

Accountable Care Organizations: The Final Rule

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Background



Delivery System Reforms:

Trying to Shift from Payment for Volume to Payment for Value

- Accountable care organizations
- Hospital value-based purchasing program
- Physician value modifier
- Medical homes
- Bundled payment initiatives



Medicare Shared Savings Program Statutory Requirements

■ ACO must:

- Enter an agreement with the Secretary to participate in the program for at least three years
- Report and eventually achieve specified quality measures
- Provide care for a minimum of 5,000 beneficiaries
- Be "patient centered"
- Have a sufficient number of primary care physicians

■ ACO must not:

- Cherry pick patients based on risk
- Force patients to stay in the ACO
- Participate in other shared savings programs or demonstrations



ACO Final Rule and Related Documents

- The Centers for Medicare & Medicaid Services (CMS) released the ACO final rule on October 20, 2011
 - The rule was published in the Federal Register on November 2nd (76 Fed. Reg. 67,802-990)
- Several related documents were released in connection with the ACO final rule:
 - CMS's Center for Medicare & Medicaid Innovation (CMMI) issued a notice announcing an ACO advance payment model
 - CMS and the Health and Human Services (HHS) Office of Inspector General (OIG) released an interim final rule establishing waivers of certain fraud and abuse laws for specified arrangements involving ACOs
 - The Federal Trade Commission and the Antitrust Division of the Department of Justice issued a "Statement of Antitrust Enforcement Policy" regarding ACOs
 - The Internal Revenue Service issued a notice concerning tax-exempt organizations for ACOs



Final Rule Highlights



Changes in ACO Final Rule

- The final rule includes a number of modifications from CMS's proposed rule aimed at reducing the burden and cost for participating ACOs, including the following:
 - Providing greater flexibility in the governance and legal structure of an ACO;
 - Reducing the number of required quality measures from 65 to 33 and simplifying quality performance standards;
 - Adjusting financial models and shared savings provisions to increase financial incentives to participate;
 - Providing greater flexibility in timing for repayment of losses;
 - Establishing multiple start dates in 2012; and
 - Providing greater fraud and abuse waiver protection for arrangements involving ACOs



What is the Potential Impact of the Shared Savings Program?

- CMS anticipates that 50-270 ACOs will be established during the first four years of the program
 - Estimates 1-5 million Medicare beneficiaries would align with these ACOs
 - Expects that most ACOs will initially choose Track 1

- Have interested entities found other, more attractive, routes to participation in ACO models?
 - CMS is expected to announce the Pioneer Program participants on November 18
 - Commercial ACOs continue to operate in certain markets (e.g., Norton Healthcare in Louisville, KY; Tucson Medical Center in Tucson, AZ; Monarch HealthCare in Irvine, CA)



Are Certain Providers More Likely to Participate?

- ACOs aligned with hospitals and other larger entities may be better able to offset start-up costs (estimated at \$580,000)
 - However, smaller entities may be eligible for pre-payment of savings through Advance Payment Model
- Location could play a role in the financial viability of ACOs
 - Beneficiaries may have more of a choice of receiving care outside of an ACO in larger metropolitan areas, lessening an ACO's ability to control beneficiary care and costs
 - Certain areas may have more “snowbirds” or patients who receive care in multiple areas, lessening control
 - Quality performance determined on a national benchmark
 - National update factor in the benchmark designed to treat preferentially Medicare low-cost areas



Will the ACO Program Reduce Medicare Spending (i.e., will it be a success)?

- Despite the fact that CMS made a number of changes in the final rule designed to make the program more financially attractive to providers, estimates for Medicare savings are actually higher than those based on the proposed rule
 - More ACO participation among providers is expected under the final rule, thus yielding larger net federal savings
- Estimates of the overall impact of ACOs on Medicare spending by the CMS Office of the Actuary vary widely, however, due to the many assumptions required
 - The final rule estimates federal savings of \$470 million from 2012 to 2015
 - Under the most extreme scenarios, however, CMS estimates that the program could produce as much as \$2 billion in savings or \$1.1 billion in increased expenditures

