



Health Care Bulletin

Health Care Law Developments

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ACOs Take Two: Major Changes in Final Regulations

The long-awaited Interim Final Rule (the “Final Rule”) on the Medicare Shared Savings Program (“MSSP”) and Accountable Care Organizations (“ACOs”) was displayed by CMS on October 20, 2011, and published in the *Federal Register* on November 2, 2011. The Final Rule is effective January 3, 2012.

After receiving significant criticism on the Proposed Rule published in March 2011 (see our [prior Client Bulletin on the Proposed Rule](#)), the Final Rule makes substantial changes to the previous Proposed Rule that significantly reduce challenges to MSSP participation.

The Final Rule implements provisions of the Affordable Care Act (“ACA”) to establish MSSP requirements for organizations to qualify and operate as ACOs. Under the MSSP, providers and suppliers furnishing Medicare Part A and Part B services to ACOs will continue to receive traditional Medicare fee-for-service payments under Parts A and B, and may also be eligible for additional shared savings payments if they meet MSSP requirements.

This Client Bulletin provides a detailed review of the Final Rule and the MSSP for ACOs.

Eligibility

The Final Rule expands the types of entities eligible to participate as ACOs beyond those set out in the Proposed Rule, while maintaining the structural, logistical, and regulatory requirements for such participation. At the highest level, as provided by Section 1899(b)(2)(A) of the Social Security Act, ACOs and their participants must “be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.”

1. General

The Final Rule finalizes a number of provisions regarding the structure of ACOs from the Proposed Rule. ACOs will be responsible for the cost-savings

of all beneficiaries who seek care from ACO providers and must sign a binding three-year participation agreement. ACOs must maintain at least 5,000 eligible beneficiaries to remain eligible for shared savings. ACOs will continue to be organizationally defined by the TINs of the ACO participants, and a particular TIN can only be a member of one ACO. Thus, even a large, geographically diverse health system operating under a single TIN can be a member of only one ACO.

2. Types of Entities Allowed to Form and Participate

Under the Final Rule, the following types of entities may form an ACO, either alone or in concert¹:

- ACO professionals (physicians, physician assistants, nurse practitioners, and clinical nurse specialists) in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Acute care hospitals employing ACO professionals
- Critical Access Hospitals billing under Method II
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)

By including FQHCs and RHCs as entities able to form ACOs independently, CMS eliminated the financial and regulatory incentives it had included in the Proposed Rule for the inclusion of FQHCs and RHCs in an ACO. While not eligible to form ACOs, CMS urges other types of providers, e.g., SNFs, ALFs, hospices, HHAs, LTCHs, etc., to participate in ACOs.

¹ The first four types of entities were authorized by the ACA to form ACOs, while the last three were authorized by CMS, under its ACA rulemaking authority, to form ACOs.

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3. Legal Structure and Governance

As under the Proposed Rule, an ACO must be a legal entity separate and distinct from its participants, with its own TIN (though Medicare program enrollment is not required), organized under state law and authorized to conduct business in any state where it operates. Shared savings will be distributed directly to this entity, not to participants in the ACO.

The Final Rule retains the requirements from the Proposed Rule that ACOs must have an identifiable governing body with transparent governing processes, a fiduciary duty to the ACO, a conflicts of interest policy, and the authority necessary to execute the functions of the ACO. In order to ensure beneficiary and participant representation in the governance of the ACO, at least 75% of the ACO's governing body must be participant representatives and there must be a beneficiary representative who is not otherwise associated with the ACO (for example, cannot be an employee of an ACO participant). If an ACO desires to operate outside of this governance structure, it must describe to CMS how the desired structure will work and how it will continue to allow participant and beneficiary representation.

The Final Rule requires a governance structure nearly identical to that set out in the Proposed Rule. An ACO must be managed by an individual whose position is under the control of the ACO's governing body and who has demonstrated ability in directing and influencing clinical practices toward improved efficiency, processes, and outcomes. Clinical management must be done by a senior-level medical director who is one of the ACO's board-certified physicians, licensed in one of the states in which the ACO operates, and who is regularly physically present in an established location of the ACO. Under the Final Rule, the medical director no longer has to be a full-time position, however, ACO participants must demonstrate a meaningful commitment to the ACO's clinical integration through either human or capital investment. CMS requires ACOs to submit documentation to verify the above requirements are being met or to explain how an innovative governance structure outside of these parameters will effectively function.

4. Patient-Centeredness, Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care

ACOs must establish and implement a focus on patient-centeredness and satisfaction that includes plans to drive adoption of procedures and remedial measures for failure to comply. While the Final Rule requires an ACO to define, establish, implement, and periodically update its processes to promote evidence-based medicine, patient engagement, and the gathering and reporting of quality and cost data,

it does not do so in a prescriptive manner, leaving ACOs freedom to define these processes in a way best suited to their own situations. CMS finalized its proposal to require ACOs to define their care coordination processes and submit individualized care plans for, at least, high-risk and multiple chronic-condition patients. ACOs must also detail how they will partner with community stakeholders, including having them serve on the ACO's governing body. The Final Rule continues (as in the Proposed Rule) the general prohibition against an ACO participant being involved in another Medicare program with shared savings, including those participating in the Pioneer ACO Model.

