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The Medicare Shared Savings Program

Overview of Agency Proposals

April 1, 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 Proposals and Opportunities for Comment Related to the Medicare Shared Savings Program

- Four documents released on March 31, 2011:
  - CMS Proposed Rule for the Medicare Shared Savings Program/ACOs
    - Comments due 60 days from the date of publication (June 6, 2011)
  - Joint CMS and OIG Proposed Rule on waiver designs addressing proposed waivers of the Civil Monetary Penalties (CMP) law, Federal Anti-Kickback Statute, and the Physician Self-Referral law
    - Comments due 60 days from the date of publication (June 6, 2011)
  - Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals participating in the Shared Savings Program
    - Comments due by May 31, 2011
  - Proposed Antitrust Policy Statement issued by the FTC and DOJ
    - Comments due by May 31, 2011

Overview of Regulatory Impact Analysis

- CMS estimates:
  - Aggregate start-up investment and first year operating expenditures for ACOs:
    - $131,643,825 to $263,287,650
  - Estimated number of participating ACOs:
    - 75-150
  - Total aggregate impact of net federal savings for 2012-2014:
    - $510 million (median estimate)

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Summary of Medicare Shared Savings Program Proposed Rule

Eligible ACOs

- Types of Eligible 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; and
  - Critical Access Hospitals that bill under Method II
- The above groups could establish ACOs that include additional Medicare-enrolled entities such as Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), post-acute facilities and other Medicare-enrolled providers and suppliers as “ACO participants”

Legal Structure, Shared Governance, Leadership and Management Structure

- Legal Structure
  - ACO must be a legal entity (e.g., corporation, partnership, LLC) with a tax ID number authorized to conduct business under state law and capable of: (a) receiving and distributing shared savings; (b) repaying shared losses; (c) establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards; and (d) performing other required ACO functions
- Shared Governance
  - ACO must have a "governing body" (e.g., a board of directors or other body that provides a mechanism for shared governance and decision-making for all ACO participants) comprised of ACO participants or their designated representatives and Medicare beneficiary representatives, with adequate authority to execute the statutory functions of an ACO and having broad responsibility for the ACO's administrative, fiduciary, and clinical operations; ACO participants must hold at least 75 percent control of the governing body
- Leadership and Management Structure
  - As part of its application, an ACO must submit supporting materials to CMS that demonstrate the ACO's 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 proposed rule provides a detailed list of the supporting materials that must be submitted in the application.

3-Year Agreement

- 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 on the January 1 following approval of an application or date specified in the agreement
- Performance Period / January 2012 Start Date
  - Unless otherwise specified, the ACO's annual performance period under the agreement must be the 12-month period beginning on January 1 of each year during the term of the agreement
  - In light of the short time frame for implementing the program for the first year, CMS is soliciting comments on any alternatives to a January 1, 2012 start date

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Distribution of Savings / 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
- Evaluating Shared Savings
  - CMS will use a 6-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.

Sufficient Number of Primary Care Providers and Beneficiaries / Required Reporting and Processes

- 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
- Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care
  - In its application, an ACO must provide CMS with documentation of its plans to: (a) promote evidence-based medicine; (b) promote beneficiary engagement; (c) internally report quality and cost metrics; and (d) coordinate care

Patient-Centeredness Criteria / Marketing Materials

- Patient-Centeredness Criteria
  - An ACO should 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
  - An ACO must demonstrate patient-centeredness by addressing many specified areas including having a beneficiary experience of care survey in place, involving patients in ACO governance, having a process for evaluating the health needs of the ACO's assigned population – among other areas
- Marketing Materials
  - Any ACO marketing materials or activities and any changes to CMS-approved marketing materials or activities, as defined in the rule, must be approved by CMS before use

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Program Integrity Requirements

- Agreement Provisions: ACOs must agree, and must require ACO participants, providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree, or to comply with the federal criminal law; False Claims Act; Anti-Kickback Statute; Civil Monetary Penalties law; and the physician self-referral law
- Compliance Plan: ACOs must have a compliance plan that includes at least the following: (a) a designated compliance official or individual who is not legal counsel and who has the ability to report directly to the ACO's governing body; (b) mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance; (c) a method for employees or contractors of the ACO, ACO participants, and ACO providers/ suppliers to report suspected problems related to the ACO; (d) compliance training; (e) a requirement to report suspected violations of law to an appropriate law enforcement agency
- Compliance With Program Requirements: Notwithstanding any relationships the ACO may have with other entities related to ACO activities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement
- Conflict of Interest: ACO governing body must have a conflicts of interest policy that applies to members of the governing body
- Screening of ACO Applicants: CMS is soliciting comments on the nature and extent of such screening and the screening results that would justify rejection of an application or increased scrutiny
- Prohibition on Certain Required Referrals and Cost-Shifting: CMS is considering prohibiting ACOs and ACO participants from conditioning participation on referrals of federal health care program business that the ACO or ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO

Data Sharing With ACOs

- CMS will share aggregate and beneficiary identifiable data with ACOs if the ACO:
  - Does not put unnecessary limitations or restrictions on use/disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO
  - Observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and complies with the terms of the data use agreement
- CMS will share aggregate data reports at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark, and each quarter thereafter
- Data will not include beneficiary identifying information, but will include deidentified claims history of the services rendered for the ACO's assigned FFS beneficiaries
- At the beginning of the agreement period and end of each performance period, CMS will, upon the ACO's request for the data for purposes of population-based activities (improving health, reducing costs, etc.) provide: beneficiary names; date of birth; and Health Insurance Claim Numbers
- Subject to a beneficiary "opt-out", CMS will, upon the ACO's request provide the ACO with monthly claims data for potentially assigned beneficiaries
  - The data must be for purposes of evaluating ACO provider/supplier performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health
  - To ensure beneficiaries have an opportunity to "opt-out" of having their claims data shared, the ACO may only request such claims data if the beneficiary did not "opt-out" and if certain notification requirements are met
- Prior to receiving any beneficiary identifiable data, ACOs must enter into a data use agreement with CMS

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
  - If changes in law or regulations require an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, changes to the quality of care, or changes in planned distribution of shared savings, the ACO will be required to submit to CMS a supplement to its original application
- Significant Changes to the ACO During 3-Year Agreement Period
  - During the 3-year agreement, an ACO may remove, but not add, ACO participants, and it may remove or add ACO providers/suppliers. ACOs must notify CMS at least 30 days prior to any "significant change" as defined in the rule
- Future Participation of Previous Shared Savings Program Participants.
  - The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in Medicare under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related ACO was terminated or withdrew voluntarily. If the ACO was terminated, the applicant must identify the cause and what safeguards are now in place to enable the applicant ACO to participate in the program.

Assignment of Beneficiaries

- Assignment is an operational process by which Medicare will determine whether a beneficiary has received a sufficient level of requisite 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
- CMS proposes to identify ACOs operationally as a collection of Medicare-enrolled tax ID numbers (TINs) practicing as a group practice arrangement or network
- Beneficiaries would be assigned to an ACO through a TIN based on the primary care services they received from primary care physicians (internal medicine, general practice, family practice, and geriatric medicine) billing under that TIN
  - CMS proposes to assign beneficiaries to an ACO if they receive a plurality (as opposed to a majority) of their primary care services (based on allowed charges) from primary care physicians within that ACO
- ACO professionals on which beneficiary assignment is based (i.e. primary care providers) must be exclusive to one ACO agreement; other ACO participants (e.g., hospitals, specialists) could participate in multiple ACOs
- CMS is proposing **retrospective beneficiary assignment**, balanced by the provision of aggregate beneficiary level data for the assigned population during the benchmark period
- CMS intends to develop a communications plan to give beneficiaries information about their utilization of services furnished by an ACO and the possibility of being assigned to an ACO; ACOs will be required to give beneficiaries a form allowing them to opt out of data sharing and inform beneficiaries if they will no longer be participating in the Shared Savings Program

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Quality Measures and Data Submission

- Proposed Quality Measures
  - ACOs that do not meet quality performance standards will not be eligible for shared savings
  - For 2012 only, an ACO will be considered to meet the ACO Quality Performance Standard if it has reported on applicable quality measures; in later years, an ACO will have to both report quality measures and achieve performance at a minimum attainment level
  - CMS proposes 65 measures in 5 key domains to serve as the basis for assessing, benchmarking, rewarding and improving ACO quality performance: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; and (5) At-Risk Population/Frail Elderly Health
  - In addition, at least 50% of an ACO's primary care physicians must be "meaningful EHR users"
  - Quality measures for the remaining 2 years of the 3 year agreement will be proposed in future rulemaking; expanded measures may address highly prevalent conditions of interest and may add measures of hospital-based care and measures for care furnished in other settings
- Data Submission
  - CMS will derive claims-based measures from claims submitted, without additional ACO reporting; other measures will be reported through the CAHPS survey or other established mechanisms
  - CMS proposes to create a CMS-specific data collection tool and a survey tool for certain proposed measures; CMS is proposing use of the Group Practice Reporting Option (GRPO) Data Collection Tool (incorporated from the Physician Quality Reporting System) to allow ACOs to submit clinical information from EHRs, registries and administrative data sources required for measurement reporting
  - Through a GRPO audit process, CMS plans to audit random samples of 30 beneficiaries for each of the quality measure domains/measure sets