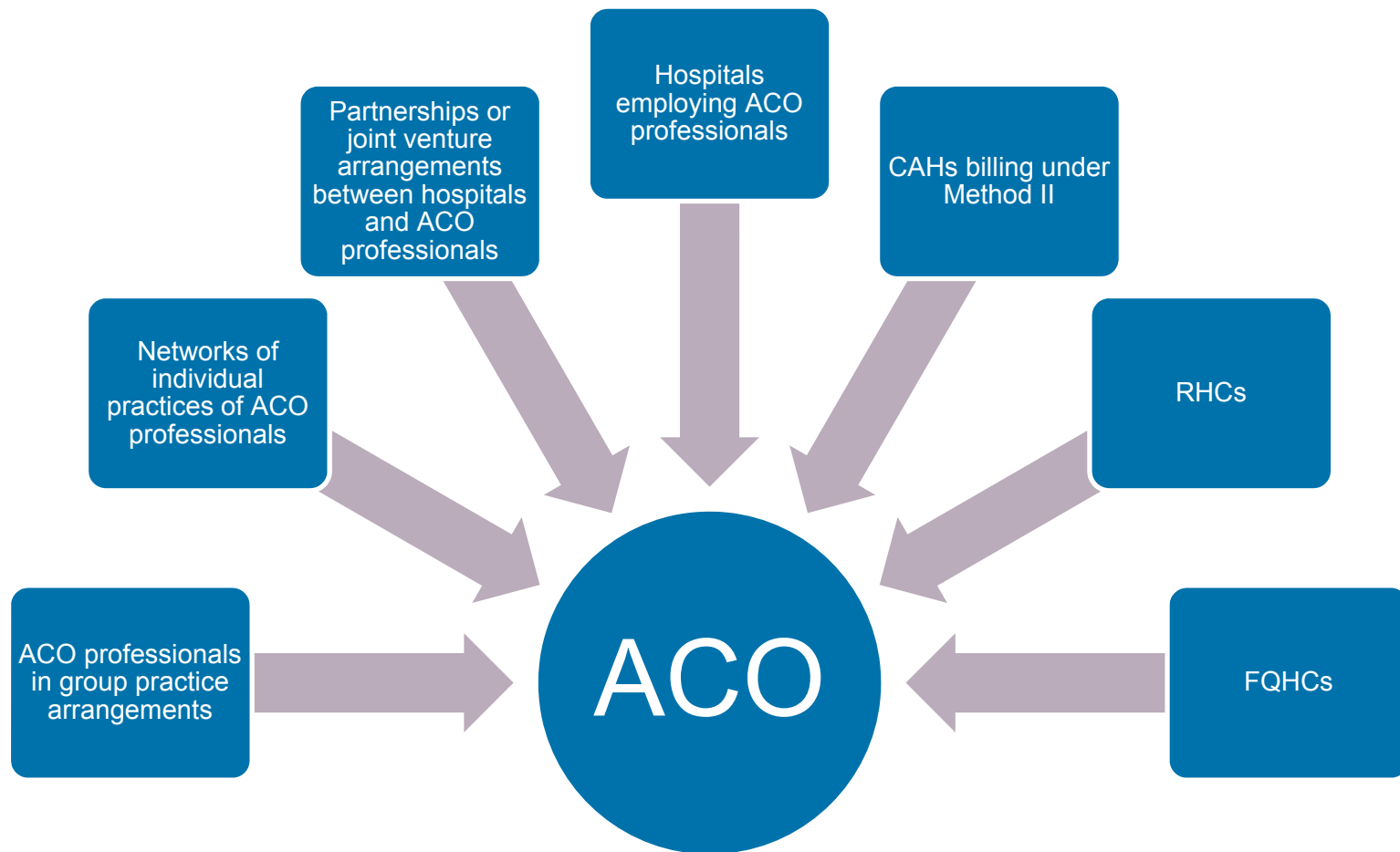




Structure and Formation of ACOs



Entities that are Permitted to *Form* an ACO



Structure and Formation of ACOs: Legal Requirements

- ACOs must be legal entities formed under applicable state, federal, or tribal law and authorized to conduct business in each state in which they operate for the purpose of all program functions, including the following:
 - Receiving and distributing shared savings;
 - Repaying shared losses or other monies determined to be owed to CMS;
 - Establishing, reporting, and ensuring compliance with health care quality criteria, including quality performance standards; and
 - Fulfilling other ACO functions identified by CMS
- An ACO formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants



Structure and Formation of ACOs: Shared Governance

- ACOs must establish an identifiable governing body with authority to execute the functions of the ACO and with responsibility for oversight and strategic direction
 - Each governing body member shall have a fiduciary duty to the ACO
 - Governing body must have a transparent governing process and adopt a conflict of interest policy applicable to members
 - Must provide for “meaningful participation” of ACO participants in control and composition of governing body
- Requirements for composition of ACO governing body
 - At least 75 percent of ACO governing body must consist of ACO participants (i.e., physicians and other providers/suppliers)
 - Must provide for beneficiary representation
 - But, the final rule provides some flexibility, for example, in states where law may prohibit or restrict beneficiary participation in the governing body (e.g., states with a corporate practice of medicine prohibition)



