Medicare coverage of inpatient SNF care. CMS proposes to permit two-sided risk track ACOs to apply for this waiver under rules similar to those that currently apply to the Pioneer ACO Models, meaning, among other things, that an ACO would need to submit its partnering SNFs to CMS for approval.
- Billing and Payment for Telehealth Services This waiver is designed to afford at-risk ACOs greater leeway so that they may develop a broader array of telehealth services in a wider range of geographic areas. Specifically, the waiver would apply to two separate telehealth requirements—one that limits telehealth payment to services furnished within certain types of geographic areas or in an entity participating in an approved federal telemedicine demonstration project, and another requirement that identifies the particular locations where the telehealth individual must be located when the service is furnished via a telecommunications system.
- Homebound Requirement Under the Home Health Benefit As a prerequisite for Medicare funding of home health services, a beneficiary must be deemed to be "home-bound" and, therefore, unable to obtain care in the less costly outpatient setting. CMS proposes to allow for a waiver of the "homebound" requirement for two-sided performance-based arrangements to promote lower overall costs of care.
- Waivers for Referrals to Post-Acute Care Settings A Medicare condition of participation requires hospitals to work with patients to determine the appropriate post-hospital discharge destination in a manner that does not limit a patient's freedom of choice of providers. To encourage ACOs to develop strong networks with post-acute care entities and enhance the continuity of care, CMS proposes "a very narrow waiver" that would permit ACOs to recommend and refer to certain post-acute providers. ACOs that seek to use the waiver may face additional documentation requirements and would be required to respect a patient's ultimate choice of provider.

The above waivers would be limited to ACO participants or ACO providers/suppliers since their incentives should be closely aligned with the ACO. In addition, CMS indicates that it intends to limit these waivers to Track 3 ACOs since they have a significant financial incentive to control patient costs and have prospectively assigned beneficiaries who would be easier to identify. Nonetheless, the agency is accepting comments on whether the waivers should instead apply to any FFS beneficiary cared for by an eligible ACO or to beneficiaries who appear on the quarterly lists of preliminarily prospectively assigned beneficiaries.

The Proposed Rule addresses these four payment and programmatic requirements only and does not address the fraud and abuse waivers previously announced by CMS and

HHS's Office of Inspector General in the November 2011 Interim Final Rule that accompanied the Final Rule establishing the MSSP.³ Therefore, the Proposed Rule's waiver provisions are comparatively limited in scope and do not address certain critical issues, such as fee arrangements or the distribution of shared savings, or financial incentives to assigned beneficiaries to remain within an ACO, such as reduced cost sharing. Nevertheless, CMS welcomes comments on the outlined waivers, as well as any additional waivers that may be used to encourage ACO participation in performance-based risk arrangements while enhancing quality of care and reducing unnecessary costs.

IV. Assignment Through Beneficiary Attestation Is Being Seriously Considered

Beneficiaries are currently assigned to an ACO if it provides a plurality of a beneficiary's primary care. That determination is based on a statistical determination of their utilization of primary care services during a performance year, with rolling data updated quarterly, leading to a final determination of assignment at the end of each performance year. CMS acknowledges that such a retrospective claims-based assignment methodology "creates more year-to-year variability or 'churn'" in assigned beneficiaries. CMS also acknowledges that commenters have suggested that beneficiaries should be able to designate their own primary care providers (and, by extension, the affiliated ACO) as responsible for managing overall care. CMS is testing such beneficiary attestation in 2015 for its Pioneer ACO Model.

While CMS does not propose allowing beneficiary attestation in the Proposed Rule, it does seek comments, which it will "carefully consider," on whether it would be an appropriate process for ACOs with two-sided risk arrangements. The fact that CMS seeks stakeholder input on 12 questions regarding operationalizing beneficiary attestation indicates that the agency is carefully considering the policy but has not yet received sufficient input to make a final decision.

V. Enhanced Data Sharing Policies and Procedures

ACO participants must develop means to report on quality and cost measures and enhance care coordination. During the original rulemaking process for the MSSP, CMS finalized a policy to provide certain aggregate and beneficiary-identifiable data (including Part A and B claims data and Part D prescription drug event data) to ACOs to facilitate their ability to assess information about the care received by their assigned beneficiaries both inside and outside the ACO. In the Proposed Rule, CMS outlines a series of modifications that are designed to strengthen and streamline its data sharing policies and procedures as follows:

• Aggregate Data Reports and Limited Identifiable Data – CMS plans to expand the scope of information provided to ACOs in aggregate data reports and in reports containing beneficiary-identifiable information on preliminarily prospectively assigned beneficiaries. Specifically, these reports would be

³ See 76 Fed. Reg. 67992 (Nov. 2, 2011).

amended to include the current four data elements (name, date of birth, health insurance claim number ("HICN"), and sex) for each beneficiary that has a primary case visit with an ACO participant that bills for primary care services that are considered in the assignment process. In addition, the reports would incorporate additional data relating to demographics, health status, utilization rates of Medicare services, and expenditure information related to utilization of services.