Agreement

As required by the ACA, and as was proposed, the Final Rule requires ACOs to enter into a three year agreement with CMS to participate in the MSSP. As also required by the ACA, the Final Rule establishes the MSSP as of January 1, 2012. However, for ACOs applying in 2012, the MSSP will use two delayed start dates, April 1 and July 1, each with slightly different participation agreement terms but with 3 performance years. For ACOs starting April 1, 2012, the participation agreement term will be 3 years and 9 months, resulting in a first performance "year" of 21 months. Likewise, for ACOs starting on July 1, 2012, the participation agreement term will be 3 years and 6 months, with a first performance "year" of 18 months. CMS appears to have taken this approach to accommodate industry stakeholder comments suggesting that ACOs may need more time to prepare to apply and begin the MSSP in 2012, particularly when the Final Rule was just released in the last quarter of 2011. Creating two staggered start dates in 2012 should enable more applicants to begin the MSSP in 2012 than if CMS had finalized a single start date of January 1, 2012, or in the early part of 2012. However, in later years the MSSP will use a calendar year cycle, which is consistent with most CMS payment and quality incentive program cycles. Accordingly, for applications approved after 2012, the MSSP start date will be January 1 and the participation agreement term will be for 3 calendar years and 12-month performance years, unless CMS indicates otherwise in the participation agreement. For each calendar year in the MSSP, the ACO must submit measures in the form and manner required by CMS for the performance year. This includes ACOs starting the program in 2012, which will need to submit measures for the calendar year that comprise the initial part of their first performance year. This is probably required because CMS needs to obtain measures on the calendar year basis for future comparison purposes and to calculate an interim payment (discussed below), even where the 2012 ACOs will have a longer first performance "year".

ACOs must submit a complete application to CMS by the application deadline. CMS anticipates that it will accept applications beginning shortly after January 1, 2012. CMS will publish a notice of intent outlining further details about the application process. As part of the application, an ACO executive with authority to bind the ACO must certify that the information in the application is accurate, complete and truthful. The ACO must also certify that its participants, providers, and suppliers will become accountable for the quality, cost, and overall care of the ACO's assigned beneficiaries. This requirement of accountability down to an individual level is echoed throughout the application requirements, as well as other MSSP requirements. ACOs must also disclose whether the ACO has, or its participants, providers or suppliers have, previously participated in the MSSP under the same or different names, or are related or affiliated with another ACO in the MSSP. If an ACO has previously been terminated, it must identify the cause of the termination and describe safeguards that have been put in place that will enable the ACO to complete a full-term participation agreement.

As part of the application, ACOs will also be required to submit various supporting materials demonstrating that the ACO meets the MSSP's eligibility requirements (described above). In particular, the ACO must provide copies of documents (participant agreements, employment contracts, operating policies) describing the rights and obligations of the ACO's participants, providers, and suppliers, how shared savings will encourage the ACO to meet quality assurance and improvement and evidence-based clinical guidelines; and how the ACO will implement patient-centeredness criteria and the remedies for failing to do so. ACOs must also provide documentation of the ACO's organization and management structure (organizational charts, list of committees and names of members, legal structures, job descriptions for senior administrative and clinical leaders), and evidence that the governing body meets MSSP requirements (described above). ACOs must also provide a copy of their compliance plans or documentation describing their compliance plans, and upon CMS' request, the ACO's formation documents (charters, bylaws, articles of incorporation, partnership or joint venture agreements, management or asset purchase agreements, financial statements, and resumes or other documentation of ACO leaders), a list of all ACO participants and their Medicare-enrolled TINs, and for each participant, their providers/suppliers and applicable NPIs, and whether each of them is a primary care physician. For ACOs with an FQHC or RHC participant (which under the Final Rule are permitted to be ACO participants) the ACO must

indicate the TINs, organizational NPIs, and other identifiers of the physicians providing primary care services. ACOs must also describe how they plan to use shared savings payments, including how the payments will be distributed among participants and providers/suppliers, and how the proposed plan will achieve the MSSP's triple aim (i.e., better care for individuals, better health for populations, and lower growth in expenditures).

All of these application requirements clearly suggest that ACOs applying for the MSSP will have to undertake significant preparation and planning to put together a complete application. ACOs will need to have taken steps not only to form the legal entity that will serve as the ACO, but also to identify participants and providers/suppliers, and ACO leaders; and to prepare major contracts and operational plans regarding use of shared savings coordination of care, and compliance. As a result, anyone considering applying to the MSSP in 2012 will be working on a very fast track to complete all necessary steps to apply for the MSSP in 2012. Due to this significant effort required to apply, it is likely that many industry stakeholders may elect instead to apply in 2013 or subsequent MSSP years to allow adequate time to consider and develop all of these critical items.