Structure and Formation of ACOs: Leadership and Management Structure

- ACO must be managed by an executive, officer, manager, or general partner whose appointment and removal are controlled by the governing body
- Clinical management and oversight of the ACO must be led by senior-level medical director who is:
 - A physician of the ACO
 - Physically present on a regular basis at an ACO location
 - Board-certified and licensed in one of the states in which ACO operates
- In the final rule, CMS eliminated its proposal to require a physician-led quality assurance committee
 - Instead, in their applications, ACOs must describe how they will establish and maintain an ongoing quality assurance and improvement program led by “an appropriately qualified health care professional”
- ACO participants and providers/suppliers must demonstrate a “meaningful commitment” to the mission of the ACO





Quality Performance Standards and Reporting



Quality Performance Standards and Reporting: Selection of Quality Measures

33 Quality Measures in 4 Domains

Patient/care
giver
experience

Care
coordination
/patient
safety

Preventive
health

At-risk
populations



Quality Performance Standards and Reporting: “Pay for Performance” Phase In

- CMS will establish a quality performance standard in each performance year
 - For performance year 1, the quality performance standard is defined as “complete and accurate reporting” for all 33 quality measures (i.e., “pay for reporting”)
 - In subsequent years, the quality performance standard will be phased in such that an ACO will be assessed based on both “pay for reporting” and “pay for performance”

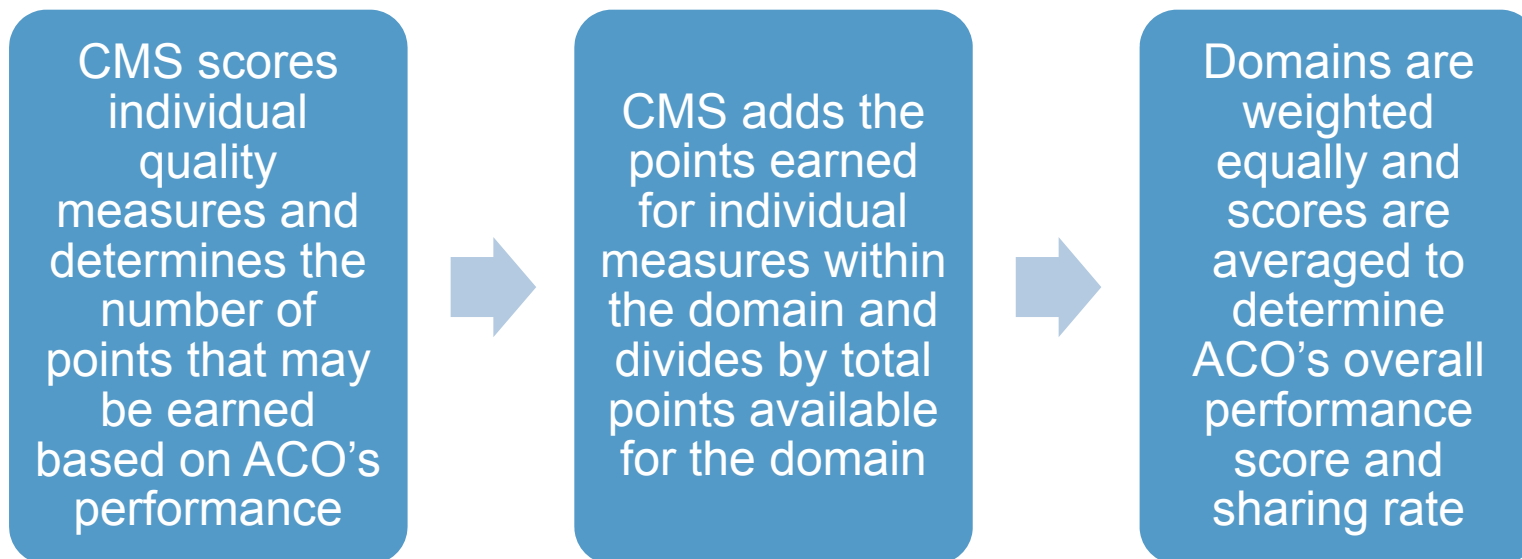
Number of ACO Quality Measures

Performance Year	Pay for Reporting	Pay for Performance
Year 1	33	None
Year 2	8	25
Year 3	1	32

Source: CMS, ACO final rule ; Table 2; 76 Fed. Reg. 67,802, 67,890 (Nov. 2, 2011)



