Proposed ACO Rule: A Giant Step Toward Reform or a Leap of Faith for Providers?

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Ropes & Gray ACO Teleconference Series

- Seventh Ropes & Gray teleconference on the legal, policy, and practical issues surrounding the creation of ACOs
- May 4th teleconference to focus on proposed rule's quality provisions
- Ropes & Gray detailed summary of proposed ACO rule available at http://www.ropesgray.com/files/upload/20110407HCAlert.pdf
- Presentations and other helpful materials available at www.healthreformresourcecenter.ropesgray.com

Agenda

1. Overview of the Proposed Rule
2. Shared Savings Calculation
3. Assignment of Beneficiaries
4. Proposed Waivers of Federal Fraud and Abuse Laws
5. State Law Implications

Overview of the Proposed Rule

History

- Health reform law enacted on March 23, 2010
- ACO proposed rule published April 7, 2011
  - CMS initially intended to publish the rule in 2010
- Comment period open until June 6, 2011
- Final rule to be published ??, 2011
- Shared Savings Program begins on January 1, 2012

ACO Eligibility and Governance

- Legal entity
  - The ACO does not need to enroll in Medicare, but all ACO participants must
- Shared governance
- Leadership and management
- Program integrity
- Patient centeredness
- Adequate number of PCPs and beneficiaries

ACO Agreement

- Initial three-year term
- Begins January 1, 2012
  - Potentially also July 1, 2012
- Must specify method for distributing shared savings
- CMS can terminate for proscribed activities (*e.g.*, fraud and abuse violations; avoiding high-risk beneficiaries)

Assignment of Beneficiaries

- Retrospective assignment based on PCP providing a plurality of services
- PCPs can participate in only a single ACO
- Covered in greater detail later in this presentation

Quality Reporting

- Required reporting of 65 quality measures
- ACO must meet quality standards in order to receive a shared savings payment
  - Shared savings rate varies based on quality performance
- Quality reporting and measurement to be covered in a Ropes & Gray teleconference scheduled for May 4

Shared Savings Methodologies

- Extremely complex
- Potential upside/downside risk will depend on selection of “one-sided” or “two-sided” risk model
- Covered in greater detail in the next section

Coordination with Other Federal Agencies

- Joint CMS/OIG fraud and abuse waivers discussed later in the presentation
- FTC/DOJ joint statement regarding antitrust scrutiny
  - Comment period open until May 31
- IRS guidance to tax-exempt entities
  - Comment period open until May 31

CMS Assumptions

- 75-150 ACOs
- Federal savings of $510 million over three years
  - $502 billion in benefits paid in 2009
- Bonus payments of $800 million
- 1.5 – 4 million enrolled beneficiaries
  - 46.3 million Medicare enrollees in 2009
  - 24% in MA plans

Question #1

Is the Shared Savings/Losses Formula An Impediment to Pursuing ACO Status?

Qualifying for Shared Savings

- To qualify for shared savings payments, an ACO must:
  - Meet quality performance and reporting standards
  - Achieve minimum savings relative to the ACO's benchmark ("minimum savings rate")
    - MSR ranges from 2% for ACOs with 60,000+ beneficiaries to 3.9% for ACOs with 5,000 beneficiaries
    - MSR is flat 2% in years in which ACO is at risk regardless of size

Eligible for Savings, At Risk for Losses

- All ACOs must bear risk at some point in the initial 3-year contract
  - Track 1: ACO is eligible to earn shared savings in contract years (CY) 1, 2, and 3 and at risk for losses in CY3
  - Track 2: ACO is eligible to earn shared savings and is at risk for losses in CYs 1, 2, and 3
- All ACOs must bear risk for the entire contract period in subsequent contracts
- CMS will withhold 25% of an ACO's shared savings each year
- In years in which ACO at risk, must demonstrate ability to repay losses

Eligible for Savings, At Risk for Losses (cont'd)

- At-risk ACOs eligible for first dollar savings
  - ACOs not at risk eligible for savings only in excess of MSR
- Shared savings are capped
  - 7.5% benchmark for ACOs not at risk
  - 10% of benchmark for at-risk ACOs
- For at-risk ACOs, once losses equal 2% of benchmark, ACO must share in first dollar losses
- Shared losses are capped
  - Track 1: Capped at 5% of benchmark in CY3
  - Track 2: Capped at 5% in CY1; 7.5% in CY2; and 10% in CY3

