

The Medicare Shared Savings Program

Overview of Agency Final Rules & Guidance

October 21, 2011

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Overview

Statutory Background

- Sec. 3022 of the Affordable Care Act (ACA) requires the Secretary to establish the Medicare Shared Savings Program by Jan. 1, 2012
- Program goals:
 - Promote accountability for a patient population
 - Coordinate items and services under Medicare Parts A and B
 - Encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery
- The program is for fee-for-service (FFS) Medicare beneficiaries
- Participating Accountable Care Organizations (ACOs) that meet quality performance standards will be eligible to receive payments for shared savings

Agency Rules and Comment / Application Opportunities Related to the Medicare Shared Savings Program

- **Five documents released on October 20, 2011:**
 - Centers for Medicare and Medicaid Services (CMS) [Final Rule](#) for the Medicare Shared Savings Program/ACOs.
 - Joint CMS and Office of Inspector General (OIG) [Interim Final Rule](#) on waiver designs addressing waivers of the Civil Monetary Penalties (CMP) law, Federal Anti-Kickback Statute, and the Physician Self-Referral law.
 - Comments due by January 2, 2012.
 - Internal Revenue Service (IRS) [Fact Sheet 2011-11](#), confirming that [Notice 2011-20](#) continues to reflect IRS expectations regarding the Shared Savings Program and ACOs, and providing additional information for charitable organizations that may wish to participate in the Shared Savings Program.
 - [Antitrust Policy Statement](#) issued by the Federal Trade Commission (FTC) and Department of Justice (DOJ).
 - [Advance Payment Solicitation](#) issued by the CMS Center for Medicare and Medicaid Innovation soliciting applications for the Advance Payment ACO Model.
 - CMMI will accept applications in “late fall 2011,” with final due date TBD.

Overview of Regulatory Impact Analysis

- **CMS estimates:**
 - **Aggregate Start-up Investment for ACOs:**
 - \$29 million to \$157 million
 - **Aggregate Ongoing Annual Operating Costs for Participating ACOs:**
 - \$63 million to \$342 million
 - **Aggregate Average Start-Up Investment and Ongoing Annual Operating Costs for ACOs for CY 2012-2015:**
 - \$451 million
 - **Total Median ACO Bonus Payments for CY 2012-2015:**
 - \$1.31 billion
 - **Estimated Number of Participating ACOs:**
 - 50-270
 - **Total Aggregate Impact of Net Federal Savings for CY 2012-2015:**
 - \$470 million (median estimate)
 - Estimated federal savings range: \$0 million to \$940 million

Medicare Shared Savings Program Final Rule

Eligible ACOs

- Entities eligible to form ACOs include:
 - 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
 - Hospitals employing ACO professionals
 - Critical Access Hospitals that bill under Method II
 - Federally Qualified Health Centers (FQHCs)
 - Rural Health Centers (RHCs)
 - *The Final Rule adds FQHCs and RHCs as eligible ACOs.*
- Any other Medicare enrolled provider or supplier may participate as an “ACO participant” by joining an ACO containing one of more of the organizations eligible to form an ACO.

Legal Structure and Shared Governance

- Legal Structure

- An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for purposes of (1) receiving and distributing shared savings; (2) repaying shared losses or other monies determined to be owed to CMS; (3) establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards; and (4) fulfilling other required ACO functions.
 - An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

- Shared Governance

- An ACO must maintain a “governing body” responsible for ACO oversight and strategic direction. The governing body must have a transparent governing process, and must act consistent with a fiduciary duty. It must also be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants. If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies other ACO requirements.
 - An ACO must provide for “meaningful participation” in composition/control of governing body for ACO participants or designated representatives. It *must* include a Medicare beneficiary representative(s) served by the ACO (with no conflict of interest). At least 75 percent control of the governing body must be held by ACO participants.
 - *The Final Rule allows ACOs that do not meet these requirements to find “innovative ways” to involve ACO participants and Medicare beneficiaries in ACO governance.*
 - The ACO governing body must have a conflict of interest policy, meeting specified criteria, that applies to members of the governing body.

Leadership and Management

- Leadership and Management
 - As part of its application, ACOs must submit supporting documentation that demonstrates the ACO leadership and management structure, including clinical and administrative systems that align with and support the goals of the Medicare Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures. The Final Rule provides a detailed list of the required documentation.
 - ACO operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the governing body and whose leadership team can influence or direct clinical practice to improve efficiency, processes, and outcomes.
 - Clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, who is physically present on a regular basis in an established ACO location, and who is board-certified and licensed in a State in which the ACO operates.
 - *The Final Rule eliminates the requirement that the medical director be full-time.*
 - Each ACO participant and each ACO provider/supplier must demonstrate a “meaningful commitment” to the ACO mission, as described in the Final Rule.
 - CMS will consider “innovative” ACOs with a management structure not meeting the above requirements.