Calculating the ACO's Quality Performance Score



ACO Payment Methodology

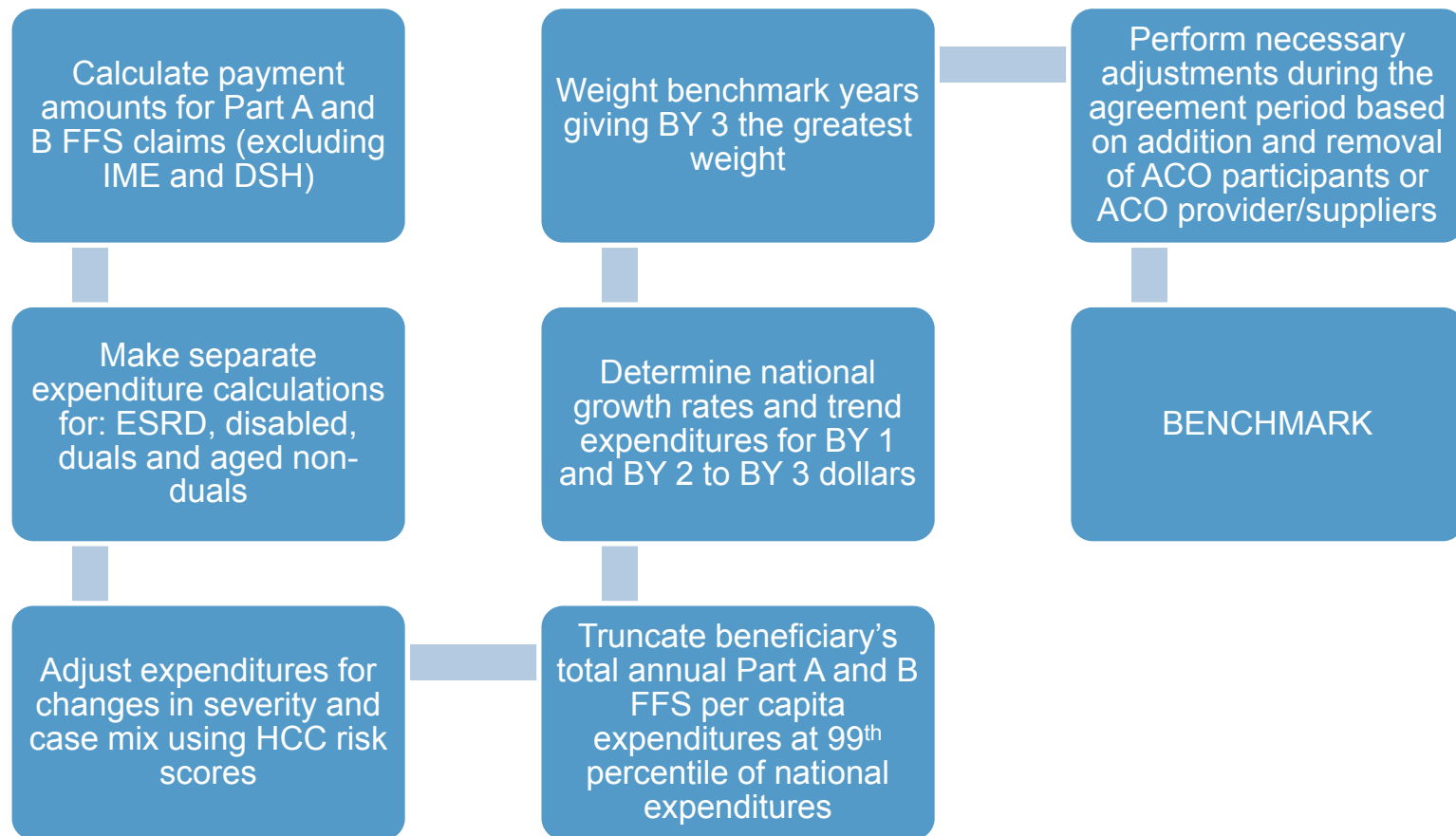


ACO Payment Overview

- ACO participants will continue to be paid FFS rates under the applicable Medicare payment system
- In addition, ACOs will be eligible to receive shared savings if:
 - ACO meets quality performance standards, and
 - Costs are below a performance target and minimum savings rates (“MSR”)
- Non-ACO participants do not share in savings
- Each ACO will decide how to internally share savings among participants



ACO Payment Mechanics: Establishing the ACO Benchmark



ACO Payment Mechanics: Updating and Resetting the Benchmark

- CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B under the original Medicare FFS program
- An ACO's benchmark will be reset at the start of each agreement period



ACO Payment Mechanics: Track 1 - Shared Savings Only

Savings Determination

- CMS determines whether expenditures are below the benchmark

Minimum Savings Rate (MSR) Calculation

- CMS uses a sliding scale based on the number of beneficiaries assigned to the ACO to calculate the MSR

Qualification for Shared Savings Payment

- If the ACO meets or exceeds the MSR and meets quality performance standards, it is eligible to share in savings

