ACCOUNTABLE CARE PROPOSED REGULATIONS AND WAIVERS

April 18, 2011

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Proposed Shared Savings Regulation

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Background

- Paradigm Shift
  - From fee-for-service to value-based payment
  - From volume to efficiency and quality
  - From payment for individual services to payment for coordinated patient care
  - From acute care to wellness
  - From regulatory scheme that limits financial relationships to one that encourages collaboration?

Background (Cont'd)

THE DARTMOUTH INSTITUTE
FOR HEALTH POLICY & CLINICAL PRACTICE
Where Knowledge Informs Change

- Dartmouth Atlas of Health Care Spending
  - Higher spending doesn't lead to better quality or outcomes.
  - If the most intensive and expensive hospitals adopted the practices of the high-quality but lower-spending centers, Medicare could save $50 billion a year.
    - » http://www.dartmouthatlas.org/
- PGP Demonstration Project

  http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Fact_Sheet.pdf

  http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf

Background - PGP Demonstration Project (2005 to 2010)

Background

- Goals: Improve care coordination of Part A and Part B, promote efficiency through investment in administrative structure and processes and reward physicians for improving health outcomes for patients with chronic disease
- 10 MD groups with over 5,000 MDs and 220,000 Medicare FFS beneficiaries; includes Billings Clinic (MT), Dartmouth-Hitchcock (NH), Geisinger Health Sys (PA), Marshfield Clinic (WI), Park Nicollet Health Services (MN), Forsyth Med Group (NC), Univ. of Michigan Faculty Practice (MI); The Everett Clinic (WA)

Structure

- First Pay-For-Performance Shared Savings Initiative for Physicians – MD groups may earn up to 80% of savings generated, capped at 5% of benchmark
- 32 measures for chronic illness and preventative care; adopted in stages.
- MD groups have flexibility to redesign care processes, invest in care mgmt, and target populations that can benefit
- Patients not 'locked in' to using provider and patients/providers don't know which patients are in pilot
- Medicare spending growth must be 2% less than benchmark; difference is available for incentives

Results

- $46 million aggregate payments to 6 of the 10 Groups for savings in Years 1-3
- Performance year 4 - all ten had benchmark performance on at least 29 of the 32 measures
- Average cost per Group of $1.2 million

DEFINITION OF ACO

- Generally - group of health care providers who are *jointly* responsible for *quality and cost* of care for a *patient population*
- PPACA Shared Savings Program - 42 USC §1395jjj
- Proposed 42 CFR §425.4
  - Legal entity under applicable State law
  - Identified by a Taxpayer Identification Number (TIN)
  - Comprised of an *eligible group of ACO participants* that
    - work together to manage and coordinate care for Medicare fee-for-service beneficiaries
    - have established a mechanism for *shared governance*

GOALS OF ACO

- Dr. Berwick's Triple Aim:
  - Better care for individuals
  - Better health for populations
  - Lower growth in expenditures
- Per CMS, an ACO should:
  - Put the beneficiary and family at center of its activities
  - Ensure coordination of beneficiary care
  - Attend carefully to care transitions
  - Manage resources, reduce waste and reduce dependence on inpatient care
  - Proactively reach out to patients with reminders and advice
  - Collect, evaluate and use data
  - Be innovative in pursuing the triple aim
  - Continually invest in development of its workforce

REGULATORY PROPOSALS

- Shared savings rule: 76 Fed. Reg. 19528 (April 7, 2011)
  - Comments due June 6
  - Eligibility and governance
  - Participation application and agreement
  - Beneficiary assignment and notice
  - Quality measures and methodology
  - Shared savings payment methodology
  - Data sharing and reporting
  - Monitoring and termination
- *CMS/OIG waiver*: 76 Fed. Reg. 19655 (April 7, 2011)
- FTC/DOJ: http://www.ftc.gov/opp/aco
- IRS: http://www.irs.gov/pub/irs-drop/n-11-20.pdf

ELIGIBLE ACO PARTICIPANTS

- Organizations that may form an ACO (42 CFR §425.5(b))
  - ACO professionals in group practices
    - Physicians and other professionals (PA, NP, CNS)
  - Networks of individual practices of ACO professionals
  - Partnerships and joint ventures between hospitals and ACO professionals
  - Hospitals employing ACO professionals
  - Critical access hospitals that bill under Method II
  - Other providers or suppliers

ELIGIBLE ACO PARTICIPANTS (Cont'd)

- Report TIN of ACO and each ACO participant to CMS
  - Also report NPIs associated with each ACO participant
  - ACO provider/supplier is a provider or a supplier that bills under the TIN of an ACO participant
- Primary care physician participants contract for three years **exclusive** to one ACO
  - Internal medicine, general practice, family practice, geriatrics
  - Proposed program requirement – 50% are meaningful EHR users by start of second year
  - Must be sufficient primary care physicians for assignment of 5,000 or more beneficiaries

ELIGIBLE ACO PARTICIPANTS (Cont'd)

- Other ACO participants contract with ACO for three years but exclusivity can not be required
- ACO whose participants have Primary Service Area share greater than 50% for any common service must obtain antitrust review and submit reviewing agency letter
- Providers/suppliers that participate in any other Medicare initiative that involves shared savings are not eligible
  - E.g., independence at home medical practice pilot

ACO LEGAL STRUCTURE

- Must be a legal entity for purposes of:
  - Receiving and distributing shared savings
  - Repaying shared losses
  - Establishing, reporting and ensuring provider compliance with quality criteria
  - Performing other required ACO functions
- Must be recognized as legal entity under State law
  - Any recognized entity – partnership, LLC, for-profit or nonprofit corporation
  - Can be new or existing – *if* meet all requirements
  - Need not be enrolled in Medicare (but participants must be)

ACO GOVERNING BODY

- Authority
  - Execute all ACO functions including processes to promote evidence-based medicine, patient engagement, quality and cost reporting, and care coordination
  - Broad responsibility for all administrative, fiduciary, clinical operations
  - Must have conflict of interest policy
- Must be separate and unique to ACO if ACO comprised of multiple independent entities

