CMS RELEASES FINAL MEDICARE SHARED SAVINGS PROGRAM RULE

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Health Care Alert

By: Trevor P. Presler, Jon S. Zucker, Richard P. Church, Steven G. Pine

On June 9, 2015, the Centers for Medicare and Medicaid Services ("CMS") published a Final Rule that provides substantial new flexibility for Medicare Shared Savings Program ("MSSP") Accountable Care Organizations ("ACOs").[1] The Final Rule is intended to encourage continued participation in the MSSP ACO program, motivate ACOs to bear greater performance-based risk, address program sustainability, and streamline and clarify certain administrative processes for program participants. Much of the Final Rule goes into effect August 3, 2015, although certain provisions will not be effective until 2016 or 2017. Providers seeking to apply for or already participating in the MSSP program should become familiar with these new requirements. This *Client Alert* provides an overview of some of the important changes ushered in by the new rule.

Most important among those changes:

- Track 1: ACOs already participating in the Track 1 shared savings model with no downside risk—a category that includes 401 of the 404 MSSP ACOs participating in the program as of April 2015[2]—will have the ability to re-enroll in Track 1 for an additional three-year period.
- Track 2: ACOs may select their own approach to the minimum savings rate and minimum loss rate, which they must meet or exceed for the ACO to be eligible to share in savings or be accountable for losses.
- Track 3: Beginning January 1, 2016, ACOs may participate in a new Track 3 model, which provides for sharing of 75% of any shared savings earned in exchange for greater assumption of downside risk in conjunction with key program changes, including prospective assignment of beneficiaries and a waiver of the Skilled Nursing Facility ("SNF") three-day qualifying hospital stay rule.
- Change to the Benchmarking Methodology: the Final Rule implemented changes to the benchmarking methodology to reduce the impact of achieved savings in prior performance years, which had been a major concern of providers. CMS will weigh the prior three years equally under the Final Rule, and will also add earned shared savings back into the revised benchmark. Under the current rule, CMS has used a weighted average, which weighed most heavily the prior year's performance, meaning savings achieved by ACOs were immediately and disproportionately held against them in attempting to achieve savings in future MSSP performance years.

BACKGROUND ON THE MEDICARE SHARED SAVINGS PROGRAM

Over the last four years, the number of Medicare payments that were made through alternative payment models

has climbed from 0% to 20%, and the Secretary of Health and Human Services announced earlier this year the goal of reaching 50% by 2018.[3] MSSP ACOs—authorized pursuant to the Affordable Care Act and codified at Section 1899 of the Social Security Act—are integral parts of this goal.

An ACO is a group of health care providers that coordinate to provide services for a population of Medicare beneficiaries in order to provide high-quality care in a cost-effective manner. ACOs that meet certain cost and quality targets receive a portion of the shared savings that result from the ACO's activities. MSSP ACOs are accountable for the cost, quality, and care of the Medicare fee-for-service ("FFS") beneficiaries who receive the preponderance of their primary care services from ACO providers, and must serve at least 5,000 affiliated FFS Medicare beneficiaries and participate in the program for a minimum of three years.

Under the Final Rule implementing the MSSP (released in November 2011),[4] MSSP ACOs have to date been able to select from two incentive models. In Track 1, participants are potentially eligible to receive up to 50% of the shared savings achieved while bearing no shared risk. This track was initially open only for a single three-year term, and was seen as a bridge necessary to allow participants to build the experience and infrastructure needed to take on shared risk. In Track 2, ACOs have an opportunity to receive up to 60% of the share savings, but in turn must agree to bear a portion of the downside risk if the costs for its beneficiaries exceed certain benchmarks.

Although the MSSP has grown to include more than 400 participating ACOs, it has not demonstrated a uniform capacity to generate sustained cost savings. With the expiration of the initial three-year cycle and the mandatory requirement to switch to Track 2 upon renewal for a second term, many observers expected to see an exodus of current Track 1 participants who were not yet prepared to assume downside risk in Track 2. Accordingly, CMS issued a Proposed Rule in December 2014 addressing this and other concerns.[5] The Final Rule codifies much of the 2014 Proposed Rule, and is designed to streamline MSSP administrative processes and improve program function in several areas. A summary of some of the key changes follows.