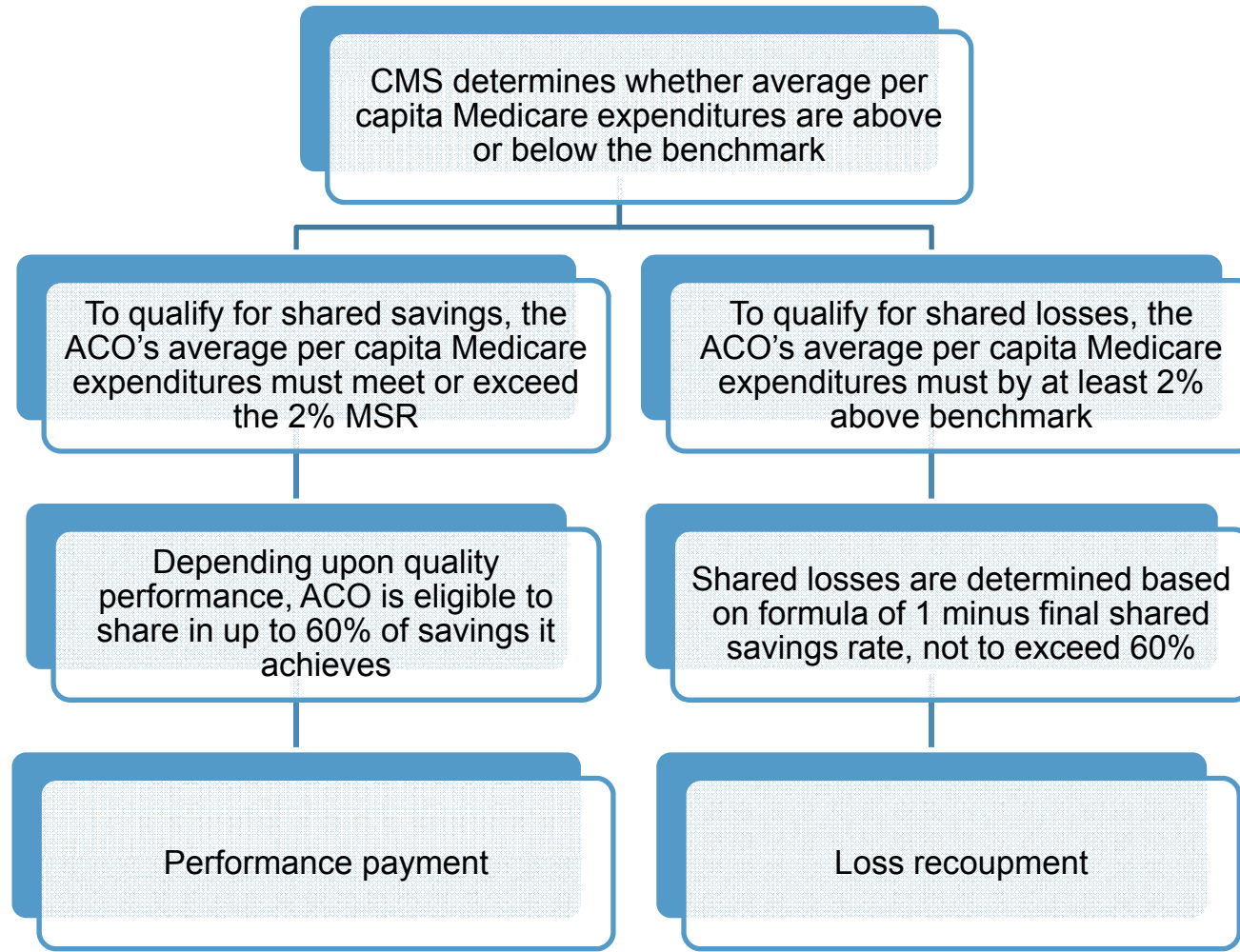
Calculation of Final Sharing Rate

- Up to 50% of all savings depending on quality performance

Performance Payment



ACO Payment Mechanics: Track 2 - Shared Savings and Shared Losses Calculation



ACO Payment Mechanics: Two Payment Tracks - Summary Table

Design Element	Track One	Track Two
Maximum Potential Share of Savings	Up to 50% based on quality performance	Up to 60% based on quality performance
Minimum Savings Rate	Ranges from 2.0% to 3.9% of the ACO's benchmark (varies by number of beneficiaries assigned to ACO)	Flat 2% of the ACO's benchmark
Minimum Loss Rate	Not applicable	Flat 2% of the ACO's benchmark
First Dollar Savings	Yes. ACOs are eligible for shared savings once the MSR is exceeded up to a cap	Yes. ACOs are eligible for shared savings once the MSR is exceeded up to a cap
Performance Payment Limit	10% of ACO benchmark	15% of ACO benchmark
Shared Losses	Not applicable	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60%
Loss Sharing Limit	Not applicable	Limit on amount of losses to be shared is phased in over 3 years, starting at 5% in year 1; 7.5% in year 2; 10 percent in year 3. Losses in excess of annual limit would not be shared



