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CMS Issues Final Rule Implementing Changes to the Medicare Shared Savings Program

On June 9, 2015, the Centers for Medicare and Medicaid Services (CMS) published a final rule (Final Rule) that revises regulations governing accountable care organizations (ACOs) that participate in the Medicare Shared Savings Program (MSSP). The Final Rule makes only limited changes to the MSSP proposed rule that CMS published in December 2014 (Proposed Rule). Below are highlights of the Final Rule, which takes effect August 3, 2015, unless noted otherwise.

SECOND TRACK 1 AGREEMENT PERIOD

Prior to the Final Rule, the MSSP offered two shared savings payment tracks in which ACOs could participate. Under the one-sided model, known as "Track 1," an ACO is eligible to receive shared savings payments but is not at risk for any losses. Under the two-sided model, known as "Track 2," an ACO is eligible to receive a greater share of shared savings payments than under Track 1, but the ACO is also liable to CMS for a portion of its losses if its expenditures are above its benchmark.

Prior MSSP regulations provided that an ACO may participate in Track 1 for one three-year agreement term and then must transition to Track 2 for subsequent agreement terms. The Final Rule removes this requirement and permits ACOs that have completed one three-year agreement term under Track 1 to stay in Track 1 for one additional three-year agreement term. ACOs participating in a second Track 1 agreement period remain eligible to receive a maximum shared savings payment of 50 percent, depending on quality performance. To participate in Track 1 for a second agreement term, the ACO must meet the MSSP renewal criteria (discussed below). Importantly, CMS did not finalize proposed renewal criteria that would have required renewing ACOs to satisfy certain financial benchmarks during the first Track 1 agreement term.

ALTERNATIVES TO ENCOURAGE PARTICIPATION IN TWO-SIDED RISK MODELS

Track 3

A number of provisions in the Final Rule aim to encourage ACOs to take on an increased level of financial risk. Principal among them is CMS's creation of a new risk-based model, "Track 3." Track 3 uses the same general payment methodology as Track 2 but offers ACOs an increased share of savings and

greater liability for potential losses. Key features of Track 3 are described below.

Beneficiary Assignment

CMS will assign beneficiaries to ACOs participating in Track 3 (Track 3 ACOs) using the same two-step algorithm currently used for Tracks 1 and 2 (described in more detail below); however, beneficiaries will be prospectively assigned to Track 3 ACOs, with reconciliation performed quarterly during the performance year that may remove certain beneficiaries from the initial list but will not add new beneficiaries to the Track 3 ACO. Beneficiaries that meet certain exclusion criteria, such as enrollment in Medicare Part A and Part B for less than one month, will be removed from the Track 3 ACO's assigned beneficiaries. A beneficiary that is prospectively assigned to a Track 3 ACO but then receives most primary care services from a separate ACO may not be reassigned to another ACO during the Track 3 ACO's performance year.

Performance Payment and Loss Recoupment Limit

As mentioned above, MSSP ACOs are eligible to receive shared savings payments from CMS. The payment amounts vary depending on which track the ACO chooses and the ACO's quality performance. Track 1 ACOs may receive up to 50 percent of any savings generated by the ACO, with a maximum payment of 10 percent of the ACO's expenditure benchmark. Track 2 ACOs may receive up to 60 percent of any savings generated by the ACO, with a maximum payment of 15 percent of the ACO's expenditure benchmark. Track 2 ACOs are also accountable for between 40 to 60 percent of financial losses under its expenditure benchmark, depending on the ACO's quality performance. A Track 2 ACO's maximum liability for losses increases progressively each performance year from 5 percent of its benchmark in the first performance year to 10 percent during the third performance year.

Under the Final Rule, Track 3 ACOs may share up to 75 percent of the savings they generate, with a maximum possible payment of 20 percent of their benchmark. Track 3 ACOs are liable for between 40 and 75 percent of financial losses but are not liable for losses that exceed 15 percent of their benchmark. The percentage of shared savings and losses will vary depending on a Track 3 ACO's quality performance.

Minimum Savings Rate and Minimum Loss Rate

To share in savings under the MSSP, an ACO must generate a minimum amount of savings, referred to as the "minimum savings rate" (MSR). A Track 2 or Track 3 ACO is not liable to CMS for a share of its financial losses unless its expenditures are greater than its benchmark by a certain minimum amount, known as the "minimum loss rate" (MLR). In the Proposed Rule, CMS proposed to set the Track 3 MSR and MLR at 2.0 percent; however, in response to public comments, the Final Rule allows Track 3 ACOs to choose from one of three MSR and MLR options. Under each option, the MLR must be equal to the negative MSR. First, the MSR/MLR may be zero, meaning the Track 3 ACO will share in savings or losses beginning at the first dollar that is above or below the benchmark. The second option allows a Track 3 ACO to choose an MSR/MLR in 0.5 percent increments between 0.5 and 2.0 percent. Under the third option, the MSR/MLR varies depending on the number of beneficiaries assigned to the Track 3 ACO, in the same manner as the MSR used for Track 1 ACOs. The MSR/MLR will range from a minimum of 2.0 percent for Track 3 ACOs with 60,000 or more beneficiaries to a maximum of 3.9 percent for Track 3 ACOs with 5,000 assigned beneficiaries. Track 3 ACOs must select their MSR/MLR prior to the start of each agreement period and may not alter their choice during the agreement period.