Quality Requirements

- In CY 1, must report on 65 quality measures in 5 quality domains
  - 1) Patient/Caregiver Experience; 2) Care Coordination; 3) Patient Safety; 4) Preventive Health; and 5) At-Risk Populations
- In CYs 2 and 3, must meet quality performance standards
  - Set of measures to be established in subsequent rulemaking
  - Scores for individual measures are converted into a Quality Performance Score percentage
  - Scores are combined to yield Shared Savings Rate

Shared Savings Rate

- Maximum Shared Savings Rate
  - 50% in year in which ACO not at risk
  - 60% in year in which ACO at risk
- Increase in Maximum Shared Savings Rate for ACOs with strong FQHC/RHC participation
  - Up to 2.5% for ACOs not at risk for total maximum of 52.5%
  - Up to 5% for at-risk ACOs for total maximum of 65%

Summary: Track 1 v. Track 2

	ACO Not At Risk (Track 1, CYs 1 &2)	ACO At Risk (Track 1, CY3; Track 2, all yrs)
Minimum Savings Rate	2% to 3.9%	2%
Shared Savings	Amount is net of MSR	First dollar savings
Shared Savings Rate	Maximum 52.5%	Maximum 65%
Shared Savings Cap	7.5% of benchmark	10% of benchmark
Minimum Loss Rate	N/A	2% of benchmark
Shared Losses	N/A	First dollar shared losses
Shared Loss Rate	N/A	1 minus Shared Savings Rate
Shared Losses Cap	N/A	Track 1: 5% in CY3 Track 2: 5% in CY1; 7.5% in CY2; 10% in CY3
Shared Savings Withhold	25%	25%

Calculating the ACO's Benchmark

- Based on prior expenditures of *historical* ACO population
  - Beneficiaries who *would have been assigned* to the ACO in the three years preceding the ACO's creation
- Adjusted for beneficiary characteristics, including health status
  - Using MA program CMS-HCC prospective risk adjustment model
- Updated annually using projected absolute amount of growth in national Medicare Part A and B expenditures

Calculating the ACO's Expenditures

- Based on the expenditures of beneficiaries *actually* assigned to the ACO in a particular year
- Risk adjusted using score for *historically* assigned population

Treatment of Supplemental & Incentive Payments

- Proposed rule excludes certain supplemental and incentive payments and penalties from benchmark and expenditure calculations:
  - PQRI, eRx, physician EHR payments and penalties
- Other payments are included:
  - Medicare DSH, IME, hospital EHR payments and penalties, and geographic payment adjustments (IPPS & GPCI)
- Silent on DGME

Summary: Benchmark & Expenditure Calculations

	Benchmark	Expenditures
Base Amount	Historically assigned beneficiary expenditures	Actual assigned beneficiary expenditures
Risk Adjustment	CMS-HCC for historically assigned beneficiaries	CMS-HCC for historically assigned beneficiaries
Growth Adjustment	Projected national absolute amount of per capita Medicare Part A & B expenditures	
Payments Included	<u>Included:</u> IME DSH Geographic Payment Adjustments (IPPS & GPCI) Hospital EHR incentives/penalties <u>Excluded</u> Incentives & Penalties under Value-Based Purchasing programs Physician EHR incentives	<u>Included:</u> IME DSH Geographic Payment Adjustments (IPPS & GPCI) Hospital EHR incentives/penalties <u>Excluded:</u> Incentives & Penalties under Value-Based Purchasing programs Physician EHR incentives

Pursuing Shared Savings: Is It Worth the Investment?

- Significant upfront investment required
  - PGP start up investments averaged $489,354 for a physician group
- Requirement to bear risk
  - All ACOs must bear risk for at least part of contract period
- Complexity of shared savings/losses calculation
- Comprehensive new set of regulatory requirements
- Disconnect between benchmark and expenditure calculations
  - Will expenditures of the historically assigned population (benchmark) reflect expenditures of actual assigned beneficiaries?
  - Will the risk profile of the historical population approximate that of the assigned population?

Pursuing Shared Savings: Is it Worth the Investment? (cont.)

