# PUBLICATION

## Medicare Shared Savings Program - 2015: What's Changed, What's New, and What's to Come? [Ober|Kaler]

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**The most recent Shared Savings Program final rule, published in the *Federal Register* on June 9, 2015, finalizes a number of the revisions to the original November 2011 final rule that CMS proposed on December 8, 2014. In addition to finalizing its proposals, CMS introduced new concepts, including a "Track 3" model, and made promises of things to come, such as a waiver for 3-day SNF stays and accommodations for telemedicine. Overall, CMS's purported goal of the final rule is to encourage continued and enhanced participation in the Medicare Shared Savings Program (MSSP) and to reduce ACOs' administrative burdens, which CMS hopes will allow ACOs to meet their goal of the triple aim.**

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Below is a summary of "What's Changed," "What's New" and "What's to Come."

## What Has Changed

### Definitions

CMS revised several definitions used with the MSSP regulations. Some of the more significant of those revisions follow.

- CMS made clarifying changes to distinguish a *participant agreement*, which is the agreement between an ACO and CMS, from an *ACO participant agreement*, which is the agreement between an ACO and an ACO participant.
- The definition of *ACO participant* has been revised to clarify that it is an entity identified by a tax identification number (TIN) that is associated with a Medicare enrollment, or a "Medicare-enrolled TIN."
- An *ACO professional* is now defined as someone who furnishes services billed through an ACO participant's TIN in the performance or benchmarking years but is not necessarily an *ACO provider/supplier*.
- The definition of *ACO provider/supplier* was revised to clarify that such term only applies to an individual or entity that, while enrolled in the Medicare program, bills for items and services furnished to Medicare FFS beneficiaries during the participant agreement period under a Medicare billing number assigned to the TIN of an ACO participant, and is included on the list of ACO providers/suppliers required by the MSSP regulations.
- The definition of *hospital* is revised to clarify that hospitals in Maryland, though subject to waiver from Medicare payment methodologies, are considered hospitals for purposes of the MSSP.

## ACO Participant Agreements

- CMS finalized its proposal to require ACO participant agreements to meet certain criteria:
  - The agreement is only between the ACO and the participant (no third parties).
  - The agreement must be signed by those authorized to bind each party to the other.
  - The agreement must **specifically state** that the ACO participant agrees, and agrees to require each ACO provider/supplier to agree, to participate in the MSSP and comply with the MSSP's requirements.
  - An ACO participant's obligations must include an obligation to update Medicare enrollment information with its Medicare Administrative Contractor (MAC), including the addition/deletion of ACO professionals through the TIN.
  - An ACO participant is required to notify the ACO within 30 days after any addition or deletion of an ACO provider/supplier. CMS considers this a reasonable requirement, as it aligns with the participant's Medicare enrollment obligations.
  - The agreement must allow the ACO to take remedial action for an ACO participant's noncompliance.
  - The agreement's term must be for at least one year (though an agreement between an ACO participant and an ACO provider/supplier need not reflect a one-year term).
  - The agreement must include close-out provisions that require the parties to exchange data for purposes of quality and outcome assessment.
- ACOs must now submit their ACO participant agreements with their initial applications. CMS noted that, while it will not routinely request copies of an ACO participant agreement or agreement between a participant and an ACO provider/supplier thereafter, it reserves its right to do so to ensure all parties have agreed to comply with the MSSP requirements.
- ACOs that submit requests to add ACO participants for inclusion on the 2017 performance year list of ACO participants will be required to have an ACO participant agreement that meets these new requirements.

## Number of Beneficiaries

CMS finalized a proposal that allows it to exercise discretion in requiring corrective action from ACOs whose beneficiary numbers fall below 5,000. As an example of the application of this discretion, CMS noted that a corrective action plan may not be necessary in the case of an ACO whose beneficiary number has fallen below 5,000 if that ACO has submitted a request to add more ACO participants in the next performance year. The assumption there is the additional participants will create additional beneficiaries.

