



DETAILED SUMMARY--MEDCIARE SHARED SAVINGS/ACCOUNTABLE CARE ORGANIZATION (ACO) PROGRAM

Definition of ACO—General Concept

An ACO refers to a group of physician and other healthcare providers and suppliers of services (e.g., hospitals) that will work together and are willing to certify a willingness to become accountable for, and report to CMS, the quality and cost and overall care of Medicare Fee-For-Service beneficiaries assigned to the ACO. The formal ACO definition provided in the rule is:

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participant(s) that is(are) defined at §425.102(a) and may also include any other ACO participants described at §425.102(b).

ACO participant means an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled Tax Identification Number (TIN), that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under §425.204(c)(5).

ACO Composition and Limitations

ACOs can be composed of ACO professionals in:

- Group practice arrangements,
- Networks of individual practices of ACO professionals,
- Partnerships or joint ventures arrangements between hospitals and ACO professionals,
- Hospitals employing ACO professionals,
- Federally Qualified Health Centers (FQHCs), Rural health Clinics (RHCs) and Critical Access Hospitals (CAHs) that employ method II billing, or
- Other Medicare providers and suppliers as determined by the Secretary.

An ACO professional is defined in the rule as a physician, as well as a physician assistant, nurse practitioner or clinical nurse specialist.

The statute also includes a provision that precludes duplication in participation in other Medicare initiatives involving shared savings. Several current initiatives in which ACO participants receive shared savings such that they would be prohibited from participation in the Shared Savings Program include Independence at Home, the PGP Transition demonstration, the Care Management for High-Cost Beneficiaries Demonstrations, and the Pioneer ACO Model through the Innovation Center.

Required Legal Structure

The rule requires an ACO to have a formal legal structure that would allow the organization under relevant state, federal or tribal law to perform all relevant functions identified in the statute e.g. receive and distribute payments for shared savings to participating providers of services and suppliers.

An ACO entity that is developed from an entity with a pre-existing legal structure that allows it to perform all the functions indicated within the statute is not required to form a new legal structure. ACOs composed of separately recognized legal entities must establish a new legal entity that is composed of the combined participants.

The ACO's legal entity may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by State law.

Required Governance

ACO must maintain an identifiable governing body with authority to execute the functions of the ACO as defined in this final rule.

- The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities.
- The governing body must have a transparent governing process.
- The governing body members shall have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.
- The ACO must have a conflicts of interest policy for the governing body.
- The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

At least 75 percent of the governing body must consist of ACO participants.

Each ACO must provide beneficiary representation on its governing body.

An ACO can request a variation from the above requirements.

Leadership, Management and Operational Requirements

The ACO must have a leadership and management structure that includes clinical and administrative systems. The ACOs must meet the following criteria:

- Operations are managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body.
- Clinical management and oversight are managed by a senior-level medical director who is a board-certified physician.
- ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO, or a meaningful human investment (for example, time and effort) in the ongoing operations of the ACO.

- The ACO must have a quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program. This committee does not have to be physician-lead.
- As part of the application process, the ACO must submit specified documentation to ensure it meets the above requirements.
- The ACO can request consideration of innovative leadership and management structures that do not meet the above requirements.

Additional Clinical and Administrative Requirements for Participation

The final rule establishes a number of additional requirements which must be satisfied by the ACO to be eligible to participate in the Shared Savings Program. These are documented plans to:

- (1) promote evidence-based medicine --- Guidelines employed must cover diagnoses with significant potential to achieve quality improvements, taking into account the circumstances of individual beneficiaries;
- (2) promote beneficiary engagement --- The ACO is required to engage in the following processes (a) evaluating the health needs of the ACO's assigned population; (b) communicating clinical knowledge/evidence-based medicine to beneficiaries; (c) beneficiary engagement and shared decision-making; and (d) written standards for beneficiary access and communication, and a process in place for beneficiaries to access their medical record;
- (3) report internally on quality and cost metrics --- provide processes and infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics to enable the ACO to monitor, provide feedback, and evaluate ACO participant and ACO provider/supplier performance and to use these results to improve care and service over time; and
- (4) provide coordinate care --- define their care coordination processes across and among primary care physicians, specialists, and acute and post acute providers. The ACO must also define its methods to manage care throughout an episode of care and during its transitions; particularly for high-risk and multiple chronic condition patients. The ACO must also address processes to partner with community stakeholders.