- Impact of Unrelated Payments/Penalties on Calculation of Shared Savings
  - Supplemental payments and incentive payments and penalties are unrelated to quality and efficiency improvements
  - Inclusion of incentive payments and penalties may skew incentives
- Medicare payment policies may inappropriately help/hinder certain ACOs
  - May incentivize ACOs to steer patients away from teaching hospitals
- At the same time, equitable calculation of shared savings may require their inclusion
  - Opportunity to earn savings associated with add-on payments
- CMS argues it lacks statutory authority to exclude certain payments from calculations

Smaller Providers

- Will smaller providers/ACOs be able to participate?
  - MSR is highest (3.9%) for smallest ACOs (5,000 beneficiaries), making it harder to achieve shared savings
  - Smaller ACOs less likely to be able to bear risk
  - Smaller ACOs less likely to have necessary start-up capital
  - Smaller ACOs more vulnerable to vagaries in benchmark/expenditure calculations

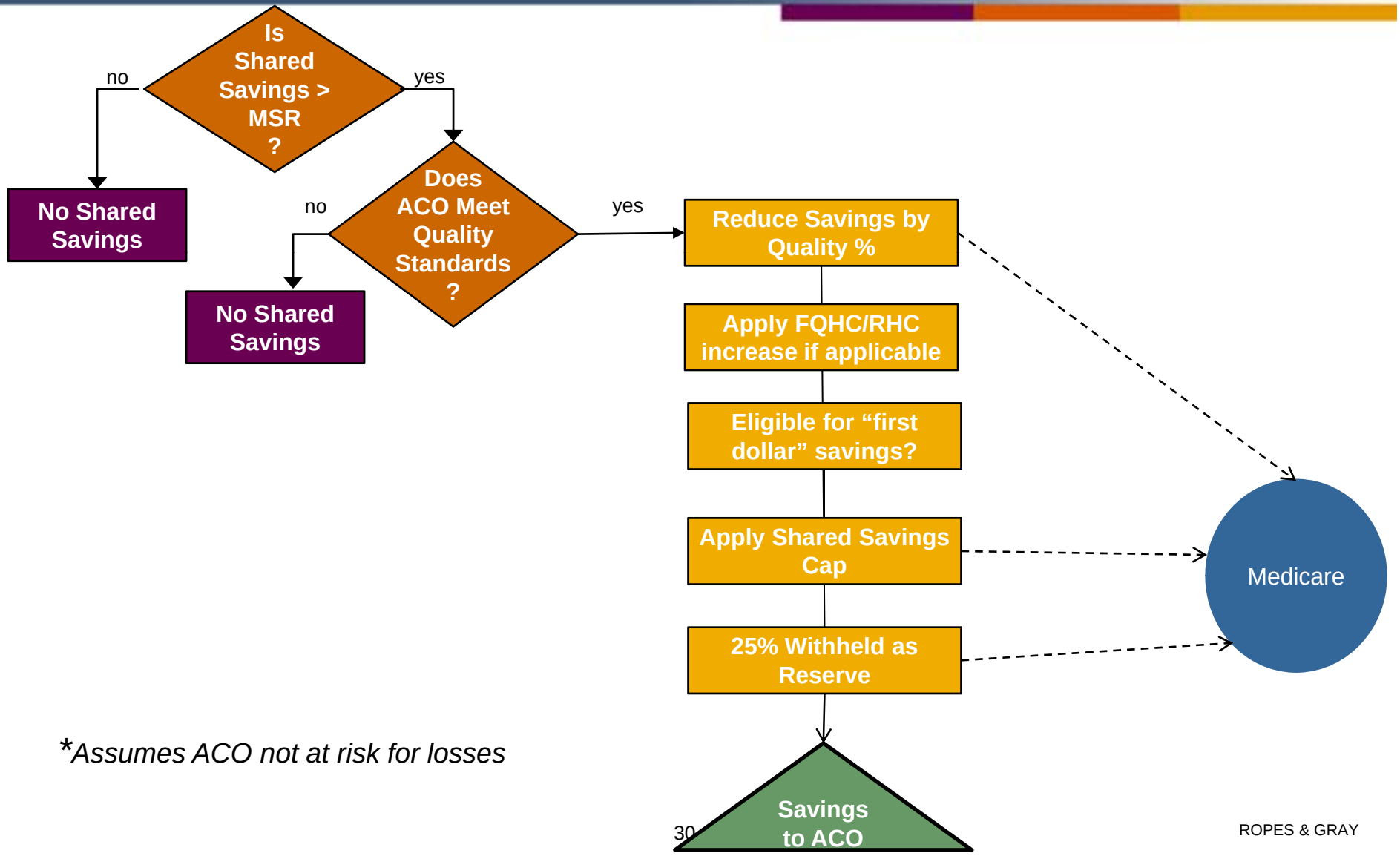
Integrated Providers

- Will systems that are already integrated be able to demonstrate savings?
  - Likely to have lower benchmarks relative to unintegrated systems
  - Proposed rule does not address this issue

Providers in High-Cost Areas

- Will ACOs in higher cost areas be able to achieve savings?
  - Updating benchmark based on national absolute amount of growth in per capita Part A & B expenditures rather than rate of increase likely to disadvantage ACOs in higher cost areas
  - CMS considered updating based on local/State absolute amount of growth; expressed concern over perpetuating existing disparities

ACO Shared Savings Process*



**Assumes ACO not at risk for losses*

Question #2

Is the Proposed Assignment Methodology the Best Means for Achieving the Program Goals?

