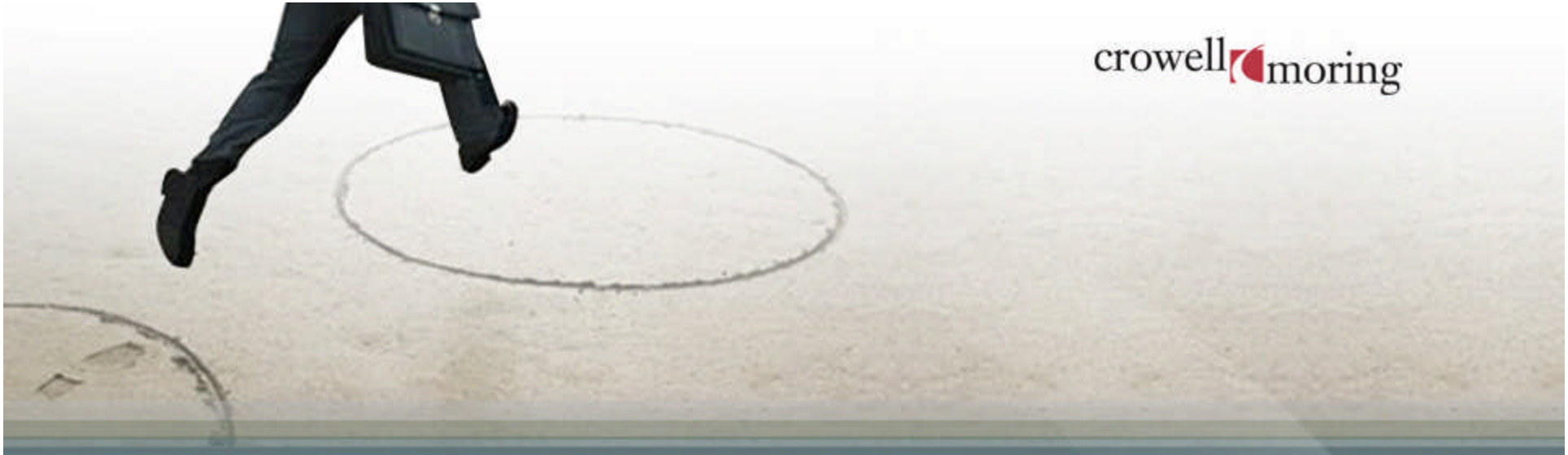

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Recent Release of the Proposed Accountable Care Organization Regulations and Related CMS, OIG, FTC, DOJ, and IRS Content: Piecing the Puzzle Together

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Accountable Care Organization Defined

- Legal entity through which the Affordable Care Act's Shared Savings Program will be implemented
- Comprised of groups of eligible ACO participants (providers and suppliers)
- Work together to manage and coordinate care for Medicare Fee-For-Service beneficiaries
- Mechanism for shared governance that provides ACO participants with proportionate control over decision-making process

ACO Eligibility Requirements: Who's In/Who's Out?

In:

- ACO professionals (physician (MD/DO), PA, NP, CNS) in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Others the Secretary deems appropriate

ACO Eligibility Requirements: Who's In/Who's Out?

Out:

- ACO cannot be federally qualified health center, rural health center, skilled nursing facility, long term care hospital, or certain type of critical access hospital
- Assignment of beneficiaries based on utilization of primary care services; CMS currently lacks the requisite data elements in the claims and payment systems required for making assignment determinations for beneficiaries of these entities
- FQHC, RHC, SNF, LTCH, CAH may qualify as ACO participant; CMS considering future ACO eligibility

ACO Legal Structure

- Single legal entity authorized to conduct business under applicable state law
- Capable of receiving and distributing payments for shared savings to ACO participants
- Must have its own tax identification number
  - ACO need not be enrolled in Medicare
  - ACO *participants* must have their own TINs and be enrolled in Medicare
- No *new* legal entity required if existing entity already structured in a manner consistent with the eligibility requirements for ACOs
  - For example, a hospital with employed physicians and other ACO professionals need not create a new legal entity
  - Unless it wants to add other ACO participants who are not part of its existing legal structure; new entity required under these circumstances
- Must certify that it is a recognized legal entity under each state law in which it operates
- Regulations focused on structure, not ownership of ACO