## Reporting Changes

- **ACO participants and ACO provider/supplier list.** CMS finalized its proposed process for maintaining, updating and submitting the ACO participant and ACO provider/supplier list. CMS does not feel such changes to the process will be burdensome, as they align with all Medicare providers' obligations to notify their MACs as to certain enrollment changes:
  - Prior to the start of the agreement and each performance year after that, ACOs must provide a complete list of ACO participants and TINs in form and manner specified by CMS. The additions to the ACO participant list must be approved by CMS before they can become effective on January 1st of a performance year. In addition ACOs must notify CMS within 30 days after the termination of an ACO participation agreement, though such removal will not affect program calculations (benchmarks, performance metrics, etc.) for the remainder of the performance year.
  - Similarly, an ACO must report any changes in ACO provider/suppliers to CMS within 30 days after the change.

  - In addition, CMS finalized its proposal to require that an ACO ensure its participants and providers/suppliers update their enrollment status properly in PECOS in accordance with the Medicare enrollment rules.
- **ACO Changes.** An ACO must notify CMS of its own significant changes, such as a change in ownership, within 30 days after the change. CMS did hint that it may consider requiring such notice in advance of a change in organizational structure, but is not doing so at this time.
- **Merged Entities.** Finally, CMS will consider an ACO's requests for a combined review of claims submitted by Medicare enrolled TINs of acquired entities or merged entities. Future guidance and operational documents will explain the process for such requests.

## Legal Structure and Governance

CMS clarified some details regarding the required governance of an ACO, which in part ensures the creation of an appropriate fiduciary relationship between the governing body and ACO. For example, when two or more participants that have separate TINs form an ACO, the ACO must be a separate legal entity from any of such participants. However, in the case of a single-participant ACO, that participant can utilize its existing governance structure as the governance structure for the ACO, provided it satisfies all other requirements applicable to a governing body, such as meeting the fiduciary obligations, which CMS clarified to include the duty of loyalty.

CMS believes the fiduciary obligation requirement may present a challenge to a governing body that is responsible for governing activities of entities that do not participate in the ACO. As an example, CMS cited to an IPA that wants to become an ACO but only some of whose affiliated group practices want to become ACO participants. CMS envisioned it would be difficult for the existing IPA's governing structure to govern and uphold its fiduciary duty to the ACO while also having the same obligations for each group practice—those participating and those not participating.

Other revisions related to an ACO's legal structure and governance include:

- **Governing Body Composition.** CMS revised the governance rules to expressly emphasize the need for “shared governance.” CMS continues to want to see ACOs incorporate beneficiary representation, but is not willing to allow a provider or supplier to constitute the beneficiary representative on the governing body. Though CMS initially had proposed to remove the regulatory flexibility given to ACOs in meeting the 75 percent requirement for ACO participant control of the governing body, it decided against doing so in the final rule
- **Management.** CMS added flexibility to the medical director requirement by amending it to allow that the medical director need not be an ACO participant or ACO provider/supplier. However, the person appointed this position must still have some connection with the ACO, e.g., familiarity with its operations and clinical processes and intimate knowledge of its organizational structure. CMS will continue to request information regarding the leadership and management in ACO applications to ensure all requirements are met, such as the qualifications and credentials of the required qualified health care professional who is responsible for the ACO's quality assurance and improvement program. CMS removed the provision allowing an ACO to request entry into the MSSP without satisfying certain operations and clinical management requirements.

## Participation Agreements with CMS

- **Application Review.** In response to its perception that some applicants misunderstood the application process, CMS made clarifying changes in the regulations related to its review and approval/denial of an application. Specifically CMS emphasized that its review is based on information received, information CMS requests and other information available to CMS, such as that

related to an ACO's integrity history. CMS has also added a provision that allows it to deny an application if the applicant fails to submit information by the CMS imposed deadlines.