Sufficient Number of Primary Care Providers and Beneficiaries / Required Reporting

- Sufficient Number of Primary Care Providers and Beneficiaries
 - CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants is 5,000 or more.
 - If at the end of a performance year, an ACO's assigned population falls below 5,000, then that ACO will be issued a warning and placed on a corrective action plan; if the ACO's assigned population has not returned to at least 5,000 by the end of the next performance year, then the agreement will be terminated and the ACO will not be eligible to share in savings for that year.
- Required Reporting on Participating ACO Professionals
 - A participating ACO must maintain, update, and annually report to CMS the following: (a) each ACO participant's tax ID number (TIN); (b) each ACO providers/supplier's National Provider Identifier and/or TIN.

Application Requirements / Evaluating Shared Savings

- **Distribution of Savings**
 - As part of its application, an ACO must describe how: (a) it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its participants; (b) the proposed plan will achieve the specific goals of the program; and (c) the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.
- **Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care, and Patient-Centeredness**
 - An ACO must provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care.
 - As part of these processes, an ACO must adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams.
- **Evaluating Shared Savings**
 - CMS will use a 3-month claims “run-out” period to calculate the benchmark and per-capita expenditures for the performance year. The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is issued for the service.
 - *The Final Rule selected a 3-month period, as opposed to a 6-month period as proposed, based upon review of public comments.*

3-Year Agreement / Performance Period

- 3-Year Agreement / General Rule
 - In order to participate in the Medicare Shared Savings Program, an ACO must enter into an agreement with CMS. CMS will determine whether to approve or deny applications from eligible organizations prior to the end of the calendar year in which the applications are submitted.
 - The participation agreement must be for a term of 3 years, starting in CY 2012.
- Performance Period / Two Start Dates
 - *The Final Rule makes significant changes to the performance period and the start date of the program.*
 - For the first year of the program (CY 2012), ACOs can begin participation on *April 1* (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or *July 1* (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months).
 - During all calendar years of the agreement period, including the partial year associated with both the April 1, 2012 and July 1, 2012 start dates, the eligible providers participating in an ACO that meets the quality performance standard but does not generate shareable savings will qualify for Physician Quality Reporting System (PQRS) incentive payments.

Changes During 3-Year Agreement Period

- New Program Standards Established During 3-Year Agreement Period
 - ACOs will be subject to all regulatory changes except: (a) eligibility requirements concerning the structure and governance of ACOs; (b) calculation of sharing rate; and (c) beneficiary assignment.
 - *The Final Rule modifies the proposal so that ACOs will 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.*
- Significant Changes to the ACO During 3-Year Agreement Period
 - *The Final Rule modifies the proposal to allow ACO participants and ACO providers/suppliers to be added and subtracted over the course of the agreement period; ACOs must notify CMS of the change within 30 days. For "significant changes" (resulting in an ACO being unable to meet requirements), the ACO must also notify CMS within 30 days.*

Coordinating the Shared Savings Program Application with Antitrust Agencies

- *The Final Rule significantly modifies the proposal and adopts a three-prong approach:*
 - (1) Antitrust Agencies will offer a voluntary expedited antitrust review to any newly formed ACO before it is approved to participate in the Shared Savings Program;
 - (2) CMS will provide the Antitrust Agencies with aggregate claims data regarding allowable charges and fee-for-service payments; and
 - (3) Antitrust Agencies will rely on their existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct and filing antitrust complaints when appropriate.
- The Final Rule eliminates the requirement of mandatory antitrust reviews and the submission of a letter from a reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging, an ACO formed after March 23, 2010, that does not qualify for the rural exception articulated in the final Antitrust Policy Statement, and that has a Primary Service Area (PSA) share above 50% for any common service that two or more ACO participants provide to patients from the same PSA.

Data Sharing With ACOs

- Expectations of Independent Identification and Data Production Processes
 - As a condition of participation, CMS expects that ACOs will have, or are working towards having, processes in place to independently identify and produce data necessary to best evaluate the health needs of their patient population; improve outcomes; monitor provider/supplier quality of care and patient experience of care; and produce efficiencies in service utilization.
- Aggregate Data Reports & Limited Beneficiary Identifiable Data
 - CMS will provide aggregate data reports at the start of each agreement period based on data for those beneficiaries historically assigned and included in calculation of the ACO's benchmark. These reports will include aggregated metrics on the beneficiary population and beneficiary utilization data.
 - CMS will also provide quarterly aggregate data reports on ACOs during the performance period based upon the most recent 12 months of data from potentially assigned beneficiaries.
 - CMS will provide the ACO with a list of beneficiary names, dates of birth (DOBs), sex, and health insurance claim numbers (HICNs) derived from beneficiaries whose data was used to generate the preliminary prospective aggregate reports.
 - *In the Final Rule, CMS will also provide names, DOBs, sex, and HICNs derived from beneficiaries whose data was used to generate quarterly aggregate reports.*