As part of the initial application, ACOs must elect participation under either Track 1 or Track 2. All ACOs applying for subsequent participation terms will be under Track 2 (Track 1 and Track 2 discussed below). ACOs applying in 2012 will have the option to request an interim payment calculation based on their first 12 months of performance and a final reconciliation at the end of their first performance year to determine overall savings or losses for that performance year. But they must request the interim payment calculation as part of their application and, as a result, cannot wait to see how the ACO is performing in its first year to decide if an interim payment calculation will likely result in a shared savings payment. Based on the results of the interim payment calculations, these ACOs may receive a shared savings payment, or if under Track 2, be liable for shared losses. ACOs applying under Track 2 or requesting an interim payment calculation under Track 1 must also submit for CMS approval in their application documentation showing that the ACO can repay any losses, such as documentation of reinsurance, escrowed funds, surety bonds, lines of credit with letters of credit the MSSP can draw on, or other similar mechanisms.

CMS will evaluate an ACO's application only on the information submitted. However, CMS will notify applicants if the ACO's application is missing information and will allow the ACO to submit

missing information by a specified date. CMS must notify applicants in writing whether their application is approved or denied, and if it is denied, CMS must specify the reasons why the ACO is not qualified and notify the ACO of its right to request reconsideration review (discussed below). If the application is approved, the ACO must agree to comply with specified laws, including the federal Stark, Anti-Kickback, and civil monetary penalties (gainsharing) laws, and False Claims Act, and the ACO must certify that all information submitted to CMS in connection with its participation in the MSSP will be accurate, complete, and truthful. ACOs must also provide a copy of their participant agreements to all participants, providers/supplier, and others involved in the ACO's governance.

Data

1. Data Sharing

In the preamble to the Final Rule, CMS acknowledges that an ACO may not have access to complete information about all of the services that are provided to its assigned beneficiaries by providers outside the ACO, but that this information would be crucial to the ACO coordination of care for its beneficiary population. Thus, CMS reaffirmed its commitment in the Proposed Rule to generate aggregate data reports, to provide limited identifying information about beneficiaries whose information serves as the basis for the aggregate reports (and who are preliminarily prospectively assigned, as described below), and to share beneficiary identifiable claims data with the ACO unless the beneficiary chooses to decline to share their data. CMS indicated that access to this information will provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO; and will enable the ACOs to ascertain their ACO participants and ACO providers/suppliers' patterns of care; and could be used to assess the ACO's performance relative to their prior years' performance.

2. Sharing Aggregate Data

CMS finalized without change its proposals related to sharing of aggregate data. Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

3. Identification of Historically Assigned Beneficiaries

In the Proposed Rule, CMS anticipated that it would make certain limited beneficiary identifiable information (name, date of birth, sex, and Health

Insurance Claim Number) available to an ACO at the beginning of the first performance year in order to assist the ACO in conducting population-based activities related to improving health or reducing costs, protocol development, case management, and care coordination. In the preamble to the Final Rule, CMS indicates that that the proposed four data points will be sufficient to aid ACOs in focusing their initial care redesign efforts going forward and that the four data points are the minimum data necessary for providers to begin the process of developing care plans in an effort to provide better care for individuals and better health for populations.

However, CMS acknowledges concerns that ACOs could use the data to avoid at-risk beneficiaries and indicates that it included safeguards and sanctions in the MSSP to guard against avoidance of at-risk beneficiaries (discussed below). CMS also notes that it will not disclose beneficiary identifiable information to an ACO until any necessary Business Associate Agreements between an ACO and its ACO participants and ACO providers/suppliers are established in accordance with HIPAA, and there is a signed Data Use Agreement ("DUA") in place with CMS.

CMS modified its proposal and in the Final Rule CMS committed to provide ACOs with additional reports on a quarterly basis. The provision of the quarterly aggregate reports and the limited identifiable information on beneficiaries used to generate the reports, combined with the opportunity to request monthly beneficiary identifiable claims data (discussed below), and the modification to allow ACOs to request claims data of beneficiaries that appear on these reports are designed to provide sufficient information for treatment and health care operations activities with the Medicare population for which the ACO is accountable.

4. Sharing Beneficiary Identifiable Claims Data

The Proposed Rule suggested giving the ACO the opportunity to request certain beneficiary identifiable claims data on a monthly basis, but to limit the available claims to those beneficiaries who received a primary care service from a primary care physician participating in the ACO during the performance year, and who have been given the opportunity to decline to have their claims data shared with the ACO, but have declined to do so. CMS also proposed that beneficiary information subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR Part 2) would only be made available if the beneficiary provided his or her prior written consent. Additionally, CMS

proposed to limit the content of the claims data to the minimum data necessary for the ACO to effectively coordinate care of its patient population, and to require ACOs to enter into a DUA prior to receipt of any beneficiary-identifiable claims data. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data that CMS provides through the MSSP with anyone outside the ACO.

