PYA

PYALeadership Briefing

Medicare ACO Road Map

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The Centers for Medicare & Medicaid Services ("CMS") has announced 106 new accountable care organizations ("ACOs") have been selected to participate in the Medicare Shared Savings Program ("MSSP") effective January 1, 2013. That brings the total number of ACOs participating in the MSSP to 222.

For a program many considered "dead on arrival" when the proposed MSSP rule was published in March 2011, provider participation in an accountable care organization seems to be moving from optional to inevitable.

The deadline for submitting an application to participate in the MSSP effective January 1, 2014, is July 31, 2013. An organization interested in submitting an application must file a Notice of Intent to Apply with CMS by May 31, 2013. CMS accepts MSSP applications once a year; the next opportunity will be summer 2014. Completing the MSSP application is no small accomplishment, and interested providers should commence work as soon as possible. The starting point should be a careful and thorough review of the requirements for MSSP participation.

The level of detail contained in the hundreds of pages of MSSP regulations and guidance can be overwhelming. PYA has merged the regulations and guidance down to their core requirements. We have arranged the information in a manner to facilitate substantive discussions and decision-making, rather than "hand-wringing" over every last regulatory provision.

Part I – Formation and Operations

Getting Started

An ACO is a distinct legal entity involving one or more Medicare-enrolled providers identified by their TIN (referred to as ACO participants) "who agree to become accountable for the quality, cost, and overall care of the Medicare *fee-for-service* beneficiaries assigned to the ACO."

An ACO that meets certain requirements (as demonstrated through an application process) may enter into a three-year agreement with CMS to participate in the MSSP. Each year of the contract is called a performance year.

1. An ACO that applies to participate effective in January 1, 2014, will be notified of CMS' decision in late 2013. CMS will refuse participation if the applicant fails to meet any regulatory requirement. CMS' decision is not appealable.
2. An ACO that elects early termination shall be subject to specified penalties.
3. The regulation lists specific grounds on which CMS may impose a corrective action plan or terminate an ACO's agreement for cause.

Required ACO Functions

An application to participate in the MSSP must show how the ACO will perform four core functions: promote evidence-based medicine, report cost and quality metrics, promote patient engagement, and coordinate care. More specifically, the ACO must:

1. Establish and maintain an ongoing quality assurance and improvement program led by an appropriately qualified healthcare professional

   Required documentation: *describe scale and scope of program, including remedial processes for non-compliant ACO participants.*
2. Promote evidence-based medicine

   Required documentation: *describe evidence-based guidelines the ACO intends to establish, implement, enforce, and periodically update; identify diagnoses with significant potential for the ACO to achieve quality improvements.*

3. Promote patient engagement

   Required documentation: *identify measures for promoting patient engagement taking into account patients' unique needs and preferences, e.g., decision-support tools and shared decision-making methods.*

4. Report on quality and cost measures

   Required documentation: *describe process to monitor internally, provide feedback, and take action based on such measures.*

5. Promote care coordination across physicians and acute and post-acute providers

   Required documentation: *identify mechanisms to promote, improve, and assess integration and consistency of care, e.g., information technology, transition of care programs, deployment of case managers in Primary Care Physician ("PCP") offices, use of predictive modeling; describe individualized care program for high-risk and multiple chronic condition patients; and identify target populations for program expansion).*

6. Drive patient-centeredness

   Required documentation: *use of patient satisfaction survey results to improve care; process for evaluating health needs of assigned population with consideration of diversity; system to identify high-risk patients and develop individualized care plans integrating community resources; policies on beneficiary access to services and medical records.*

ACO Governing Body

1. With the exception of a single-entity ACO, an ACO must have a distinct and separate governing body with responsibility for oversight and strategic direction through a transparent process.

2. ACO participants (as defined below) must hold 75% of voting rights on the governing body. At least one member of the governing body must be a Medicare fee-for-service beneficiary who receives services from an ACO participant. CMS may waive these governing body requirements if the ACO demonstrates good cause for non-compliance.

3. Members of the governing body owe a fiduciary duty to the ACO and must be subject to a conflict-of-interest policy requiring disclosure of a member's financial interests.

