



**Medicare Shared Savings Program: Accountable Care Organizations
Highlights of Proposed Rule
April 13, 2011**

The Centers for Medicare and Medicaid Services (CMS) put on display at the Office of the Federal Register proposed rules implementing section 3022 of the Affordable Care Act that established the Medicare Shared Savings Program through participation in Accountable Care Organizations (ACOs) on March 31, 2011. On April 7, the proposed rule was published in the *Federal Register*.

ACOs were created to encourage groups of health care providers to coordinate the care furnished to Medicare beneficiaries across Parts A and B, create incentives to enhance quality, encourage investment in infrastructure, improve outcomes, and increase the value of care. The ACO, accordingly, must be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiary assigned. ACOs that successfully meet quality and savings requirements will share a percentage of the savings achieved.

CMS will accept public comments on the proposed rule until June 6, 2011. The document is available at this link: <http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf>.

This rule is complex and sets a new Medicare reimbursement framework. Below is an overview of key elements. Understanding all of the contents of the rule will be necessary to evaluate and make participation decisions.

Eligibility

An ACO is a legal entity recognized and authorized under applicable State law, identified by a Taxpayer Identification Number (TIN), and comprised of eligible ACO participants. Eligible groups of ACO participants are 1) ACO professionals in group practice arrangements; 2) networks of individual practices of ACO professionals (such as independent practice arrangements); 3) partnerships or joint venture arrangements between hospitals and ACO professionals; and 4) hospitals employing ACO professionals. ACO professionals are defined as internists, family practice physicians, general practice physicians, and geriatric medicine physicians.

Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) are not eligible to become ACOs, but may be a part of an ACO's structure. Critical Access Hospitals that bill with "Method II" (submitting bills for both the facility and the professional services to a fiscal intermediary) would generally be eligible to form an ACO.

In addition, ACOs must also have the primary care capacity to care for a minimum of 5,000 beneficiaries, structures in place to distribute shared savings, and be prepared to enter into an agreement with the Secretary of Health and Human Services for a three-year term of participation. However, ACOs can resign from the program with 60 day notification to CMS. Those terminating before the enrollment term is up, forfeit withholds.

As part of the application process, ACOs must demonstrate many things, including, that they have a beneficiary experience of care survey in place, have patient participation on the governing board, have a process for evaluating the health needs of their patient population, systems in place to identify high-risk individuals, processes for individualized care plans, coordination of care mechanisms (including care coordinators on staff), and electronic infrastructure sufficient to support such activities.

Legal Structure and Governance

Existing ACOs do not have to change their current governance if they meet the criteria, which include having a governing body with beneficiary representation in addition to having Medicare providers comprise 75 percent of the governing body. There must be a leadership team with demonstrated ability to direct clinical practice, and clinical management by a senior-level medical director. Processes to promote and monitor clinical improvements based on evidence-based practice or clinical guidelines are required, as is an infrastructure to collect and evaluate data in order to provide feedback to providers. ACOs must also have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.

ACO Marketing Materials and Communications

ACO marketing materials and communications to beneficiaries must be approved by CMS prior to use. Examples of covered actions and materials are brochures, advertising, outreach activities, letters, websites, and mailings. Not covered by this requirement is information customized to a specific subset of beneficiaries, individual health related issues, referrals, and specific billing/claims issues.

Beneficiary Assignment

CMS is proposing to use a combination of retrospective and prospective assignment approaches to assign beneficiaries to ACOs. CMS will retrospectively assign beneficiaries to an ACO if they receive a plurality of their primary care services based on allowable charges, from a primary care physician within that ACO. Historical claims data for these beneficiaries will be the basis of calculating the benchmark, the expenditure target.

Shared Savings Determination Process

CMS estimates the benchmark for an ACO based upon the assigned beneficiaries' claims of the prior three most recent available years using the per capita Parts A and B fee-for-service (FFS) expenditures, which are adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC (Hierarchical Condition Category, the risk adjustment methodology used in Medicare Advantage (MA)). The benchmark will be updated annually based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

The benchmark is compared to actual ACO expenditures. The difference is “gross shared savings”. This is the “savings threshold” set to account for random statistical fluctuations, a function of the size of the enrolled population. It is an amount of savings that must be attained before shared savings begin to be tallied for possible sharing; it is effectively deducted from the gross shared savings. The minimum savings rate (MSR) minimum is 2 percent of shared savings along a sliding scale based on size of enrolled population, with a maximum of 3.9 percent. Small ACOs, those with fewer than 10,000 beneficiaries, meeting other criteria, will be exempt from the MSR.

Quality measures factor into the equation. In year one, all of 65 measures must be reported (in CMS’s words “accurately and completely”, or not be eligible for shared savings). In subsequent years, each measure will be scored as a percentage, depending on attainment of performance criteria. This percentage is applied to the gross shared savings, the result of which is split between CMS and the ACO. The split is up to 50 percent for track one participants and 60 percent for track two (with up to 2.5 and 5 percent additional incentives for including FQHC/RHCs in the ACO’s structure, respectively). There is a cap on the amounts that may be paid out to ACOs. That cap is 7.5 percent of the benchmark for track one, and 10 percent of the benchmark for track two.

For those in track two, and year three of track one, sharing loss risk is involved. This is also capped and has a graduated loss corridor with a maximum loss sharing of 5 percent of the benchmark for year one, 7.5 percent for year two, and 10 percent of year three. Losses in excess of the cap are absorbed by CMS. Losses below the cap are paid back by the ACO to CMS. To reserve money for this purpose, a 25 percent withhold applies.