Assignment of Beneficiaries

- ACA directs the Secretary to:

  "determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided [by a physician]"

- CMS proposes *retrospectively* assigning beneficiaries to an ACO based on the *primary care physician* providing the *plurality* of their PCP services
  - Each PCP can participate in only a single ACO

Assignment of Beneficiaries

- CMS considered two options:
  - Prospective Assignment
    - Assignment at start of performance year based on beneficiary utilization data from prior period
  - Retrospective Assignment
    - Assignment at end of performance year based on actual services furnished to beneficiaries during the performance year
  - CMS proposes to use the retrospective assignment methodology

Prospective vs. Retrospective Assignment

- Prospective Assignment
  - Easier to manage to a defined population
  - Easier to monitor and adjust performance in real time
  - Can provide for patient buy-in process
  - May be inherently inaccurate unless patient choice is restricted
    - PGP Demo data shows 25% yearly variation in assignment
  - May encourage ACO to focus on the care only of assigned beneficiaries

Prospective vs. Retrospective Assignment

- Retrospective Assignment
  - ACOs would be held accountable for actual beneficiaries seen during the performance year
  - Difficulty in targeting care improvements to assigned beneficiaries
  - CMS proposes providing ACOs with data about the expected population they will “likely be responsible for”

Data Sharing

- CMS proposes to provide the following data:
  - Aggregate data
    - Based on historical beneficiaries
    - Quarterly reports for potentially assigned beneficiaries
    - Includes financial, quality performance, beneficiary metrics, historical utilization
  - Data about beneficiaries used to generate benchmark
    - Beneficiary name, DOB, HICN
  - Upon request, monthly beneficiary claims data (subject to opt out)
- Would data sharing suffice to address concerns about retrospective assignment?

Plurality Assignment

- Retrospective assignment would be based on plurality of primary care services
- CMS considered two methods for calculating plurality:
  - Simple Service Count
  - Accumulated Allowed Charges
    - Acts as a proxy for resource use of underlying PCP services
    - Need for “tie breakers” is unlikely
- CMS proposes to adopt the accumulated allowed charges methodology

Plurality and the PGP Demonstration Experience

- PGP Demo
  - Beneficiary assignment based on the plurality of primary care services
  - According to CMS data, the plurality assignment method captured 77-88% of patients receiving primary care service at the PGP
  - Assigned beneficiaries received, on average, 95% of their primary care services at the PGP

Majority versus Plurality Approach

- Alternative proposal was to base beneficiary assignment on where the majority of primary care services are provided
  - Does this better capture alignment with an ACO than the plurality method?
  - Would it enhance an ACO's sense of responsibility for beneficiaries?
  - Would the majority approach be too strict a standard?
    - Would it result in too many unassigned beneficiaries (*e.g.*, beneficiaries who see two or more PCPs)

Issues Regarding Plurality Assignment

- Under a plurality approach, should there be a minimum threshold number of services before a beneficiary can be assigned to an ACO?
- Assignment based on allowed charges, not visits, may result in beneficiaries not being assigned to the ACO where they are seen most frequently

Assignment Based on Primary Care Physician Services

- CMS proposes assigning beneficiaries to primary care physicians providing designated primary care services
  - PCP limited to internal medicine, general practice, family practice, geriatric medicine
  - Primary care services – defined based on set of HCPCS codes identified in section 5501 of the ACA
- What about primary care services provided by specialists and/or non-physician practitioners?
  - Areas with PCP shortages?
  - Goes against growth in use of non-physicians as PCPs?
  - CMS proposed a “step-wise” approach

FQHCs and RHCs

- Assignment based on HCPCS codes effectively excludes FQHC and RHC patients
  - FQHC and RHC claims do not include necessary HCPCS codes identifying services provided
  - RHC services are often provided by non-physicians such as NPs and PAs
  - FQHC and RHC patients would not be considered in assignment process
  - While FQHCs and RHCs cannot form ACOs on their own, they can join other ACOs

Question #3

Are the Proposed Waivers of Federal Fraud and Abuse Laws Adequate?

