Preconference I: CMS ACO Regulations Part 2
A Deep Dive into the Revised Regulations

November 1, 2011

Bruce Merlin Fried
SNR Denton
Bruce.Fried@snrdenton.com
(202) 408-9159

Mara McDermott
Akin Gump
mmcdermott@akingump.com
(202) 887-4337

SNR DENTON

AKIN GUMP
STRAUSS HAUER & FELD LLP

The Final Medicare Shared Savings Program (MSSP) ACO Regulation

- Roadmap of Presentation
  - Overview of Affordable Care Act ACO Provision
  - Release of Final ACO Rule
  - ACO Payment Overview
  - How to Assess Potential Value
  - Example
  - Payment Model Changes from Proposed Rule
  - ACO Structure and Formation
  - Quality Performance Standards
  - Beneficiary Assignment
  - Compliance and Program Integrity
  - Marketing
  - Advance Payments for Certain ACOs
  - Other Government Guidance (FWA, Antitrust, Tax)

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 Requirements in the Affordable Care Act

- 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

Medicare Shared Savings Program Final Rule

ACO Final Rule and Related Documents

- The Centers for Medicare & Medicaid Services (CMS) released the ACO final rule on October 20, 2011
  - The rule will be published in the Federal Register on November 2nd
- 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 advanced 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

Three-Year Participation Agreement with CMS

- CMS estimates 50-270 ACOs providing care to 1-5 million Medicare fee-for-service beneficiaries.
- In order to participate in the program, an ACO must enter into an agreement with CMS for a period of at least 3 years
- Applications will be released this Fall and will be due in early 2012. (Dates to be determined by CMS)

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

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")

ACO Payment Risk Models

One-sided Risk Model (Track 1)

- Eligible for up to 50% of the savings, not to exceed 10% of its benchmark
- MSR from 2% to 3.9% of its benchmark; must exceed MSR to share savings, at which point ACO receives “first dollar” savings
- Must transition to two-sided risk model after first three-year agreement period

Two-sided Risk Model (Track 2)

- Eligible for up to 60% of the savings, not to exceed 15% of the benchmark
- MSR and Minimum loss rate (MLR) is 2% of the benchmark; must exceed to share savings or pay share of losses; applies to first dollar savings/losses
- Also at risk of sharing up to 60% of the losses, capped at 5% of the benchmark in year one, 7.5% in year two, and 10% in year three

How to Assess Potential Value

- Overall value proposition in final regulation appears very similar to proposed regulation (though some changes help)
- Key elements in determining potential cost/benefit to ACO:
  - Benchmark: CMS assigns ACO a benchmark measurement of Parts A and B spending for beneficiaries who would have been assigned to the ACO in the past, based on prior three years of data trended forward and risk adjusted
  - Potential savings/losses: Determined by CMS for each year of the agreement period, by comparing actual Medicare FFS costs of beneficiaries assigned to the ACO to the benchmark; also risk adjusted
  - Quality scores: Scores on various measures in 4 “domains” are calculated by CMS and then averaged to determine an overall quality score; impacts can be significant
  - Risk model: As noted, the risk model selected by the ACO determines the percentage of savings that might apply, as well as any losses that might have to be paid

How to Assess Potential Value

Key formulas include:

- Payment option 1: (benchmark) x (% savings below the benchmark) x (quality score) x (50% sharing rate) x (12 months) x (# of assigned beneficiaries)
- Payment option 2:
  - Savings: (benchmark) x (% savings below the benchmark) x (quality score) x (60% sharing rate) x (12 months) x (# of assigned beneficiaries).
  - Losses: (benchmark) x (% costs above the benchmark) x [1- (quality score x 60% sharing rate); not to exceed 60%] x (12 months) x (# of assigned beneficiaries)
- Quality score: [(Domain 1 quality points earned/maximum available points) + (Domain 2 quality points earned/maximum available points) + (Domain 3 quality points earned/maximum available points + Domain 4 quality points earned/maximum available points)] / 4