Minimum Beneficiary and Primary Care Requirements

The ACO must serve at least 5000 Medicare beneficiaries.

The ACO must include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO. An ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the three-year benchmarking period using the ACO participant tax identification numbers (TINs) exceeds the 5,000 threshold for each year.

Additional Contractual Agreements with the Secretary

The ACO must agree to participate for no less than a 3 year period. A roll-out start up structure will be implemented in 2012 with start dates of April and July. For ACOs starting in 2012, their first year performance periods will extend until December 31, 2013 with a three month “claims run-out” period to ensure including the predominance of claims over that time period.

The ACO agrees to be responsible for all regulatory changes in policy during the length of the contract except for: the eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and beneficiary assignment. ACOs have the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the agreement period which the ACO believes will impact the ability of the ACO to continue to participate in the Shared Savings Program.

ACO participants and providers/suppliers can be added and subtracted over the course of the agreement period upon at least 30-day notification to CMS.

Beneficiary (Attribution) Assignment Process

Beneficiaries will be assigned on a prospective basis using a two-step process.

- Beneficiaries are first assigned to ACOs on the basis of those primary care physicians (i.e. internal medicine, family practice, general practice, geriatric medicine) participating in the ACO that provide a plurality (allowed charges) of defined primary care services (HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350), the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) to the beneficiary.
- If assignment is not possible under step one, then an attempt will be made to assign the beneficiary to an ACO on the basis of receiving a plurality of primary care services from physicians and other healthcare professions (e.g. nurse practitioners, physician assistants) participating within the ACO.

CMS will update the list of preliminary prospectively assigned beneficiaries during the performance year, and at the end of the year will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year.

The final rule clarified that ACO providers through which assignment is based must be exclusive to one ACO only if they solely bill for their services through a TIN used to define that ACO. This allows for clear beneficiary attribution. Such providers can participate in multiple ACOs if they bill under separate TINs for each ACO.

Physicians and other providers not considered in the assignment process can participate in multiple ACOs.

Shared Saving Options

Savings/loss determinations are based upon the difference between FFS expenditures (Parts A and B) for the defined population for the year and a risk-adjusted benchmark that is an estimate of the Part A and B Medicare expenditures that would have occurred in the defined population in the absence of the ACO. The expenditure benchmark is based on the previous 3 year expenditures history (Medicare Parts A and B) of prospectively assigned beneficiaries to the ACO. IME and DSH payments are excluded from the benchmark calculation. The benchmark will be:

- adjusted each year based upon changes in the defined population and the demographics of the continuing population.
- adjusted each year based on the national projected growth in expenditures.
- adjustments will be made separately for the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

ACO's can choose one of two shared savings risk models (tracks):

One-sided risk --- the ACO would operate under a shared savings only model (no loss potential) for the three years of the initial contract. This would be more suitable for smaller ACO's and those with minimal experience with this type of accountable care activity. These groups would be limited to a maximum of 50% of obtained savings each year. This one-sided risk option is only available during the first 3-year contract.

Two-sided risk --- participants would be at risk of a portion of losses for each year of the 3 year period. These groups could earn up to a maximum of 60% of obtained savings. Losses must be over 2% of benchmark to be considered. Once above this minimum, these ACO's would be responsible for paying losses on a "first dollar" basis calculated by multiplying the loss amount (excess above benchmark) by 1 minus their final sharing rate (maximum shared rate (60 percent) adjusted by quality score). Maximum loss sharing limits are 5 percent, 7.5 percent and 10 percent of the benchmark over the first three years of the contract. ACOs under this track must provide a loss repayment mechanism in its application that ensures repayment of potential losses to at least 1 percent of assigned beneficiaries Part A and B expenditures.