- **Participant Agreement Renewal.** CMS finalized its proposed process for renewing participant agreements to require the submission of only a renewal request prior to termination, as opposed to filing a new or shortened application. CMS belives this process will be more streamlined and less burdensome. The time, form and manner of the renewal request will be set forth in CMS guidance. CMS will review and approve/deny a renewal request based on the ACO's satisfaction of the criteria for operating an ACO, its history of compliance with the MSPP requirements, its compliance with eligibility requirements, its satisfaction of quality performance standards, the results of a program integrity screening and whether it repaid losses under the Two-Sided model.
- **Compliance Requirements.** CMS clarified that ACOs must comply with regulatory changes that occur during the participant agreement period, except for those related to governance and the sharing rate. While changes to beneficiary assignment previously did not impact an ACO during its agreement period, CMS has removed that exception and changes to beneficiary assignment now will apply to ACOs, even if such changes occur mid-term. In addition, to address an ambiguity in the previous definition of agreement period that would have allowed ACOs to indefinitely avoid compliance with changing governance and sharing calculation structures, CMS revised the definition of agreement period to include three performance years. Thus, when the clock "resets" at the beginning of a new agreement period, an ACO will be subject to regulatory changes regarding governance and sharing that became effective during the previous three-year agreement period.

## Provision of Aggregate and Beneficiary Data

CMS continues to believe that each ACO must independently identify and produce its own beneficiary data in order to evaluate, improve and monitor its patient population health, to understand its population and to help its patients address their needs. However, CMS recognizes that the information an ACO has is limited in that the data only relates to services and care provided by its own ACO providers/suppliers, and that additional information would enable an ACO to achieve its patient care goals. Accordingly, CMS finalized some proposed regulatory revisions which will allow ACOs to obtain a broader scope of information:

- **Beneficiary Data.** ACOs in Tracks 1 and 2 may receive data on all beneficiaries who had a primary care service visit during the prior 12 months with an ACO participant who submitted claims for services considered in the assignment process. Further, the scope of information was also expanded to include information related to demographics, health status, utilization rates of Medicare services and expenditures. ACOs in Track 3, described below, are limited to the data related to prospectively assigned beneficiaries.
- **Claims Data.** CMS will also begin sharing beneficiary identifiable claims data with ACOs upon request. With regard to Track 1 and 2, such data, similar to above, will be related to beneficiaries who are included in an ACO's preliminary prospective assigned beneficiary list or who have received primary care services from an ACO participant upon whom assignment is based during the recent 12 months. ACOs in Track 3 may receive such claims data, but it will be limited to data for beneficiaries in their prospective assignment list.
- **Beneficiary Opt-out.** Beneficiaries will be reminded of their ability to restrict claims sharing data in a sufficient amount of time in advance of these changes becoming effective on January 1, 2016. However, beneficiaries may opt-out only by contacting CMS, not the ACO.

## Beneficiary Assignment

- **Beneficiary Assignment Process.** CMS codified its criteria for assigning a beneficiary to a specific ACO to require that the beneficiary: (1) has at least one month of Medicare Part A and Part B enrollment and no months of only Part A or B enrollment; (2) does not have any month of Medicare

group or private enrollment, and (3) is not assigned to any other Medicare Shared Savings initiative and lives in the U.S. or U.S. territories

- **Primary Care Services.** The final rule's provisions related to beneficiary assignment also update the definition of primary care services to include both transition care management (TCM) codes and chronic care management (CCM) codes. Any future revisions to this definition will be through the physician fee schedule rule-making.
- **Two-step Method Revised.** CMS finalized its proposal to include claims for services furnished by nurse practitioners, physician assistants and clinical nurse specialists under Step 1, which identifies all primary care services rendered to a beneficiary during the prior 12 months or performance year. Step 2, which reviews the scope of primary care services received by a beneficiary, now excludes services provided by certain specialties including allergy/immunology, gastroenterology, hospice and palliative medicine, infectious diseases, rheumatology and interventional cardiology. CMS hopes this addresses the concern that certain specialists billing for E&M codes will be viewed as rendering primary care services and assigned to that ACO. The goal of the change was to provide a better picture of the scope of primary care services.
- **ACOs Including FQHCs, RHCs, CAH or ETA Hospitals**