Example

Assume an ACO with the following attributes:

- 5,300 assigned beneficiaries
- 4.5% savings on the one hand, and 4.5% losses on the other hand, compared to benchmark (exceeds minimum savings and minimum loss rates)
- 5,300 assigned beneficiaries
- Benchmark of $739.30

Example

Domain	Total Individual Measures/Total Measures for Scoring	Maximum Number of Points Available	Points	Domain Score
Patient/Caregiver Experience	7/2	4	3.7	92.5%
Care Coordination/patient safety	6/6 (including double weighted EHR)	14	10.5	75.0%
Preventive Health	8/8	16	16	100.0%
At-Risk Population	12/7	14	11.9	85.0%
Total	**33/23**	**48**		**—**
Final Quality Performance Score (each domain is weighted 25%)				**81.25%**

Example

	Quality Score in Example (0.8125)	Lower Quality Score (0.5)
Savings: Payment Option 1	[$739.30 x .045 x 0.8125 x 0.5] x 12 x 5,300 **= $859,574.87**	[$739.30 x .045 x 0.5 x 0.5] x 12 x 5,300 **= $528,969.15**
Savings: Payment Option 2	[$739.30 x .045 x 0.8125 x 0.6] x 12 x 5,300 **= $1,031, 489.84**	[$739.30 x .045 x 0.5 x 0.6] x 12 x 5,300 **= $634,762.98**
Losses: Payment Option 2	Shared loss rate = lesser of [1-(0.8125x0.6)] and 0.6 = lesser of 0.5125 and 0.6 = 0.5125 [$739.30 x .045 x 0.5125] x 12 x 5,300 **= $1,084,386.76**	Shared loss rate = lesser of [1-(0.5x0.6)] and 0.6 = lesser of 0.7 and 0.6 = 0.6 [$739.30 x .045 x 0.6] x 12 x 5,300 **= $1,269,525.90**

Payment Model
Changes from Proposed Rule

- Changes between the proposed and final regulation that might affect the value proposition include the following:
  - Can elect 1-sided-only risk, and get first dollar savings
  - Shared savings payment caps are higher (1-sided risk cap goes from 7.5% in proposed regulation to 10%; 2-sided risk cap goes from 10%-15%)
  - No 25% withhold
  - CMS has capped the shared loss rate
  - Some changes will be made to risk scores to reflect the population actually assigned to the ACO (proposed regulation would have locked in risk scores)

ACO Structure and Formation
Entities that are Permitted to *Form* an ACO

AKIN GUMP STRAUSS HAUER & FELD LLP
SNR DENTON

ACO Structure and Formation
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