ACO Management

1. The governing body must appoint a manager to have operational oversight.

2. An ACO must have a medical director, who is a board-certified physician licensed and present in one of the states in which the ACO operates, to provide clinical oversight.

3. An ACO must have a compliance officer responsible for maintaining a compliance program that incorporates the Office of the Inspector General's ("OIG") seven elements of an effective program.

4. An ACO must adhere to specific audit and record retention requirements.

ACO Composition

1. An ACO is comprised of one or more ACO participants. An ACO participant is an individual or group of providers/suppliers that is identified by a Medicare-enrolled TIN. An ACO's MSSP application must list the TIN for each of its ACO participants.

2. Each ACO participant must commit to remaining in the ACO for three years. A written agreement between the ACO and its ACO participants should describe the parties' respective rights and responsibilities.

3. An ACO provider/supplier is a Medicare-enrolled provider or supplier that bills for items or services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant (e.g., solo practice, group practice, hospital, federally-qualified health center). Each ACO provider/supplier billing under an ACO participant's TIN must individually agree in writing to comply with all MSSP requirements in advance of the ACO submitting its MSSP application.

4. The MSSP regulations do not specify the types of providers/suppliers an ACO must include, except that an ACO must have a sufficient number of physicians to maintain 5,000 attributed Medicare fee-for-service beneficiaries (see Section II.C for a discussion of the attribution rules).

5. If an ACO participant bills Medicare for any primary care services (defined to include HCPSC codes 99201-15; 99304-40; 99342-50; G0402; G0438 and 39; and revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011)) rendered by one of its physician, that ACO participant is limited to participating in one MSSP ACO. However, a physician billing under multiple TINs (i.e., a physician who has reassigned his/her billing rights to more than one entity) could participate in multiple ACOs, each under a different TIN.

6. Any Medicare-enrolled provider/supplier may be identified on an application as an "other entity" affiliated with an ACO (although not included as an ACO participant). Such provider/supplier still may be involved in the ACO's activities and receive shared savings distributions. CMS will not consider any "other entity" for beneficiary attribution, and thus such provider/supplier does not have to be exclusive to one ACO.

7. The IRS has issued guidance on the manner in which a tax-exempt organization may participate in an ACO without jeopardizing its tax-exempt status or having to pay unrelated business income tax on its shared savings distribution.

Fraud and Abuse Waivers

The Secretary of Health and Human Services has statutory authority to waive requirements of the Stark Law, the Federal Anti-Kickback Statute, and the civil monetary penalties law as necessary to carry out the MSSP. Concurrent with the publication of the final rule, CMS and OIG promulgated five specific waivers. The following arrangements will not be subject to the fraud and abuse laws (provided all requirements listed in the waivers are satisfied):

1. **ACO pre-participation waiver.** Board-authorized and properly documented arrangements undertaken as part of a diligent effort to develop an ACO up to one year prior to the MSSP application deadline.

2. **ACO participation waiver.** Board-authorized and properly documented arrangements between ACO participants reasonably related to the purposes of the MSSP.

3. **Shared savings distribution waiver.** Distribution of shared savings among ACO participants and/or use of such monies to support ACO operations.

4. **Compliance with Stark Law waiver.** An arrangement between ACO participants that meets an existing Stark Law exception also is deemed to comply with the Anti-Kickback Statute and the civil monetary penalties law.

5. **Patient-incentive waiver**. Items or services offered to a beneficiary by an ACO or an ACO participant for free or below fair market value that are reasonable related to the beneficiary's medical care.

Antitrust Analysis

Concurrent with the publication of the final rule, the Federal Trade Commission ("FTC") and Department of Justice ("DOJ") published their statement of antitrust enforcement policy regarding MSSP ACOs.

1. **Antitrust safety zone.** If (a) none of an ACO's primary service area shares exceed 30% (as calculated in the manner specified in the statement and subject to certain exceptions), and (b) none of the ACO's hospitals or Ambulatory Surgery Centers ("ASCs") are exclusive to that ACO, the agencies will not challenge the agreement absent extraordinary circumstances.