Sharing Additional Beneficiary Identifiable Information

- ACOs may request from CMS additional, beneficiary identifiable information on a monthly basis provided that the ACO: (1) Submits formal data request explaining how it intends to use the data; (2) Has entered into a Data Use Agreement (DUA) with CMS that prohibits the ACO from sharing Medicare claims data provided by CMS through the Shared Savings Program with anyone outside the ACO; and (3) Has notified the beneficiary of the ACO's participation in the Shared Savings Program, the ACO's intent to request their beneficiary identifiable data, and the beneficiary's opportunity to decline the allowance of this data sharing.
- *In the Final Rule, CMS modified the beneficiary data request notification and opt-out mechanism to eliminate the requirement that this beneficiary notification (of data use and opportunity to decline the allowance of data) occur during a primary care service visit with an ACO-participating primary care physician after the commencement of the performance year. As an alternative, the Final Rule provides that ACOs may 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 performance year.*
- If, after a period of 30 days from the date the ACO provides beneficiary notification, neither the ACO nor CMS has received notification from the beneficiary to decline data sharing, the ACOs would be able to request beneficiary identifiable data—but will be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary.
- Minimum necessary data elements that may be requested by ACOs as additional beneficiary identifiable information include, but are not limited to: procedure code; diagnosis code; beneficiary ID; DOB; gender; claim ID; provider/service type; claim payment type; and provider NPI and/or TIN.

Assignment of Beneficiaries

- *The Final Rule provides for **preliminary prospective beneficiary assignment**, based on the most recent data available, and reconciliation at the end of the performance year to determine the beneficiaries assigned to the ACO for that performance year, rather than pure retrospective beneficiary assignment, as called for in the Proposed Rule.*
 - CMS will update the preliminary beneficiary assignment on a quarterly basis.
- Assignment is an operational process by which Medicare will determine whether a beneficiary has received a sufficient level of primary care services from physicians associated with a specific ACO such that that ACO may be designated as exercising basic responsibility for the beneficiary's care.
- Beneficiaries will be assigned to an ACO through a "step-wise" process after identifying all beneficiaries who had at least one primary care service with one of the ACO's physicians:
 - A beneficiary will be prospectively assigned to an ACO if he or she received a primary care service from one of the ACO's primary care physicians ("PCPs") in the past 12 months (for preliminary prospective assignment) or in the performance year (for final assignment), and if the allowed charges for the beneficiary's primary care services by all PCPs in the ACO are greater than those of PCPs who are ACO providers/suppliers in any other ACO or PCPs not affiliated with an ACO.
 - A beneficiary will be prospectively assigned to an ACO if he or she received a primary care service from one of the ACO's non-primary care physicians (but not from a PCP) and the allowed charges for the beneficiary's primary care services by all ACO professionals are greater than those of all ACO professionals who are ACO providers/suppliers in any other ACO or other physicians/NPs/PAs/CNSs not affiliated with an ACO.
- Beneficiaries can be assigned to ACOs based on services provided by FQHCs or RHCs.
- Assignment does not restrict the rights of beneficiaries to choose a provider outside of the ACO.

Quality Measures and Data Submission

- Quality Measures

- Before an ACO can share in savings, it must demonstrate that it met quality performance standards for the year.
- *The Final Rule scales back to 33 quality measures (from 65 in the Proposed Rule) in 4 key domains to serve as the basis for assessing, benchmarking, and rewarding ACO quality performance: (1) Patient/Caregiver Experience; (2) Care Coordination/Patient Safety; (3) Preventive Health; and (4) At-Risk Population.*
- *In Year 1, an ACO will meet the ACO Quality Performance Standard if it has reported on all applicable quality measures; in Year 2, an ACO will have to report on 8 quality measures and achieve performance at a minimum attainment level for 25 measures; in Year 3, an ACO will have to report on 1 quality measure and achieve performance at a minimum attainment level for 32 measures.*
- *Instead of requiring at least 50% of an ACO's primary care physicians to be "meaningful EHR users" to continue to participate, as originally proposed, CMS will double-weight quality measure related to EHR meaningful use.*

- Data Submission

- CMS will derive claims-based measures from claims submitted, without additional ACO reporting; other measures will be reported through the CAHPS survey and other established mechanisms (claims-based measures that are not finalized will be used for reporting only).
- CMS will administer and pay for the CAHPS survey for 2012 and 2013; ACOs will be responsible for selecting and paying for a CMS-certified vendor to administer the patient experience of care survey beginning in 2014.
- The first quality data will be collected on a calendar year basis, beginning January 1, 2013 - December 31, 2013.
- CMS may audit and validate an ACO's reported quality data.