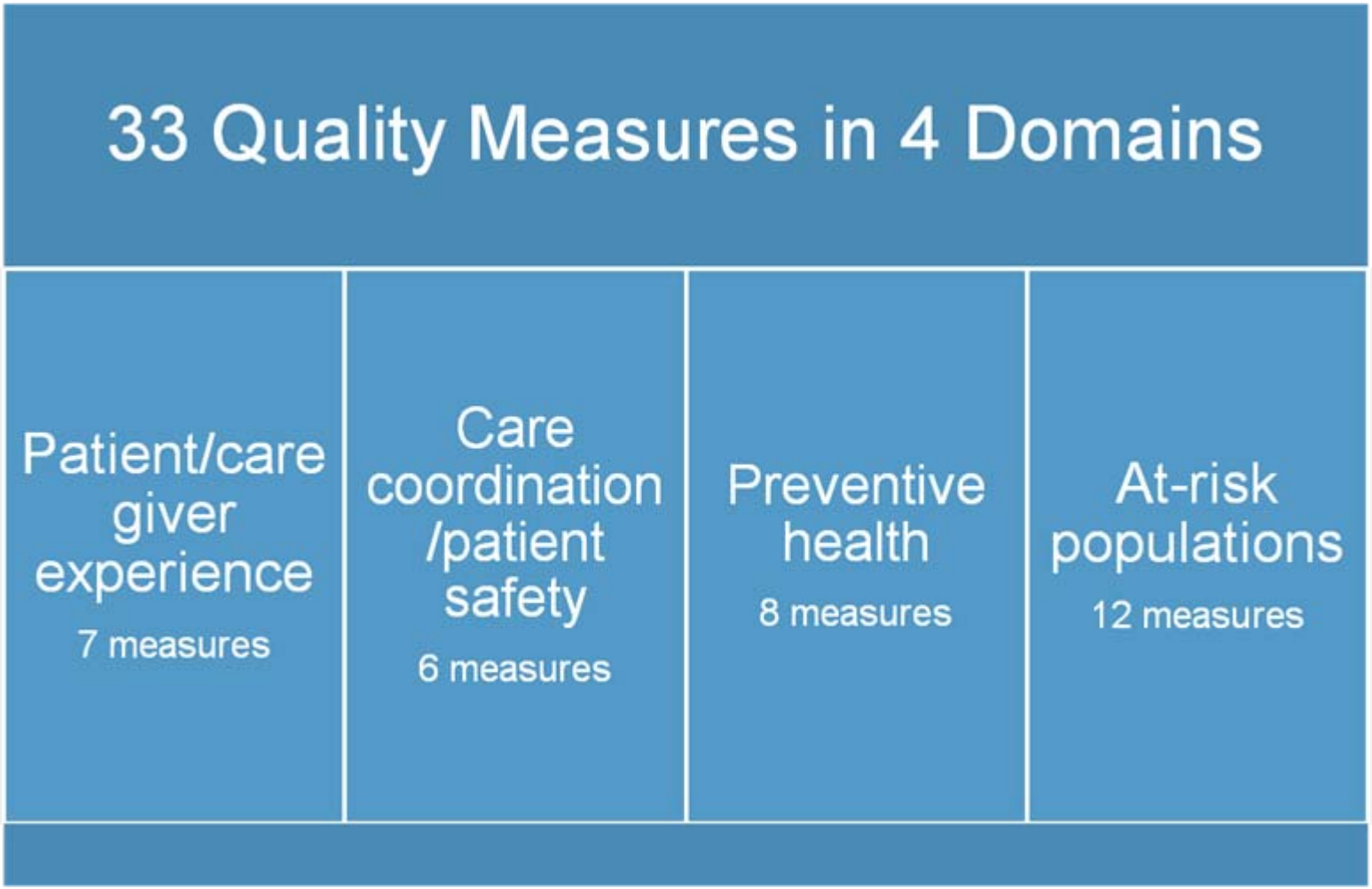
ACO Structure and Formation
Shared Governance

- 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)

ACO Structure and Formation
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
Selection of Quality Measures