In order to be eligible for shared savings, the ACO must first meet specified quality and performance benchmarks, and then achieve savings above a defined minimum savings rate (no less than 2% -- varies based on the size of the ACO; smaller number of beneficiaries, higher the required minimum up to 3.9%) to reduce savings/loss outcomes based on random variation. Shared earnings will be based on "first dollar" under both options, once the minimum rate below the benchmark is achieved.

Maximum shared earning payment under Track One is 10 percent of benchmark, and 15 percent of benchmark under Track Two.

All shared savings go directly to the ACO as identified by its TIN --- rule does not specify how shared savings must be distributed.

Performance and Quality Measures

CMS has finalized 33 quality measures to be used in the ACO from four key domains: patient/caregiver experience, preventive health, care coordination/patient safety and at-risk populations. These are predominately nationally recognized/vetted measures (e.g. NQF approved) and/or aligned with the measures used in other CMS programs (e.g. PQRS).

Data collection is from multiple sources: 7 via patient survey, 3 via claims, 1 via EHR Incentive Program data and 22 via the CMS GPRO web interface (which will allow for direct uploading from EHRs).

CMS has finalized the CG-CAHPS Survey as the measure of patient experience of care. CMS will fund the administration of this survey for ACOs participating in the shared savings program for 2012 and 2013.

CMS is encouraging providers to participate in the Shared Savings Program in 2012 by setting the quality performance standard for the first year to reporting only and will phase in pay for performance over years 2 and 3. All quality data will have a 12-month calendar year reporting period regardless of start date.

The amount (rate) of shared earnings that will be distributed to the ACO or losses returned to CMS is a function of the ACO's performance on the quality measures. Points (0-2) can be earned on each measure based on national (determined from FFS and Medicare Advantage data) benchmarks. CMS will use a methodology that provides scores for each domain, and then weigh each domain equally, to determine an overall quality score.

The final rule establishes the minimum quality attainment level for each measure at a national flat 30 percent of the national Medicare FFS or MA performance. ACOs will have to score at or above the minimum attainment level in order to receive any credit for reporting the quality measure.

ACOs will also be required to achieve the minimal quality performance standard on 70 percent of the measures in each domain during each performance year. If an ACO fails to achieve the minimal quality performance standard on at least 70 percent of the measures in each domain, the ACO will be placed on a corrective action plan and be re-evaluated the following year. If the ACO continues to underperform in the following year, the agreement would be terminated.

An ACO that successfully reports the quality measures of its participating providers required under the Shared Savings Program would also be deemed automatically eligible for the PQRS bonus. An ACO does not have to qualify for any shared savings to qualify for the PQRS.

Beneficiary Notification

ACO participants are required to post signs in their facilities indicating their participation in the Shared Savings Program and to make available standardized written notices developed by CMS

to Medicare FFS beneficiaries whom they serve. ACOs may choose to provide advanced notification of their participation to the beneficiaries who appear on the preliminary prospective assignment list and quarterly assignment lists.

Beneficiaries do not have the right to opt out of the ACO assignment, while they do have the right to decline data sharing. Beneficiary assignment to an ACO is solely for purposes of determining the population of Medicare FFS beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings, and in no way diminishes or restricts the rights of beneficiaries to exercise free choice in determining where to receive health care services.

Beneficiary Data Sharing

CMS recognizes the need to provide data to the ACO for care planning purposes, and to assist them in providing services consistent with the goals of improved individual health, improved population health, and lower costs. Data use must be HIPAA compliant and consistent with a Data Use Agreement, which includes the prohibition of sharing the data outside of the ACO, required as part of the application process.

CMS will provide ACOs with aggregated (de-identified) data on beneficiary use of health care within their defined population at the start of the agreement period (data from preliminary prospectively assigned beneficiaries), quarterly and yearly.

CMS will also provide ACOs with a list of beneficiary names, dates of birth, sex and Health Insurance Claims Numbers (HICN) derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports and in conjunction with each quarter aggregate report.