Governing Body

- Shared decision-making for all ACO participants
- Medicare beneficiaries part of Governing Body
- GB is separate and unique to the ACO – except when ACO is an existing qualifying entity
- ACO participants must comprise 75% of GB
  - Allows non-Medicare entities to comprise 25%
  - Nod to providers who lack capital and infrastructure necessary to meet eligibility requirements;
- Each ACO participant must be represented on GB; together with beneficiary representation, potentially unwieldy requirement

Clinical and Administrative Leadership

- Executive under control of the Governing Body
- Clinical management and oversight under direction of senior-level medical director
- ACO participants with “meaningful commitment” to clinical integration program (financial or human investment)
- Physician-directed quality assurance and process improvement committee
- Evidence-based medical practice and guidelines
- Infrastructure to enable ACO to collect and evaluate data
- Compliance with these requirements determined by submission of supporting documentation, including provider contracts, organizational/corporate records, operating policies (documents not typically required for submission by Medicare providers)

Participation Agreement/Compliance Plan

- Each ACO must enter into a three year participation agreement
- Agreement includes acknowledgement that the ACO agrees to comply with all requirements for participation in the Shared Savings Program
- Authorized executive of the ACO must certify that all ACO participants agree to comply with the requirements of the agreement (no small certification)
- Penalties for early termination (25% withhold of shared savings to offset future losses)
- ACO required to have compliance plan to address how legal requirements will be met; traditional compliance plan elements must be incorporated into plan

Sufficient Numbers of PCPs and Beneficiaries

- Minimum of 5000 beneficiaries required per ACO
- Assumption that if the ACO meets this eligibility requirement, then the ACO also contains a sufficient number of PCPs to provide care to these beneficiaries.
- If ACO falls below 5000 beneficiaries during the course of the 3-year agreement, warning is issued and corrective action plan imposed.
- If deficiency continues at end of second year, termination and no shared savings

Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care

- Statute requires an ACO to define processes to promote evidence-based medicine, patient engagement, quality and cost measures reporting, coordination of care
- Citing concerns that a "prescriptive approach" might impede innovation, CMS passes on identifying specific criteria required to meet these requirements
- Instead proposes that ACOs provide documentation in their applications that presents "evidence of concrete and effective plans" to fulfill these requirements
- How CMS will assess whether the evidence provided is sufficient remains to be seen

Assignment of Medicare Fee-for-Service Beneficiaries

- Beneficiary assignment to ACO based on utilization of primary care provider ("PCP") services
- PCPs defined to include internal medicine, geriatric medicine, family practice, or general practice physicians
- PCP services defined to include Evaluation & Management HCSPCS codes (office visits, wellness, home, and visits to patients in nursing facilities/rest homes)
- Assignment based on where patient received a "plurality" of PC services; plurality defined by allowed charges, not number of visits
- Retrospective assignment at end of performance year based on utilization data demonstrating the provision of PCP services during this year
- Theory is that retrospective assignment holds ACO accountable for the actual population it cared for during initial performance year

Challenges of Retrospective Beneficiary Assignment

- Deprives ACOs ability to exercise fundamental population management principles - understanding patient population, identifying individuals at high risk, proactively developing care plans, etc.
- Inability to track prospective targeted expenses and gauge results throughout the performance year
- Fear of the unknown – ACOs will not know their actual assigned beneficiaries until the end of the performance or measurement year
- While CMS proposes to share beneficiary-identifiable data about the ACOs "expected" assigned population during the prior three years, the actual assigned population at the end of the performance year may vary significantly from this group

CMS Data Sharing with ACOs

- Initial and quarterly aggregate data reports to help ACOs identify priority areas of care.
- Limited beneficiary identifiable information (i.e., name, DOB, sex and HICN) on individuals used to prepare aggregate reports:
  - Allow ACO providers to identify beneficiaries, review records, and identify ACO processes that may need to change.
  - Help ACO identify beneficiaries for better care coordination.