2. **Conduct to avoid.** The agencies warn ACOs outside the safety zone from engaging in certain potentially anti-competitive conduct including improper exchanges of prices and other competitively sensitive information among ACO participants and pursuing certain arrangements with private payers.

3. **Expedited voluntary antitrust review.** A newly formed ACO desiring further antitrust guidance regarding its structure and operations may request a 90-day expedited review from the agencies prior to its entrance into the MSSP.

Interactions with Medicare Fee-for-Service Beneficiaries

1. Every ACO participant must give each Medicare beneficiary to whom that ACO participant furnishes services (excluding those enrolled in a Medicare Advantage Plan) a standard written notice stating the ACO participant is part of an ACO, as well as a data use opt-out form (*see* Section II.C.3 below). Also, each ACO participant must post a similar notice at its facility.

2. Neither an ACO nor its participants may (a) impose restrictions on a beneficiary's right to seek services from non-ACO participants, or (b) attempt to avoid at-risk (high cost) beneficiaries.

3. Any marketing materials an ACO intends to use (and any revisions to those materials) must be submitted to CMS prior to any use. Such materials will be deemed approved following expiration of a five-day review period.

Part II – Shared Savings Payments

An ACO participant will receive the same Part A and Part B fee-for-service payments as a provider who does not participate in an ACO. An ACO is eligible for an annual payment based on Medicare savings, i.e., the difference between Medicare's projected total expenditures for the ACO's assigned beneficiaries (benchmark) and Medicare's actual total expenditures for those same beneficiaries.

Keep in mind the savings are not based exclusively on fee-for-service payments to ACO Participants; they are based on fee-for-service payments to all providers, including those who are not ACO Participants.

For example, an ACO that includes only physician practices as ACO participants would realize shared savings through reduced hospitalizations, reduced utilization of independent diagnostics testing facilities, etc.

One-Sided vs. Two-Sided ACOs

In submitting its application, an ACO must state whether it wishes to participate initially as a one-sided or two-sided ACO.

A one-sided ACO is eligible for an annual shared savings payment, but does not pay any penalty if actual expenditures exceed the benchmark. An ACO may elect the one-sided model for its first three-year agreement period only.

A two-sided ACO pays a penalty based on a percentage of actual expenditures in excess of its benchmark. In exchange for accepting this risk, a two-sided ACO receives a higher percentage of the shared savings if actual expenditures are less than its benchmark.

See Appendix A for a sample calculation of shared savings and shared losses (for a two-sided ACO).

Beneficiary Assignment

1. The first step in determining whether and how much of a shared savings payment an ACO will receive is the assignment of Medicare fee-for-service beneficiaries to the ACO. CMS notes "the term 'assignment'… in no way implies any limits, restrictions, or diminishment of the rights of [beneficiaries] to exercise complete freedom of choice in the [providers] from whom they receive their services." CMS "characterize[s] the process more as an 'alignment' of beneficiaries with an ACO," based on a beneficiary's utilization of primary care services.

2. CMS will use the following step-wise process for beneficiary assignment:

- Assign to an ACO each beneficiary who received a primary care service (as defined previously) from one of the ACO's primary care physicians[1] during the most recent 12-month period if the total allowed charges for primary care services furnished to that beneficiary by the ACO's PCPs during that time period are greater than the allowed charges for primary care services furnished by PCPs who are part of another ACO and those not affiliated with any ACO.

- Assign to an ACO each beneficiary who received primary care services from an ACO Participant but has not had such services rendered by a PCP either inside or outside the ACO during the most recent 12-month period if the total allowed charges for primary care services furnished by all ACO professionals[2] during that time period is greater than the allowed charges for primary care services furnished by ACO professionals who are part of another ACO and those not affiliated with any ACO.

3. Employing this step-wise process, CMS will make preliminary assignments at the beginning of a performance year for the ACO's planning purposes, based on most recent available data. CMS then will update those assignments quarterly, based on the most recent 12 months of data. Final assignment, which is used to calculate shared savings, will be based on actual data from the performance year.

4. Upon request, CMS will furnish the following information to an ACO: (a) aggregate claims data for those beneficiaries preliminarily assigned to the ACO; and (b) certain beneficiary identifiable claims data, but only if (i) the ACO has signed a data use agreement, and (ii) the beneficiary has not formally opted out of such data sharing.