Proposed Waivers of Fraud and Abuse Laws

- Proposed waivers released by CMS/OIG simultaneous with the release of the proposed ACO regulation
  - Did not include proposed regulatory language
- Comment period open until June 6, 2011

Proposed Waivers of Fraud and Abuse Laws: Stark Law

- Stark Law
  - CMS and OIG propose waiving the Stark Law's referral prohibition for distributions of ***shared savings*** received by an ACO:
    - "to or among ACO participants, ACO providers/suppliers and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO"
    - to providers/suppliers outside the ACO "for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program"

Proposed Waivers of Fraud and Abuse Laws: AKS and CMP

- The Anti-Kickback Statute
  - Proposed waiver protects financial arrangements otherwise protected by the new Stark waiver or existing Stark exceptions
  - Existing safe harbors still apply
- Civil Monetary Penalties Law
  - The proposed CMP statute waiver would apply to distribution of shared savings from an ACO hospital to an ACO physician if payments are not knowingly made to induce physicians to reduce or limit medically necessary services

Proposed Waivers of Fraud and Abuse Laws: Duration

- The proposed waivers would protect participants for actions arising only during their three year agreement period with CMS
  - Includes shared savings earned during the agreement period but distributed afterwards

Should the Fraud and Abuse Waivers be Broader?

- Should the waivers be expanded to cover the following:
  - Capital investments in ACO infrastructure?
  - Remuneration between ACO participants related to ACO operations and goals?
  - Distribution of shared savings from private payers?

- Is the "necessary for and directly related to" standard applicable to payments to non-ACO providers too restrictive?

Should the Fraud and Abuse Waivers be Broader?

- Should the scope of the waiver be expanded in order to encourage providers to expand the shared savings model beyond Medicare?

- Will this waiver be incorporated into state fraud and abuse laws?

Question #4

Will ACO Formation be Hindered by State Law?

Potentially Implicated State Laws

- Federal regulations do not waive relevant state laws
- State laws that could be implicated include:
  - Corporate practice of medicine
  - Insurance laws
  - Fraud & abuse (already discussed)

Regulatory Language

- Proposed 42 C.F.R. § 425.5(d)(7)

  (i) An ACO must be constituted as a legal entity for purposes of all of the following:

  (A) Receiving and distributing shared savings

  (B) Repaying shared losses

  (C) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards

  (D) Other ACO functions identified in this part

  (ii) An ACO must certify that it is recognized as a legal entity in the State in which it was established and that it is authorized to conduct business in each State in which it operates.

ACO Activities

- Regulatory requirements:
  - Receiving and distributing shared savings and repaying shared losses
  - Assuming responsibility for compliance with quality criteria
- In practice:
  - ACOs will need to bear some risk
  - ACOs will need to coordinate care to meet quality/cost thresholds

Corporate Practice of Medicine (CPM)

- State law doctrine prohibiting corporations from "practicing" medicine; scope of prohibited activities varies by state
- California:
  - Corporate entities generally cannot employ physicians
  - AG opinions have limited the activities of management services organizations
  - California Medical Association has taken the position that "captive" PCs may violate CPM
- New York:
  - Broad restrictions, but Article 28 hospitals may employ physicians

CPM Implications

- State law exceptions exist
  - *E.g.*, NY exception for Article 28 hospitals
- Hospitals have developed ways to work within CPM restrictions
  - Establish foundations / “captive” PCs
  - Contract with IPAs
  - Hospitalist and co-management agreements
- Do these models meet the requirements of an ACO?

CPM Implications (con't)

- Relationship between ACO and physicians will vary by state
- Should consider likely response from state medical societies and state medical boards
  - Often primary advocates for CPM restrictions

ACOs as Insurance Companies

- ACOs must accept downside risk by the third year of their contract with CMS
- CMS recognizes possibility that state regulatory bodies will treat ACOs as risk-bearing entities:
  - "[W]e emphasize that, under our proposal for a two-sided model under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries"
  - CMS requested comments on whether "any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws"

Implications of State Insurance Laws

- State-by-state analysis, and may depend on Department of Insurance application of state insurance laws
  - State insurance laws are extremely complex
- Will ACOs be able/willing to comply with state regulatory framework?
  - Could include licensure; financial filings; financial solvency requirements, including minimum operating reserves
  - CA Department of Managed Health Care stated its belief that ACOs will need to be licensed

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