Quality Performance Standards and Reporting Requirements

- **Quality Performance Standards**
 - CMS will score ACOs based on performance on each measure, which will determine the ACO's eligibility for shared savings and the percentage of savings that the ACO will share.
 - For each measure, CMS will set a performance benchmark and a minimum attainment level: for "pay for performance" measures, the minimum level will be set at 30% or the national 30th percentile; benchmarks will be set based on Medicare FFS or Medicare Advantage rates for each measure and will be released at the start of the second performance year.
 - Performance at or above the minimum attainment level will receive points on sliding scale, and performance at or above 90% or the 90th percentile will earn the maximum points for the measure; failure to reach the minimum attainment level for at least 70% of the measures in each domain will result in the ACO being placed in a Corrective Action Plan.
 - CMS will set a quality standard for each domain and divide points earned on all measures in a domain by total possible points in that domain; CMS will treat each domain equally regardless of the number of measures within the domain.
 - CMS also will use certain measures for monitoring purposes to ensure ACOs are not avoiding at-risk patients or otherwise abusing the system.
- **Incorporation of Physician Quality Reporting System (PQRS) Reporting Requirements**
 - ACOs will report and submit data on behalf of eligible professionals to qualify for the PQRS incentive as a group practice by fully reporting required clinical quality measures through the ACO Group Practice Reporting Option web interface (they may not also seek to qualify outside the Shared Savings Program, but it is possible to earn the PQRS incentive and not qualify for shared savings as an ACO).
 - ACOs will need to report on all measures in order to receive both the Shared Savings Program shared savings and the PQRS incentive.

Shared Savings and Losses: Overview

- Providers and suppliers participating in ACOs will continue to receive FFS payments under Medicare Parts A and B.
- To calculate savings or losses, the ACO's per capita, risk-adjusted Medicare expenditures in each performance year will be compared to its updated benchmark.
 - If actual expenditures are lower than the benchmark and savings meet or exceed the “**minimum savings rate**”, the ACO will be eligible for shared savings.
 - Under the two-sided model, if actual expenditures are higher than the benchmark and losses meet or exceed the “**minimum loss rate**”, a loss is incurred.
- An ACO's “**benchmark**” is a surrogate measure of what the Medicare fee-for-service Parts A and B expenditures would otherwise have been in the absence of the ACO and is the baseline against which the ACO's financial performance will be measured.
- The “**sharing rate**” is the percentage of the savings which an ACO that exceeds the minimum savings rate will be allowed to retain; the “**shared loss rate**” is the percentage of losses that an ACO that exceeds the minimum loss rate must pay back to CMS.
- The “**sharing cap**” is the limit on the total amount of shared savings that may be paid to an ACO; a “**shared loss cap**” applies to ACOs in the “two-sided” model.

Determining ACO Benchmarks

- To determine an ACO's benchmark, CMS will use the Parts A and B FFS expenditures for beneficiaries that *would have been assigned* to the ACO (based on the step-wise assignment methodology described above) in any of the 3 years prior to the agreement period (as opposed to the expenditures for beneficiaries actually assigned to the ACO for the agreement period).
 - The 3 most recent available years of claims records of ACO participants (based on taxpayer ID number) will determine the list of beneficiaries who would have been assigned to the ACO.
- An initial benchmark will be calculated from per capita Parts A and B FFS expenditures in the 3 prior years for these beneficiaries, trended forward to the most recent benchmark year's dollars (which is weighted more heavily than the first two benchmark years) and adjusted for beneficiary characteristics using the CMS-HCC risk adjustment model.
 - To minimize variation from catastrophic claims, CMS will truncate an assigned beneficiary's total annual expenditures at the 99th percentile of national Medicare FFS expenditures (determined each benchmark year).
 - *Under the Final Rule, CMS will make calculations (including risk adjusting, trending and updating the benchmark) within the following categories: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible.*
 - CMS will annually update an ACO's risk scores for newly assigned beneficiaries and recalculate the risk scores for continuously assigned beneficiaries; if continuously assigned beneficiaries risk score has declined, CMS will use the lower risk score (if not, then adjustment for this population will use demographic factors only).
- Incentive payments and penalties paid outside of claims (e.g., Physician Quality Reporting System incentives) excluded from the computation of benchmarks and actual expenditures, *as well as (contrary to the proposed rule) indirect medical education (IME) payments and disproportionate share hospital (DSH) payments.*
- Benchmarks will be updated annually during the agreement period by the projected absolute amount of growth in national per capita expenditures for Parts A and B Services in FFS Medicare, and reset at the start of each agreement period.