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Quality Performance Standards and Reporting Requirements

- Quality Performance Standards
  - CMS proposes to score ACOs based on performance on each measure, expressed as a score in each “domain,” and an overall total performance score; aggregated domain scores will determine the ACO’s eligibility for sharing savings and the percentage of savings that the ACO will share
  - For each measure, CMS proposes to set a performance benchmark and a minimum attainment level: benchmarks would be set based on Medicare FFS or Medicare Advantage (MA) rates for each measure, and benchmark levels would be made available to ACOs prior to the start of each annual performance period
  - Quality Points (maximum of 2 points per measure) would be assigned based on an ACO’s performance: Performance at or above the minimum attainment level but below the performance benchmark would receive points on sliding scale (with several exceptions) and the minimum attainment level is set at the 30th percentile of Medicare FFS or the MA rate, depending on what performance data are available
  - CMS proposes to 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 would treat each domain equally regardless of the number of measures within the domain
  - After 2012, the percent of potential sharable savings will vary based on the ACO’s overall quality score
  - As an alternative to setting quality performance standards, CMS solicits comments on an option of setting a minimum quality threshold
- Incorporation of Physician Quality Reporting System (PQRS) Reporting Requirements
  - ACOs would report and submit data on behalf of eligible professionals to try to qualify for the PQRS incentive as a group practice; CMS proposes criteria for satisfactory reporting for purposes of the PQRS incentive
  - ACOs will need to report on all measures in order to receive both the Shared Savings Program shared savings and the PQRS incentive
- Requirements for Public Reporting
  - CMS proposes that ACO’s publicly report information on: (1) providers and suppliers participating in the ACO; (2) parties sharing in the governance of the ACO; (3) quality performance standard scores; and (4) general information on how an ACO shares savings with its members; CMS will provide a standardized format for this reporting through guidance

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Payments and Shared Savings: Overview

- Providers and suppliers participating in ACOs (“ACO participants”) will continue to receive FFS payments under Parts A and B
- ACOs are eligible to receive shared savings payments if they meet all contract requirements and quality performance standards, and achieve savings exceeding the ACO’s “**minimum savings rate**”—the percentage that Parts A and B expenditures must be below the benchmark in order to ensure that savings are not attributable to normal variation in expenditures (a “**minimum loss rate**” also applies in the case of ACOs in the “two-sided” model)
- An ACO’s “**benchmark**” is essentially the baseline measure of Medicare Parts A and B expenditures 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 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**” also applies in the case of ACOs in the “two-sided” model

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Determining ACO Benchmarks

- To determine an ACO's benchmark, CMS proposes to use the Parts A and B expenditures for beneficiaries that *would have been assigned* to the ACO (based on the assignment methodology described above) in the 3 years prior to the agreement period, as opposed to the expenditures for beneficiaries actually assigned to the ACO for the agreement period
- That is, claims records of ACO participants (based on taxpayer ID number) would determine the list of beneficiaries who received a plurality of their primary care services from primary care physicians in the ACO in each of the 3 most recent available years of claims data
- A fixed benchmark would be estimated from per capita Parts A and B FFS expenditures in the 3 prior years for these beneficiaries, trended forward to current year dollars and adjusted for overall growth and beneficiary characteristics
    - Adjusting for beneficiary characteristics would include demographics as well as health status, using a single risk score calculated by applying the CMS-HCC risk adjustment model to the assigned beneficiary population in each year of the 3-year benchmark
- Technical adjustment to benchmarks to exclude expenditures/savings for incentive payments and penalties for Section 1848 value-based purchasing initiatives (e.g., Physician Quality Reporting System, eRx, EHR incentives) from the computation of benchmarks and actual expenditures
    - CMS considered but did not propose technical adjustments to benchmarks to account for indirect medical education (IME) payments, disproportionate share hospital (DSH) payments, or geographic payment adjustments; CMS states it does not have authority to exclude incentive payments or penalties under sections other than section 1848 of the statute
- Benchmarks would 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
- Benchmarks will be 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 would choose between two "Tracks"
  - Track 1 or "One-Sided" Approach: ACOs would be eligible for shared savings and not responsible for losses in first 2 years of 3-year agreement; transition to "two-sided" model in year 3 and responsible for some losses
  - Track 2 or "Two-Sided" Approach: "More experienced ACOs" eligible for higher percentage of shared savings, starting with first-dollar savings, but also responsible for shared losses throughout agreement period
- The **MSR** an ACO must achieve in order to be eligible to share savings would vary based on the number of beneficiaries in the ACO and which track is selected (with an MSR floor of 2%)
  - For Track 1, a sliding scale confidence interval would determine the MSR, ranging from an MSR of 3.9% for ACOs with 5,000 beneficiaries to an MSR of 2.0% for ACOs with 60,000 or more beneficiaries
    - That is, an ACO with 5,000 beneficiaries must achieve savings of at least 3.9% in order to be eligible to share any savings while an ACO with 60,000 or more beneficiaries must achieve savings of at least 2.0% to share any savings
  - For Track 2, a flat 2.0% MSR would apply, regardless of the size of the ACO's assigned population