CMS Data Sharing with ACOs

- Beneficiary identifiable claims information
  - Data Use Agreement will be required
  - Considered permissible disclosure under HIPAA for "health care operations"
  - Parts A, B and D claims data
- Beneficiaries have "opt-out" right to disclosure of their claims data to ACOs

ACO Agreements

- No less than 3-year agreement period by statute.
- Although program start date is January 1, 2012, no application deadline is proposed.
- ACO agreements will start on January 1 following CMS approval of application.
- Performance period is a 12-month period and commences January 1.

Shared Savings Determination

- Basic rule:
- ACO that meets both quality performance standards and demonstrates achieved savings against benchmark of expected average per capita Medicare FFS expenditures will receive payment for shared Medicare savings.

What is the Benchmark?

- Surrogate measure of what the Medicare FFS Parts A and B expenditures would otherwise have been in the absence of the ACO.
- Once the savings realized by the ACO exceed a margin for normal changes in FFS expenditures from year-to-year (the Minimum Savings Rate or "MSR"), difference between actual expenditures of the ACO's assigned beneficiaries during each year of the agreement period and ACO's benchmark should reflect how well the ACO is coordinating care for its beneficiaries and improving the overall efficiency of their care.

Calculating the Benchmark

- Option 1: Starting point is TINs of ACO participants. Use ACO participants' claims records to get list of beneficiaries who received plurality of primary care services from PCPs participating in ACO for prior 3 years. Estimate benchmark from per capita Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in the 3 prior years.

Calculating the Benchmark

- Option 2: CMS calculates per capita Parts A and B FFS expenditures during each of the 3 years immediately preceding year 1 of agreement for each beneficiary assigned to the ACO during the agreement period.
- Proposed rule adopts Option 1 but seeks comments on both options.
- 6-month claims run-out used to address lag.

Role of Risk Adjustment

- ACO eligible for shared savings "only if estimated average per capita Medicare expenditures . . . *adjusted for beneficiary characteristics*" are below the benchmark.
- Benchmark "shall be adjusted for *beneficiary characteristics"* and other factors determined by Secretary.

Role of Risk Adjustment

- Savings against benchmark could be a function of two factors:
  - Reduced expenditure growth as a result of greater quality and efficiency in delivery of health care services.
  - Changes in the characteristics of the beneficiaries who are under the care of the ACO.
- Without risk adjustment,
  - Some ACOs may realize savings merely because of treating a patient mix with better health status than the patient population reflected in the benchmark.
  - Other ACOs may share in savings on a risk adjusted basis but would not have shared in savings if expenditures were not risk adjusted.

Risk Adjustment Factors

- Demographic factors: age, sex, Medicaid status, and grounds for Medicare eligibility (whether age, disability, or end-stage renal disease).
- Diagnostic data. CMS hierarchical condition categories (CMS-HCC) prospective risk adjustment model. Currently used to determine capitation payments to Medicare Advantage organizations.

CMS Rules for Risk Adjustment under Medicare Advantage

- Goal of risk adjustment under MA is payment accuracy, but CMS has tough data rules.
- Risk adjustment diagnosis must be based on clinical medical record documentation from a face-to-face encounter, coded according to the ICD-9-CM Guidelines for Coding and Reporting; assigned based on dates of service within the data collection period, and submitted to the MA organization from an appropriate risk adjustment provider type and an appropriate risk adjustment physician data source.
- For data validations, MA organizations must select the "one best medical record" to support the member HCC.

Risk-Based Payment Models

- ACOs will be accountable for downside risk and will have to repay Medicare for a portion of losses (expenditures above its benchmark).
- Proposed rule allows an ACO to choose one of two program tracks to ease into risk assumption.
  - Track 1: ACO operates on a shared savings only track for the first two years, but is required to assume the risk for shared losses in the third year.
  - Track 2: ACO shares in savings and risk liability for losses beginning in first performance year, in return for a higher share of any savings it generates.

Partial Capitation

- Refers to payment system that incorporates both FFS and capitated payments.
- CMS intent to design and test partial capitation models before adopting them for Shared Savings Program.