Quality Performance Standards and Reporting "Pay for Performance" Phase In

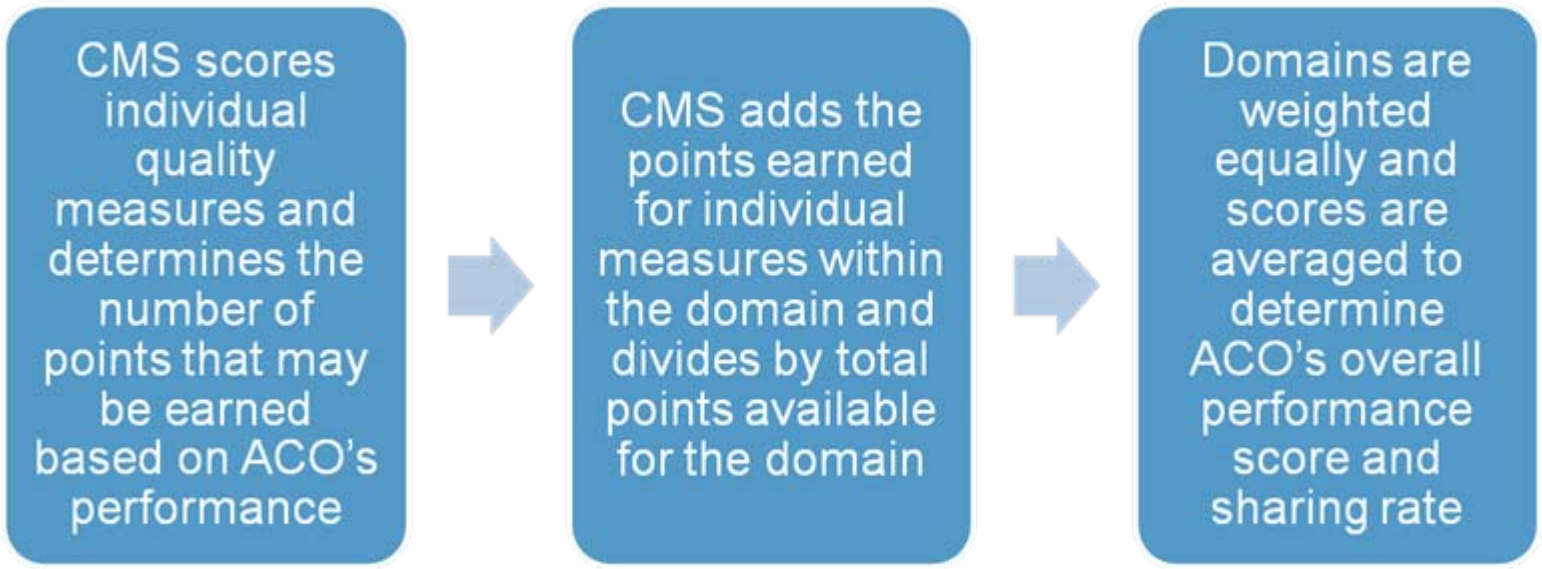
- CMS will establish a quality performance standard in each performance year
  - For performance year 1, the quality performance standard is defined as "complete and accurate reporting" for all 33 quality measures (i.e., "pay for reporting")
  - In subsequent years, the quality performance standard will 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

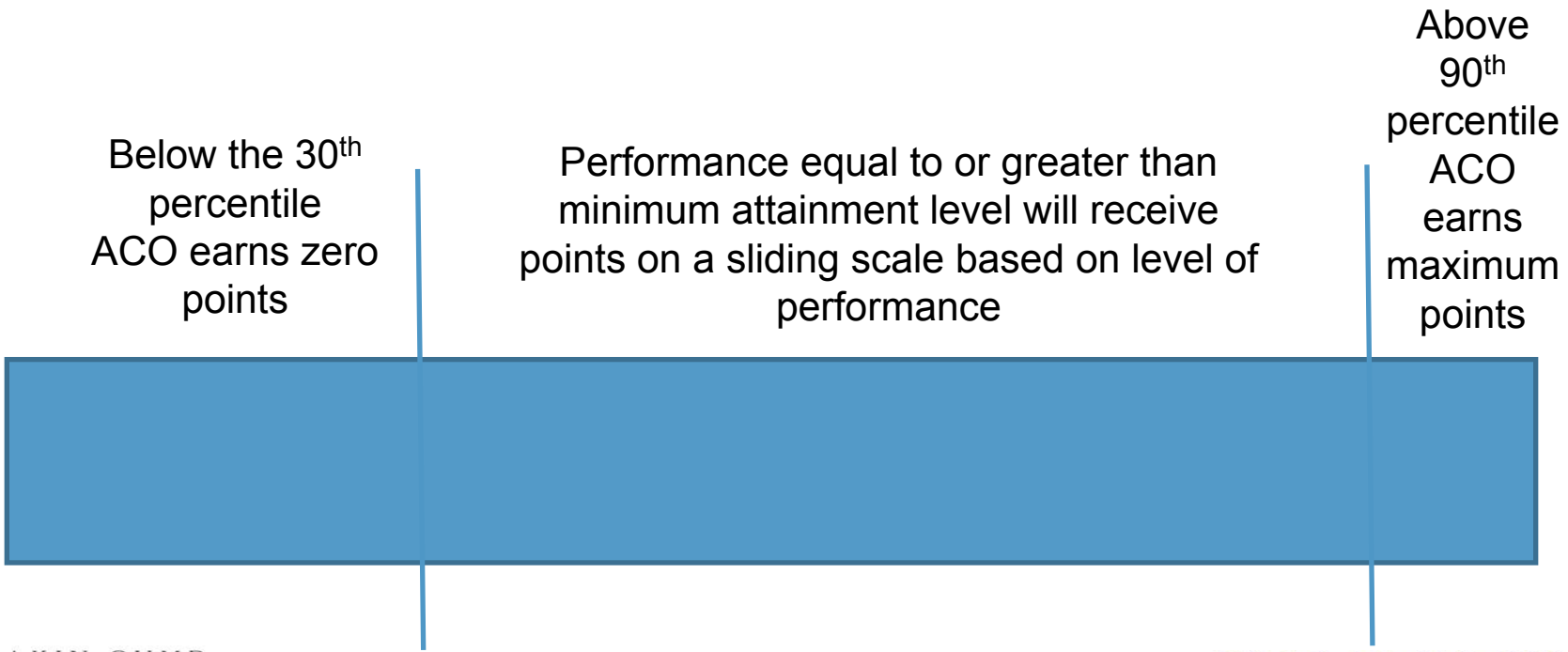
Source: CMS, ACO final rule (Oct. 20, 2011), Table 2 (p. 327 of display version)