ACO GOVERNING BODY (Cont'd)

- Composition
  - ACO participants or their representatives must have at least 75% control
    - Each ACO participant must have "appropriate proportionate control"
  - Must include at least one Medicare beneficiary
  - May include non-participants up to 25%
    - E.g., health plan, management company
  - May include community stakeholder(s)

ACO LEADERSHIP AND MANAGEMENT

- Must demonstrate structure to CMS that aligns with and supports ACO program goals
  - Meet following or have innovative structure approved by CMS
- Chief Executive who reports to governing body
  - Leadership team that has demonstrated ability to influence or direct clinical practice to improve efficiency processes and outcomes
- Senior-level medical director
  - Full-time, physically present at an ACO location, board-certified
- Physician-directed quality assurance and process improvement committee

ACO LEADERSHIP AND MANAGEMENT (Cont'd)

- ACO participants and ACO providers/suppliers must have meaningful commitment to ACO
  - Financial investment or human investment (time and effort)
- ACO must implement evidence-based medical practice or clinical guidelines and processes
  - ACO participants and providers/suppliers must agree to comply
  - Also subject to performance evaluation and remedial actions
  - ACO must have policies and procedures for expulsion
- ACO must have infrastructure such as information technology
  - Able to collect and evaluate data and provide feedback to participants

COMPLIANCE PLAN

- ACO must have a plan with the following elements:
  - Compliance officer that is not legal counsel and reports directly to governing body
  - Mechanisms to identify and address compliance issues relating to ACO's operations
  - Method for suspected problems related to the ACO to be reported
  - Compliance training
  - Requirement to report suspected violations of law to law enforcement agencies
- CMS is also considering whether to screen participants and how to avoid incentive for overutilization in non-assigned population

MARKETING AND PUBLIC REPORTING

- CMS review and approval is required prior to use for all ACO marketing materials or activities
  - *Includes* brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings and other communications and activities used to educate, solicit, notify or contact Medicare beneficiaries or providers and suppliers regarding the ACO and its participation in the shared savings program
  - *Excludes* information materials customized to a subset of beneficiaries, materials that do not include information about the ACO, materials that cover beneficiary-specific issues, education on specific medical conditions, or referrals
- Standardized written notice of participation/data opt-out rights anticipated

MARKETING AND PUBLIC REPORTING (Cont'd)

- CMS also to develop a beneficiary communication plan
- ACO must publicly report the following in a standardized format:
  - Name, location and primary contact
  - Participating providers and suppliers, and participants in any joint venture between hospitals and ACO professionals
  - Members of governing body, and list of committees and committee leadership
  - Quality performance standard scores
  - Shared savings or losses information
  - Total proportion of savings distributed and proportion used to support the triple aim

Patient-Centeredness

- ACO must address patient-centeredness through all of the following:
  - Have a beneficiary experience of care survey and describe how its results will be used to improve care
  - Patient involvement in governance
  - Process for evaluating and addressing health needs of ACO's assigned population
  - Systems to identify and update high-risk individuals and develop individualized care plans for targeted populations, including integration of community resources
    - Must promote improved outcomes for high-risk and multiple chronic condition patients
    - Must be tailored to beneficiary's health and psychosocial needs, account for beneficiary preferences, and identify resources to support beneficiary

Patient-Centeredness (Cont'd)

- Mechanism for coordination of care
  - Including a process to exchange summary of care information on patient transitions (or a clear path to develop that process)
  - Consistent with meaningful use if enrolled in electronic exchange of information
- Process for communicating clinical knowledge to beneficiaries in an understandable manner
- Process for beneficiary engagement and shared decision-making
- Written standards for beneficiary access and communication, and process for beneficiary access to medical record
- Internal processes for measuring clinical or service performance by physicians across practices, and using results to improve

Quality Measures

- Measures are grouped into five domains:
  - Patient/caregiver experience (PY1 – 7 measures)
  - Care coordination (PY1 – 16 measures)
  - Patient safety (PY1 – 2 measures)
  - Preventative health (PY1 – 9 measures)
  - At-risk population/frail elderly health (PY1 – 31 measures)
- Data sources:
  - Patient claims
  - E-prescribing and HITECH program data
  - Hospital Compare or CDC
  - Group Practice Reporting Option
    - Based on PQRS data collection tool and PGP demonstration
    - CMS to make tool available to all ACOs
  - Survey instruments (such as CAHPS)

Quality Measures (Cont'd)

- Requirement for Performance Year One
  - Report accurately on 100% of measures
  - Reporting only – no performance criteria
- Requirement after Performance Year One
  - Scoring system based on point system for each measure
  - Percentage of total potential points achieved for each domain calculated
  - Average of the five domain scores would determine how much of the available percentage of shared savings is payable

APPLICATION

- ACO must apply to participate
- Application must
  - Describe how ACO will partner with community stakeholders
  - Describe how shared savings will be used to meet program goals
  - Describe plans to promote evidence-based medicine, promote beneficiary engagement, report internally on cost and quality metrics, and coordinate care
  - Describe how beneficiary experience of care survey results will be used to improve care
  - Describe process for evaluating health needs of assigned population

APPLICATION (Cont'd)

- Provide written standards for beneficiary access and communication
- Describe process for beneficiaries to access medical records
- Describe ACO's individualized care program, provide a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, high-risk and multiple chronic condition patients
- Provide documentation for repayment mechanism for shared losses
- Describe remedial process for ACO participant who fails to comply with requirements

APPLICATION (Cont'd)

  - Application must be accompanied by supporting materials, including ACO documents that describe ACO participants' rights and obligations, documents describing quality assurance and clinical integration program and materials documenting organization and management structure
  - Accuracy of application must be certified
- Applications proposed to be accepted annually, with January 1 start date
  - CMS to establish deadline for application
  - Potential for alternative July 1, 2012 date