Special Rules for ACOs Beginning April 1 or July 1, 2012

- For April 1 and July 1 “starters,” the first year performance will be based on --
 - Optional interim payment calculation based on ACO’s first 12 months of participation, and
 - Final reconciliation at the end of the first performance year (defined as 21 or 18 months respectively) ending December 31, 2013



Repaying Losses

- CMS requires that ACOs have the ability to repay losses for which they may be liable and other monies that may be owed upon first performance year reconciliation (for April 1 and July 1 starters)
 - The mechanism for repayment must be equal to at least 1 percent of the ACO's total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries based on either expenditures for the most recent performance year or for the benchmark expenditures
- The proposed 25 percent withhold of shared savings earned by the ACO has been deleted from the final rule
- ACOs may demonstrate their ability to repay losses or other monies by:

Obtaining
reinsurance

Placing funds in
escrow

Obtaining surety
bonds

Establishing a
line of credit

Or other
appropriate
repayment
mechanism





Beneficiary Assignment to ACOs



Beneficiary Assignment Timing: Preliminary Prospective Assignment

- Medicare assigns beneficiaries in a preliminary manner at the beginning of the performance year based on available data
- Assignment will be updated quarterly based on the most recent 12 months of data
- Final assignment is determined after the end of each performance year, based on data from the performance year



Beneficiary Assignment Process

Step 1: Primary Care Provider Assignment



Identify all primary care services rendered by PCPs



Assign beneficiary to ACO if allowed charges for primary care services by physicians who are ACO provider/suppliers in the ACO are greater than those in any other ACO and not affiliated with an ACO

Step 2: Assign remaining beneficiaries who have received at least one primary care service from an ACO physician, as appropriate



Beneficiary will be assigned to ACO if allowed charges for primary care services furnished to beneficiary by all ACO professionals who are ACO providers/suppliers are greater than the combined allowed charges for primary care services furnished by: 1) all professionals who are ACO providers/suppliers in any other ACO, and 2) other physicians, nurse practitioners, PAs, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN



Beneficiary Assignment to ACOs

- Definition of “primary care services” is based on a set of services described by certain HCPCS codes
 - Final rule expands the list of primary care services to include the “Welcome to Medicare” visit and annual wellness visits
- Definition of “primary care physician” includes a physician who has a primary specialty designation of:

Internal
Medicine

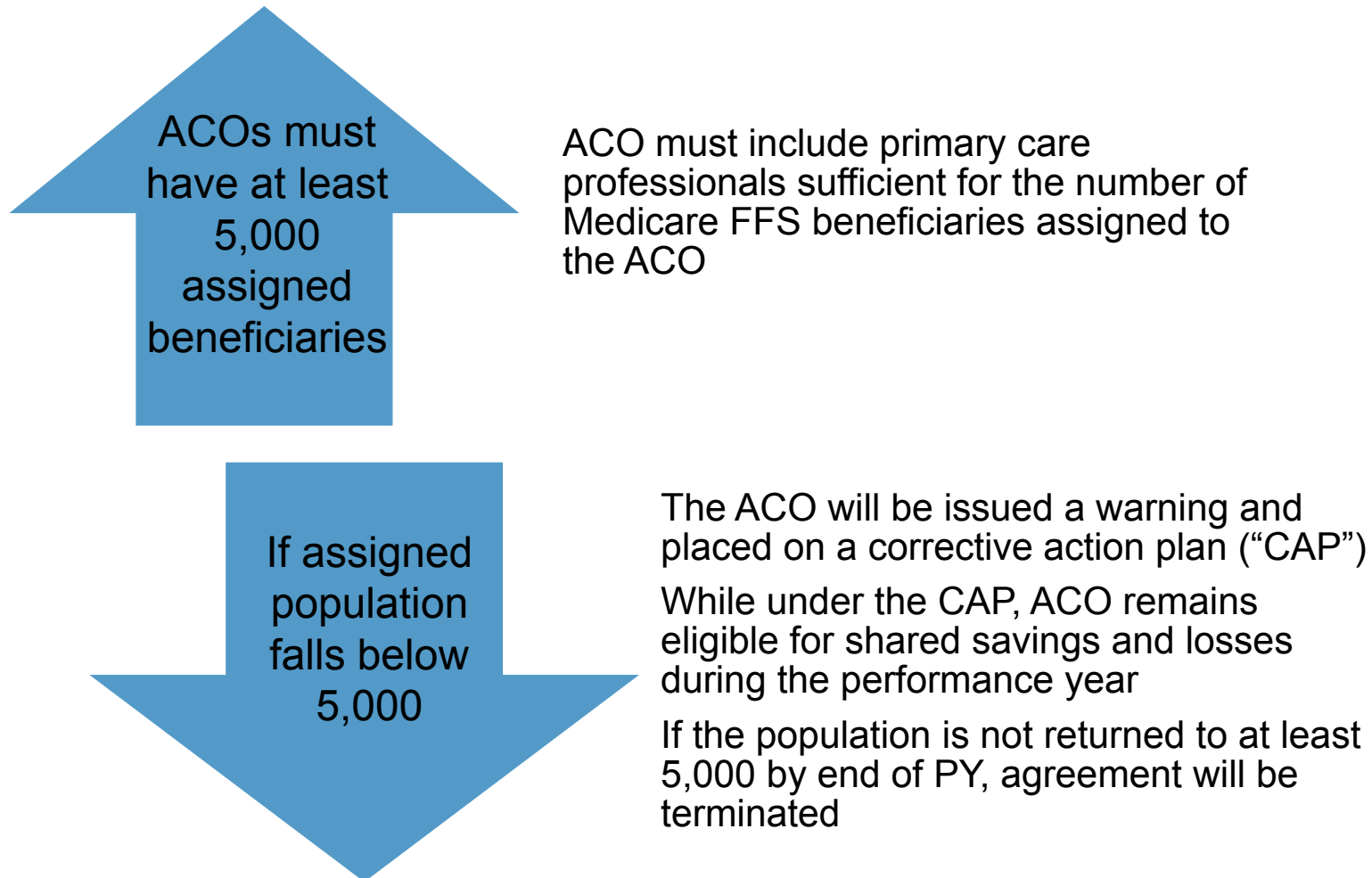
General
Practice

Geriatric
Medicine

Family
Practice



Required Number of ACO Professionals and Beneficiaries



Application Requirements



Application Requirements: Three-Year Agreement with CMS

- ACOs must submit complete applications to the agency
- Content of the application includes:
 - Certification that ACO, its participants, and providers/suppliers have agreed to become accountable for quality, cost, and overall care of assigned Medicare beneficiaries
 - Documentation that ACO meets eligibility criteria (e.g., information related to governing body and compliance plan)
 - Description of how the ACO plans to distribute shared savings
 - Selection of track and option for interim payment calculation (if applying for 2012 start date)
 - Documentation demonstrating that ACO will have the ability to pay back losses for which it may be liable (e.g., if participating in two-sided model)



Participation Agreement: Three-Year Agreement with CMS

- In order to participate in the program, an ACO must enter into an agreement with CMS for a period of at least 3 years

Term of Agreement

Start Date	Length of Term
April 1, 2012	3 years and 9 months
July 1, 2012	3 years and 6 months
January 1, 2013 and beyond	3 years



Advance Payment Model



Advance Payment Model (APM)

- CMS announced the APM for certain ACOs participating in the Medicare Shared Savings Program
 - CMS published a notice on the APM in the Federal Register on November 2nd (76 Fed. Reg. 68012)
- The Innovation Center is committing up to \$170 million to the APM to test whether:
 - Pre-paying a portion of future shared savings could increase participation in the Shared Savings Program
 - Advance payments increase the amount of and speed at which ACOs can effectively coordinate care to generate Medicare savings
- The application for the APM must be submitted at the same time as the Medicare Shared Savings Program application



APM: Eligibility

- The APM is open to two types of organizations participating in the Shared Savings Program
 - ACOs that do not include any inpatient facilities AND have less than \$50 million total annual revenue
 - ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals AND have less than \$80 million in total annual revenue
- ACOs that are co-owned with a health plan will be ineligible, regardless of whether they fall into one of the above categories
- Only ACOs that enter the Shared Savings Program in April or July 2012 will be eligible



APM: Payments

- Selected ACOs will receive three types of payments:
 - An up-front, fixed payment – \$250,000 in the first month of the Shared Savings Program;
 - An up-front variable payment – payment in the first month of the Shared Savings Program equivalent to the number of preliminary, prospectively assigned beneficiaries times \$36; and
 - A monthly payment of varying amount depending on the number of Medicare beneficiaries historically attributed to the ACO – each ACO will receive a monthly payment equal to the number of its preliminary, prospectively assigned beneficiaries times \$8.
- In general, advance payments will be recouped through the ACO's earned shared savings
 - However, should an ACO not have earned sufficient shared savings in the first agreement period to fully repay advance payments, and not enter a second agreement period, CMS will not pursue full recoupment of remaining advance payments from that ACO
- ACOs that meet eligibility criteria above will be scored according to a rubric and will be evaluated based on the quality of their “spend plans”