Ensuring Repayment of ACO Losses

- 25% withhold applies under both Track 1 and Track 2.
- Track 2 ACOs must also establish acceptable repayment mechanism:
  - Reinsurance
  - Escrow
  - Line of credit
  - Other
- Unpaid losses carried forward into subsequent performance years and agreement periods.

Comparison of Track 1 and Track 2

Design Element	Track 1 (performance years 1 and 2)	Track 2
Maximum Sharing Rate	52.5%	65%
Quality Scoring	Sharing rate up to 50% based on quality performance	Sharing rate up to 50% based on quality performance
FQHC/RHC Participating Incentives	Up to 2.5 percentage points	Up to 5 percentage points
Minimum Savings Rate	Varies by population	Flat 2% regardless of size

Comparison of Track 1 and Track 2

Design Element	Track 1 (performance years 1 and 2)	Track 2
Minimum Loss Rate	None	Flat 2% regardless of size
Maximum Sharing Cap	Payment capped at 7.5% of ACO's benchmark	Payment capped at 10% of ACO's benchmark
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2% threshold; up to 52.5% of net savings up to cap.	Savings shared once MSR is exceeded; up to 65% of gross savings up to cap.

Comparison of Track 1 and Track 2

Design Element	Track 1 (performance years 1 and 2)	Track 2
Shared Losses	None	1st dollar shared losses once minimum loss rate is exceeded. Cap on the amount of losses to be shared phased in over 3 years: 5%, 7.5% and 10%. Losses in excess of annual cap not shared. Actual amount of shared losses based on final sharing rate that reflects ACO quality performance and any additional incentives for including FQHCs and/or RHCs using the following methodology (1 minus final sharing rate).

CMS/OIG Joint Notice of Proposed Waivers

- Proposed waivers of *certain* laws with respect to *certain* financial arrangements:
  - Certain laws:
    - Stark Law
    - Anti-Kickback Statute
    - 'Gainsharing' CMP provision
  - Certain financial arrangements:
    - Distribution of shared savings
    - Those that implicate & satisfy Stark Law exception
- Agencies solicit comments on different, broader waivers and waiver design considerations

Proposed Waivers – Stark Law

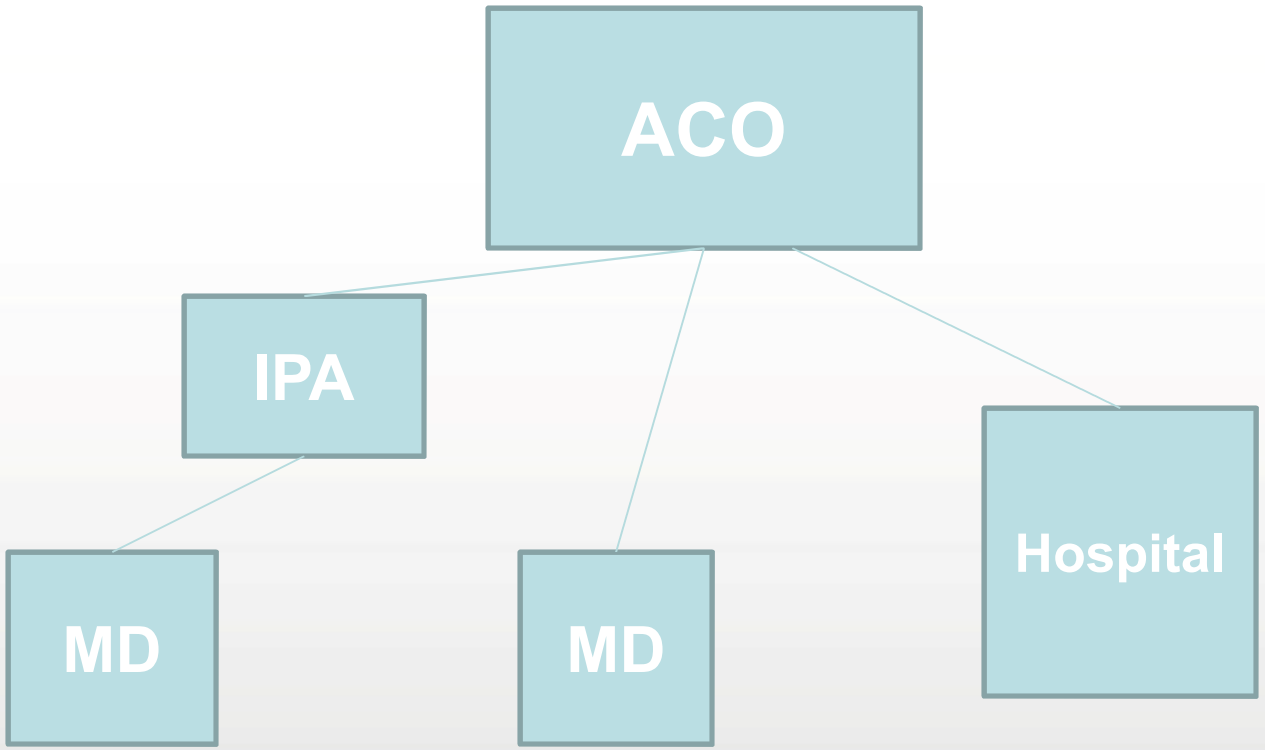
- Waiver for distribution of shared savings received by ACOs:
  - (1) to or among ACO participants, ACO providers/suppliers, and individuals & entities that were such during year in which savings were earned; or
  - (2) for activities necessary for and directly related to ACO's participation in and operations under the Program
    - To protect distributions *outside* the ACO, but only if 'closely related to the purpose of the ACO'
- No other financial relationships subject to waiver