CHANGES TO FINANCIAL PERFORMANCE TRACKS

Extension of One-Sided Risk Model

Prior regulations required that ACOs participating in Track 1—which allows for upside shared savings payment with no risk of shared losses—transition to a performance-based, two-sided risk model at the end of their the initial three-year agreement period. The Final Rule permits qualifying Track 1 ACOs to participate in an additional three-year agreement period under Track 1. The new regulations, codified at § 425.224, provide that the additional period will only be available to ACOs that have met the quality performance benchmarks in at least one of the first two years of the initial three-year agreement term and are otherwise in good standing with the MSSP. ACOs that renew their participation in Track 1 will continue to be eligible for 50% maximum shared savings rate, as CMS did not incorporate the provision from the Proposed Rule that would have lowered the maximum shared savings rate to 40% for renewing Track 1 participants.

Modifications to Track 2

In each performance year, CMS determines an updated benchmark based on the ACO's historical per capita expenditures for Medicare fee-for-service beneficiaries for Parts A and B services as compared to national per

capita expenditures.[6] In order to qualify for a shared savings distribution in a given performance year—or to be held responsible for shared losses— a Track 2 ACO's average per capita Medicare expenditures for Parts A and B fee-for-service beneficiaries must be lower or higher than the benchmark, respectively. Currently, the minimum savings rate ("MSR") and minimum loss rate ("MLR") for Track 2 ACOs is set at a flat rate of 2%.

The Final Rule modifies Track 2 to allow ACOs to choose from one of three options for establishing their MSR/MLR:

- 0% (i.e., the ACO would share in savings or losses based on any deviation around the updated benchmark);
- A symmetrical MSR/MLR between 0.5% and 2% percent, selected by the ACO in 0.5% increments; or
- A symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries using the methodology established for Track 1.

This flexible approach is also extended to ACOs participating in Track 3 described below. For both Track 2 and Track 3, ACOs must select their MSR/MLR prior to the start of each performance period, and may not change their selection during the performance year.

Creation of New Risk Bearing Track 3

In addition to extending Track 1, the Final Rule adds a new performance-based risk model: Track 3. This new track offers a higher sharing rate than Tracks 1 and 2, but holds ACOs responsible for a greater percentage of costs in the event there are shared savings losses.

Track 3 also introduces a number of key concepts that ACOs have generally argued would increase their ability to achieve the triple aim of the MSSP. Track 3 prospectively assigns ACO beneficiaries in advance of the performance year rather than basing assignment on a preliminary assignment followed by a retrospective reconciliation. Prospective assignment provides an ACO with clarity on the exact patient population they will be responsible for during an assignment period and can help ensure that care coordination efforts are aligned with the ACO's beneficiaries' needs.

Track 3 also provides ACOs with an opportunity to obtain a waiver from the SNF three-day qualifying hospital stay rule for services furnished on or after January 1, 2017. Track 3 ACOs must specifically apply for this waiver, and in the application process the ACO must demonstrate that the waiver will be implemented in a manner that ensures Medicare program integrity concerns are addressed. CMS chose not to finalize other proposed waivers at this time, including waivers of certain telehealth service requirements, the homebound requirement for home health, or waiver conditions of participation related to discharge planning and referrals to post-acute care settings. In this regard, CMS stated it will explore whether to provide additional waivers in future rulemaking, after it obtains data on the success of these waivers in other demonstration projects, including the ACO Next Generation Model.

CMS stated that in future rulemaking it may consider allowing an ACO to split its participants between two different risk tracks, allowing participants prepared to bear additional risk to move in the higher tracks, while other participants remain in the lower track.

A link to CMS's chart summarizing the changes to Track 1 and 2 and outlining the new Track 3 is available at the end of this Client Alert.

CHANGES TO ACO IMPACTING PERFORMANCE CALCULATIONS

Financial Benchmarking

The Final Rule implements certain CMS proposals for recalibrating an ACO's benchmark at the start of its second or subsequent agreement period. The key change addresses a significant concern, particularly for risk-sharing tracks, that any shared savings earned in early years of the MSSP would be subject to future repayment as a result of the failure to meet future savings targets. In this regard, under the current rule, an ACO's benchmarked spending was determined based on weighting the three prior measurement years at 10%, 30%, and 60%. Accordingly, savings achieved in the most recent year disproportionately adjusted the ACO's target in future years. Under the Final Rule, CMS will weight these years equally to reduce the impact of the most recently achieved savings on future targets.

In addition, CMS will account for and add back in earned shared savings payments when calculating an updated benchmark. Under the new methodology, CMS will calculate an average per capita amount of shared savings generated during the performance period, which is added to the rebased benchmark. This change will help protect providers that are successful in achieving shared savings during a performance period from facing a lower benchmark in the next period, due to those savings.