Fraud and Abuse Waivers



Fraud and Abuse Waivers: Interim Final Rule with Comment Period

- In connection with the ACO final rule, CMS and the OIG issued an interim final rule with comment period establishing waivers of the application of fraud and abuse laws to specified arrangements involving ACOs
 - The waivers address the Physician Self- Referral Law (“Stark Law”), the federal Anti-Kickback Statute, and provisions of the Civil Monetary Penalties (“CMP”) Law (so-called “Gainsharing CMP” Law and “Beneficiary Inducements CMP” Law)
 - In April 2011, CMS and OIG published a notice with comment period proposing certain waivers and discussing waiver design issues applicable to ACOs under the shared savings program
 - Interim final rule was issued pursuant to HHS Secretary’s statutory authority to waive the application of certain fraud and abuse laws “as may be necessary” to implement the ACO shared savings program
 - The rule was published in the Federal Register on November 2, 2011 (76 Fed. Reg. 67,992-68,010) and the deadline for submitting comments is 5 pm on January 3, 2012



Fraud and Abuse Waivers: Waivers in General

- The interim final rule outlines five waivers covering different arrangements involving ACOs, which apply provided that certain conditions in the rule are met
- These waivers cover:
 - ACO pre-participation: certain ACO start-up arrangements provided by the would-be ACO, its participants, and its providers/suppliers
 - ACO participation: certain arrangements between and among the ACO, its participants, and its providers/suppliers
 - Distribution of shared savings earned by the ACO
 - Arrangements that comply with Stark Law exceptions
 - Certain patient incentives: in-kind items or services provided by the ACO, its participants, or its providers/suppliers to beneficiaries for free or below fair market value





IRS Guidance for Tax-Exempt ACO Participants



IRS Fact Sheet 2011-11 (10/20/2011)

- In the Fact Sheet, the IRS confirms that IRS Notice 2011-20 (04/18/2011) generally continues to reflect the IRS's expectations about the federal tax consequences to tax-exempt participants in an ACO
- The Fact Sheet also helps clarify several positions stated in the earlier Notice and provides useful additional guidance



IRS Notice 2011-20

- In the Notice, the IRS stated that a tax-exempt organization (EO) could participate in the Medicare Shared Savings Program (MSSP) through an ACO without adverse federal tax consequences if five factors were satisfied:
 - Terms of the EO's participation in the ACO are negotiated at arm's length and set out in advance in writing
 - CMS has accepted the ACO into, and not terminated it from, the MSSP
 - The EO's share of economic benefits from the ACO (including MSSP payments) is proportional to the benefits or contributions the EO provides to the ACO
 - The EO's share of ACO losses do not exceed its share of the economic benefits
 - All contracts and transactions between the EO and the ACO and its participants, and by the ACO with the ACO's participants and any third parties are at fair market value



Clarification of the Five Factors

- Not all 5 factors are required and no one factor is determinative;
- An EO's economic contributions and benefits to, and received from, an ACO is "proportional" based on the totality of the circumstances and includes any form of economic contribution (cash, property or services) and benefit received (including shared savings payments); and
- EO participants in an ACO that is treated as a partnership for tax purposes do not necessarily need to control an ACO whose activities are limited to participation in the MSSP



Additional Clarification as to when non-MSSP ACO Activities do not Produce adverse Federal Tax Consequences

- In the Notice, the IRS declined to address whether and under what circumstances an EO's participation in an ACO engaged in non-MSSP activities would produce adverse tax consequences to the EO
- In the Fact Sheet, the IRS clarified that an EO could, in some circumstances, participate in an ACO that is engaged in non-MSSP activities without adverse federal tax consequences -- based on an analysis using the general tax principles applicable to charitable organizations looking at all relevant facts and circumstances



Additional Guidance in IRS Fact Sheet 2011-11

- An ACO that participates in the MSSP and engages in non-MSSP activities could be recognized as a § 501(c)(3) organization if it is not classified as a partnership for tax purposes and otherwise meets the requirements of § 501(c)(3)
- Electronic Health Records Technology – the Fact Sheet states that the standards provided in a 2007 IRS memorandum will govern whether, and the extent to which, a tax-exempt hospital may provide financial assistance to staff physicians to obtain and implement EHR technology through an ACO



Antitrust Statement



Antitrust Policy Statement Overview

- In support of the MSSP final rule, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued antitrust guidelines
- The guidelines assure ACO applicants that an ACO can operate in the commercial market without facing summary antitrust challenge for price fixing if they
 - Are accepted into the ACO program
 - Satisfy the standards for qualifying as an ACO



Antitrust Policy Statement Overview

- The guidelines create a “safety zone” from antitrust challenge for ACOs below a certain size
 - Note: safety zone does not immunize an ACO from private antitrust challenge
- Outside of the safety zone
 - ACOs are advised to avoid certain anti-competitive behaviors
 - ACOs are afforded the option to request expedited 90 day review from DOJ and the FTC
 - The Agency will examine whether the ACO will likely harm competition by increasing its ability or incentive to raise prices above competitive levels or reduce output, quality, service or innovation below what would prevail absent the ACO
- CMS will not require an ACO applicant to undergo antitrust agency review prior to acceptance in the MSSP