In the Final Rule, CMS states that ACOs are expected only to request data from CMS that will be useful to the ACO for conducting the kinds of activities that are described in the Proposed Rule. ACOs may request data as frequently as each month or less frequently if monthly reports are not necessary to suit their needs. CMS agreed that not all ACOs may have the capability, desire, or need to handle large volumes of claims data in a way that will complement the ACO's activities to improve care processes. For that reason, CMS is not requiring all ACOs to submit DUAs or request monthly beneficiary identifiable claims data. Before receiving any data, the ACO will be required to explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers; conduct quality assessment and improvement activities; and conduct population-based activities to improve the health of its assigned beneficiary population.

The minimum necessary Parts A and B data elements may include but are not limited to the following data elements: (1) beneficiary ID, (2) procedure code, (3) gender, (4) diagnosis code, (5) claim ID, (6) the from and through dates of service, (7) the provider or supplier ID, (8) the claim payment type, (9) date of birth and death, if applicable, (10) TIN, and (11) NPI. The minimum necessary Part D data elements may include but are not limited to the following data elements: (1) beneficiary ID, (2) prescriber ID, (3) drug service date, (4) drug product service ID, (5) quantity dispensed, (6) days supplied, (7) brand name, (8) generic name, (9) drug strength, (10) TIN, (11) NPI, (12) indication if on formulary, and (13) gross drug cost. In the preamble to the Final Rule, CMS clarifies that these lists of data elements were provided in order to offer examples of the types of data elements that an ACO might need, but that it was not CMS' intention that these would be the only data elements that an ACO could request. Rather, an ACO could request additional data elements provided it could demonstrate how the additional requested information would be necessary to performing the functions and activities of the ACO. Thus, the Final Rule clarifies that the minimum necessary data elements may include, but are not limited to, the list of Parts A and B data elements and the list of Part D data elements that were specifically included in the Proposed Rule.

5. Giving Beneficiaries the Opportunity to Decline Data Sharing

CMS proposed to require that the ACO inform beneficiaries of its ability to request claims data about them if they do not object. Specifically, CMS proposed that when a beneficiary has a visit with their primary care physician, the physician would inform them at this visit that he or she is an ACO participant or an ACO provider/supplier and that the ACO would like to be able to request claims information from CMS in order to better coordinate the beneficiary's care. ACOs would only be allowed to request beneficiary identifiable claims data for beneficiaries who have: (1) visited a primary care participating provider during the performance year; and (2) have not chosen to decline claims data sharing.

The Final Rule modifies CMS' proposed approach. CMS will continue to require ACOs to notify patients at the point of care that they are participating in an ACO, that they will be requesting protected health information data, and that the beneficiary has the right to decline to share this data with the ACO. However, CMS will also provide a mechanism by which ACOs can notify beneficiaries and request beneficiary identifiable data in advance of the point of care visit using the lists of preliminary prospectively assigned patients provided to the ACO at the start of the agreement period and quarterly during the performance year.

Upon signing participation agreements and a DUA, ACOs will be provided with a list of preliminary prospectively assigned set of beneficiaries that would have historically been assigned and who are likely to be assigned to the ACO in future performance years. ACOs may utilize this initial preliminary prospectively assigned list, along with the quarterly lists, to provide beneficiaries with advance notification prior to a primary care service visit of their participation in the MSSP and their intention to request their beneficiary identifiable data. Beneficiaries will be given the opportunity to decline this data sharing as part of this notification. After a period of 30 days from the date the ACO provides such notification, ACOs will be able to request beneficiary identifiable data from CMS absent an opt-out request from the beneficiary. This additional flexibility may be particularly important in the case of beneficiaries who do not schedule an appointment with a primary care practitioner until later in the year or not at all in a given year.

Assignment

The Final Rule differs substantially from the Proposed Rule with regard to the assignment of beneficiaries to ACOs. The Proposed Rule assigned

Medicare fee-for-service beneficiaries to ACOs through a retrospective review of primary care utilization patterns over the past performance year. The official commentary to the Final Rule reveals that “commenters were overwhelmingly in favor of prospective assignment.”

The Final Rule replaces the Proposed Rule’s retrospective assignment with a prospective assignment followed by a retrospective reconciliation. Medicare beneficiaries will be assigned to an ACO “in a preliminary manner” at the beginning of a performance year based upon the most recent data available. Assignment will then be updated quarterly, based upon the most recent twelve months of data. Final assignment will be determined after the end of the performance year based on the data from that performance year.

The Proposed Rule included a one-step assignment process. Medicare beneficiaries would have been assigned on the basis of a plurality of allowed charges for primary care services rendered by primary care physicians without any consideration of primary care services rendered by specialists. The Final Rule establishes a two-step assignment process that includes beneficiaries whose sole source of primary care services was specialist physicians:

- A beneficiary who received at least one primary care service from a primary care physician will be assigned to the ACO from which the beneficiary received the plurality of her primary care services.
- A beneficiary who did not receive any primary care services from primary care physicians but who received primary care services from specialist physicians will be assigned to the ACO from which the beneficiary received the plurality of her primary care services.