Quality Performance Standards and Reporting
Calculating the ACO's Total Quality Performance Score



Quality Performance Standards and Reporting
Calculating the Individual Measures Score

- CMS will designate a performance benchmark and minimum attainment level for each measure and establish a point scale
- Performance benchmarks will be based on national Medicare FFS rates, national MA quality measures rates, or a national flat percentage



Quality Performance Standards and Reporting
Calculating the Domain Measures Score

- To satisfy domain performance requirements
  - ACO must report all measures in a domain
  - ACO must score above the minimum attainment level on 70% of the measures in each domain
- If the ACO achieves the minimum attainment level for at least one measure in each of the four domains, and satisfies the other program requirements, the ACO may receive a proportion of shared savings
- If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated

Quality Performance Standards and Reporting Interaction with other Quality Programs

- Physician Quality Reporting System (PQRS)
  - The final rule allows eligible professionals to qualify for PQRS without additional reporting outside of the Shared Savings Program
- Electronic Health Records (EHR)
  - ACOs are encouraged to develop a robust EHR infrastructure
  - The quality measure regarding EHR adoption will be weighted twice that of other measures
  - The proposed requirement that 50% of the ACO's primary care physicians be meaningful users by the second performance year is eliminated in the final rule

Beneficiary Assignment
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 (i.e., retrospective)

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 as appropriate

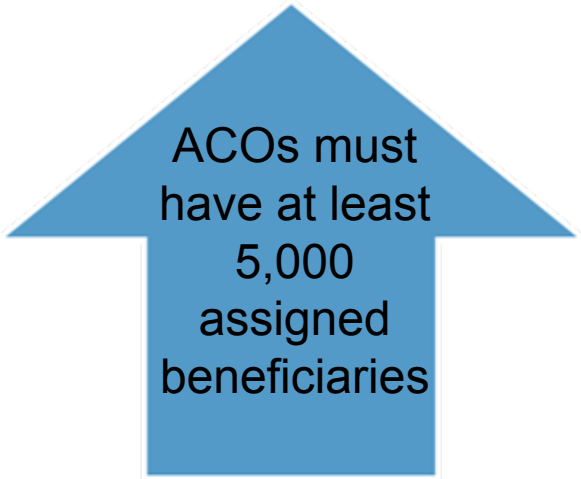
Beneficiary will be assigned to ACO if allowed charges for primary care services furnished to beneficiary by all ACO professionals who are ACO providers/suppliers are greater than the combined allowed charges for primary care services furnished by: 1) all professionals who are ACO providers/suppliers 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
Important Definitions