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Determining Shared Savings, continued

- Once an ACO surpasses its MSR, a Track 1 ACO would share in the net savings that exceed 2% of its benchmark and a Track 2 ACO would share in net savings on a first-dollar basis (i.e., any savings as compared to the benchmark)
  - Certain Track 1 ACOs (e.g., ACOs with primarily non-urban residents or comprised only of ACO professionals) with fewer than 10,000 beneficiaries would be exempt from the 2% threshold, instead sharing first-dollar savings
- The **sharing rate** would be determined based on quality performance (up to 50% for Track 1 ACOs and 60% for Track 2 ACOs) plus any additional increase for including FQHCs or rural health centers in the ACO (up to 2.5% additional for Track 1 ACOs and up to 5% additional for Track 2 ACOs)
- Shared savings would be capped at 7.5% of the benchmark for Track 1 ACOs and 10% of the benchmark for Track 2 ACOs
- Thus, an ACO’s shared savings payment is calculated as the net savings as compared to the benchmark (beyond 2% of the benchmark for non-exempted Track 1 ACOs), multiplied by the sharing rate, up to the sharing cap
- CMS would notify an ACO in writing as to whether it qualifies for a shared savings payment; ACOs must submit a written request, with a certification of compliance with program requirements and the accuracy of information, to receive shared savings

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Determining Shared Losses

- Track 2 ACOs and Track 1 ACOs in the third year of the 3-year agreement period 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
  - For Track 2 ACOs, the shared loss cap would 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
  - For Track 1 ACOs that are transitioned to the two-sided model in the third year of their agreement, a 5% shared loss cap would apply
- To ensure repayment of shared losses CMS proposes:
  - A flat 25% withholding of any shared savings payment (to be repaid if an ACO has a positive balance at the end of an agreement period)
  - To require ACOs to establish in the application a method for repaying losses equal to at least 1% of per capita expenditures from the most recent year of data; methods might include recouping funds from Medicare payments to ACO participants, reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit or other repayment mechanism, subject to CMS approval
  - Losses that cannot be recouped in a given year would be carried forward until repaid
- CMS would notify an ACO in writing regarding the amount of shared losses; ACOs must make payment in full within 30 days of receipt and would also need to submit a certification of compliance and accuracy of information

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Monitoring, Termination and Administrative Review

- In general, CMS proposes to employ methods used for monitoring Medicare Advantage and Part D contracts in the Medicare Shared Savings Program, such as analysis of financial and quality data, site visits, assessment and investigation of beneficiary and provider complaints, and audits
- If CMS concludes that an ACO's performance may subject it to termination, CMS in its sole discretion could provide a warning notice, request a corrective action plan or place the ACO on a special monitoring plan
- CMS proposes record-keeping and inspection rules for ACOs, ACO participants, ACO providers/ suppliers and contracted entities (any party that enters into an arrangement with an ACO to provide services to the ACO or its assigned beneficiaries)
- ACOs would 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 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 would warn the ACO and re-evaluate the following year; continued underperformance would result in termination
- CMS proposes authority to terminate an agreement with an ACO before the end of the agreement period for a variety of reasons, including the reasons stated above, material changes that impact the ACO's ability to meet the eligibility requirements, failure of the ACO to demonstrate adequate resources to repay losses, and many other reasons
- CMS would require 60 days' notice if an ACO elects to terminate participation (which would forfeit its 25% withhold of shared savings)
- CMS proposes 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 element (i.e. the multi-payer advanced primary care demonstration)
  - Physician Group Practice (PGP) Transition Demonstration
    - The Proposed Rule includes discussion of transition of PGP Demonstration Sites into the Medicare Shared Savings Program
- Participation in multiple programs may be possible where patient populations in each program are unique and there is no duplication in shared savings
- CMS intends to coordinate efforts to ensure that there is no duplication of participation in the Medicare Shared Savings Program and other shared savings models tested by the Center for Medicare and Medicaid Innovation (CMMI)