AGREEMENT

- ACO must agree to participate for 3-year term
- Agree to comply with all program requirements throughout term
  - ACO is subject to changes in rules during that term, except structure and governance eligibility requirement, calculation of sharing rate, and beneficiary assignment
  - All participants, providers/suppliers and contractors must agree to comply with ACO's obligations
  - Copy of agreement must be provided to ACO participants and providers/suppliers
- ACO may terminate agreement with 60 days advance notice
  - If it does so, it forfeits withheld shared savings

ASSIGNMENT OF BENEFICIARIES

- Beneficiaries are assigned based on *primary care physicians* from whom they receive a *plurality* of their *primary care services*
  - Plurality proposed to be determined based on charges
- Beneficiaries retain complete freedom of choice
  - Must be notified of participation in ACO – written notice and signage
  - Must be given ability to opt-out of having beneficiary identifiable data shared

ASSIGNMENT OF BENEFICIARIES (Cont'd)

- Determination of beneficiaries for purposes of shared savings is made *retrospectively* at end of performance period

- CMS addresses negative impact of retrospective assignment of beneficiaries on ability of ACO to manage care through provision of information identifying probable beneficiary population and aggregate beneficiary data for the benchmark period

Payment and Treatment of Savings

- Establishing a Benchmark
  - CMS will retrospectively estimate an ACO's benchmark for an agreement period
  - CMS will compute per capita Medicare expenditures for beneficiaries who would have been assigned to the ACO in any of the prior three most recent available years, using:
    - Claims records of ACO participants
    - Beneficiary assignment methodology previously discussed

Payment and Treatment of Savings

- Benchmark is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC (hierarchical condition category) adjustments

- Benchmark updated annually during the agreement period
  - Based on the absolute amount of growth in national per capita expenditures for Parts A and B services under Medicare fee-for-service

Payment and Treatment of Savings

- Adjustments to benchmark
  - Minimize variation from catastrophically large claims by truncating an assigned beneficiary's total Parts A and B expenditures at the 99th percentile for each benchmark year
  - Determine national growth trend indices and trend them to the third benchmark year (BY3)
  - Establish health status indices for each year and adjust to restate for BY3 risk
  - Compute a 3-year risk-and-growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years

Payment and Treatment of Savings

- To make sure that the benchmark more accurately reflects the latest expenditure and health status of the ACO's assigned beneficiary population, CMS weighs:
  - BY3 at 60%
  - BY2 at 30%
  - BY1 at 10%

Payment and Treatment of Savings

- CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under Medicare fee-for-service

- CMS does not take into consideration expenditure increases or decreases related to value-based purchasing programs or the HITECH Act (e.g., Physician Quality Reporting Initiative, electronic prescribing program, HITECH Act incentives for EHRs)

Payment and Treatment of Savings

- Two different "models"
  - One-Sided ("Track 1")
    - ACO may share savings with Medicare but is not liable for sharing any losses
    - Converts to two-sided model after second year
  - Two-Sided ("Track 2")
    - ACO may share savings with Medicare but is also liable for sharing losses

Payment and Treatment of Savings

- Savings under the One-Sided Model
  - Calculated each performance year
  - CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is below the applicable benchmark

Payment and Treatment of Savings

- Shared Savings under the One-Sided Model, cont'd.
- To qualify for a shared savings payment, the ACO's average per capita Medicare expenditures must be below the benchmark by more than a minimum savings rate ("MSR")
- MSR is a function of the number of beneficiaries in the ACO
  - 5,000-5,999 — 3.9% to 3.6%
  - 6,000-6,999 — 3.6% to 3.4%
  - 7,000-7,999 — 3.4% to 3.2%

  all the way down to…..
  - 60,000 plus — 2.0%

Payment and Treatment of Savings

- Shared Savings under the One-Sided Model, cont'd.
- To qualify for shared savings payment, an ACO must:
  - Exceed its MSR
  - Meet the minimum quality performance standards
  - Maintain its eligibility to participate in the Shared Savings Program
- Okay, but how is the sharing part determined?
  - We're almost there…

Payment and Treatment of Savings

- But not quite.
- Before calculating the shared savings, CMS first gives a haircut off the savings equal to 2% of the benchmark.
- But ACOs with less than 10,000 assigned beneficiaries are exempt from this 2% net savings "adjustment" if:
  - All ACO participants are physicians or physician groups;
  - 75% or more of the ACO's assigned beneficiaries reside in counties outside a MSA; or
  - 50% or more of an ACO's assigned beneficiaries had at least one encounter with a participating FQHC or RHC.

Payment and Treatment of Savings

- So we have:
  - Established savings below the benchmark
  - Confirmed that the savings exceeds the benchmark by more than the MSR
  - Taken the 2% haircut off of the savings (unless we're physicians, primarily rural, or are using FQHCs/RHCs a lot)
- Are we ready to calculate the shared savings yet?
  - Sort of.

Payment and Treatment of Savings

- Calculation of Final Sharing Rate
  - Take the ACO's earned quality performance sharing rate, plus
  - An additional increase of up to 2.5% for ACOs that include an FQHC or an RHC
    - Determined on a sliding scale, depending on the percentage of assigned ACO beneficiaries with one or more visits to a FQHC/RHC during the performance year (1-10 percent = .5% increase; 41-50 percent = 2.5% increase)
- ACO under the one-sided model is eligible to share up to 50% of the calculated savings (as adjusted)
  - Capped at 7.5% of the ACO's benchmark
  - Subject to 25% withholding to ensure repayment of losses

Payment and Treatment of Savings

- Shared Savings under the Two-Sided Model
- Same basic calculation as with one-sided model
  - Calculated per performance year
  - Determine if estimated average per capita Medicare expenditures, adjusted for beneficiary characteristics, are below the applicable benchmark
- But unlike under the one-sided model, the MSR is a flat 2%, regardless of the number of beneficiaries in the ACO
- Likewise, for purposes of calculating shared losses, the minimum loss rate is also 2% (i.e., average per capita expenditures exceed benchmark by 2%)