  - FQHCs and RHCs – Because these hospitals do not bill for physician services, to identify beneficiaries assignable to an ACO,CMS is utilizing a physician attestation by which an ACO identifies the names and NPIs of the physicians who provide direct patient primary care services to its FHCQ or RHC participants.
  - With regard to CAHs,CMS did not finalize any change but noted it would continue considering the process necessary related to the assignment methodology. More on this is to come.

## What's New

### Changes to Application Submissions to Encourage Care Coordination

- CMS finalized a new MSSP eligibility criterion that requires ACOs to describe, in their applications, how they will promote the use of technologies in their coordination of care efforts. Examples include EHR, telehealth, health information exchange services.
- CMS also finalized a requirement that ACO applicants describe their intentions to partner with long term care and post acute care providers for improved care coordination. (See the discussion of the SNF 3-day rule waiver below. ) While CMS is not requiring ACO participants to submit targets used to assess the progress of these elements, CMS clearly stated that it considers such a evaluation to be a key element of the care coordination sought by the MSSP.

### MSSP Opportunities for Pioneers

Previously, an MSSP program applicant could not be a participant in any other shared savings program. Consequentially, Pioneer ACOs could not also participate in the MSSP. Now, however, CMS is allowing Pioneer ACOs to apply to the MSSP, using a condensed application, provided (1) the ACO is the same entity as the Pioneer ACO; (2) all of the TINS on the applicant's ACO participant list have been on the “Confirmed Annual TIN/NPI list” of the Pioneer ACO in the last full performance year; and (3) the application applies to a two-sided model. Pioneer ACOs transitioning into the MSSP would be subject to standard program integrity screening and an evaluation of their overall compliance with the Pioneer ACO Model.

### Modifications to the Existing Payment Tracks

- Track 1 – Acknowledging ACOs' desire to gain additional experience in the MSSP before sharing in any risk, CMS finalized its proposal to allow ACOs to participate in a second agreement period under Track 1. Under these circumstances an ACO will not be subject to additional financial criteria and the Minimum Savings Rate (MSR) will remain the same in the second agreement period.

- Track 2 – CMS decided to provide ACOs in Track 2 with a menu of choices for setting their MSRs and Minimum Loss Rates (MLR) as part of their initial or renewal applications. ACOs may choose to set these rates at 0 percent or between .5–2 percent in increments of .5 percent. Changes to the MSR and MLR selections will not be permitted during the agreement periods. CMS hopes these options retain symmetry between an ACO's upside and downside risk.

### New Payment Track

To encourage a move toward greater risk acceptance, CMS has implemented greater shared savings opportunities for ACOs in the form of a new risk-based payment track, Track 3. Track 3 will operate in a similar manner to Tracks 1 and 2 in many areas, including eligibility, data sharing, benchmarking and quality performance, with several differences of significance:

- **Prospective Assignment.** CMS will assign beneficiaries on a prospective basis to Track 3 ACOs and perform quarterly reviews for purposes of excluding (not adding) beneficiaries. Assignment will be based on a 12-month assignment window. Assigned beneficiaries will not be reassigned to a different ACO during a performance year, even if they receive a plurality of their primary care services from that different ACO.
- **Sharing and Performance Payments.** Track 3 ACOs will enjoy a shared savings rate of up to 75 percent but must accept the same rate of risk on all losses, depending on quality performance. There will be, however, a performance payment cap on the savings of 20 percent of the benchmark, as well as a limit on the loss equal to 15 percent of the benchmark.
- **Minimum Savings Rate and Minimum Loss Rate.** Similar to the modifications made to Track 2, CMS finalized its proposal to allow Track 3 ACOs to select a symmetrical MSR/MLR option before the start of their agreement periods.