The Stark Law and ACOs

- All direct compensation arrangements implicate the Stark Law, but not all *indirect* compensation arrangements do so
- Who are the DHS entities within an ACO?
- Will an ACO distribute savings directly to physicians and physician organizations?
- Unlikely that an ACO will either bill Medicare for DHS or perform DHS (*i.e.*, unlikely that the ACO will be a DHS entity)

The Stark Law and ACOs

» Distributions of shared savings



The Stark Law and ACOs

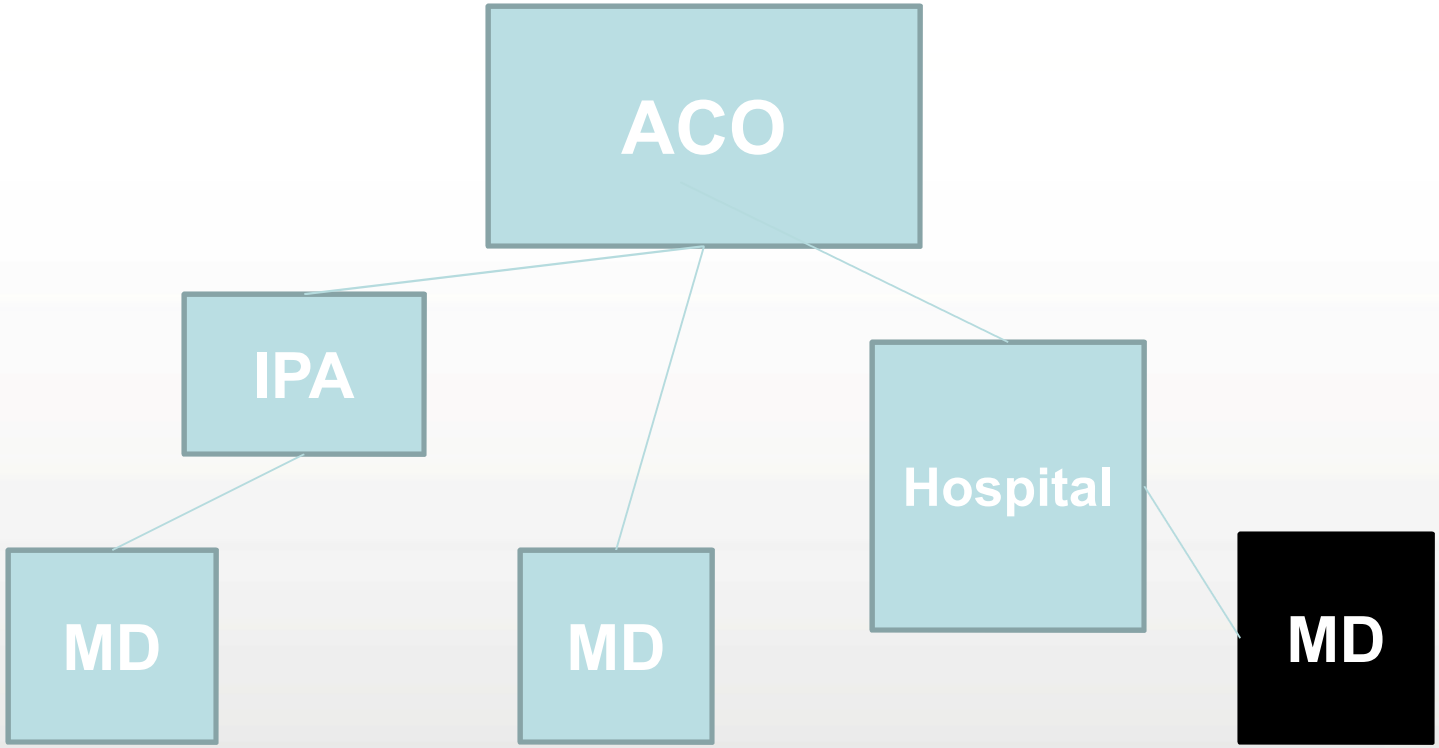
- Distribution of shared savings *may* effectuate indirect compensation arrangement between referring physicians and DHS entity/ies within ACO
- Will aggregate compensation received by physician (vis-à-vis distribution) vary with, or take into account, volume or value of referrals or other business generated by doctor *for* DHS entity?
- If not – Stark Law not implicated. See 42 C.F.R. 411.354(c)(2)