Payment and Treatment of Savings

- No net savings threshold (the “haircut”), so ACOs in the two-sided model are eligible to share in savings from the first dollar above the MSR

Payment and Treatment of Savings

- Final Sharing Rate (two-sided model)
  - ACO's earned quality performance sharing rate, plus
  - An additional increase of up to 5% for ACOs that include an FQHC or an RHC
    - Determined on a sliding scale, depending on the percentage of assigned ACO beneficiaries with one or more visits to a FQHC/RHC during the performance year. But the additional increase is more generous than under the one-sided model (1-10 percent = 1% increase; 41-50 percent = 5% increase)
- ACO under the two-sided model is eligible to share up to 60% of the calculated savings (as adjusted)
  - Capped at 10% of the ACO's benchmark
  - Subject to 25% withholding to ensure repayment of losses

Payment and Treatment of Savings

- Shared Losses under the Two-Sided Model
- Shared loss rate is the inverse of the final sharing rate (i.e., 1 minus shared savings rate)
- Amount of shared losses may not exceed
  - 5% of benchmark in first year under two-sided model (and in third year under the one-sided model)
  - 7.5% of benchmark in second year under two-sided model
  - 10% of benchmark in third year under two-sided model

Payment and Treatment of Savings

- To ensure repayment of losses, ACOs must (in advance of entering a period of participation):
  - Obtain reinsurance
  - Place funds in escrow
  - Obtain surety bonds
  - Establish letter of credit
  - Establish other appropriate repayment mechanism
- CMS will determine the adequacy of an ACO's repayment mechanism
- Any unrecouped losses for a performance year will be carried forward into subsequent performance years to be recouped against additional financial reserves or offset against earned shared savings

Data Submission Requirements

- ACOs must submit data in a form and manner specified by CMS on the quality measures selected by CMS for purposes of calculating the quality performance standard

- Eligible professionals submitting such data are considered satisfactory reporters for purposes of the Physician Quality Reporting System incentive

Data Sharing

- CMS will share both aggregate and beneficiary-identifiable data with ACOs
  - ACO may not impose unnecessary limitations or restrictions on the use or disclosure of individually identifiable health information
  - ACO must observe all relevant statutory and regulatory provisions regarding use and disclosure of data

Data Sharing

- Sharing aggregate data
  - This is “de-identified” data under HIPAA privacy rule
  - CMS will share aggregate data report:
    - At the start of the agreement period based on the historical beneficiaries used to calculate the benchmark
    - Quarterly thereafter based on the most recent 12 months of data for beneficiaries that could potentially be assigned to the ACO
  - Aggregate data reports should include:
    - Financial performance
    - Quality performance scores
    - Aggregated metrics on the assigned beneficiary population
    - Utilization data at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark

Data Sharing

- Upon request by ACO, CMS shall, at the beginning of agreement period and the end of each performance period, give the ACO the following data for purposes of population-based activities related to improving health care costs, protocol development, case management and care coordination:
  - Name
  - DOB
  - Gender
  - HICN

Data Sharing

- Sharing beneficiary-identifiable data
  - Subject to opt-out right of beneficiary
  - ACO must request and must enter into Data Use Agreement
  - Monthly claims data
  - Permitted for same purposes as above

Data Sharing

- ACO must certify that it is requesting claims data about:
  - Its own patients, as a HIPAA covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations
  - The patients of its HIPAA covered entity participants, as the business associate of those participants
    - Data must be minimum necessary for performing QA and improvement or credentialing and peer review activities

Data Sharing

- ACO may request beneficiary claims data only if:
  - Beneficiary has been seen in the office of a participating primary care physician during the performance year
  - Beneficiary was informed about how the ACO intends to use beneficiary-identifiable claims data
  - Beneficiary did not exercise his/her opt-out right

Data Sharing

- For Parts A and B, data elements may include:
  - Beneficiary ID
  - DOB
  - Gender
  - Date of death
  - Claim ID
  - “From” and “through” dates of service
  - Provider or supplier ID
  - Claim payment type

Data Sharing

- For Part D, data elements may include:
  - Beneficiary ID
  - Prescriber ID
  - Drug service date
  - Drug product service ID
  - Quantity dispensed
  - Days supplied
  - Gross drug cost
  - Brand name
  - Generic name
  - Drug strength
  - Indication if drug is on formulary, as designated by CMS

Data Sharing

- Prior to receiving beneficiary-identifiable data, ACO must enter into a Data Use Agreement with CMS
  - Specifies that the ACO will comply with limitations on the use and disclosure of information under HIPAA and other applicable requirements
  - Prohibits the ACO from using the data received for any prohibited use
  - Specifies potential penalties for misuse or wrongful disclosure of data
    - No longer eligible to receive data
    - Termination from program
    - Additional sanctions and penalties available under law

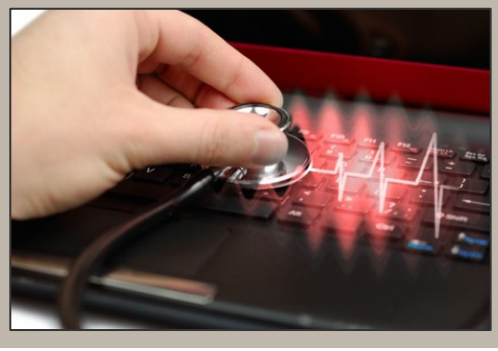
Data Sharing

- Beneficiary opt-out
  - ACO must inform beneficiary that it may request PHI about the beneficiary for care coordination and quality improvement
  - Must give the beneficiary a meaningful opportunity to opt-out of having his/her claims information shared with the ACO
  - ACO must supply an opt-out form to each beneficiary as part of an office visit with a primary care physician
  - Opt-out does not apply to data points that CMS provides ACOs for individuals in the 3-year base set
    - Name
    - DOB
    - Gender
    - HICN

