

Medicare's Shared Savings Program: Accountable Care Organizations Proposed Rule

On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) issued its proposed rule on Medicare's Shared Savings Program: Accountable Care Organizations (ACOs). CMS was mandated under Section 3022 of the Patient Protection and Affordable Care Act (ACA) to establish such a program to promote accountability for beneficiary care and coordinate items and services provided to beneficiaries under Part A and B.

The Shared Savings Program must be in place by January 1, 2012. The proposal will be published in the Federal Register on April 7, 2011, and comments will be accepted until June 6, 2011.

Accountable Care Organizations (ACO's)

CMS defines an Accountable Care Organization, ACO Participant and ACO Provider/Supplier as follows:

ACO: A legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare FFS beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.

ACO participant: a Medicare-enrolled provider of services and/or a supplier, as identified by a TIN.

ACO provider/supplier: A provider of services and/or a supplier that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

ACO's three-part aim is better care for individuals, better health for populations, and lower growth in health care expenditures.

Eligible Entities

As described by statute, the following groups of providers are eligible to participate as an ACO:

- ACO professionals (ie, physicians, practitioners, hospitals, and certain critical access hospitals) in group practice arrangements
- Networks of individual practices of ACO professionals

- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other Medicare providers and suppliers as determined by the Secretary

ACOs must put in place a formal legal structure that allows the entity to receive and distribute payments for shared savings to its participating providers. In addition, ACO's must establish a shared governance mechanism that provides ACO participants with at least 75% control of the governing body.

Application for Participation in the Shared Savings Program as an ACO

ACO's must complete an application to participate in the Shared Savings Program. ACOs must accept responsibility for at least 5,000 Medicare beneficiaries and enter into a binding agreement with CMS to participate in the Shared Savings Program for a minimum of three years, if their application is accepted. ACOs must have a sufficient number of primary care professionals to manage at least 5,000 beneficiaries that are assigned to the ACO.

ACO's must also, as part of its application, describe how they will partner with community stakeholders. This requirement can be satisfied by having a community stakeholder organization representative on the ACO's governing body. Furthermore, ACO's must have a beneficiary representative on its governing body.

Legal Issues Surrounding ACO's

CMS has worked closely with other federal agencies, such as the Federal Trade Commission and Department of Justice, to ensure that its eligibility criteria do not conflict with antitrust requirements. To combat a number of antitrust issues, the proposed rule puts in place detailed criteria ACO's should meet. Those criteria are

- The ACO's operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success, such as a financial or human investment.

- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.
- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the three-part aim.
- The ACO would have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization.

In the absence of meeting these criteria, the ACO must explain how it would be able to achieve the ACO's three-part aim.

In order to determine an ACO's compliance in meeting the aforementioned criteria, as part of the application process, CMS proposes to require ACO's to submit a number of documents, such as participation agreements between the ACO and its participants, organizational charts, and governing body rosters, among many other documents.

Distribution of Shared Savings

CMS proposes that payments would be forwarded to the ACO, as identified by its TIN. While CMS does not have any statutory discretion in how those shared savings are distributed to ACO participants, CMS proposes to require ACO's to include in its application a description of the criteria the ACO will use to distribute savings to ACO participants and providers, as well as how any shared savings will be used to align with the three ACO aims.

Improving the Quality of Care

To achieve the three-part aim, CMS proposes that applications from ACO's must include a description for how it intends to

- Promote evidence-based medicine
- Promote beneficiary engagement
- Report internally on quality and cost metrics
- Coordinate care

CMS proposes to prohibit ACOs from developing any policies that would restrict a beneficiary's freedom to seek care from providers outside the ACO.

Patient-centeredness is also a cornerstone of the ACO concept; therefore, CMS proposes that an ACO would be considered patient-centered if it meets the following

- A beneficiary experience of care survey in place and a description in the ACO application how the ACO will use the results to improve care over time. (Clinician and Group CAHPS Survey)
- Patient involvement in ACO governance (ie, beneficiary representative on the governing body)
- A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in their patient populations, and a plan to address the needs of their population.
- Systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs.
- A mechanism in place for the coordination of care and a process to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO, consistent with meaningful use requirements under the EHR Incentive program.
- A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical record.
- Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

Marketing the ACO

The statute is silent on marketing by ACO's, however the agency is concerned about beneficiaries being misled about services offered by ACO's. As a result, CMS proposes that all marketing materials related to the ACO be approved by CMS prior to their use. In addition, all revisions to marketing materials must be approved. Failure to meet this requirement can result in corrective action or termination from the Shared Savings Program.

Program Integrity Issues

CMS proposes to require ACO's to adopt a compliance plan addressing how it will comply with legal requirements. Contracts and agreements between and among the ACO and its participants, providers, and other entities furnishing services related to ACO activities must be in compliance, as well.