Determining Shared Savings

- The amount of shared savings an ACO receives depends on the **minimum savings rate** (MSR) and the **sharing rate** that apply to the ACO.
- Participating ACOs will choose between two “Tracks”
 - Track 1 or “One-Sided” Approach: ACOs would be eligible for shared savings and *not responsible for any losses during the ACO’s first agreement period (ACOs that select Track 1 must transition to the two-sided model for subsequent agreement periods, not in year 3 of the first agreement period, as CMS had proposed).*
 - Track 2 or “Two-Sided” Approach: “More experienced ACOs” eligible for higher percentage of shared savings, but also responsible for shared losses throughout agreement period.
- The **MSR** an ACO must achieve in order to be eligible to share savings will vary based on which track is selected and (under Track 1) the number of beneficiaries in the ACO:
 - For Track 1, a sliding scale confidence interval based on the size of the ACO will determine the MSR—for ACOs with 5,000 beneficiaries, a 3.9% MSR will apply; for ACOs with 60,000 or more beneficiaries, a 2.0% MSR will apply.
 - For Track 2, a flat 2.0% MSR will apply, regardless of the size of the ACO’s assigned population.
- The **sharing rate** will be determined based on quality performance, with a maximum of 50% for Track 1 ACOs and 60% for Track 2 ACOs.
 - *Due to the addition of FQHCs and RHCs to the list of entities permitted to form an ACO, CMS has removed the potential increases to the sharing rate for including these entities in an ACO.*

Determining Shared Savings, continued

- Once an ACO surpasses its MSR, the ACO will share in the net savings on a first-dollar basis (i.e., any savings as compared to the benchmark).
 - *Under the Final Rule, first-dollar shared savings may be awarded to ACOs under either Track, rather than only under Track 2, as proposed.*
- Shared savings will be capped at 10% of the updated benchmark for Track 1 ACOs and 15% of the benchmark for Track 2 ACOs.
 - *Caps increased from the proposed rule's 7.5% and 10%, respectively.*
- **Thus, an ACO's shared savings payment is calculated as the net savings as compared to the updated benchmark multiplied by the sharing rate, up to the sharing cap.**
- CMS will notify an ACO in writing as to whether it qualifies for a shared savings payment.
- *Under the Final Rule, ACOs with start dates of April 1, 2012 and July 1, 2012 may opt for an interim payment calculation at the end of their first 12 months to determine shared savings and losses at that point.*
 - *Track 1 ACOs requesting interim payments must demonstrate at the time of application an adequate repayment mechanism in the case that final reconciliation determines an overpayment made pursuant to the interim calculation.*

Determining Shared Losses

- Track 2 ACOs will share both savings and losses with CMS.
 - First-dollar shared losses once the minimum loss rate of 2% of benchmark is exceeded.
 - Shared loss rate based on the ACO's sharing rate: loss rate is 1 minus sharing rate (e.g., if the quality performance-based sharing rate is 55%, the shared loss rate would be 45%).
 - *Under the Final Rule, CMS is setting a maximum shared loss rate of 60%.*
 - Shared loss cap will be phased in over a 3-year period: 5% of the benchmark in year 1 of the program; 7.5% in year 2; and 10% in year 3.
- Track 2 ACOs must demonstrate in the application process and annually an established a repayment mechanism sufficient to ensure repayment of potential losses of at least 1% of total per capita expenditures from the most recent year of data, including specifying how liability for losses will be shared among ACO participants and ACO providers/suppliers.
 - *CMS' proposals to withhold 25% of any shared savings payment and to carry forward losses into future program years have not been finalized.*
- CMS will notify an ACO in writing regarding the amount of shared losses; ACOs must make payment in full within 90 days (rather than 30 under the proposed rule) of receipt.