Monitoring

- CMS shall monitor and assess the performance of ACOs and their participating providers/suppliers

- Monitoring methods may include:
  - Analysis of financial and quality measurement data reported by the ACO
  - Site visits
  - Analysis of beneficiary and provider complaints
  - Audits



Monitoring

- CMS will monitor
  - ACO avoidance of at-risk beneficiaries
  - Compliance with quality performance standards
  - Changes to ACO eligibility requirements
  - Beneficiary notification of the provider and supplier's role in the ACO and the ability for the beneficiary to opt-out of sharing claims data
  - ACO marketing materials and activities
- Sanctions available to CMS for violations:
  - Require the ACO to submit and implement a CAP
  - Re-request required information (or explanation for reporting failure)
  - Terminate the ACO for continuing violations

Actions Prior to Termination

- CMS may take one or more of the following actions prior to termination
  - Provide a warning notice
  - Request a CAP
  - Place the ACO on a special monitoring plan
- Pre-termination procedures do not:
  - Apply to determinations of antitrust violations
  - Apply to determinations made by other governmental agencies

Termination, Suspension and Repayment

- Grounds for terminating an ACO
  - Avoidance of at-risk beneficiaries
  - Failure to meet quality performance standards
  - Failure to completely and accurately report required information
  - Non-compliance with eligibility requirements
  - Inability to effectuate required regulatory changes
  - Noncompliance with beneficiary notification requirements
  - Noncompliance with public reporting requirements
  - Failure to submit approvable CAP or implement approved CAP
  - Violate Stark, AKS or other Medicare law, rule or regulation that is “relevant to ACO operations.”
  - Submit false, inaccurate or incomplete information

Termination, Suspension and Repayment

- Grounds for terminating an ACO cont'd.
  - Use of marketing materials or beneficiary communications that are subject to CMS review and approval but that have not been approved by CMS
  - Failure to maintain at least 5,000 beneficiaries
  - Failure to offer beneficiaries opt-out of sharing claims information
  - Limit or restrict medical records from other providers/suppliers to the extent permitted by law
  - Improperly use or disclose claims information in violation of HIPAA
  - Fail to demonstrate that the ACO has adequate resources in place to repay losses

Termination, Suspension and Repayment

- Reapplication after termination
  - Terminated ACO may reapply only after the end of the original 3-year period
  - Must demonstrate that it has corrected the previous deficiencies
  - May re-enter only under the two-sided model
- Forfeiture of mandatory withholding after termination
- Notice requirements
  - 60 day notice to ACO participants
  - ACO participants must notify beneficiaries of termination in a timely manner

Reconsideration Review Process

- No reconsideration, appeals, or review for following determinations:
  - Specification of quality and performance standards
  - Assessment of the quality of care furnished by ACO under the established performance standards
  - Assignment of beneficiaries
  - Determination of eligibility for, or amount of, shared savings
  - Termination of ACO for failure to meet quality performance standards
  - Determinations by antitrust agencies

Reconsideration Review Process

- ACOs may appeal other initial determinations
  - Request review by CMS reconsideration official
  - Burden of proof is on ACO to demonstrate that initial determination is inconsistent with CMS' regulations or statutory authority
  - Second-level "on the record" appeal to independent CMS official
  - CMS decision after review of reconsideration official's recommendation is final and binding
  - If termination is upheld, effective date of termination is the date indicated on the initial notice of termination

Future Participation of Previous Shared Savings Program Participant

- ACO must disclose to CMS whether the ACO or its participants, providers and suppliers participated in the shared savings program (or is related to or has an affiliation with another participating ACO)

- ACO must disclose whether it (or the related ACO) was terminated or withdrew voluntarily

Audits and Record Retention

- ACO and participants must grant HHS the right to audit, inspect and evaluate books and records that pertain to:
  - The ACO's compliance with program requirements
  - The quality of services performed and determination of amount due to or from CMS
  - The ability of the ACO to bear the risk of losses and to repay losses to CMS