To receive the shared savings payment, the ACO must make a written request to CMS for payment and certify it is in compliance.

ACO governing bodies must also have in place a conflict of interest (COI) policy.

One-Sided Model vs. Two-Sided Model

ACOs can decide between two tracks of participation in the Shared Savings Program. Under the “one-sided” model, the ACO would operate on a shared savings only track for the first two years, but would be required to assume the risk for shared losses in the third year. The second track, or “two-sided” risk model would allow ACOs to share in savings and risk liability for losses beginning in their first performance year, in return for a higher share of any savings in generates. ACOs that choose the one-sided model must transition to the two-sided model in their third year of the initial agreement period. Once an ACO has transitioned to the two-sided model, it cannot go back to the one-sided model if it enters into a subsequent Shared Savings Program agreement with CMS in future years.

CMS will utilize the same eligibility requirement and methodology for the two-sided model as it has for the one-sided model, however, CMS will include additional requirements for those entering into the two-sided track to provide assurances that the ACO could repay incurred losses.

Performance Payment Limit/Minimum Loss Rate

CMS proposes a maximum performance payment that an ACO can receive in any given performance years. While CMS agrees there must be a significant opportunity to receive shared savings through improved quality and care coordination, it must also ensure that ACOs do not excessively underutilize services to the detriment of beneficiaries in order to realize a significant shared savings incentive payment. CMS proposes to set the payment limit at 7.5 percent for the first two years of the one-sided model and 10 percent for all three years under the two-sided model.

CMS is also proposing a minimum loss rate for purposes of computing shared losses when an ACOs actual expenditures exceed its benchmark. CMS is also proposing a cap on the loss sharing rate under the two-sided model. CMS proposes that ACOs establish a self-executing method for repaying losses to the Medicare program by indicating that funds may be recoupled from Medicare payments to the ACOs participants, obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit the Medicare can draw upon, or establishing another repayment mechanism. ACOs would be required to outline its repayment mechanism for approval by CMS, as part of its application.

To further protect the Medicare program, CMS proposes a 25 percent withholding rate to be applied annually to any earned performance payment. This withholding will help ensure ACOs have an adequate repayment mechanism in the event they incur losses.

At-Risk Beneficiaries

Avoiding at-risk beneficiaries is a concern, particularly with ACOs that chose the two-sided model, because there is an increased incentive to lower costs. CMS proposes mechanisms to monitor ACP avoidance of at-risk beneficiaries, including analysis of claims and examination of other beneficiary documentations. At-risk beneficiaries are defined as those who have a high risk score on the CMS-HCC risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are dual-eligibles, have high utilization patterns, have one or more chronic conditions, or a recent diagnosis that is expected to result in increased costs (ie, newly diagnosed cancer).

Determination of Shared Savings and Sharing Aggregate Data

CMS is proposing to use a 6-month run out of claims data to calculate the benchmark and per capita expenditures for a performance year. CMS proposes to provide aggregate data reports, including aggregated metrics on the assigned beneficiary population and beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark. These data will be provided in conjunction with yearly financial and quality performance reports. CMS also proposes to provide quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries.

Assignment of Beneficiaries to ACOs

ACOs will be operationally identified as a set of one or more Tax Identification Numbers (TIN), and beneficiaries will be assigned to an ACO through a TIN based on the primary care services they received from the physician billing under that TIN. Specifically, beneficiaries will be assigned to an ACO if they receive a plurality (allowed charges) of their primary care services from primary care physicians within that ACO.

Primary care physicians will be exclusive to one ACO agreement by whom beneficiary assignment is established. Other ACO participants, such as specialists, would not be restricted to participation in a single ACO, and are free to join more than one ACO. CMS proposes that ACOs submit the NPIs for all ACO professionals as part of its application, as well as a list that separately identifies physicians that provide primary care.

Primary Care Services

Primary care services are defined as a set of services identified by the following HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350, as well as G0402 (Welcome to Medicare visit) and G0438 and G0439 (annual wellness visits).

Beneficiaries are assigned to ACOs based on their utilization of primary care services provided by a physician. CMS proposes to assign beneficiaries with physicians designated as primary

care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care service to beneficiaries.

Identifying Assigned Beneficiaries and Sharing Claims Data

While CMS proposes to retrospectively assign beneficiaries to ACOs, the agency proposes to disclose the name, date of birth, sex and Health Insurance Claim Number of the historically assigned beneficiary population to ACOs at the beginning of the first performance year, if requested. This would allow ACOs to improve care coordination strategies based on care it has provided in the past for beneficiaries who may return to the ACO during the performance year. This proposal is consistent with the Health Insurance Portability and Accountability Act (HIPPA) Privacy Regulations.