CMS notes that the expanded data reports would only apply to ACOs participating in Tracks 1 and 2. For Track 3, the beneficiary-identifiable data included in the reports would be limited to beneficiaries who appear on the ACO's prospective list of beneficiaries at the start of a performance year.

Claims Data Sharing and Beneficiary Opt-Out - Under current data sharing procedures, ACOs may obtain beneficiary-identifiable claims data only after providing beneficiaries with an opportunity to decline to share their data. ACOs are required to give notice of the opt-out to beneficiaries during primary care visits or through mailed notifications. In light of complaints from ACOs and beneficiaries about the burdens and confusion arising from these procedures, CMS proposes the following revisions: (1) beneficiaries may decline data sharing by directly contacting CMS through 1-800-MEDICARE, rather than through the ACO; (2) FFS beneficiaries will receive advance notice of their opt-out rights through disseminated CMS materials, such as the Medicare & You Handbook; (3) ACOs will no longer be required to mail notifications to beneficiaries; and (4) ACO participants would no longer be required to inform beneficiaries at the point of care through written forms, but instead may communicate the requisite information through posted signs that include updated template language. Finally, CMS proposes to give ACOs expedited access to beneficiary data to facilitate more timely care interventions. To this end, ACOs participating in Tracks 1 and 2 would be able to access beneficiary-identifiable claims data on preliminarily prospectively assigned beneficiaries on a monthly basis. Track 3 ACOs would be given access to similar information for prospectively assigned beneficiaries within the same time frame.

VI. Flexibility Offered for Smaller ACOs

While the new requirements discussed above, along with extensive new processes for identifying program participants, create processes and burdens for ACOs, CMS proposes the following refinements in policies to provide greater flexibility to ACOs:

• **Sufficient Number of Beneficiaries** – ACOs are required to maintain a beneficiary population of at least 5,000 and a primary care pool sufficient to support that number. Under current regulations, if, during a given performance year, the beneficiary population assigned to the ACO falls below 5,000, CMS is required to issue a warning letter and place the ACO on a corrective action plan ("CAP"). Should the ACO fail to increase the number of beneficiaries to at least

5,000 during the next performance year, the ACO will be terminated from the MSSP and may not share in savings for that performance year. By the time an ACO is notified of its deficiency it is often too late to make corrections to salvage its participation for the subsequent performance year.

Acknowledging that this structure is rigid and not well suited to timely adjustment (i.e., increase) of the assigned beneficiaries by the ACO for the next performance year, CMS proposes to allow a beneficiary-deficient ACO reasonable time to successfully complete a CAP. Further, CMS proposes to make imposition of remedial measures, such as issuance of warning letters and CAPs, discretionary rather than mandatory.

 Leadership and Management Structure – CMS proposes to allow additional flexibility regarding the qualifications of the ACO medical director. Specifically, the medical director would no longer have to be an ACO provider/supplier, thereby permitting a medical director who may have been previously associated with an ACO participant but who is not an ACO provider/supplier.

VII. Minor Refinements to Risk Adjustment Methodology

For risk adjusting the updated benchmarks for Track 3 ACOs, CMS proposes to utilize the same risk adjustment methodology used under Tracks 1 and 2. This methodology differentiates between newly assigned beneficiaries (those assigned in the current performance year) and continuously assigned beneficiaries (those assigned to or who received primary care services from the ACO during the prior year). CMS updates changes in the severity and case mix for *newly* assigned population using the updated CMS-HCC (Hierarchical Condition Categories) prospective risk scores. Under its current methodology, the level of severity and case mix for the *continuously* assigned population may only be reduced. Therefore, the risk scores for this population may only be increased based on demographic factors.

Apart from minor changes to the definitions of newly and continuously assigned beneficiaries to allow for risk adjustments of the Track 3 benchmark year, CMS is not proposing any other changes to its risk adjustment methodology.

Many of the same issues that have been raised regarding updates to the benchmarks in future performance periods may also apply to risk adjustment. Thus, it may be important for CMS to allow some method of recognizing that the case mix of an ACO could change considerably over a five- to six-year period. Stakeholders should consider commenting on how CMS's risk adjustment can better capture changes in health status of continuously assigned beneficiaries.

VIII. Conclusion

Further refinement to the risk adjustment and benchmark update methodologies are two examples of additional changes CMS should consider to make the MSSP more

attractive to ACOs to take on more risk. CMS is actively seeking stakeholder input and, by all indications, this input will be seriously considered in the policy decisions that are adopted in the final MSSP rule. This presents a unique opportunity for stakeholders to play an important role in shaping the future direction of the MSSP.

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This Client Alert was authored by S. Lawrence Kocot, Thomas E. Hutchinson, John S. Linehan, and Philo D. Hall. If you would like to discuss submitting comments, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.

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