[1] Defined as physicians with specialty designations of internal medicine, general practice, family practice, or geriatric medicine, or, for services furnished in a Federally Qualified Health Center or Rural Health Clinic, physicians listed on an attestation submitted with the ACO's application.

[2] Defined as a physician, physician assistant, nurse practitioner, or clinical nurse specialist

Expenditure Benchmark

1. The ACO's contract with CMS will state the ACO's specific expenditure benchmark. The formula for arriving at this benchmark is complicated, and involves the following:

- CMS will calculate a preliminary benchmark based on actual Part A and Part B expenditures (excluding IME and DSH payments) for beneficiaries who would have been assigned to the ACO for the prior three-year period.
- The initial benchmark then will be trended forward to current year dollars and adjusted each performance year for overall growth and beneficiary characteristics. Also, technical adjustments will be made to eliminate the financial impact of current value-based purchasing initiatives.

2. CMS will update an ACO's benchmark annually, based on the projected absolute amount of growth in national per capita expenditures under Parts A and B.

Minimum Savings (Loss) Rate

An ACO must achieve a minimum savings rate ("MSR") (a set percentage by which actual expenditures are less than the ACO's benchmark) to be eligible for shared savings payments.

1. For one-sided ACOs, the MSR ranges from 3.9% for ACOs with 5,000 assigned beneficiaries to 2.0% for ACOs with 60,000 or more beneficiaries.
2. For two-sided ACOs, a flat 2% MSR applies, regardless of the number of assigned beneficiaries. On the flip side, these ACOs will not share in a loss of less than 2%.

Both one-sided and two-sided ACOs receive first-dollar savings; CMS does not withhold the initial savings for itself. *See* Appendix A for a sample calculation of shared savings and shared losses (for a two-sided ACO).

Performance Standards (Quality Measures)

To be eligible for any shared savings payment for a given year, the ACO must meet minimum performance standards based on 33 specified quality measures. This prerequisite is intended to prevent ACO participants from achieving savings by withholding necessary services.

1. Seven of the 33 measures address patient/caregiver experience of care; six relate to care coordination/patient safety; eight are categorized as preventive health; and 12 concern at-risk populations (diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease). Each measure has National Quality Forum endorsement or is currently used in other CMS quality programs.

2. For Year One, an ACO that reports on all measures will receive the highest percentage of shared savings available to it (*see* Section F). For Year Two, the ACO's performance score (and thus its percentage of shared savings) will be based on a combination of reporting on some measures and the ACO's actual performance on others.

3. Thereafter, the ACO's actual performance on all 33 quality measures (expressed as a percentage of total points available) will determine the percentage of shared savings the ACO will receive. If the ACO's scores fall below a specified level, it will not receive any shared savings payment.

Savings (Loss) Sharing Rate and Savings (Loss) Cap

One-sided ACO

1. In its first year, a one-sided ACO will have a savings sharing rate of 50% (i.e., it will receive 50% of the savings, with CMS retaining the rest) if it submits reports on all 33 quality measures, regardless of its scores on those measures.

2. In its second year, a one-sided ACO with a 100% performance score also will have a 50% savings sharing rate. ACOs with lower performance scores will have correspondingly lower savings sharing rates (i.e., receive less than 50% of the savings).

3. A one-sided ACO's shared savings payment (actual dollars) cap is an amount equal to 10% of the ACO's expenditure benchmark (i.e., if the benchmark is $10,000,000, the ACO's payment could not exceed $1,000,000).

Two-sided ACO

1. A two-sided ACO with a 100% performance score will have a savings sharing rate of 605 (i.e., it will receive 60% of the savings). During the first year, a two-sided ACO will receive a 100% performance score if it reports on all 33 measures, regardless of its scores. Again, ACOs with lower performance scores will have correspondingly lower savings sharing rates.

2. A two-sided ACO's shared savings payment (actual dollars) is capped at an amount equal to 15% of the ACO's expenditure benchmark (i.e., if the benchmark is $10,000,000, the ACO's payment could not exceed $1,500,000).