As did the Proposed Rule, the Final Rule emphasizes that the sole purpose of assignment of beneficiaries to ACOs is the determination of whether the ACOs have achieved savings benchmarks. Assignment does not diminish or restrict the right of beneficiaries to exercise free choice in determining where they will receive health care services.

Quality & Reporting

Under the Final Rule, ACOs must meet quality performance measures established by CMS to be eligible

for the MSSP. A significant change to the quality reporting requirements is the reduction in the number of quality measures that ACOs must meet from 65 in the Proposed Rule to 33 in the Final Rule. CMS received many negative comments regarding the number and complexity of quality measures in the Proposed Rule. CMS reduced the number of quality reporting measures to alleviate administrative impediments to participating in the MSSP.

Table 1 of the Final Rule sets forth the 33 quality measures, which are grouped into the following domains:

1. Patient/caregiver experience
2. Care coordination/patient safety
3. Preventive health
4. At-risk populations, which include:
 - a. Diabetes
 - b. Hypertension
 - c. Ischemic vascular disease
 - d. Heart failure
 - e. Coronary artery disease

CMS modified the Proposed Rule domain structure by combining the care coordination and patient safety domains to better align with other CMS initiatives and the National Quality Strategy. Each of the four domains will be weighted at 25% in calculating an ACO’s overall quality performance score for purposes of determining its final shared savings. ACOs must achieve the quality performance standard determined by CMS on 70% of all measures in each domain, as contrasted with the 100% required under the Proposed Rule.

Another significant change in the Final Rule is the longer phase-in for performing quality measures. In the first year of ACO participation in the MSSP, CMS defines the quality performance standard at the level of complete and accurate reporting. During subsequent performance years, the quality performance standard will be phased in such that the ACO will be assessed on performance based on the minimum attainment level of certain measures. The table below summarizes the number of measures required as pay-for-reporting and pay-for-performance during the initial three year period.

	Performance Year 1	Performance Year 2	Performance Year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

The Final Rule keeps the Proposed Rule incentive payment for meeting reporting requirements under the Medicare Physician Quality Reporting System (“PQRS”). Specifically, ACOs can qualify for an additional incentive if they submit PQRS data on behalf of their eligible professionals. This PQRS incentive is equal to 0.5% of the ACO’s eligible professionals’ total estimated Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year.

Under the Final Rule, meaningful use of certified EHR technology is no longer required to participate in the MSSP. Alternatively, the quality measure regarding EHR adoption will be weighted twice that of any other measure for scoring purposes.

Under the Final Rule, CMS retains the right to perform an audit to validate the quality of data reported by an ACO. The audit process consists of three phases of medical record review. If the audit proves a discrepancy of greater than 10% exists between the ACO reported data and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this discrepancy exists. Consistent with the Proposed Rule, CMS can terminate or sanction an ACO for failure to report quality measure data accurately, completely, and in a timely manner.

The Final Rule also requires that beginning in 2014 and for subsequent performance years, ACOs select a CMS-certified vendor to administer a patient experience of care survey and report the results to CMS.

Savings & Losses

As with the ACA and the Proposed Rule, under the Final Rule providers and suppliers furnishing Medicare Part A and Part B services to ACO beneficiaries will continue to bill for and receive Medicare fee-for-service payments for those services. Under the MSSP, ACOs can receive a different payment from CMS – which is a shared savings distribution from CMS to the ACO – if the ACO meets MSSP requirements. These requirements generally involve meeting contractual requirements of the participation agreement, quality performance standards, and realizing savings as compared to an expenditure benchmark that exceeds a “minimum savings rate” (discussed below). Each ACO will determine, based on its unique agreements with its participants, providers and suppliers, how any shared savings payments may be distributed among them. However, as indicated above, the MSSP does require that ACOs use part of the shared savings payment to further CMS’ triple aim.

1. Selection of Risk Model.

For its initial participation agreement period, an ACO must elect to operate under either Track 1 (the

one-sided model sharing savings with CMS in all three years) or Track 2 (the two-sided model sharing both savings and losses with CMS in all three years) for the agreement period (Track 1 and Track 2 discussed below). In any subsequent agreement periods, ACOs must operate under Track 2.

In a change from the Proposed Rule, under the Final Rule CMS modified Track 1 so that it is a shared savings-only model for the duration of the initial three year participation term. By contrast, under Track 2, ACOs will share in both savings and losses with CMS in all three years .

CMS also finalized that if an ACO experiences a net loss during its first agreement period, it may reapply to participate in the MSSP under Track 2 under specified conditions. However, the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings during the subsequent agreement period.