Finally, CMS reiterated its intent to initiate rulemaking later this year to further revise the benchmarking methodology to: 1) hold ACOs accountable for beneficiaries who have self-designated the ACO's practitioners as being responsible for their care; and 2) place greater emphasis on regional trends in FFS costs rather than benchmarking the ACO solely against the beneficiary expenses associated with its assigned beneficiaries. These planned changes track similar features in the Next Generation ACO model that CMS announced earlier this year, and are designed to address ACO sustainability.[7]

Assignment of Medicare FFS Beneficiaries

Beneficiaries are assigned to MSSP ACOs on the basis of the beneficiary's utilization of primary care services provided by a health care professional affiliated with the ACO. "Assignment" in this context refers to Medicare's methodology for determining whether an ACO can be said to exercise basic responsibility for the beneficiary's care, which in turn is a function of whether a beneficiary has received a threshold level of primary care services from the ACO's participating providers. Assignment is then used by CMS to determine whether the ACO qualifies to participate in the MSSP by having responsibility for 5,000 Medicare beneficiaries and to calculate the ACO's ultimate financial performance, as these assigned beneficiaries are then used for benchmarking and performance purposes.

The previous methodology used a two-step process to assign beneficiaries to an ACO. Step One reviewed all primary care services rendered by a primary care physician over the prior performance year, and assigned to the ACO the beneficiaries who had received more than 50% of their primary care services (by cost) by a primary care physician affiliated with that ACO. Any lives not assigned under Step One could still be assigned to the ACO if: 1) the beneficiary received at least one primary care service from an ACO-affiliated physician; 2) the beneficiary

received no primary services directly from any primary care physician; and 3) the allowable charges for the beneficiary's primary care services provided by the ACO's providers/suppliers exceed those provided by another ACO's providers and from other Medicare-participating providers.

The Final Rule increases the emphasis on primary care services in the beneficiary assignment methodology in several ways:

- It removes services-whether coded as primary care or not-provided by certain specialties, such as palliative care physicians, from the analysis to narrow the focus to actual primary care services provided by primary care specialties. The change means physician practices exclusively providing services in these specialties can now participate in multiple MSSP ACOs without fear of running afoul of the requirement that practice Tax Identification Numbers ("TINs") must be exclusive to one MSSP.
- It expands the definition of primary care services at 425.20 to include certain new Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes for transitional care management and chronic care management.
- It amends §425.402(a) to include claims for primary care services furnished by non-physician providers (i.e., Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists) in Step One the beneficiary assignment methodology.

This new methodology will be used beginning in performance year 2016.

Finally, while not codified in the Final Rule, CMS stated that in future rulemaking it intends—for Track 2 and Track 3 ACOs only—to allow beneficiaries to attest that a physician is their main doctor and request to be assigned to the ACO in which that physician is participating regardless of CMS's assignment methodology.

CHANGES TO ACO DATA SHARING

Additional Data Sharing

Recognizing that access to patient information is important for care coordination across multiple sites and settings of care, (e.g., outpatient, acute, and post-acute), CMS is placing a greater emphasis on real-time data sharing. Going forward, MSSP applicants will be required to describe how they will encourage and promote the use of technologies to improve care coordination. Enabling technologies might include greater use of electronic health records and other information technologies (e.g., population health management and data aggregation and analytic tools), and greater opportunities for beneficiaries to access patient engagement tools such as telehealth services (including remote patient monitoring) and health information exchange services.

CMS has also expanded the group of beneficiaries for which it will provide data to ACOs to better ensure that ACOs have access to claims data on all FFS participants who may be assigned to the ACO at the end of the year. Therefore, beginning January 1, 2016, ACOs participating in Tracks 1 and 2 that meet the requirements for data sharing will be able to request beneficiary identifiable claims data at the start of the ACO's agreement period for beneficiaries who: 1) are included on their preliminary prospective assigned beneficiary list; or 2) have received a primary care service from an ACO participant upon whom assignment may be based during the most recent 12-month period. Track 3 ACOs will be able to request beneficiary identifiable claims data for all beneficiaries who are included on their prospectively assigned beneficiary list.

Beneficiary Opt-Out Rules

Currently, prior to requesting access to a beneficiary's claims data, an ACO is required to inform the beneficiary that it may request access to their claims data, and give the beneficiary an opportunity to decline such data sharing by contacting the ACO, which significantly slows the initial release of beneficiary data to an ACO. The Final Rule eliminates the requirement that the ACO mail notifications to beneficiaries prior to accessing claims data. Instead, the Final Rule modifies §425.112 to allow beneficiaries to use 1-800-MEDICARE to obtain more information about ACOs and claims data sharing and to opt out of such data sharing if they so desire. However, the Final Rule retains the requirement that ACO participants must notify beneficiaries at the point of care that the providers and suppliers are participating in the MSSP.