3. In the event of a loss (actual expenditures exceed benchmark by more than 2%), the ACO's loss sharing rate will equal one, minus the ACO's savings sharing rate based on its percentage performance score. For example, if the ACO's performance score would have resulted in a 45% savings sharing rate, the ACO's loss sharing rate would be 55%. In that event, the ACO would owe CMS an amount equal to 55% of the amount by which the actual expenditures exceeded the benchmark.

4. For two-sided ACOs, the shared loss cap (i.e., the upper limit on the ACO's liability to CMS for losses) would be phased in over a three-year period starting in the year the ACO first participates in the two-sided model: 5% of the benchmark in Year One, 7.5% in Year Two, and 10% thereafter.

See Appendix A for a sample calculation of shared savings and shared losses (for a two-sided ACO).

Payments From and To CMS

1. CMS will notify an ACO in writing if it is entitled to a shared savings payment and, if so, the amount of that payment. Upon receipt, the ACO must distribute the funds using the pre-determined formula specified in its application.

2. For a two-sided ACO whose expenditures exceed the benchmark by more than 2%, CMS will make a written demand for repayment. The ACO must make payment in full within 30 days, and submit a certification of compliance and accuracy of information.

3. As part of its application, an ACO that elects the two-sided model must identify an acceptable method for repaying losses equal to at least 1% of per capita expenditures from the most recent year of data. Such methods may include recouping funds from Medicare payments to ACO participants, reinsurance, placing funds in escrow, obtaining surety bonds, or establishing a line of credit or other repayment mechanism.

4. There is no right of appeal with respect to CMS' determinations relating to the amount of shared savings or losses.

Part III – Other ACO Options – Private payers

Private payors are developing products similar to the MSSP, such as the Blue Cross Blue Shield of Massachusetts Alternative Quality Program. Several products incorporate partial capitation, virtual partial capitation, condition-specific capitation, and medical home payments. Most involve prospective assignment of beneficiaries, thus creating an incentive to manage those specific patients more aggressively, as opposed to the MSSP, which gives ACO participates the incentive to improve overall quality and efficiency in providing services to their entire patient population.

Providers who have made the commitment to form an ACO in compliance with the MSSP regulations should not wait for private payers to come knocking. Instead, there is a tremendous opportunity for even a fledgling ACO to approach private payers and even employers with new contracting opportunities.

We are, as they say, building it as we fly it when it comes to new payment and delivery models. Providers, therefore, should take every opportunity to chart their own course, rather than waiting for a flight plan.

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Appendix A - Example of Shared Savings/Loss Calculations

ONE-SIDED ACO	
Number of Beneficiaries	5,000
Adjusted Per Capita Benchmark	$9,000
Aggregate Benchmark	$45,000,000
Actual FFS Expenditures	(42,750,000)
TOTAL SAVINGS (5%)	$2,250,000
Minimum Savings Rate @ 5,000 Benef. (3.9%)	$1,755,000 (exceeded)
Savings Sharing Rate (Assume 100% Performance Score)	50%
ACO SHARE OF SAVINGS	$1,125,000

Appendix A - Example of Shared Savings/Loss Calculations

TWO-SIDED ACO (Savings)	
Number of Beneficiaries	5,000
Adjusted Per Capita Benchmark	$9,000
Aggregate Benchmark	$45,000,000
Actual FFS Expenditures	(42,750,000)
TOTAL SAVINGS (5%)	$2,250,000
Minimum Savings Rate Flat 2%	$900,000 (exceeded)
Savings Sharing Rate (Assume 100% Performance Score)	60%
ACO SHARE OF SAVINGS	$1,350,000

TWO-SIDED ACO (Loss)	
Number of Beneficiaries	5,000
Adjusted Per Capita Benchmark	$9,000
Aggregate Benchmark	$45,000,000
Actual FFS Expenditures	(47,250,000)
TOTAL LOSS (5%)	$2,250,000
Minimum Loss Rate Flat 2%	$900,000 (exceeded)
Loss Sharing Rate (Assume 100% Performance Score)	40%
REFUND OWED TO CMS BY ACO	$900,000