2. Establishing the Benchmark.

For each ACO in the MSSP, CMS will establish a per capita benchmark for Part A and Part B expenditures for the three year agreement period. The benchmark is used to determine whether the ACO has achieved savings during the three performance years of the agreement. Generally, to set the benchmark, CMS must identify which expenditures are included and the applicable patient populations on which the benchmark is calculated. It must also make certain adjustments for beneficiary characteristics and other adjustments, and establish an appropriate methodology for trending the three year benchmark over the three performance years to update it for growth in national per capita Part A and B expenditures. To determine whether the ACO has achieved any savings and may be eligible for a shared savings payment, CMS will compare the benchmark to the actual assigned beneficiary per capita Medicare expenditures in each of the three performance years. A new benchmark will be established consistent with these requirements at the start of each new participation agreement term. Under the Final Rule, CMS will compute the ACO’s fixed historical benchmark by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the three most recent years prior to the agreement period. CMS will use the ACO participants’ TINs identified at the start of the agreement period to identify the beneficiaries and the expenditure benchmark will be reset at the start of each agreement period. In particular, CMS will:

1. Calculate the payment amounts under Parts A and B fee-for-service claims for assigned beneficiaries using a 3-month claims run out

- (the Proposed Rule used a 6-month claims run out period, which was deemed too long) with a completion factor (including payments made under demonstration pilot or time-limited program; adjustments for Part A and B claims such as geographic payment adjustment and HVBP payments, but excluding indirect medical education and disproportionate share hospital payments; hospital outlier payments; Part C and D payments; GME PQRS; eRX; and EHR incentive payments);
2. Make separate expenditure calculations for specified populations of beneficiaries (ESRD, disabled, aged/dual eligibles and aged/non-dual eligibles);
 3. Adjust expenditures for changes in severity and case mix using prospective HCC risk scores;
 4. Truncate an assigned beneficiary’s total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for each benchmark year to minimize variation from catastrophically large claims;
 5. Determine national growth rates and trends expenditures for each of the first 2 benchmark years to the third benchmark year using CMS Office of the Actuary national Medicare expenditure data, and trend forward the benchmark to current year dollars to set the benchmark, using separate calculations for specified expenditure categories (ESRD, disabled, aged/dual eligible beneficiaries, aged/non-dual eligible beneficiaries);
 6. Restate benchmark years 1 and 2 trended and risk adjusted expenditures in benchmark year

- 3 proportions of ESRD, disabled, aged/dual eligibles etc.;
7. Weight each year of the benchmark as follows: benchmark year 3 at 60%; benchmark year 2 at 30%; benchmark year 1 at 10%; and
- 8 Adjust the ACO’s benchmark for the addition and removal of ACO participants or ACO providers/suppliers during the agreement period.

CMS will update the historical benchmark annually for each year of the agreement based on the flat dollar equivalent of the projected absolute amount of the growth in national per capita expenditures for Parts A and B services under the Medicare fee-for-service program. It will also update this fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the fee-for service program using CMS’ Office of the Actuary data. To update the benchmark, CMS will make calculations for specified categories of assigned beneficiaries (ESRD, disabled, aged/dual eligibles, aged/non-dual eligibles). Finally, CMS will reset an ACO’s benchmark at the start of each participation agreement period.

5. Determining Shared Savings

Under the MSSP, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services – adjusted for beneficiary characteristics – meets or exceeds a percent set by CMS, known as the Minimum Savings Rate (“MSR”). CMS finalized the proposal to use a sliding scale, based on the size of the ACO’s assigned population, to establish the MSR for Track 1 ACOs. Thus, under the Final Rule, for Track 1 ACOs, the MSR is as follows:

Number of Beneficiaries	MSR (low end of assigned beneficiaries)	MSR (high end of assigned beneficiaries)
5,000 - 5,999	3.9%	3.6%
6,000 - 6,999	3.6%	3.4%
7,000 - 7,999	3.4%	3.2%
8,000 - 8,999	3.2%	3.1%
9,000 - 9,999	3.1%	3.0%
10,000 - 14,999	3.0%	2.7%
15,000 - 19,999	2.7%	2.5%
20,000 – 49,999	2.5%	2.2%
50,000 – 59,999	2.2%	2.0%
60,000 +		2.0%

For Track 2 ACOs, the Final Rule also remains the same as proposed: there is a flat MSR of 2%.

CMS finalized the proposal that Track 1 ACOs can earn up to 50% of total savings based on quality performance and that Track 2 ACOs can earn up to 60% of total savings based on quality performance.

In a change from the Proposed Rule, the Final Rule does not contain a sliding scale-based increase in the shared savings rate, up to an additional 2.5% under Track 1 and up to an additional 5.0% under Track 2, for ACOs that include an FQHC or RHC as an ACO participant (given their ability to participate independently in ACOs discussed above). CMS declined to adopt any other additional incentives for other factors, such as care of dual-eligibles, composition of the ACO, or participating in similar shared savings arrangements with other payors.

Under the Final Rule, both Track 1 ACOs and Track 2 ACOs will share on first dollar savings once the ACO achieves savings in excess of the MSR. This is a change from the Proposed Rule, which previously only provided first dollar savings for Track 2 ACOs, but required Track 1 ACOs to share savings only beyond a 2% threshold (this was known as the “Net Sharing Rate”). CMS acknowledged that this Net Sharing Rate for Track 1 ACOs would have deterred participation and, therefore, CMS eliminated the Net Sharing Rate in the Final Rule.