Additional Program Requirements and Beneficiary Protections

- CMS is finalizing the following beneficiary protection provisions:
 - Notification of ACO provider/supplier participation in the Shared Savings Program and the availability of data sharing opt-out.
 - Marketing materials and activities may be used/conducted 5 days after submission to CMS if the ACO certifies compliance with the marketing requirements (e.g., using CMS template language) and CMS does not disapprove the materials/activities.
 - Public reporting of certain information about the ACO (e.g. organizational information and information on shared savings/losses, patient experience of care survey and claims-based quality measures).
- CMS will monitor and assess ACO performance using a range of methods such as analysis of financial and quality data and beneficiary or provider complaints and audits. ACOs and ACO participants and providers/suppliers will be specifically monitored for:
 - Avoidance of at-risk beneficiaries (e.g., high risk score, high cost due to hospitalizations, dual eligibles, high utilization pattern, or one or more chronic conditions) and would be subject to a corrective action plan (CAP) or termination if found to have avoided such beneficiaries.
 - Compliance with quality performance standards: if minimum attainment levels are not met for one or more domains, CMS will warn the ACO and may subject it to a CAP, and will re-evaluate the following year (under the Final Rule, CMS may immediately terminate the participation agreement depending on the severity of the noncompliance); continued underperformance would result in termination.
- ACOs must have a compliance plan that includes particular elements (e.g. a compliance officer and reporting of problems or probable violations of law) and a conflict of interest policy that applies to members of the governing body.

Program Requirements and Beneficiary Protections, continued

- Program Integrity Requirements
 - For data and information generated/submitted by ACOs, ACO participants and ACO providers/suppliers, an individual with authority to legally bind the entity must certify, to the best of his/her knowledge, information and belief, the accuracy, completeness and truthfulness; at the end of each performance year, such an individual must similarly certify compliance with program requirements and the accuracy, completeness and truthfulness of data/information generated or submitted.
 - Applicants' program integrity history will be reviewed/screened, which may subject them to denial from the program or additional safeguards while in the program.
 - ACOs, ACO participants and ACO providers/suppliers may not condition the participation of entities in the ACO on referrals of federal health care program business that they know or should know is being/would be provided to beneficiaries who are not assigned to the ACO; nor may they require that beneficiaries be referred only within the ACO (with exceptions for employment relationships).
 - Prohibition on beneficiary inducements.
- ACOs (and participating entities) must agree to government audit and inspection rights and maintenance of records.
- CMS may terminate an agreement with an ACO before the end of the agreement period for a variety of reasons, including failure to comply with any of the requirements under the regulations, and may or may not take pre-termination actions such as warning notices and CAPs.
- ACOs must provide at least 60 days' notice if it elects to terminate the participation agreement.
- CMS has established an administrative process to request review of certain determinations, e.g., denial of initial application, termination for reasons other than those exempted by statute.

Overlap with Other Medicare Programs and the Role of the CMS Innovation Center

- A Medicare-enrolled TIN may not participate in both the Medicare Shared Savings Program and any one of the following:
 - The Independence at Home Medical Practice Demonstration program
 - Medicare Health Care Quality Demonstration Programs
 - Medical home demonstrations with a shared savings arrangement (i.e. the multi-payer advanced primary care demonstration)
 - Physician Group Practice (PGP) Transition Demonstration
 - *The Final Rule includes discussion of transition of PGP Demonstration Sites into the Medicare Shared Savings Program.*
 - Care Management for High-Cost Beneficiaries Demonstrations
 - Pioneer ACO Model
- The Bundled Payment for Care Improvement Initiatives would not exclude ACO participants from participating in the Shared Savings Program.
- TINs that are already participating in another Medicare program/demonstration involving shared savings will be prohibited from participating in the Medicare Shared Savings Program.
- If other programs/demonstrations involving shared savings do not assign beneficiaries based upon TINs of health care providers from whom they receive care, but uses an alternative beneficiary assignment methodology, CMS will work with the developers to devise an appropriate method to ensure no duplication in shared savings.

Waiver of Fraud and Abuse Interim Final Rule

Waiver of Fraud and Abuse Laws

- CMS and the HHS Office of the Inspector General jointly issued an Interim Final Rule with comment period and proposed five waivers for ACOs participating in the Medicare Shared Savings Program (two retained from the Waivers Design Notice and three that are new):
 - ACO Pre-Participation Waiver (new): Waiver of application of the Physician Self-Referral Law (“Stark Law”), Gainsharing CMP, and Anti-Kickback Statute (“AKS”) with respect to start-up arrangements that pre-date an ACO’s participation agreement if (1) the arrangement is undertaken by parties acting in good faith to submit an application, (2) the parties are taking steps to develop an eligible ACO, (3) the purpose of the arrangement is reasonably related to the Shared Savings Program, (4) the arrangement(s) and the steps to form an ACO are documented contemporaneously and publicly disclosed, and (5) if the ACO does not submit an application, it submits a statement stating why it was unable to. The waiver period would begin on the date of publication of the rule or one year before the application submission date, and it would end on the ACO’s start date, denial date, or date of a statement that the ACO is unable to apply.
 - ACO Participation Waiver (new): Waiver of application of the Stark Law, Gainsharing CMP, and AKS with respect to any arrangement of an ACO or its participants/providers if (1) the ACO has entered into a participation agreement and meets governance/leadership standards, (2) the purpose of the arrangement is reasonably related to the Shared Savings Program, and (3) the arrangement is documented contemporaneously and publicly disclosed. The waiver period would begin on the start date of the participation agreement and end 6 months after the agreement ends or when the ACO terminates.

