ROPES & GRAY

ALERT

Health Care

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Medicare Shared Savings Program: CMS Finalizes Changes Affecting All ACOs

On June 4, 2015, the Centers for Medicare & Medicaid Services ("CMS"), issued a final rule (the "Final Rule") implementing changes to the Medicare Shared Savings Program ("MSSP"). The Final Rule addresses matters raised in a proposed rule published December 2014 (the "Proposed Rule"), which we summarized in a prior alert.

The Final Rule adopts changes intended to entice providers to participate in the MSSP while encouraging them to adopt two-sided risk models. The most notable of these changes are:

- allowing current Track 1 Accountable Care Organizations ("ACOs") to extend the period that they can participate without assuming any financial risk;
- the establishment of a new risk-based ACO track ("Track 3"), a two-sided model with a higher sharing rate (75%), prospective beneficiary assignment and the opportunity to apply for a waiver of the three-day skilled nursing facility ("SNF") rule;
- revisions to the ACO beneficiary assignment algorithm to heighten the focus on primary care services; and
- key administrative changes, including codifying the requirements for ACO participation agreements and reducing the administrative barriers associated with data sharing.

CMS also finalized minor changes, including revisions to the methodology for establishing, updating and resetting the financial benchmarks used for determining shared savings and losses and modifications to the eligibility requirements for ACO participation.

Opportunity to Continue Track 1 Participation

Originally, the MSSP provided two tracks through which ACOs could participate: a one-sided risk model under which ACOs qualify to share in savings but are not responsible for losses ("Track 1"), and a two-sided risk model under which ACOs qualify to share in savings with an increased sharing rate but must take on risk for sharing in losses ("Track 2"). CMS intended for Track 1 to serve as an "on ramp," attracting participants to the program and introducing value-based purchasing to many providers and suppliers for the first time. Under the prior rule, ACOs that participated under Track 1 during their first three-year agreement period were required to transition to Track 2, and share both financial losses and savings, for all subsequent agreement periods if they wished to continue participating in the program.

Based on its experience with the MSSP, CMS has recognized that many ACOs are risk-averse and have not yet developed the infrastructure and readiness to manage increased performance-based risk. For this reason, and to encourage continued participation in the MSSP, the Final Rule offers the opportunity for ACOs to continue participating under a one-sided participation agreement after their first three-year agreement. The Final Rule permits ACOs to participate for an additional three-year agreement period under one-sided risk with the same maximum sharing rate (50%) as was available to them under the first agreement period, provided they meet the criteria established under the Final Rule for ACOs seeking to renew their participation agreements.

A New ACO Model ("Track 3")

The Final Rule establishes Track 3, a two-sided model that allows ACOs to harvest greater financial rewards in exchange for accepting higher levels of risk. Key differences between existing Tracks 1 and 2 and new Track 3 include a modified beneficiary assignment methodology, an increased sharing rate and performance payment and loss sharing limits. These differences are intended to encourage participation in the MSSP and to incentivize Track 1 ACOs to adopt more risk. The establishment of Track 3, which incorporates many design elements of the Pioneer ACO program, suggests that CMS intends to steer providers that are interested in greater financial rewards, in exchange for assuming a larger share of financial risk, to Track 3 or "Next Generation" ACOs. We summarized the "Next Generation" ACO model in a prior alert.

Most notably, Track 3 ACOs are eligible for a shared savings rate of up to 75% in exchange for accepting risk for up to 75% of all losses, depending on performance quality. ACOs with high quality performance would be subject to a shared loss rate of 40%. The Final Rule also applies a performance payment limit such that shared savings do not exceed 20% of the Track 3 ACOs' updated benchmark, and loss recoupment is limited to 15% of the Track 3 ACOs' updated benchmark. The increased sharing rate, maximum loss rate, minimum loss rate and performance payment limit differentiate Track 3 from Track 2 for ACOs that are considering assuming greater risk in exchange for greater reward.

In addition, before the start of each agreement period, Track 3 ACOs may select a symmetrical Minimum Savings Rate ("MSR") and Minimum Loss Rate ("MLR"), the thresholds an ACO's expenditures must meet or exceed for the ACO to be eligible to share in savings or be accountable for losses, from a set of options (0% MSR/MLR; symmetrical MSR/MLR in a 0.5% increment between 0.5% – 2.0%; and symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries).

Drawing on its experience with the Pioneer ACO model, CMS also adopted a prospective beneficiary assignment for Track 3 ACOs. Once a beneficiary is prospectively assigned to a Track 3 ACO, the beneficiary will not be eligible for assignment to a different ACO, even if the beneficiary chooses to receive a plurality of his or her primary care services from a different ACO. Prospective beneficiary assignment is intended to eliminate the reshuffling of beneficiaries under the Track 1 and 2 assignment methodology, to provide Track 3 ACOs with a more targeted set of beneficiaries on whom to focus their care redesign efforts and to help ACOs accurately gauge the impact of new care programs and protocols.