The MSSP sets a maximum limit on the amount of savings an ACO can receive. The limit is set as a percentage of the ACO’s updated benchmark and is known as the “Performance Payment Limit.” The Final Rule raises the Performance Payment Limits for both Track 1 ACOs and Track 2 ACOs. For Track 1 ACOs, the Performance Payment Limit is 10% in the Final Rule (up from the 7.5% in the Proposed Rule). For Track 2 ACOs, the Performance Payment Limit is 15% in the Final Rule (up from the 10% in the Proposed Rule).

6. Calculating Sharing in Losses

In the Final Rule, CMS eliminated the provisions requiring Track 1 ACOs to accept the downside risk of sharing in losses. The calculation rate for sharing in losses for Track 2 ACOs remains largely the same in the Final Rule as proposed, with a few notable differences. The method for calculating losses mirrors the methodology for calculating savings. First, a Track 2 ACO must have expenditures that exceed a minimum percentage around the benchmark to trigger losses. This percentage is known as the Minimum Loss Rate (“MLR”) and is a flat 2%. If an ACO has expenditures exceeding

the MLR, then the ACO will be required to pay a share of those excess expenditures, on a first dollar basis, calculated by multiplying the amount of excess above the updated benchmark by the Shared Loss Rate (defined as one minus the final sharing rate). The Shared Loss Rate is capped, under the Final Rule, at 60% (which is consistent, as an inverse, with the maximum rate for shared savings). Also, CMS finalized the proposed shared loss limits of 5% in the first performance year, 7.5% in the second performance year, and 10% in the third performance year.

7. Repayment

The Final Rule retains the requirement that Track 2 ACOs demonstrate a satisfactory repayment mechanism prior to the start of each performance year. Track 1 ACOs requesting interim payments must also demonstrate a satisfactory repayment mechanism at the time of application. Under the Proposed Rule, an ACO would have been required to repay losses within 30 days of notification. The Final Rule modifies this to increase the payment period to 90 days from notification. CMS eliminated entirely the concept of withholding payments to Track 2 ACOs to ensure their ability to repay losses. Thus, the proposed 25% withhold of payments for Track 2 ACOs is not part of the Final Rule.

8. First Year Performance in 2012

Under the Final Rule, ACOs with start dates of April 1, 2012, or July 1, 2012, may opt for an interim payment calculation as of the end of their first 12 months of MSSP participation. Generally, the same methodology for determining shared savings and losses will apply to the interim calculation. However, for ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the 18-month or 21-month completion of the ACO’s first performance year (as discussed above).

Protections

1. Monitoring

The Final Rule makes no substantive changes to the monitoring activities CMS may engage in with respect to ACOs and their participants, providers/suppliers, and contracted entities that perform functions or services on behalf of the ACO, including data analysis, site visits, analysis of beneficiary and provider complaints, and audits. Specific conduct CMS will be looking for through these monitoring activities includes: (1) avoidance of

“at-risk beneficiaries”² (i.e., “cherry-picking”); (2) compliance with quality performance standards; (3) changes to ACO eligibility; (4) beneficiary notifications of provider and supplier roles in the ACO and beneficiary’s ability to opt-out of sharing claims data; and (5) compliance with guidelines for ACO marketing materials. The Final Rule provides CMS with several remedies for addressing non-compliance with program requirements, including Corrective Action Plans (“CAP”), warnings, and termination of the ACO’s participation in the MSSP. The availability of each of these remedies depends on the type of noncompliance.

2. Actions Prior to Termination

The Final Rule retains what CMS had proposed as courses of action that CMS may take (alone or in combination) prior to terminating an ACO from the MSSP, including: issuance of a warning, request for a CAP from the ACO, and placement of the ACO on a special monitoring plan.

3. Termination; Reapplication after Termination

The Final Rule removes the laundry list of grounds for terminating an ACO’s participation in the MSSP and replaces that list with a much shorter, more general list of grounds for termination. In shortening the list, CMS did not intend to say that any of the reasons included in the Proposed Rule do not still constitute grounds for termination, but rather that CMS did not want the list to be seen as all-inclusive. CMS believes those reasons are encompassed within this shorter list: (1) failure to comply with MSSP requirements; (2) noncompliance with eligibility and other requirements; (3) the imposition of sanctions or other actions against the ACO by an accrediting organization, state, federal, or local government agency leading to the inability of the ACO to comply with MSSP requirements; (4) the ACO violates the Stark law, Anti-Kickback Statute, Civil Monetary Penalty Laws (to the extent not waived), or other antifraud or antitrust law or other Medicare law/regulation relevant to ACOs.

² Examples of “at-risk beneficiaries” include beneficiaries with a high score on the CMS-HCC risk adjustment model, who have two or more hospitalizations or emergency room visits per year, are dually eligible for Medicare and Medicaid, who have a high utilization pattern, who have one or more chronic conditions, or who have a recent diagnosis that is expected to result in increased cost. In addition, the Final Rule added two new categories of “at-risk beneficiaries”: patients entitled to Medicaid because of disability, and patients with mental health or substance abuse disorders.