CMS also proposes to share beneficiary-identifiable claims data (Parts A, B and D) with ACOs, if the ACO requests such data as part of its application and enters into a Data Use Agreement (DUA) with CMS. The ACO can request to receive this data on a monthly basis, and CMS will provide minimum necessary information on beneficiaries being served by the ACO participants and the ACO providers, if they have not opted out. The ACO must indicate how it will use the data in support of the three-part goal of ACOs. Information received by the ACO under the DUA cannot be shared with anyone outside the ACO.

Regulatory Changes during ACO Agreement Periods

The proposed rule explains that ACOs in the Shared Savings Program will be subject to future changes in regulations with the exception of the following program areas

- Eligibility requirements concerning the structure and governance of ACOs
- Calculation of sharing rate
- Beneficiary assignment

ACOs would still be subject to all requirements applicable to fee-for-service Medicare, such as routine CMS business operations updates and changes in coverage decisions.

Changes in the ACOs processes resulting from regulatory modifications will require the ACO to submit to CMS an explanation of how they will address the changes.

Other Changes during ACO Agreement Periods

CMS proposes that ACOs may not add ACO participants during the course of the agreement, however it may remove them. ACOs may add or remove ACO providers and suppliers. ACOs must notify CMS of such changes within 30 days to determine if the ACO is still eligible to participate in the program.

Quality and Reporting Requirements

ACOs must submit data to the Secretary in order to evaluate the quality of care furnished by the ACO. CMS proposes 65 measures (see pages 174-194 of the display copy of the proposed rule) for use in calculation of the ACO quality performance standard. ACOs must report quality measures for all three years of the agreement. ACOs that do not meet the quality performance threshold so for all proposed measures would not be eligible for shared savings, regardless of how much per capita costs were reduced. If the ACO does not meet the quality performance standard in the second year, the agreement would be terminated. Results for the first program year will be measured via claims data.

In subsequent years, CMS will refine and expand the ACO measures. CMS proposes to expand measure to include other highly prevalent conditions and settings. For example, CMS expects to add quality measures for care furnished in nursing homes.

With respect to data submission, the majority of measures included in the Shared Savings Program are already being submitted through various other quality reporting programs in CMS, such as the Physician Quality Reporting System (PQRS) and Electronic Health Record (EHR) Incentive Program. Some measures will require use of an updated version of the Group Practice Reporting Option (GPRO) tool. Some measures will require ACO attestation. CMS proposes to reserve the right to conduct audits to validate data entered in the GPRO tool.

CMS defines the first reporting year as beginning January 1, 2012 and ending December 31, 2012. CMS will use rulemaking to update the quality measure requirements and mechanisms.

Calculation of Quality Performance Standard

CMS proposes to use a performance score approach to calculating the quality performance standard and determining whether an ACO has met quality performance goals, and therefore, eligible to receive a shared savings payment.

The proposed rule describes 5 domains (patient experience, care coordination, patient safety, preventive health and at-risk population) that each of the 65 measures will fall into.

Performance scores will be generated at the individual measure and domain level. The percentage of points earned for each domain will be aggregated using a weighted method. The aggregated domain scores will determine if the ACO is eligible for sharing up to 50 percent of the total savings under the one-sided model or 60 percent of the total savings under the two-sided model.

CMS proposes to set the quality performance standard for individual measures and domains in the first year of the program at the reporting level. CMS will set the standard at a higher rate in

subsequent years. As a result, the performance score generated for the first year would be used for informational purposes only.

PQRS and EHR Reporting Requirements

CMS proposes to incorporate a PQRS GPRO under the Shared Savings Program. Specifically, eligible professionals can participate in the PQRS and earn a bonus by allowing the ACO to submit data on their behalf as a group practice. Measures would be chosen from the list of 65 that are included in the Shared Savings Program. Eligible professionals that satisfactorily report during the reporting period would qualify for an incentive payment of 0.5 percent of the ACO's eligible professionals total estimated Medicare Part B fee-for-service allowed charges for covered professional services furnished during the first performance period.

Eligible professionals cannot qualify for the PQRS incentive under the ACO as a group practice, and also as an individual.

Professionals may still qualify for the EHR Incentive Program or Electronic Prescribing Incentive Program as individuals under the Shared Savings Program.

“Meaningful Use” in the Shared Savings Program

CMS proposes that 50% of the primary care physicians in an ACO must be “meaningful EHR” users by the start of the second year of the Shared Savings Program. CMS proposes to update the GPRO tool to allow the EHR system to automatically populate. CMS anticipates that certified EHR technology will be an additional measure reporting mechanism used by ACOs in future years.

Public Reporting of ACO Information and Data

CMS proposes to make information on ACOs available to the public information. Specifically, the agency proposes to provide information on providers and suppliers that participate in the ACO, parties sharing in the governance of the ACO, quality performance standard scores, and general information on how ACOs share savings with its members. ACOs will need to make this information publicly available in a standardized format that will be described in future CMS communications.