Waiver of Fraud and Abuse Laws, continued

- Shared Savings Distribution Waiver (proposed earlier): Waiver of application of the Stark Law, Gainsharing CMP, and AKS with respect to shared savings (1) distributed among ACO participants and participants/providers, or (2) used for activities reasonably related to an ACO's participation in the Shared Savings Program. Distributions from a hospital to a physician may not be made to induce the physician to reduce or limit medically necessary items or services.
- Compliance with the Stark Law Waiver (proposed earlier): Waiver of the Gainsharing CMP and AKS for an arrangement that implicates the Stark Law if it is reasonably relate to the Shared Savings Program and meets a Stark Law exception. The waiver period would begin on start date of the participation agreement and end 6 months after the agreement ends or when the ACO terminates.
- Patient Incentives Waiver (new): Waiver of the Beneficiary Inducement CMP and AKS with respect to preventive or follow-up items or services provided for no charge by an ACO to a beneficiary (not limited to beneficiaries assigned to the ACO).

Solicitation of Comments on Fraud and Abuse Waivers

- The OIG solicits comments on the following aspects of its proposed waivers:
 - Its general approach and whether the proposed waivers are specific enough
 - Whether the Pre-Participation Waiver should require the ACO to submit a notice of intent to apply, be limited after 2013 to those that actually apply, or be curtailed in future years
 - Whether the Compliance with the Stark Law Waiver should continue for a period of time after the termination of an ACO's participation
 - Whether the Patient Incentives Waiver should be limited to beneficiaries assigned to the ACO
 - Whether it is necessary to define "reasonably related to purposes of the Shared Savings Program"
 - Whether an ACO under a Corrective Action Plan ("CAP") should be in compliance with the CAP as a condition of the waiver
 - Whether waivers should exclude outside party arrangements
 - Whether waivers covering participants should have to be commercially reasonable, fair market value, and/or non-exclusive

Antitrust Issues

Antitrust Issues

- **FTC/DOJ Released Final Enforcement Policy for ACOs**
 - Concerned ACO collaboration may result in diminished competition / increased costs.
 - Recognize potential procompetitive benefits of ACOs with clinical and financial integration.
 - Applies to all collaborations under ACA.
- **Antitrust Safety Zone for Proposed ACOs**
 - Safety Zone: Combined share of <30% for each common service (whenever two or more ACO participants provide that service to patients from that PSA); No review required; will not be challenged absent extraordinary circumstances.
 - Outside Safety Zone: Proposed ACO participants can seek expedited voluntary review; Provides list of potential anticompetitive conduct to avoid.
- **Complicated Calculation of Primary Service Areas (PSA) Shares**
 - Requires determination of: (1) PSA and (2) Common Services by Medicare Specialty Code (MSC).
 - Inpatient facilities will have three separate PSAs to consider for: (1) inpatient services; (2) outpatient services and (3) physician services (provided by employees).
- **Expedited Voluntary Antitrust Review Process (90 days)**
 - Requires submission of materials and data from parties.
 - One agency assigned to review (DOJ or FTC).
 - Within 90 days, agency will analyze the proposed ACO and advise the participants of whether it believes the proposed ACO is likely to raise competitive concerns.
- **Agencies Will Apply Rule of Reason Analysis to ACOs (balancing benefits and harm)**
 - Will apply to ACOs that satisfy CMS eligibility criteria (even with commercial payers).
 - ACOs may propose other ways to establish clinical integration.

IRS Fact-Sheet: Treatment of Tax-Exempt ACOs

Treatment of Tax-Exempt ACOs

- Internal Revenue Service (IRS) Notice 2011-20, released earlier this year based on the proposed ACO regulations, outlines the IRS expectations as to how existing IRS guidance may apply to tax-exempt charitable organizations (such as charitable hospitals) participating in the Shared Savings Program through ACOs.
 - Notice 2011-20 also requested comments on additional guidance that might be needed. The Notice may be found at <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>. The comment period ended on May 31, 2011.
- IRS Fact Sheet:
 - Confirms that Notice 2011-20 continues to reflect IRS expectations regarding participation of tax-exempt organizations in the Shared Savings Program and ACOs under the final ACO regulations.
 - Provides, in question and answer format, additional information for tax-exempt charitable organizations that which to participate in an ACO and for ACOs that wish to apply for tax-exempt status.