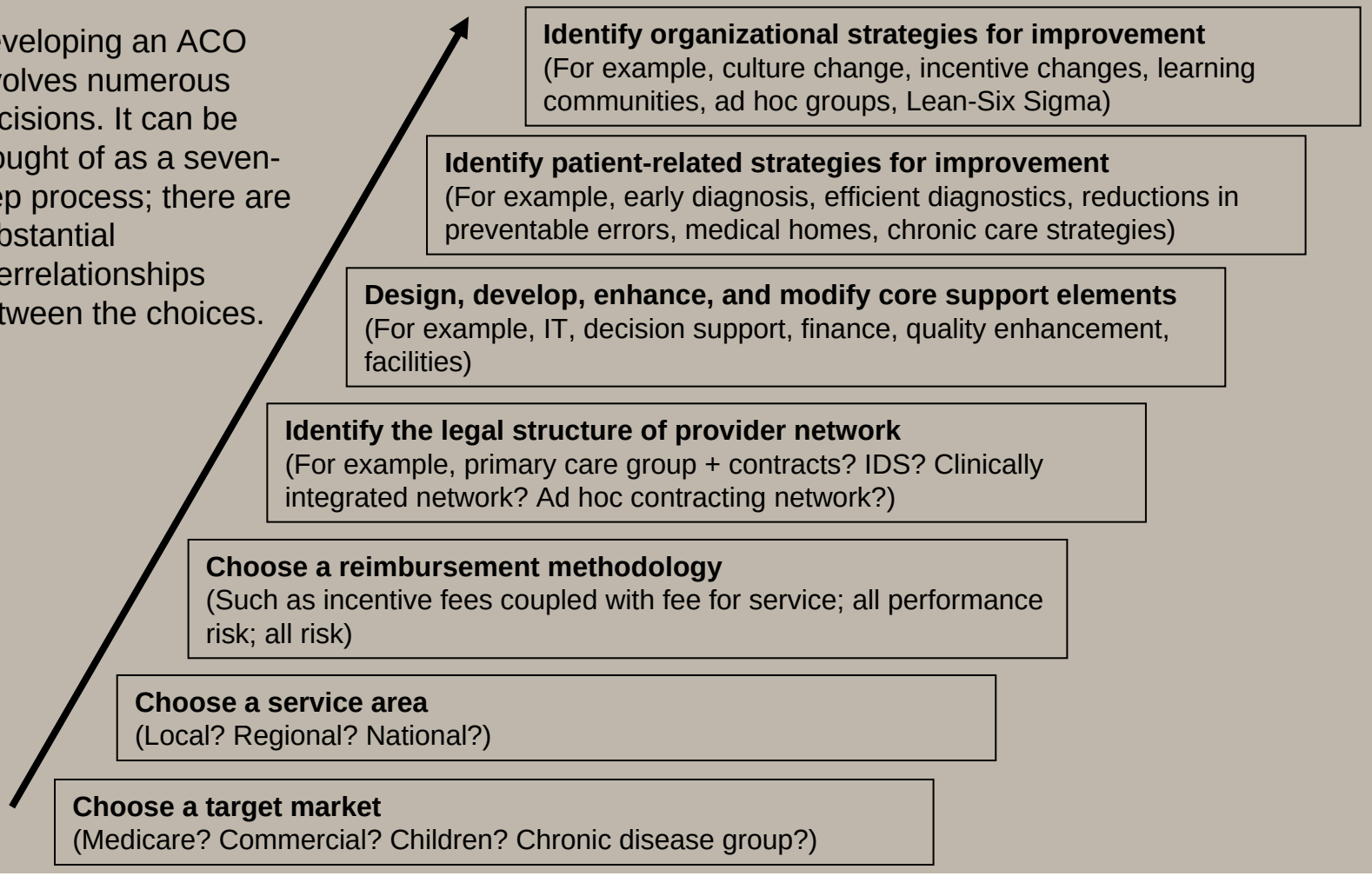
- ACO and participants must retain records for 10 years

ESTIMATES OF PARTICIPATION AND COSTS/BENEFITS

- CMS estimates between 75 and 150 ACOs will be formed and approved
  - Serve between 1.5 million and 4 million beneficiaries
- Estimates total bonuses of $800 million over 3 years
  - Some ACOs to repay a total of $40 million under risk-sharing
- Aggregate first year start up and operation costs for ACOs between $132 million and $263 million
  - PGP Demonstration average cost per group of $1.2 million
- Estimate aggregate median impact of $512 million in net federal savings for initial 3-year period

ACO Strategic Planning

Developing an ACO involves numerous decisions. It can be thought of as a seven-step process; there are substantial interrelationships between the choices.



Source: HFM, Magazine of the Healthcare Financial Management Association (August 2010)

Proposed CMS/OIG Waiver for Accountable Care Organizations

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Conditions for waiver eligibility

- Conditions for waiver eligibility
  - Agreement with CMS to participate in ACO shared savings program
  - ACO and its participants and providers/suppliers comply with agreement and regulations
- Laws Addressed
  - Stark Law
  - Anti-Kickback Statute
  - CMP Law

Laws Addressed in Waiver – Stark Law

- Stark Law
  - Prohibits a physician from referring Medicare patients to entities with which the physician has a financial relationship for the provision of "designated health services" ("DHS") and prohibits entities from billing for DHS furnished pursuant to a prohibited referral
  - DHS includes hospital inpatient and outpatient services and many ancillary services provided by physicians in their offices

Laws Addressed in Waiver – Stark Law (Cont'd)

- Existing Stark Law does not specifically address shared savings programs with physicians
  - 2008 Proposed Shared Savings/Incentive Payment Stark Exception not finalized
  - Structure to meet employment, personal services, fair market value or indirect compensation exception
  - May be able to use exception for prepaid plans and/or for risk-sharing arrangements
  - Physician incentive plan provisions
  - Exceptions for community-wide health information systems, e-prescribing and donation of electronic health records may apply to portions of relationship

Laws Addressed in Waiver – Stark Law (Cont'd)

- Uncertainties in applying current Stark Law exceptions
  - Is payment for shared savings/efficiency directly or indirectly related to volume or value of referrals?
  - Does a change in physician behavior constitute "identifiable services" under employment exception?
  - What is the fair market value of physician activities promoting quality and cost savings?
  - How can payments that may reduce or limit service be addressed?
  - How can hospital fund infrastructure needs without creating a financial relationship?

PROPOSED CMS/OIG WAIVER – Stark Law

- Waiver for distribution of the shared savings received from CMS
  - To all participants and providers/suppliers who participated during the year the savings were earned
  - To others for activities necessary for and directly related to ACO's participation in shared savings program
    - CMS specifically requests comments on the standard of "necessary for and directly related to" ACO's participation

Laws Addressed in Waiver – Anti-Kickback Statute

- Anti-Kickback Statute
  - 42 U.S.C. §1320a-7b
  - Criminal and civil penalties for knowingly or willfully paying or offering to pay, soliciting or receiving, remuneration for referral of patients or for arranging for or recommending the purchase of goods or services

Laws Addressed in Waiver – Anti-Kickback Statute (Cont'd)

- Safe harbors
  - Employment, personal services - cannot pay based on percentage of cost savings, aggregate compensation must be set in advance
  - Medicare managed care, risk-sharing arrangements – in managed care context
  - Electronic Health Record

- Potential Anti-Kickback Concerns
  - Are payments shared in a way that reflects the ability of recipients to direct referrals?
  - Are payments to physicians under the program inflated to encourage referrals?
  - Are discounted payments offered by post-acute care participants to induce referrals from hospitals?