The Stark Law and ACOs

- If *so*, the indirect compensation arrangement could either:
  - satisfy the indirect compensation arrangement exception (411.357(p))
    - FMV, set out in writing, signed by parties, specifies the services subject to the arrangement, does not violate the anti-kickback statute; **OR**
  - be subject to CMS' proposed Stark Law waivers
- If terms of the distribution are in the same contract as the terms of a personal service to be provided, will the waiver cover both?

The Stark Law and ACOs

» Distributions of shared savings



The Stark Law and ACOs

- If hospital (or any DHS entity within ACO) redistributes shared savings to referring physicians, the redistribution must either:
  - satisfy an exception for *direct* compensation arrangements (*e.g.*, bona fide employment, personal services, fair market value compensation); **or**
  - be subject to CMS' proposed Stark Law waivers

Proposed Waivers – Anti-Kickback Statute

- Waiver for distribution of shared savings received by ACOs:
  - (1) to or among ACO participants, ACO providers/suppliers, and individuals & entities that were such during year in which savings were earned; or
  - (2) for activities necessary for and directly related to ACO's participation in and operations under the Program
- Also….

Proposed Waivers – Anti-Kickback Statute

- Waiver for *any* financial relationship:
  - (1) between or among ACO participants and/or ACO providers/suppliers; **and**
  - (2) that is necessary for and directly related to ACO's Program participation and operations; **and**
  - (3) that implicates the Stark Law; **and**
  - (4) that satisfies a Stark Law exception
- Applies to more than distributions, yet narrowly:
  - Contemplates physicians and DHS entities only
  - Within ACO framework, most of such financial relationships may not implicate Stark Law
  - Satisfy Stark Law exception? Unlikely to violate AKS

Proposed Waivers – Gainsharing CMP Provisions

- Waiver for distribution of shared savings received by ACOs if distribution (or redistribution) is made from a hospital to a physician, and if:
  - (1) payments not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and
  - (2) the hospital and physician are ACO participants (or ACO providers/suppliers)
- Waiver for financial relationships that implicate and satisfy a Stark Law exception

Proposed Waivers - Duration

- Waivers related to distributions of shared savings would apply to distributions of shared savings earned during term of ACO's agreement with CMS, even if distributions made after expiration
- Waivers of AKS and CMP provisions on account of the financial relationship satisfying a Stark Law exception would apply during – *but not before or after* – the term of the ACO's agreement with CMS
  - Practical difficulties?