ACOs will also be able to formally request beneficiary identifiable claims data on a monthly basis from those beneficiaries:

- who received a primary care service from a primary care physician participating in the ACO, and
- who have had the opportunity to decline such data sharing.

ACO will also be able to contact beneficiaries from the list of preliminary assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data -- beneficiaries will have 30 days to decline data sharing. These beneficiaries will have a second opportunity to be notified of the ACO's program participation and to decline data sharing during the next face-to-face clinical encounter within the ACO.

Public Reporting

The final rule strongly supports the transparency of information within the health care sector. As such, ACOs will be required to publicly report:

- Organizational information regarding the ACO including identification of participants and members of the governing board.

- Shared savings performance payments received and shared losses own.
- Total proportion of shared savings invested in infrastructure, redesign and other efforts to support better care at lower cost.
- Total proportion of shared savings distributed to ACO participants.
- Results of patient experience of care survey and claims based measures. Quality measures reported using the GPRO web interface will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

Impact Statement

CMS estimates a total aggregate median impact of \$470 million in net Federal savings for calendar years (CY) 2012 through 2015 from the implementation of the Shared Savings Program.

CMS anticipates a participation rate of 50 to 270 ACOs during CY 2012 – 2015.

The estimated aggregate cost associated with the start-up investment of ACOs participating in the Shared Savings Program will range from \$29 million to \$157 million. Furthermore, aggregate ongoing annual operating costs for the participating ACOs are estimated to range from \$63 million to \$342 million. Based on these estimates, the average start-up investment for a participating ACO would be approximately \$580,000; with average on-going annual operating costs of approximately \$1,260,000.

CMS has also estimated a total aggregate median impact of \$1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015. Combined with the above cost estimates, CMS further estimates a benefit (bonus)/cost ratio of 2.9 for participating ACOs for the three year contract period.

Protected from Existing Antitrust, Gain-sharing, and Similar Laws that Currently Restrict the Ability of Providers to Coordinate Care and Collaborate

In coordination with release of the ACO final rule, the following statements have also been released:

1. An interim final rule released by CMS, and the Office of the Inspector General (OIG) of HHS that sets forth waivers to certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing Civil Monetary Penalty and the Beneficiary Inducement Civil Monetary Penalty to ACOs formed in connection with the Shared Savings Program. The waivers cover both pre-participation and participation periods.
2. A Final Joint FTC and DOJ Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement). This statement, while indicating that these agencies will continue to vigorously enforce the antitrust laws,
 - States that these agencies will not challenge as a “per se” violation shared savings programs that jointly negotiate with private insurers to serve patients in the commercial market if the

ACO complies with CMS' ACO eligibility requirements and uses the same governance, leadership structures, and clinical and administrative processes to serve patients both in the commercial and Medicare markets,

- Provides "safety zones" regarding shares of ACO participants that provide a common service within a Primary Service Area.
- Provides examples of conduct that under certain circumstances may raise competitive concerns.
- Offers a voluntary, expedited (90 day) review for newly formed ACOs. Agency review is not required under this final statement.

3. An IRS notice, Notice 2011-20 regarding participation by tax-exempt organizations in the Medicare Shared Savings Program through ACOs.

Advanced Payment ACO Model

The Center for Medicare and Medicaid Innovation (CMMI) released, at the same time as the final rule, a demonstration initiative for selected participants of the Shared Savings Programs to receive advanced payments that will be recouped from the shared savings earned. The program is designed to improve access to capital specifically to smaller ACO entities that are physician-owned and/or in rural locations.

Selected participants will receive:

- An upfront, fixed payment of \$250,000 in the first month of the Shared Savings Program.
- An upfront, variable payment in the first month of the Shared Savings Program of \$36 for each preliminary, prospectively assigned beneficiary.
- A monthly payment of \$8 for each for each preliminary, prospectively assigned beneficiary.

CMS will not pursue recoupment of any advanced payments not repaid from shared earning, if the ACO completes the full 3 year contract term and decides not to accept a second three year contract.