CMS also finalized one of the four waivers of Medicare reimbursement rules for Track 3 ACO participants that were included in the Proposed Rule. The Final Rule gives Track 3 ACOs the opportunity to apply for a waiver of the three-day SNF rule to permit payment for otherwise-covered SNF services when a prospectively assigned beneficiary is admitted to a SNF without a prior three-day inpatient stay. This waiver will be effective for services furnished on or after January 1, 2017. CMS did not adopt proposed waivers that would (i) remove geographic and originating site requirements for telehealth services provided by Track 3 ACOs; (ii) permit Track 3 ACOs to provide home health services to non-home bound beneficiaries that are prospectively assigned to the ACO; and (iii) permit hospitals to make referrals to specified post-acute care providers.

Track 3 ACOs, offering a higher reward opportunity, are expected to garner the attention of providers that considered the rewards previously available through the MSSP insufficient to justify the necessary investments. These higher reward opportunities, however, come with higher risk, a formula that presents both practical and legal considerations. Among these legal considerations, providers that are considering adopting a risk-bearing model should assess whether the increased risk profile will trigger state registration or certification requirements.

Changes to the Beneficiary Assignment Methodology

The Final Rule also revises the beneficiary assignment methodology. The methodology under the prior rule assigned beneficiaries in two steps, based on the plurality of primary care services furnished by (i) primary care physicians

and (ii) specialists. This two-step methodology was designed to maintain a focus on primary care services while recognizing the role played by specialists in providing primary care services, such as in areas with primary care physician shortages. While the Final Rule maintains the step-wise assignment methodology, it does make several revisions.

First, the Final Rule re-defines "primary care services" to include the transitional care management codes and the chronic care management code. Furthermore, in order to respond more quickly to HCPCS/CPT coding changes, future revisions to the definition of primary care service codes will be made through the annual Physician Fee Schedule rulemaking process. Second, the Final Rule includes claims for primary care services furnished by nurse practitioners ("NPs"), physician assistants ("PAs") and clinical nurse specialists ("CNSs") under step 1 of the assignment process. This change helps to ensure that a beneficiary is assigned to the ACO that actually provides the plurality of primary care to that beneficiary and thus should be responsible for managing the patient's overall care. Third, the Final Rule excludes from step 2 those services provided by certain physician specialties not likely indicative of primary care services, such as dermatology and gastroenterology.

The current assignment methodology will continue to be used for performance year 2015, including the final retrospective reconciliation set to occur in mid-2016, while the new methodology will be used for operations related to performance year 2016, including during application review for ACOs that are applying or renewing for a 2016 start date.

Additional Topics Covered in the 2015 MSSP Final Rule

ACO Eligibility Requirements: The Final Rule clarifies and codifies current guidance related to ACO participant agreements and issues related to maintaining, updating and submitting ACO participant and ACO provider/supplier lists. Minor modifications to the eligibility requirements for ACO participation include the following:

- The Final Rule codifies and expands requirements related to the agreements between ACOs and Medicare-enrolled entities to ensure that ACO participants understand their obligations and responsibilities and to enhance transparency between and among the ACO, ACO participants, and ACO professionals. For example, such agreements must include information about how the ACO plans to distribute shared savings and a statement that the ACO participant will assist with quality reporting. These changes largely codify existing guidance, and while ACOs are encouraged to incorporate these changes into their ACO participant agreements as soon as possible, CMS does not require these changes to be incorporated into any ACO participant agreement submitted to CMS for the 2016 performance year.
- The Final Rule clarifies rules related to the type of legal entity that may become an ACO's legal entity and governing body to ensure that ACO decision-making is governed by individuals who have a fiduciary duty to the ACO alone. For instance, the rule clarifies regulation text regarding when an ACO must be formed as a separate legal entity. It also provides additional flexibility surrounding ACO leadership and management structure, including removing the requirement that the ACO's medical director must be an ACO provider/supplier.
- The Final Rule requires ACOs to articulate in their applications how they will encourage and promote the use of enabling technologies for improving care coordination and how they intend to partner with long-term and post-acute care providers to improve care coordination.
- The Final Rule clarifies application procedures, establishing a streamlined process to allow prior Pioneer ACOs to apply for participation in the MSSP using a condensed application, provided that certain criteria are satisfied.

Methodology for Establishing, Updating and Resetting Benchmarks: CMS has revised the methodology for establishing, updating and resetting the financial benchmarks used for determining shared savings and losses. The intent is to help to ensure that the MSSP remains attractive to ACOs and to encourage ACOs to improve their

performance, particularly those that have achieved shared savings. The Final Rule finalized the following methods for resetting the ACO's benchmark at the start of its second or subsequent agreement period:

- CMS will weigh equally each historical benchmark year, as opposed to weighting these years at 10% for benchmark year 1, 30% for benchmark year 2, and 60% for benchmark year 3. This change creates less of a need for ACOs to demonstrate year-over-year improvements to generate savings.
- CMS will account for savings generated by the ACO in its first agreement period when setting the benchmarks for its second agreement period, taking into account the average per capita amount of savings earned by the ACO in its first agreement period and the number of assigned beneficiaries during that period. By making the historical benchmark more reflective of the total cost of care for the beneficiaries during the prior agreement period, CMS hopes to encourage ongoing program participation by ACOs that have achieved success. Without this adjustment, successful ACOs may elect to terminate participation in the program, rather than face a lower benchmark that reflects the lower costs for its patient population achieved during the three most recent prior years.