In addition, the Final Rule eliminates the mandatory 25% withhold (as discussed above). Thus, the Final Rule does not include the proposed provision that would have caused an ACO to forfeit its mandatory 25% withhold of shared savings if the ACO’s agreement with CMS for participation in the MSSP was terminated for any reason before the three year agreement period was completed. The Final Rule retains the ability for an ACO to terminate its participation in the MSSP with 60 days notice to CMS and the ACO’s participants, but removes the requirement that ACOs must provide timely notice to beneficiaries of such termination. The Final Rule retains the provision prohibiting ACOs terminated from the MSSP from reapplying to the program until after the end of the original agreement period. However, under the Final Rule, CMS will allow an ACO reapplying to the program to re-enter under Track 1 if the ACO terminated its original agreement less than halfway through that agreement term (the Proposed Rule would have only permitted re-entry under Track 2).

4. Reconsideration Review Process

CMS made no significant substantive changes to the reconsideration review process in the Final Rule. Under the Final Rule, ACOs are not entitled to seek reconsideration of determinations related to the following: (1) quality/performance standards; (2) quality of care; (3) assignment of Medicare fee-for-service beneficiaries; (4) eligibility of the ACO for shared savings; (4) the amount of shared savings; (6) the percent of shared savings specified by the HHS Secretary and the limit on total shared savings; and (7) the termination of an ACO from the MSSP for failure to meet quality performance standards. CMS eliminated the exception for a determination of a reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO due to a change in the antitrust review process. All other initial determinations are reviewable.

There are two stages of additional review: reconsideration and an “on the record” review. The ACO is permitted to remain operational during the reconsideration and review process. If an ACO’s termination from the MSSP is upheld, it is effective as of the date in the initial notice of termination. However, if an ACO’s termination is reversed, the ACO’s participation is reinstated retroactively.

Requests for reconsideration must be received by CMS within 15 days of notice of the initial determination. The burden of proof is on the ACO to demonstrate with convincing evidence that the initial determination was not consistent with CMS regula-

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tions and/or applicable law. The review is limited to evidence submitted by the deadline specified by CMS unless additional evidence is requested by the reviewing official, but it is important to note that no evidence that was not previously timely submitted to CMS prior to the initial determination will be considered. The reviewing official will announce his recommendation based on the evidence submitted. Any party can request an “on the record” review of the reviewing official’s recommendation. No new evidence may be submitted for this “on the record” review. The final CMS determination is final and binding on all parties.

5. Audits and Record Retention

CMS made no substantive changes to the audit and record retention provisions of the Proposed Rule. ACOs and their participants, providers/suppliers, and contracted entities that perform functions or services on behalf of an ACO must agree to allow CMS, HHS, the Comptroller General, the OIG (and their designees) the right to audit and inspect the books, contracts, records, documents, and other evidence (collectively, “Records”) pertaining to the ACO’s compliance with MSSP requirements; the quality of services provided and a determination of the amount due to/from CMS; and the ability of the ACO to bear the risk of potential losses and to repay any losses sustained.

Records must be maintained for 10 years from the later of the final date of the agreement period or the date of completion of any audit, evaluation, or inspection, except (1) in the case of a reasonable possibility of fraud or similar fault by an ACO or its participants, in which case CMS may audit the ACO’s Records at any time; (2) if CMS determines there is a special need to retain a particular record or group of records longer and notifies the ACO at least 30 days prior to the disposition date; or (3) if there has been a termination, dispute, or allegation of fraud or similar fault by the ACO or its participants, in which case the ACO must retain Records for 6 years from the date of any final resolution of such allegation of fraud or similar fault, termination, or dispute.

The Final Rule clarifies that if, as a result of an audit, evaluation, or inspection, it is determined that the amount of shared savings due to an ACO, or the amount of shared losses owed by an ACO was calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. In addition, the Final Rule also clarifies that the Record retention rules do not limit the OIG’s authority to audit, evaluate, investigate, or inspect an ACO and its participants, providers/suppliers, and contracted entities that perform functions or services on behalf of the ACO.

Conclusion

The Final Rule reflects CMS’ effort to address industry stakeholder concerns raised in the over 1300 comments it received on the Proposed Rule published last March. CMS made several key changes in the Final Rule (including removing any sharing of losses in Track 1, reducing the number of quality measures, and changing beneficiary assignment from a retrospective to a prospective method) in an effort to eliminate obstacles to participation in the MSSP. CMS also retained in the Final Rule many features of the Proposed Rule aimed at achieving CMS’ overall goal of transforming health care delivery to further its triple aim. Due to these changes, the Final Rule has been favorably received by many industry stakeholders and commentators to date. As a result, it seems likely that many of the hospitals and health systems, as well as physicians and other industry players, that previously decided not to participate may now reconsider whether they should take steps to form an ACO and apply to participate in the MSSP.

This Client Bulletin was prepared by Chris Bennington, Shannon DeBra, Bryn Hunt, David Johnston, Allen Killworth, Jennifer Nelson Carney, and Claire Turcotte.