Proposed Waivers Fail to Address…

- Arrangements related to ACO establishment
  - Financing initial investments and startup expenses
  - Donation of EHR and other technology
- Arrangements related to ACO operations (other than distributions)
  - Service / management agreements
  - Administrative agreements
- Distributions of shared savings received from private payers ('look-alike' ACOs)
- Arrangements with beneficiaries

ACO Certifications (Proposed)

- To the best of the ACO executive's knowledge, information, and belief, all ACO participants and ACO providers and suppliers agree to comply with all requirements in the ACO's agreement with CMS
- All information contained in ACO's Shared Savings application, 3-year agreement with CMS, and submissions of quality data and information to CMS, are accurate, complete, and truthful
- ACO has complied with MSSP requirements for relevant performance period

ACO Certifications (Proposed)

- Any information submitted by the ACO or any ACO participant or ACO provider or supplier, or by another entity, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for and amount of a shared savings payment (or the amount owed by an ACO to CMS) is accurate, complete, and truthful
  - Certification in request for shared savings payment
  - To the extent such data is generated by an ACO participant or another individual or entity, or contractor or subcontractor of the ACO or the ACO participant, such ACO participant, individual, entity, contractor, or subcontractor must similarly certify to the accuracy, completeness, and truthfulness of such data
  - Does any inaccuracy in quality data imperil entire payment?

New Proposed FTC – DOJ Antitrust Guidance on Medicare ACOs and CMS Treatment of Antitrust Issues

- CMS process for review and contracting with ACOs contains unprecedented antitrust linkage
- Federal Trade Commission ("FTC") and Department of Justice Antitrust Division ("DOJ") have proposed an enforcement policy ("Enforcement Policy") on application of the antitrust laws to those provider network organizations . . .
  - formed "in whole or in part" after March 23, 2010; and
  - that seek to participate as ACOs under the Medicare Shared Savings Program ("SSP").

CMS Incorporates Antitrust Considerations into ACO Contracting

- CMS identifies alignment of thinking with FTC and DOJ on types of clinical and financial integration that can foster successful ACO activity and so seeks to "harmonize" ACO eligibility criteria with antitrust standards
  - CMS would require that ACOs with more than a 50% share in any service within any defined "Primary Service Area" served by its providers will be ineligible for participation in the Shared Savings Program unless it submits a letter from the FTC or DOJ confirming it has no present intent to challenge or recommend challenging the proposed ACO
  - ACOs outside new antitrust safety zone, but below mandatory review threshold, may proceed at their own risk, but if they get a voluntary, but unfavorable, antitrust review letter they will be barred
  - Material changes in network composition for ACO in program may require new antitrust review
  - Reorganization or conduct restrictions on an ACO already in the SSP to resolve antitrust concerns will require review by CMS of continued eligibility
  - Violation of the antitrust laws or an antitrust agency statement that it is likely to challenge or recommend challenging the ACO following a material change in its network composition are each grounds for termination of ACO contract by CMS

CMS Places Value on Competition

- CMS posits that competition promotes quality where price is regulated (as it is in Medicare)
- CMS fears that ACO with market power can charge higher prices in commercial sector, which may make its providers less willing to serve Medicare patients at lower prices

Scope of Proposed FTC/DOJ Guidance

- Applicable to Medicare ACOs, including those that wish also to contract with commercial payers
- New "safety zone" for ACOs meeting specific standards
- Criteria and procedures for advance antitrust review mandated by CMS of ACOs seeking to participate in the Medicare SSP if their provider membership exceeds particular thresholds in defined "Primary Service Areas" ("PSAs").