CMS has indicated its intent to propose and seek comment on the components of and procedures for calculating a regionally based rebased benchmark through a proposed rule to be issued later this summer. Such a methodology would reset ACO benchmarks in part based on trends in regional fee-for-service costs rather than solely ACOs' own recent spending. The intent behind such change is to more effectively account for the influence of cost trends in the surrounding region or local market on the ACO's financial performance, and to respond to concerns that the cost-saving potential of a successful ACO is not infinite. CMS anticipates that the revised rebasing methodology would be used for the first time to set benchmarks for ACOs beginning new agreement periods in 2017. ACOs beginning new agreement periods in 2016 would convert to the revised methodology at the beginning of their next agreement period in 2019.

Modifications to Track 2 Financial Model: To further smooth the "on ramp" toward taking on greater performance-based risk, the Final Rule modifies the financial thresholds under Track 2 to reduce the risk that ACOs must be willing to accept in order to participate. Under Track 2, an ACO will now have the choice of several symmetrical MSR and MLR options: (1) 0% MSR/MLR; (2) symmetrical MSR/MLR in a 0.5% increment between 0.5 and 2.0%; and (3) symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model. ACOs must select their MSR/MLR prior to the start of each agreement period in which they participate under Track 2 and may not change the selection during the agreement period.

Renewal of Participation Agreements: The Final Rule establishes a process for an ACO to renew its three-year participation agreement for an additional agreement period. It articulates rules for renewing the three-year agreement, including the factors that CMS will use to determine whether an ACO may renew its agreement. Such factors include the ACO's history of compliance with program rules, whether the ACO met quality performance standards in at least one of the first two years of its initial three-year agreement, and, for ACOs under a two-sided model, whether the ACO repaid losses owed to the program that it generated during the first two years of the previous agreement period.

Reduction of Barriers to Data Sharing: The Final Rule expands the kinds of beneficiary-identifiable data that will be made available to ACOs in various reports under the MSSP, and simplifies the process for beneficiaries to decline claims data sharing to reduce burden and confusion. The prior rule permitted CMS to share claims data with ACOs, but only after ACOs entered into data use agreements with CMS, requested from CMS the minimum data necessary to conduct health care operations, and notified beneficiaries and provided them an opportunity to decline to have their data shared with the ACO, among other requirements. ACOs could provide written notice to beneficiaries at the time of the first visit with an ACO participant, or could mail notices to beneficiaries and wait 30 days before requesting data. Informal feedback from ACOs and beneficiaries revealed that this process created beneficiary confusion and delays in data sharing.

To address these concerns, the Final Rule streamlines the process for ACOs to access the Medicare beneficiary claims data necessary for health care operations, while retaining the opportunity for beneficiaries to decline to have their Medicare claims data shared with the ACO. Rather than providing for mailed notifications, the Final Rule requires the ACO to provide notification at the point of care through posted signs that include template language, and provide beneficiaries the opportunity to decline data sharing directly by calling 1-800-Medicare, rather than through the ACO.

Beneficiary Eligibility Requirements: The Final Rule codifies the existing eligibility criteria for beneficiary assignment to an ACO. The Final Rule also clarifies that the assignment methodology applies for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation and prospective assignment.

Federally Qualified Health Centers and Rural Health Clinics: The Final Rule also clarifies how primary care services furnished in federally qualified health centers ("FQHCs") and rural health clinics ("RHCs") are considered in the assignment process. In recognition of the unique needs and challenges of rural communities and the importance of rural providers in assuring access to health care, the Final Rule requires ACOs that include FQHCs and RHCs to identify, through an attestation process, the physicians who provide direct patient primary care services in their ACO participant FQHCs or RHCs. Under the rule, the FQHC/RHC physician attestation information will be used only for purposes of determining beneficiary eligibility for assignment to an ACO. If a beneficiary is identified as "assignable," claims for primary care services furnished by all ACO professionals submitted by the FQHC or RHC will be used to determine whether the beneficiary received a plurality of primary care services from the ACO.

Other Upcoming Modifications to Program Rules: CMS has expressed its intent to address other modifications to program rules to improve ACO willingness to assume performance-based risk, including: modifying the assignment methodology to incorporate beneficiary attestation; operational processes to develop a methodology that would permit ACOs to split ACO providers/suppliers into two different risk tracks; and, as noted above, modifying the methodology for resetting benchmarks by incorporating regional trends and costs.

CMS indicated that it will conduct further development and testing of selected waivers discussed in the Proposed Rule, including waivers regarding telehealth services, through the CMS Innovative Center prior to deciding whether it is necessary to incorporate such waivers in the MSSP.

Should you have questions regarding this alert, please contact your usual Ropes & Gray advisor.