PROPOSED CMS/OIG WAIVER – Anti-Kickback Statute

- Anti-Kickback Statute
  - Waiver for distribution of shared savings identical to Stark Law waiver
  - Other financial relationships among ACO, participants and providers/suppliers necessary for and directly related to ACO's participation in shared savings program if it (a) implicates the Stark Law and (b) meets a Stark Law exception

Laws Addressed in Waiver – CMP Law

- Civil Monetary Penalty (CMP) Law
  - 42 U.S.C. § 1320a-7a(b); SSA § 1128A(b)
  - Penalty against hospital that "knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who … are entitled to benefits under [Medicare or Medicaid] … and are under the direct care of the physician"
  - Hospitals and physicians liable for civil monetary penalties of up to $2000 per patient

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Laws Addressed in Waiver – CMP Law (Cont'd)

- OIG Perspective
  - Special Advisory Bulletin on Gainsharing – July 1999
  - CMP proscription is very broad and payment need not be tied to actual reduction in care
  - "[A]ny hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute"
  - Violation can occur regardless of whether service is medically necessary or appropriate
  - Series of Advisory Opinions allowed programs with safeguards

PROPOSED CMS/OIG WAIVER – CMP Law

- CMP Law
  - Distributions of CMS shared savings from hospital to physician if
    - Both are ACO participants or providers/suppliers
    - Not made knowingly to induce physician to limit *medically necessary* items or services
  - Other financial relationships - similar to Anti-Kickback Statute waiver

Not Addressed in Waiver – Beneficiary Inducements

- Beneficiary Inducements
  - 42 U.S.C. Section 1320a-7a(a)(5)
  - Anyone who provides remuneration to a Medicare beneficiary to influence him/her to receive items or services from a particular provider is subject to civil monetary penalties
  - Ability to provide free transportation, in-home assistance technology to assure patients obtain care and save costs
  - Ability to promote compliance with patient management of chronic conditions
  - MedPAC has proposed beneficiaries potentially sharing in ACO cost savings
  - NOT INCLUDED in scope of proposed waiver

PROPOSED CMS/OIG WAIVER – Request for Comments

- Request for comments on additional waivers
  - Explain why necessary and not covered by existing exception
  - Protect arrangements establishing the ACO?
  - Protect arrangements related to ongoing operations and achievement of goals?
  - Protect other arrangements with those outside the ACO?
  - Extend to shared savings from other payers?
  - Additional protection for ACOs in two-sided model?
  - 2013 sunset date under EHR exception/safe harbor?
- Other comments requested
  - Duration of waivers, scope of waivers, additional safeguards
  - Need for waiver addressing beneficiary inducements

Proposed Antitrust Enforcement Policy for Accountable Care Organizations

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FTC/DOJ Actively Enforce Antitrust Laws in Health Care Industry

"No Higher Priority"

Title of presentation made by
Richard Feinstein
Director, Bureau of Competition
Federal Trade Commission
May 24, 2010

Section 1 of the Sherman Act

"Every contract, combination ... or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."

Elements of Section 1 Violation

- Contract, combination, or conspiracy
- Affecting interstate commerce
- Which imposes an “unreasonable restraint of trade”

Unreasonable Restraint of Trade

- Per Se
- Rule of Reason

Per Se

- Conduct illegal irrespective of pro-competitive benefits or business justification
  - Price-fixing
  - Bid-rigging
  - Allocation of territories
  - Allocation of customers
  - Certain tying arrangements

Rule of Reason

- Weighs the pro-competitive benefits of the agreement against its anti-competitive effects
- Requires demonstration of market power
- Concerted activities that might otherwise constitute per se violations subject to rule of reason where agreement is ancillary to a legitimate joint venture or other efficiency-enhancing integration

Health Care Statements

- Jointly issued by DOJ and FTC in 1994 and amended in 1996
- Set forth the agencies' analytical approach to various ventures and activities in the Health Care field
- Statement 8: physician network joint ventures
- Statement 9: multi provider networks

Substantial Integration

- Financial Integration
- Clinical Integration
- Safety Zones - 20% if exclusive
  30% if non-exclusive

Important Factors to Consider in Achieving Sufficient Clinical Integration

- Advisory opinions from the FTC provide guidance on processes and practices understood by Agencies to foster collaboration that improves quality and efficiency of patient care
- Clinical integration requires, among other things, ongoing evaluation of physician and network performance and some communication to payers regarding the network's success in meeting and complying with network's goals
- A network may combine aspects of clinical and financial integration
- Joint contracting activities should not commence until a proposed clinical integration is substantially complete and operational

Applying Antitrust Principles to ACOs

- FTC and DOJ worked with CMS
- Issued Proposed Policy Statement on March 31
- Applies to ACOs formed after March 23, 2010 (Date the Affordable Care Act was signed by President Obama)
- Consistent with past enforcement and guidance
- Recognizes that Medicare ACOs will want to compete in commercially insured patient market

Key Features of Proposed Policy Statement

- Rule of reason for CMS-approved ACOs
- Specific criteria for market-share calculation
- Safety zones
- Mandatory pre-clearance of large ACOs

Rule of Reason for CMS-Approved ACOs

- Bright-line rule avoids per se analysis
- CMS approval means that ACO will have

1. Formal structure to receive/distribute shared savings
2. Integrated clinical and administrative processes
3. Processes promoting evidence-based medicine
4. Quality and cost measures/reporting
5. Coordinated patient care

Calculation of ACO "Market" Shares

- Initial step in antitrust analysis for ACO
- ACO responsible for calculating
- Focus on share of "common services" in "Primary Service Area"
- "Common Services" are services provided by two or more otherwise independent ACO participants
- "Primary Service Area" is lowest number of contiguous zip codes from which ACO participant draws 75% of its patients for common service

Calculation of ACO "Market" Shares

- Identify each common service provided by at least two independent ACO participants
- Identify Primary Service Area for each such participant
- Calculate ACO's share of common service in each common PSA
  - CMS will provide Medicare fee-for-service data by zip code and services