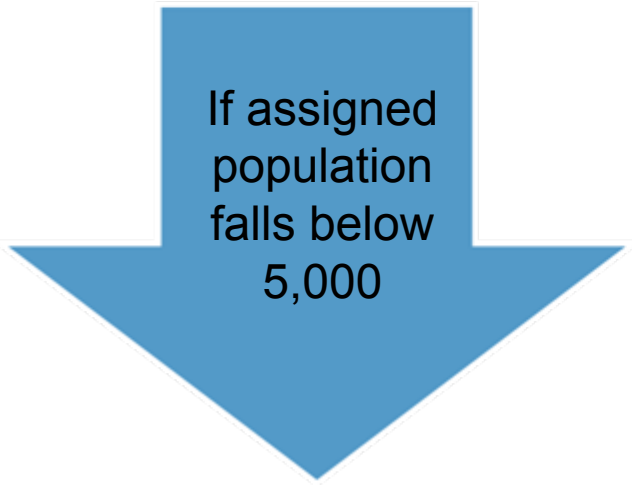
- Definition of “primary care services” is based on a set of services described by certain HCPCS codes
  - Final rule expands the list of primary care services to include the “Welcome to Medicare” visit and annual wellness visits
- Definition of “primary care physician” includes a physician who has a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

Internal Medicine	General Practice	Geriatric Medicine	Family Practice

Beneficiary Assignment
Required Number of ACO Professionals and Beneficiaries



ACO must include primary care professionals sufficient for the number of Medicare FFS beneficiaries assigned to the ACO



The ACO will be issued a warning and placed on a corrective action plan ("CAP")

While under the CAP, ACO remains eligible for shared savings and losses during the performance year

If the population is not returned to at least 5,000 by end of PY, agreement will be terminated

ACO Compliance and Program Integrity

- ACOs are required to establish a compliance program, including
  - A Compliance Officer who reports to the board, cannot be the ACO's counsel
  - Mechanisms to identify and address compliance problems
  - Methods for employees/contractors to report suspected problems
  - Compliance training
- An ACO executive must certify accuracy, truthfulness and completeness of
  - the application, and
  - any information submitted to CMS by the ACO
- ACO must have a conflicts of interest policy

ACO Marketing Rules

- Marketing materials must be submitted to CMS prior to use
  - "File and Use"
    - May be used five days after submission to CMS if CMS does not disapprove of the marketing materials
- Materials and activities include brochures, ads, events, letters to beneficiaries, web pages, opt out letters, mailings, social media when used to educate, solicit, notify or contact beneficiaries or providers or suppliers
- CMS will provide template language for some materials.
- "File and Use" may be withdrawn if CMS finds marketing violations.

Participation in other Shared Savings Initiatives

- ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative involving shared savings
- CMS will determine a method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, when such shared savings programs have an assignment methodology that differs from the Shared Savings Program

Advance Payment Model

Advance Payment Model (APM)

- CMS announced the APM for certain ACOs participating in the Medicare Shared Savings Program
- 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
- 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"

Additional ACO Guidance

Fraud and Abuse Waivers
Antitrust Guidance

Fraud and Abuse Waivers: Interim Final Rule with Comment Period

- In connection with the ACO final rule, CMS and the OIG released 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

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

FTC/DOJ

- Final Statement of Enforcement Policy Regarding ACOs Participating in the MSSP
- "Rule of reason" will apply to the treatment of an ACO
  - Must satisfy statutory requirements outlined in the Affordable Care Act
  - Must satisfy CMS final rule restrictions
  - Must use the same governance and leadership structures and clinical and administrative processes in the MSSP to serve patients in the commercial market
- 90-day voluntary expedited review process for ACOs that want antitrust guidance
- No mandatory review process for certain ACOs, as proposed
- FTC/DOJ, with CMS' help, will monitor ACO formation and conduct

Questions?