Waiver of the Skilled Nursing Facility Three-Day Rule

To further encourage participation in two-sided risk models, CMS will waive application of the Medicare skilled nursing facility (SNF) three-day rule (SNF Three-Day Rule) for Track 3 ACOs. The SNF Three-Day Rule provides that Medicare will cover a beneficiary's inpatient SNF stay only if the beneficiary has an inpatient hospital stay of at least three consecutive days. The waiver eliminates this three-day inpatient stay prerequisite where a Track 3 ACO provider/supplier admits a prospectively assigned beneficiary to an SNF for otherwise covered services. Track 3 ACOs must apply to CMS for the waiver as part of their initial application process. The waiver will be effective for services provided on or after January 1, 2017.

CMS stated in the Final Rule that it is considering additional waivers, including a telehealth waiver that will be tested under the Next Generation ACO model. CMS stated that a telehealth waiver may be available to ACOs in January 2017.

New Provisions Applicable to Track 2 ACOs and Track 3 ACOs

Lower Track 2 Risk

In contrast to the fixed MSR and MLR currently applicable to Track 2 ACOs, the Final Rule allows Track 2 ACOs with MSSP agreement periods beginning January 2016 or later to choose one of the three MSR/MLR options offered to Track 3 ACOs, described above. Track 2 ACOs must select their MSR/MLR prior to the start of an applicable agreement period and cannot change their selection during that agreement period.

Modifications to Repayment Mechanisms

Track 2 and Track 3 ACOs must establish a repayment mechanism that is adequate to repay 1.0 percent of their expenditure benchmark to demonstrate to CMS the ability to repay potential losses they may owe at the end of a performance year. Prior to the Final Rule, an ACO was required to establish its repayment mechanism at the time it applied to the MSSP and again at the beginning of each performance year. An ACO's annual financial reconciliation is not complete until its next performance year has already begun. ACOs are required to maintain two separate repayment mechanisms — one for the current year and one for the prior year — until the prior year's finances are reconciled.

The Final Rule eliminates the need for duplicate repayment mechanisms by requiring Track 2 ACOs and Track 3 ACOs to establish a single repayment mechanism at the beginning of their three-year MSSP participation agreement. The repayment mechanism must cover shared loss payments during the entire agreement period and for a reasonable time period after the end of the agreement. If a Track 2 or Track 3 ACO uses any portion of its repayment mechanism to repay shared losses to CMS, it must replenish its repayment mechanism within 90 days.

Current MSSP regulations permit an ACO to use the following repayment mechanisms: reinsurance, escrow accounts, surety bonds, lines of credit, or "another appropriate repayment mechanism." The Final Rule eliminates reinsurance or the previously ambiguous "appropriate alternative repayment mechanism" as available options. Under the Final Rule, CMS also clarifies that ACOs may use a combination of the three available repayment mechanisms to demonstrate their ability to repay potential losses.

ACO ELIGIBILITY REQUIREMENTS

Legal Structure and Governing Body

The Final Rule establishes three additional requirements concerning an ACO's governing body. First, its governing body must be the same as the governing body of the legal entity that is the ACO. Second, if the ACO is made up of multiple ACO participants, the governing body may not be identical to the governing body of any single ACO participant. Third, the governing body must satisfy all other requirements set forth in the MSSP regulations, including that it has a fiduciary duty to the ACO. The Final Rule also clarifies that an ACO formed by only one ACO participant may use its existing legal entity and governing body as long as it satisfies the other applicable MSSP governing body requirements. The Final Rule revises current regulations to specifically prohibit an ACO provider/supplier from serving as the beneficiary representative on the governing body.

In the Proposed Rule, CMS planned to eliminate the current regulations that allow an ACO to deviate in certain circumstances from the requirement that 75 percent of its governing body be controlled by ACO

participants. CMS decided not to adopt this proposal in the Final Rule, instead opting to retain the limited exception to the 75 percent requirement; however, CMS stated it will permit such exception in very limited circumstances, such as when an ACO cannot comply with the 75 percent requirement due to a conflict with state law.