Antitrust Safety Zone

- 30% or smaller service share – Agencies will not challenge absent extraordinary circumstances
- Any hospital or ambulatory surgical center participating in an ACO within the safety zone must be non-exclusive to the ACO
- 30% to 50% service share -- *may* seek review from Antitrust Agencies
- 50%+ service share -- *must* obtain pre-clearance from Antitrust Agencies

Rural Exception Safety Zone

- ACO can qualify for Rural Exception where ACO includes one physician per specialty in each rural county served, even if it results in a greater than 30% share in any ACO participant's PSA for that common service
- May include Rural Hospital in ACO even if that results in ACO's share of a common service in excess of 30% in any participant's PSA for that service
- Such Physicians and Rural Hospitals must be non-exclusive to ACO

Dominant Provider Exception Safety Zone

ACO service share may exceed 50% if:

- No other ACO participant provides service
- ACO contracts with payers on non-exclusive basis
- ACO contracts with Dominant Provider on non-exclusive basis

More on Safety Zones

- Continue to apply if share later exceeds 30% only because ACO attracts more patients (no punishment for success)
- Applies to an ACO's commercial market activities if it uses same structure and processes used for Medicare market

Mandatory Review

- ACO exceeding 50% service share
- ACO must be pre-cleared by Agencies
- ACO must establish:

  "substantial pro-competitive justification for why the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market"

ACOs between 30% and 50% Share

- Agency review not required
- ACO that does not impede functioning of competitive market and engages in procompetitive activities will not raise competitive concerns
- If no review, avoiding the following activities can reduce chances of investigation:
  1. discouraging payors from directing patients to non-ACO participants
  2. tying ACO services to payor's purchase of services outside ACO
  3. contracting on exclusive basis (except for PCPs)
  4. restricting payor's ability to promote clinical and administrative efficiencies for patients
  5. sharing competitively sensitive information that could lead to price-setting outside ACO

Expedited Review

- FTC and DOJ have committed to provide expedited review for both mandatory and voluntary requests
- Proposed Policy Statement describes types of information and documents that must be provided
- Within 90 days of receiving required information, the Agency designated to respond to the requested review will inform potential ACO of its intention to challenge or not challenge formation

IRS GUIDANCE ON EXEMPT ORGANIZATION ACO PARTICIPATION

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IRS Guidance for Tax-Exempt Organizations

- Notice 2011-20
- Guidance regarding how EOs can participate in MSSP without implicating private inurement and private benefit prohibitions
- Requested comments regarding additional guidance for MSSP participation
- Also requested comments regarding participation in non-MSSP activities through an ACO

IRS Guidance for Tax-Exempt Organizations

- Overview of Legal Principles:
  - Private Inurement
  - Private Benefit
  - Definition of “Charitable”
    - Lessening the Burdens of Government
    - Promotion of Health
  - Unrelated Business Income

IRS Guidance for Tax-Exempt Organizations

- An EO's participation in a MSSP through an ACO will *not* result in impermissible private inurement or private benefit if:
  - The terms of the EO's participation (including its share of MSSP payments or losses and expenses) are set forth in advance in a written, arm's length agreement
  - The ACO has been accepted and not terminated by CMS
  - The EO's share of economic benefits derived from the ACO is proportional to the benefits or contributions the EO provides to the ACO
  - If the EO receives an ownership interest in the ACO, it must be proportional and equal in value to its capital contributions and returns, allocations and distributions are proportionate to ownership

IRS Guidance for Tax-Exempt Organizations

- An EO's participation in a MSSP through an ACO will ***not*** result in impermissible private inurement or private benefit if:
  - The EO's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the EO is entitled
  - All contracts and transactions entered into by the EO with the ACO and ACO participants, and by the ACO with the ACO participants and any other parties, are at fair market value

IRS Guidance for Tax-Exempt Organizations

- An EO's participation in a MSSP through an ACO will ***not*** result in unrelated business income if:
  - Activities of the ACO generating MSSP payments are substantially related to the EO's charitable purposes
  - "Substantial relationship" to charitable purposes is presumed absent private benefit or inurement and the ACO meets CMS eligibility requirements for MSSP participation
  - Substantial relationship is presumed under a "lessening the burdens of government" theory

IRS Guidance for Tax-Exempt Organizations

- Observations Regarding Guidance for MSSP-Related Activities
  - Heavy reliance on the regulatory framework set forth by CMS as a shield against private benefit or inurement
  - Past IRS guidance on EO participation in joint venture arrangements will frame the IRS' case-by-case analysis of EO involvement in ACO activities
  - Guidance affords EOs some level of comfort for participation in MSSP-related activities, but additional guidance is necessary

IRS Guidance for Tax-Exempt Organizations

- ACO Activities Unrelated to the MSSP
  - Shared savings arrangements with other types of health insurance payers
  - How do these activities further (and substantially relate to) an EO's charitable purpose?
  - No "lessening the burdens of government" argument
  - Promotion of health is not always, in and of itself, a charitable activity

IRS Guidance for Tax-Exempt Organizations

- ACO Activities Unrelated to the MSSP
  - IRS is seeking comments regarding how EO participation in non-MSSP activities through an ACO substantially relate to the EO's charitable purpose
  - What non-MSSP activities will the EO participate in and how do they relate to the EO's charitable purposes?
  - What criteria, requirements and safeguards would ensure the furtherance of such purposes?
  - Is the promotion of health a reliable theory?
  - How do you address attribution of ACO non-MSSP activities to the EO if the ACO is organized as a partnership for federal tax-purposes?

IRS Guidance for Tax-Exempt Organizations

- Observations Regarding Guidance for Non-MSSP Related Activities
  - By relying on a "lessening the burdens of government" theory to justify EO involvement in MSSP-related activity, EOs have an uphill battle to justify non-MSSP activities
  - How the issues for which the IRS seeks comments are addressed may be critical for the development of non-MSSP ACO activities
  - Possible alternative – house non-MSSP ACO activities in separate, for-profit corporation?

QUESTIONS?

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