CHANGES TO ACO ELIGIBILITY AND PARTICIPATION REQUIREMENTS

CMS codified existing guidance and provided additional clarity on a number of key requirements related to the eligibility, enrollment and operations of ACOs. Included are these key changes:

- Codification of guidance on ACO participant agreements, enumerating the requirements for agreements between an ACO and an ACO participant or an ACO provider/supplier;
- Consolidation and revisions of the existing regulations regarding the requirements for maintaining and reporting ACO participant and ACO provider/supplier lists, and preventing the addition of new ACO participants until the start of the following performance year;
- Revisions allowing greater flexibility to address situations in which an ACO's beneficiary enrollment falls below the mandatory minimum of 5,000 beneficiaries;
- Modifications to clarify CMS' authority to determine when an ACO has experienced a significant change (even when the ACO has failed to make the required notification);
- Codification of existing guidance on the treatment of claims billed by merged or acquired TINs;
- Clarification that an ACO formed by two or more ACO participants, each identified by a unique TIN, must be a distinct legal entity;
- Revisions to ACO governing board requirements, including duties owed by ACO board members that ultimately prevent an ACO from including participants in the ACO that do not participate in the MSSP (but do, for example, participate in commercial contracting); and
- Addition of new eligibility requirement that an ACO prospectively identify and describe its methods of promoting patient care coordination.

IMPLICATIONS

The Shared Savings Program is by far Medicare's most popular alternative payment model. The program's ultimate success will likely hinge on the ability of the Track 1 ACOs, which account for 99% of the program's

current participants, to transition to a shared risk model in future years. Without a clear demonstration of uniform shared savings, however, many of the program's ACOs were expected to exit rather than take on exposure to downside risk.

The Final Rule grants these ACOs—and perhaps the MSSP ACO model—a reprieve by extending the Track One option for an additional cycle. Further, CMS's changes to Track 2 and the benchmarking methodology are designed to encourage ACOs to have more confidence to take on Track 2 downside risks. However, ACOs must weigh whether CMS has done enough to convince them to remain in the MSSP when facing the potential of being responsible for shared losses on patient population that is utilizing an open network and not ultimately determined until the end of performance year. The addition of a new Track 3, including prospective assignment of beneficiaries, is a key acknowledgement that further changes may be required.

In addition to these strategic financial questions, providers contemplating participating in the MSSP or those already participating in it should carefully review with counsel the changes to MSSP eligibility and participation requirements, as changes implemented in the Final Rule will become effective on a rolling basis starting as early as August of 2015 and continuing through January 1, 2017. Existing MSSP organizational documents and structures, contracts, and policies may need to be updated to remain in compliance with these changes.

Click here to download CMS's chart summarizing the changes to Tracks 1 and 2 and outlining the new Track 3.[8]

NOTES:

[1] *See* Medicare Shared Savings Program: Accountable Care Organizations (Updated Rule), 80 Fed. Reg. 32,692 (June 9, 2015) (to be codified at 42 C.F.R. pt. 425).

[2] *See* Center for Medicare & Medicaid Services, FAST FACTS - All Medicare Shared Savings Program ACOs (April 2015), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/All-Starts-MSSP-ACO.pdf.

[3] *See Better, Smarter, Healthier: Health Care Payment Learning and Action Network kick off to advance value and quality in health care*, U.S. Department of Health & Human Services (March 25, 2015), *available at* http://www.hhs.gov/news/press/2015pres/03/20150325b.html.

[4] Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802 (Nov. 2, 2011).

[5] Medicare Shared Savings Program: Accountable Care Organizations (Updated Rule), 79 Fed. Reg. 72,762 (proposed Dec. 8, 2014) (to be codified at 42 C.F.R. pt. 425).

[6] The ACO's benchmark is reset at the beginning of each period. The initial benchmark is determined using a formula that adjusts for historical growth and beneficiary characteristics, including health status.

[7] When announcing its launch of the Next Generation ACO model, CMS included measures that would address concerns about ACO sustainability by de-emphasizing recent ACO costs, and by rewarding attainment of cost and quality measures rather than continued improvements on those scores. For more information on the Next Generation ACO model, see http://www.klgates.com/cms-announces-the-next-generation-of-accountable-care-organizations-aimed-at-increased-risk-sharing-and-program-sustainability-04-09-2015/.

[8] Adapted from 80 Fed. Reg. 32,692 at 32,811-32,812.