Treatment of Tax-Exempt ACOs

- ACO Structure Impacts Tax-Treatment
 - An ACO structured as a corporation for federal tax purposes generally will be treated as a separate taxable entity from its participants. If an ACO is structured as a partnership for federal tax purposes, its activities will generally be attributed to its partners. An ACO structured as an LLC generally may choose to be treated as a corporation or as a partnership or an entity that is disregarded for tax purposes.
- ACO Participation by Charitable Organizations
 - If a charitable organizations participate in the Shared Savings Program through an ACO along with private parties, the charitable organization must be sure that it continues to meet the requirements for tax exemption to avoid adverse tax consequences.
- Tax-Status of ACOs
 - An ACO engaged exclusively in Shared Savings Program activities can qualify for tax-exemption under § 501(c)(3) if it meets all of the requirements under that section.
 - An ACO engaged in both Shared Savings Program and non-Shared Savings Program activities can qualify for tax-exemption under § 501(c)(3) provided it engages exclusively in activities that accomplish one or more charitable purposes and meets all of the other requirements under that section.
- Electronic Health Records (EHR) Technology
 - The 2007 IRS memorandum relating to EHR applies to a charitable organization participating in the Shared Savings Program through an ACO.

**Center for Medicare and Medicaid Innovation (CMMI):
Advancement Payment ACO Model Solicitation**

Advance Payments for ACOs

- In conjunction with the release of the ACO Final Rule, CMMI released a solicitation for applications for the Advanced Payment ACO Model.
- **Applications Due:** Concurrent with due dates for Shared Savings Program applications.
- In the Advance Payment Model, selected organizations who are enrolled as ACOs in the Medicare Shared Savings Program will receive an advance on the shared savings they are expected to earn, including:
 - \$250,000 payment in the first month of the Shared Savings Program.
 - Payment in the first month of the Shared Savings Program equivalent to the number of its preliminary, prospectively assigned beneficiaries times \$36.
 - Monthly payments equal to the number of its preliminary, prospectively assigned beneficiaries times \$8.
- CMMI will allocate up to \$170 million for this payment model, and will enroll up to 50 ACOs. Sixty percent of funds available for ACOs whose Shared Savings Program agreement period begins April 2012, and 40 percent available for ACOs whose agreement period begins in July 2012.
- Advance payments recouped through ACOs' earned shared savings in Shared Savings Program.
- If the ACO does not generate sufficient savings at the time of the settlement in mid-2014 to fully repay advance payments, CMS will recoup balance from earned shared savings in subsequent two years, and in additional years if the ACO chooses to enter a second agreement period.
- CMS will not pursue full recoupment of remaining advance payments from an ACO that has not earned sufficient savings during the first agreement period and chooses to not enter a second agreement period (in the Shared Savings Program).
- CMS will recoup all advance payments up to the total shared savings earned by the ACO, but will not pursue amounts in excess of the earned shared savings.

ACO Eligibility for Advance Payments

- **Eligibility:** To be eligible, an ACO must meet one of the two following criteria—
 - An ACO that does not include any inpatient facilities and has less than \$50 million in total annual revenue; or
 - An ACO in which the only inpatient facilities are critical access hospitals (CAHs) or low-volume hospitals (as defined in Title XVIII of the Social Security Act) and has less than \$80 million in total annual revenue.
- **Revenue Assessment:** Applicants will be asked to attest to total gross revenue (averaged over past 3 years) of the ACO's providers/suppliers. If an ACO, or any ACO participant, provider/supplier, is directly or indirectly owned (5% or more ownership interest) by another organization, then the revenue of that organization should be included in the calculation of total revenue of the ACO.
- **Medicaid Reliance Assessment:** Applicant ACOs will be asked to attest to the percentage of total patient revenue that is derived from Medicaid, averaged over the past three years (FFS and managed care) for all of its providers and suppliers.
- **Rural Location Assessment:** CMMI will assess whether locations where patients receive care from the ACO are located in either nonmetropolitan counties or areas within metropolitan counties that have a Rural-Urban Commuting Area code of 4-10.
- **Spend Plan Evaluation:** All eligible applications will be reviewed for spend plan soundness by CMMI staff, and will be evaluated as "Unacceptable," "Acceptable," "Good" or "Exceptional" according to:
 - Procurements/activities/hiring are described in detail, along with estimated costs
 - Feasible timeframe for procurement/activities/hiring within the first 18 months of the Agreement
 - Compelling rationales for how each procurement/activity/hiring will support population care management, financial management, or other essential ACO functions
 - Explanation of how investments will build upon existing infrastructure and experience in care coordination, information management, working with community partners, and other essential ACO functions
 - Documentation and level of ACO's own investments in infrastructure
 - Overall strength of plan and business case for investment