Leadership and Management Structure

CMS finalized its proposal to remove the requirement that an ACO's medical director be an ACO provider/supplier. The Final Rule eliminates CMS's ability to approve ACO applications from ACOs that do not strictly meet all MSSP leadership and management requirements. Furthermore, under the Final Rule, MSSP applicants are now required to submit certain documentation to CMS to demonstrate the qualifications of the health care professional responsible for the ACO's quality assurance and improvement program.

Calculation of the Number of ACO Beneficiaries

The MSSP requires that each ACO serve a beneficiary population of at least 5,000. The Final Rule codifies CMS's current practice concerning the calculation of the number of beneficiaries assigned to an ACO in the benchmark year immediately prior to the ACO's first performance year. CMS will continue to calculate an ACO's assigned beneficiaries based on complete claims data for benchmark years one and two, and an estimate for benchmark year three. The estimate is based on claims data from the first nine months of benchmark year three, with a three-month claims run-out, combined with claims data from the last three months of benchmark year two. The Final Rule also permits CMS discretion on whether to institute remedial action against or to terminate an ACO whose number of assigned beneficiaries falls below 5,000 during a performance year.

Furthermore, the Final Rule codifies current CMS guidance permitting ACOs, for the purpose of beneficiary assignment and historical benchmarking, to include claims and attribute billings of entities that an ACO participant acquires through a purchase or merger. CMS's guidance requires that (1) the ACO participant completely absorb the acquired entity's taxpayer identification number (TIN), (2) all providers and suppliers reassign their Medicare payment rights to the ACO participant's TIN, (3) the acquired entity cease billing Medicare using its TIN, (4) the ACO include the acquired entity's TIN on the ACO participant list, and (5) the ACO submit to CMS documentation that demonstrates the ACO participant's acquisition.

Under the Final Rule, ACOs may also annually request that CMS include claims submitted by TINs of entities acquired by ACO participants. CMS is planning to publish more detailed information on the manner, format, and timelines of such requests.

BENEFICIARY ASSIGNMENT METHODOLOGY

CMS assigns beneficiaries to ACOs using a two-step process based on beneficiaries' historical utilization of "primary care services" furnished by primary care physicians. A beneficiary who receives the plurality of primary care services over the previous year from an ACO's physicians is assigned to that ACO under step 1 (Step 1). A beneficiary not assigned under step 1 is assigned under step 2 based on primary care services received from all of an ACO's professionals, including nurse practitioners, physician assistants, and certified nurse specialists (collectively, nonphysician practitioners) (Step 2).

Revisions to the Definition of "Primary Care Services"

The Final Rule expands the definition of primary care services to include transitional care management services following a patient's discharge from a hospital or an SNF and chronic care management services for patients with two or more chronic conditions. The Final Rule revises Step 1 to include services provided by nonphysician practitioners.

The Final Rule further revises current regulations to exclude from the beneficiary assignment process certain physician specialties, such as surgeons, anesthesiologists, dermatologists, and radiologists even

if such physicians provide primary care services. As a result, physician groups composed of these specialists are able to participate in multiple ACOs. The beneficiary assignment methodology continues to include services that psychiatrists, pediatricians, and osteopaths provide.

CMS will use the revised assignment methodology described in this section for ACO operations beginning in performance year 2016.

ACO PARTICIPATION AGREEMENT REQUIREMENTS

Renewal Process

The Final Rule establishes a process by which an ACO may renew its participation agreement and continue participation in the MSSP for an additional three-year period without interruption. It directs CMS to determine whether to renew an ACO's participation agreement based on a number of performance factors, including the ACO's history of compliance with MSSP requirements, whether the ACO met the quality performance standards during at least one of the first two years of the previous agreement period, and, if applicable, whether the ACO repaid its losses to CMS.

Termination Process

The Final Rule requires that an ACO perform certain closeout procedures with CMS when terminating its participation in the MSSP. ACOs that voluntarily terminate their participation agreement prior to the end of the agreement period may still receive shared savings payments, provided certain requirements are met. The Final Rule also allows CMS the ability to terminate an ACO from the MSSP if it does not timely comply with CMS's document requests or submits false or fraudulent data.

Care Coordination

CMS requires that an ACO applying to the MSSP describe in its application how it will promote using technology to improve care coordination for beneficiaries. The Final Rule also requires that ACO applicants describe their plans for partnering with long-term and post-acute care providers to improve care coordination for assigned beneficiaries. Notably, CMS did not include in the Final Rule its proposal to mandate that each ACO define and submit to CMS milestones related to implementing its care coordination procedures.

Changes to MSSP Requirements During an Agreement Period

Currently, MSSP ACOs are subject to all changes made to the MSSP regulations that become effective during an ACO's agreement period except changes to (1) the eligibility criteria related to the ACO structure and governance, (2) the calculation of the shared savings rate, and (3) the beneficiary assignment process. The Final Rule removes as an exception regulatory changes that affect beneficiary assignment. All ACOs, therefore, even those in the middle of an agreement period, are subject to regulatory changes regarding beneficiary assignment; however, such changes do not become effective until the beginning of the performance year following the regulation's effective date.