Waiver of Fraud and Abuse Laws

Waiver of Fraud and Abuse Laws

- The HHS Office of the Inspector General proposes the following waivers *for ACOs participating in the Medicare Shared Savings Program* :
  - Waiver of application of the Physician Self-Referral Law to distributions of shared savings: (1) among ACO, participants, and providers/suppliers; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program
  - Waiver of application of the Anti-Kickback Statute with respect to:
    - Distributions of shared savings: (1) among ACO participants and providers/suppliers; or (2) for activities necessary for and directly related to an ACO's participation in the Shared Savings Program
    - Any financial relationship between or among the ACO, participants, and providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program
  - Waiver of application of the prohibition on hospital payments to physicians to induce reductions or limitation of services with respect to:
    - Distributions of shared savings from a hospital to a physician, provided that: (1) The payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and (2) the hospital and physician are ACO participants or providers/suppliers.
    - Any financial relationship between or among the ACO, participants, and providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicates the Physician-Self Referral Law and fully complies with an exception.
- These waivers would apply uniformly to all qualified ACOs and participants in the Medicare Shared Savings Program during the term of an ACO's agreement
- OIG anticipates issuing waivers applicable to participating ACOs concurrently with CMS's publication of final regulations

Solicitation of Comments on Fraud and Abuse Waivers

- The OIG solicits comments on its proposed waivers and additional waivers that may be necessary. The OIG is seeking input on:
  - The necessary waivers for arrangements related to establishing the ACO
  - The necessary waivers for arrangements between or among ACO participants and/or ACO
  - The necessary waivers for arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities
  - The necessary waivers for distributions of shared savings or similar payments received from private payers
  - Other financial arrangements for which a waiver would be necessary and where no current exception or safe harbor would apply
  - Duration of waivers
  - Additional safeguards that might be necessary for and effective to protect patients and the Federal health care programs
  - Whether the proposed waivers are too broad or too narrow, and recommended changes
  - Whether additional or different fraud and abuse waivers might be appropriate for ACOs participating in the two-sided risk model
  - Use of existing exception and safe harbor for electronic health records arrangements
  - Whether and under what circumstances waivers are needed related to the prohibition on inducements offered to Medicare and Medicaid beneficiaries
  - When the OIG should publish final waivers
- The OIG also solicits comments on how it should use its separate waiver authority related to CMMI demonstrations

Antitrust Issues

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Antitrust Issues

- FTC/DOJ Released Proposed 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
- Three Categories for Proposed ACOs
  - (1) Safety Zone: Combined share of <30% for each common service; No expedited review required; Won't be challenged absent extraordinary circumstances
  - (2) Mandatory Review: Combined share of >50% in ANY common service; Requires expedited review by antitrust agencies; Single common service >50% share requires mandatory review
  - (3) Discretionary Review: Combined share between 30%-50% for each common service; May seek expedited review if desired; Provides list of conduct to avoid
- Complicated Calculation of Shares
  - Requires determination of: (1) Primary Service Areas and (2) Common Services (by Medicare Specialty Code (MSC))
- Expedited 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 and advise the ACO that either: (1) it has no present intent to challenge the ACO as describe or (2) it is likely to or plans to challenge if the ACO proceeds
  - CMS will not approve an ACO for the Shared Savings Program if it receives notification that an Agency is likely to challenge (or recommends challenging) the ACO
- Agencies Will Apply Rule of Reason Analysis (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

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Treatment of Tax-Exempt ACOs

Treatment of Tax-Exempt ACOs

- In Notice 2011-20, the IRS solicits comments on whether existing guidance for tax-exempt organizations is sufficient for tax-exempt organizations planning to participate in the Medicare Shared Savings Program
  - The IRS advises that, to avoid adverse tax consequences, the tax-exempt organization must ensure that its participation in the Shared Savings Program is structured so as not to result in its net earnings inuring to the benefit of its insiders or in its being operated for the benefit of private parties participating in the ACO. Because of CMS regulation and oversight, the IRS generally expects that it will not consider a tax-exempt organization's participation in an ACO to result in inurement or impermissible private benefit to the private party ACO in various circumstances listed in the Notice.
  - Although the issue may arise, the IRS expects that activities generating shared savings payments received by a tax-exempt organization participating in an ACO will generally be substantially related to the performance of the organization's charitable purposes, meaning that such payments will likely **not** be subject to unrelated business income tax (UBIT).
- The IRS also solicits comments on whether guidance is needed regarding the tax implications for tax-exempt organizations participating in shared savings arrangements, with commercial health insurance payers or others, through ACOs outside of the Medicare Shared Savings Program