### Modifications to Repayment Mechanism Requirements

- **Amount and Repayment.** CMS finalized its proposed requirement that two-sided ACOs establish a repayment mechanism at the start of the agreement period. CMS encouraged ACOs to choose a single repayment mechanism for the entire agreement and tail period and now requires that ACOs demonstrate their ability to repay shared losses incurred at any time during the agreement period. ACOs must also be able to repay 1 percent of their total per capita Medicare Parts A and B fee-for-service expenditures based on the expenditures used to establish their benchmarks. In addition, CMS decided to allow up to 90 days for replenishment of repayment mechanism funds.
- **Permissible Repayment Mechanisms.** CMS narrowed the scope of permissible repayment mechanisms to include placing funds in escrow, establishing a new line of credit, obtaining surety bonds, or a combination thereof. ACOs can no longer rely on reinsurance or other alternative mechanisms for repayment.

### Establishing, Updating, and Resetting the Benchmark

- CMS will continue to provide ACOs with preliminary historical benchmarks just prior to the start of their agreement periods.
- For ACOs in their second and subsequent years, CMS will revise the benchmarking process by giving equal weight to the prior three benchmarking years and adjust the historical benchmark to account for the average per capita amount of savings earned by the ACO in the first agreement period. If an ACO failed to generate net savings, CMS will not make any adjustment to the rebased historical benchmark.
- ACOs should stay tuned for rules regarding the components of and procedures for calculating a regionally trended rebased benchmark.

### New Waiver - SNF 3-Day Rule

CMS adopted a new waiver applicable to Track 3 ACOs. Effective January 1, 2017, these ACOS no longer need to satisfy Medicare's "SNF 3-Day Rule," which requires a minimum three-day inpatient stay prior to a SNF admission. To take advantage of this waiver, the SNF to whom beneficiaries are admitted must have a "SNF Affiliate Agreement" with the ACO and have a quality rating of 3 stars or more.

### Beneficiary Protections

- **Public Reporting and Transparency.** ACOs must keep dedicated websites on which they report specified information using CMS's approved template such as the identity of key clinical and administrative leaders; types of ACO participants; quality measure performance; and shared savings/losses information. In turn, CMS may publicly report information specific to individual ACOs to support transparency.
- **Terminating Program Participation.** Under the finalized regulations, ACO agreements may be terminated for failure to comply with requests for information and documentation by CMS's specified due date, and for the submission of false or fraudulent data. When a participation agreement is terminated prior to its expiration, or when an ACO chooses not to renew its agreement upon expiration, the ACO must adhere to close-out procedures as specified by CMS.
- **Reconsideration Review Process.** Moving forward, CMS will allow reviews of reconsideration requests only when they are "on-the-record." Under the reconsideration review process, the ACO and CMS may each submit a single brief to support their positions.

## What Is Still to Come

Though CMS instituted numerous proposed policy revisions in this rule, it also made note of future changes to come. Accordingly, those interested should be on the look-out for future rule-makings that:

- Modify beneficiary assignment to hold ACOs accountable for beneficiaries that have designated ACO practitioners as being responsible for their care.
- Waive the geographic requirement related to beneficiary assignment to account for the use of telehealth.
- Modify the method of resetting benchmarks by incorporating regional trends and costs.
- Address assignment of beneficiaries in critical access hospitals.

## Ober | Kaler's Comments

It is interesting to note CMS's reference, in the final rule, to the Secretary's Health Care Payment Learning and Action Network. Within this program, HHS is working with private payers, employers, consumers, providers and states and Medicaid to expand the adoption of alternative payment models. CMS's view is that alignment among all payors in adopting new payment strategies will be most effective in changing providers' behaviors and improve operations. Following, in the wake of such changes to behavior and operations is when CMS believes noticeable change in quality and cost reduction will occur. Accordingly, it may be possible to see an increase in these models or "commercial ACOs" in the near future.