Quality Measurement and Reporting

CMS proposes that ACOs will report on 65 quality measures from the outset. CMS has categorized the measures into five domains which will serve as the basis to assess, and reward ACO quality performance: 1) patient/caregiver experience, 2) care coordination, 3) patient safety, 4) preventive health, and 5) at-risk population/frail elderly health. For the first year only, ACOs will achieve maximum performance by simply submitting data for all 65 measures. For the second and subsequent years, ACOs must meet a quality performance standard, i.e., the measures will be scored for attaining performance criteria.

A minimum aggregate threshold of 30 percent must be attained in order to garner any shared savings. Greater attainments will yield greater shared savings as per Table 3 from the rule below:

Table 3: Sliding Scale Measure Scoring Approach
ACO Performance Level Quality Points

90+ percentile FFS/MA Rate or 90+ percent	2 points
80+ percentile FFS/MA Rate or 80+ percent	1.85 points
70+ percentile FFS/MA Rate or 70+ percent	1.7 points
60+ percentile FFS/MA Rate or 60+ percent	1.55 points
50+ percentile FFS/MA Rate or 50+ percent	1.4 points
40+ percentile FFS/MA Rate or 40+ percent	1.25 points
30+ percentile FFS/MA Rate or 30+ percent	1.10 point
<30 percentile FFS/MA Rate or <30 percent	No points

Measures will evolve and change over time. CMS has stated its objective to harmonize measures in various Federal reporting programs such as the Physician Quality Reporting System (PQRS), hospital quality reporting, and eventually private initiatives, to the extent possible. Reporting on the quality measures will be done through claims, the Group Practice Reporting Option data collection tool, and surveys, depending on the measure.

Health Insurance Portability and Accountability Act (HIPAA) Considerations

ACOs will be required to enter into a Data Use Agreement with CMS that will prohibit them from sharing the Medicare claims data of their beneficiaries outside of the ACO. ACOs must also give beneficiaries advance notification of ACO plans to use claims data for performance evaluation of providers and to improve the health of its patient population.

Beneficiaries can choose to opt-out of sharing claims data with the ACO. Opting out will have no effect on use of the data for assigning beneficiaries to ACOs, tracking per capita costs, or benchmarking activities essential to the functioning of ACOs. The opt-out provision has no effect on the ability of ACO providers to share patient information for the purposes of care coordination or other health care operations activities, pursuant to the current HIPAA regulatory framework.

CMS and HHS' Office of Inspector General (OIG) Waiver Proposals

Several additional documents which have a bearing on ACOs were released with the shared savings proposed rule. The first, a joint CMS and OIG notice, solicits public comments, and addresses the application of the Physician Self-Referral Law, the Federal Anti-Kickback Statute, and the Civil Monetary Penalties Law, to ACOs participating in the Shared Savings Program. CMS and OIG have outlined proposals to waive these laws in three circumstances:

- 1) The distribution of Program's shared savings payments received by an ACO to or among qualified ACO participants and ACO providers/suppliers described in the notice with comment period.
- 2) An ACO's distribution of program's shared savings payments to other individuals or entities for activities necessary for and directly related to the ACO's participation in the Shared Savings Program.
- 3) For the anti-kickback statute and CMP *only*, certain financial relationships that are necessary for and directly related to the ACO's participation in the Shared Savings Program *and* fully comply with an exception to the physician self-referral law.

These waivers would cover shared savings earned during the agreement period with CMS and, as applicable, financial relationships existing during the term.

Federal Trade Commission (FTC) and Department of Justice (DOJ) Proposed ACO Antitrust Policy

The Statement applies to collaborations, not including mergers, among otherwise independent providers formed after March 23, 2010 seeking to participate in the Medicare Shared Savings Program. DOJ and FTC will provide "rule of reason" treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the program.

There are three levels of antitrust enforcement: 1) The Safety Zone, 2) Mandatory Antitrust Review, and 3) ACOs outside Safety Zone and below the 50% threshold.

To fall within the Safety Zone and be free from antitrust concerns, independent ACO participants that provide a common service must have a combined share of 30 percent or less of the market for each common service in each participant's Primary Service Area (PSA), wherever two or more ACO participants provide that service to patients from that PSA. The ACO calculates its PSA shares.

If providers in the ACO represent more than 50 percent of the market for any common service that two or more independent ACO participants provide to patients in the same PSA, they are subject to automatic review by the DOJ and the FTC. DOJ and FTC have committed to a 90-day expedited review of ACOs that exceed the 50 percent PSA share threshold.

To obtain review, ACOs must submit documents relating to the ability of the ACO participants to compete with the ACO, discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets and the ACO's likely impact on the prices, cost, or quality of any service provided, and showing the formation of any ACO or ACO participant that was formed in whole, or in part, or otherwise affiliated with the ACO, after March 23, 2010.

ACOs that are outside the Safety Zone and below the 50 percent mandatory review threshold that do not impede the functioning of a competitive market and that engage in pro-competitive activities will not raise competitive concerns and may participate in the Shared Savings Program without Antitrust Agency review.

The Agencies identified five types of conduct that an ACO can avoid to significantly reduce the likelihood of an antitrust investigation:

- 1) Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO
- 2) Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO
- 3) With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis
- 4) Restricting a commercial payer's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information
- 5) Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO

An ACO desiring greater antitrust certainty can voluntarily seek an expedited review.

Tax-Exempt Organizations

A tax-exempt organization participating in an ACO must ensure that its ACO activities will not yield earnings that benefit insiders. The Internal Revenue Service is soliciting comments regarding whether additional guidance is needed to facilitate participation by tax-exempt organizations in the Shared Savings Program through ACOs.