ACO PARTICIPANTS AND PROVIDERS/SUPPLIERS

Reporting Requirements

Under the Final Rule, CMS requires ACOs to comply with additional requirements and processes when maintaining, updating, and submitting to CMS their ACO participant and ACO provider/supplier lists. Currently, each ACO must annually provide CMS with a complete list of ACO participants and their TINs, as well as a list of its providers/suppliers, including their national provider identifiers (NPIs). The Final

Rule still requires ACOs to annually submit to CMS a list of ACO participants and their TINs; however, CMS will provide the ACO with a list of NPIs associated with each ACO participant, and the ACO must certify that the CMS-provided list is correct and, if necessary, make revisions to the list.

The Final Rule also requires that each ACO report to CMS within 30 days of any changes in the Medicare enrollment status of its ACO participants and ACO providers/suppliers or of termination of any ACO participant agreement. Further, if an ACO intends to add an ACO participant, it must obtain CMS's approval of the addition. The addition of an ACO participant is effective at the beginning of the performance year following CMS's approval. Following an approved change in an ACO's participant list, CMS will adjust an ACO's historical benchmark, assignment, quality reporting sample, and obligation to report on behalf of certain eligible professionals.

Content of ACO Participant and ACO Provider/Supplier Agreements

The Final Rule codifies CMS guidance on the content of ACO participant and ACO provider/supplier agreements, which are applicable to agreements submitted to CMS for the 2016 MSSP performance year. In addition to provisions set forth in the current CMS guidance, the Final Rule requires ACO participant and ACO provider/supplier agreements to contain the following provisions:

- The ACO participant must agree to update its enrollment information within 30 days of adding or deleting a provider/supplier.
- The term must be for at least one MSSP performance year (except that agreements directly between the ACO and providers/suppliers may be for less than one year).
- The agreement must require the ACO participant to complete a closeout process upon termination or expiration of the agreement.
- The agreement must permit the ACO to take remedial action against the ACO participant and require the ACO participant to take remedial action against ACO providers/suppliers for noncompliance with applicable laws and regulations.

As part of the application process and upon request, an ACO must submit to CMS documentation showing that ACO participants and providers/suppliers are required to comply with the MSSP requirements. This documentation may include copies of the agreements among the ACO, ACO participants, and providers/suppliers.

ADDITIONAL HIGHLIGHTS OF THE PROPOSED RULE

Data Sharing and Opt-Out

Under current MSSP regulations, CMS may provide each ACO with certain data related to its assigned beneficiaries, including claims data identifying assigned beneficiaries. Beginning with the 2016 performance year, the Final Rule allows CMS to share with an ACO information relating to any beneficiary, even if the beneficiary is not assigned to the ACO, as long as the beneficiary receives a primary care service from an ACO participant and the beneficiary assignment process considers such service in the previous year. With respect to preliminarily prospectively assigned beneficiaries, CMS may also provide ACOs the minimum data set necessary for the ACO to conduct certain population-based activities. Examples of such data include demographic, risk profile, and utilization information. Track 3 ACOs may only receive information concerning their prospectively assigned beneficiaries for the particular performance year.

Beginning November 1, 2015, CMS will institute a streamlined process whereby beneficiaries may opt out of sharing their claims data by contacting CMS directly, as opposed to opting out through the ACO as is currently required.

Public Reporting

The Final Rule creates a requirement that ACOs maintain a web page on which it must report certain information. CMS will make a template available for ACOs to report such information. Additionally, the Final Rule requires ACOs to publicly identify key clinical and administrative leaders, as well as the types of the ACO's participants or combinations of participants. It also requires ACOs to publicly report their performance on all quality measures used to assess the quality of care furnished by the ACO.

Beneficiary Attestation

In the Proposed Rule, CMS solicited comments on adding a process by which beneficiaries can attest to voluntarily align themselves with ACOs. While the Final Rule does not adopt beneficiary attestation, CMS noted that it is testing beneficiary attestation in the Pioneer ACO model and the Next Generation ACO model.

CONCLUSION

The option for ACOs to participate in an additional Track 1 agreement period may allow some ACOs unwilling to take on downside risk to remain in the MSSP. Similarly, the revisions to the MSR and MLR under Track 2, as well as the SNF Three-Day Rule, may provide sufficient incentive for ACOs to enter a two-sided risk model. ACOs may also consider encouraging certain physician specialty groups to join their ACO, as the Final Rule relaxed the requirements related to physician/ACO exclusivity. Finally, ACOs currently participating in the MSSP may have to slightly change the composition of their governing bodies to comply with the new requirements of the Final Rule.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

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