Rule of Reason Treatment of Medicare ACO Negotiations with Commercial Payers

- Prior antitrust guidance indicated that providers could avoid application of so-called "*per se*" rule against price-fixing for joint negotiations with payers if they are (1) financially integrated via risk sharing or (2) clinically integrated and price negotiation by the provider network is reasonably necessary for the venture.
  - 1996 policy statement said that clinical integration can be shown by implementing an active and ongoing program to evaluate and modify practice patterns by provider participants and creating a high degree of interdependence and cooperation among providers to control costs and ensure quality.
  - While agencies have reviewed selected clinical integration initiatives, they have not adopted any specific set of minimal elements such a clinical integration program must employ.
- New Enforcement Policy would confirm that satisfaction of CMS's requirements to be an ACO under the SSP would be sufficient to defeat *per se* pricing treatment of joint price negotiations by the ACO with commercial payers:
  - [I]f a CMS-approved ACO provides the same or essentially the same services in the commercial market, . . . [t]he [CMS] integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services. . . . [T]he Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes.

New Antitrust "Safety Zone"

- The Agencies will not challenge Medicare ACOs that fall within a new "safety zone," absent extraordinary circumstances.
- To qualify, independent ACO participants (e.g., a physician group, individual practitioner, or hospital) that provide the same service ('common service") must have a combined share of 30% or less of each common service in each participant's Primary Service Area, wherever two or more ACO participants provide that service to patients from that PSA.
  - PSA is the "lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its patients."
  - PSA to be score separately for each independent provider in ACO. CMS to make Medicare data available for calculations

Limitations on Safety Zone

- Hospitals and ambulatory surgery centers must be "non-exclusive" to the ACO to be in the safety zone, regardless of PSA share.
  - To be non-exclusive, the provider must be allowed to contract individually or affiliate with other ACOs or commercial payers.
  - Exclusivity will be assessed based on practical realities, rather than simply by nominal phrasing of organizational documents or contracts.
- "Dominant provider limitation" if an individual provider in the ACO has a share in a PSA greater than 50% of any service that no other ACO participant provides to patients in the PSA.
  - Where the limitation applies, the provider must be non-exclusive to the ACO in order to qualify for the safety zone.

Special, but Limited, Additional Latitude for Rural Areas

- An ACO may have one physician (but apparently not more than one even if the physician is in a group practice) per specialty from each rural county as defined by the Census Bureau on a non-exclusive basis and still qualify for the safety zone, even if the inclusion of these physicians causes the ACO's share of any common service to exceed 30 percent in a PSA.
  - The rural exception appears to have limited scope, particularly if it requires ACOs to contract with only one individual member of a multi-practitioner group.
- The 30% safety zone cap will also not apply to an ACO in a rural area that includes a Sole Community Hospital or Critical Access Hospital, as defined by CMS, on a non-exclusive basis, not to exceed one per county.

Mandatory Antitrust Review of ACOs Exceeding 50% PSA Share Threshold

- ACO that does not qualify for the rural safety zone exception cannot participate in the SSP if its share of providers exceeds 50% for any common service that two or more independent ACO participants provide to patients in the same PSA, unless the ACO submits to CMS a letter from the FTC or DOJ stating it has no intention to challenge or recommend challenging ACO under the antitrust laws.
- Information to be submitted for with request for review –
  - All documentation submitted to CMS
  - Information on exclusivity or incentives for exclusivity
  - Business strategy documents.
  - Info demonstrating ACO formative activities post-March 23, 2010.
- Agencies provide detailed instructions on calculation of PSA shares for Medicare and commercial payers.
- Request for review, with documentation, must be submitted 90 days prior to deadline for submission of application to CMS.

Beyond the Numbers

- The antitrust agencies will consider a range of information suggesting that PSA shares may not reflect actual market power
- They will also consider pro-competitive justifications
- Agencies will provide process for voluntary requests for review

Steps to Mitigate Antitrust Risk

- For ACOs exceeding the 50% threshold, or for ACOs outside the safety zone, but not required to seek mandatory advance review, the guidance identifies factors that can reduce risk:
  - Don't use anti-steering, guaranteed inclusion, product participation, price parity or other similar clauses to prevent or discourage commercial payers from directing or incentivizing patients to choose particular providers;
  - Do not tie purchase of the ACO for commercial plans to purchase of other services from affiliates of providers in the ACO that are outside the ACO's own scope;
  - Do not contract with providers on an exclusive basis, except for primary care physicians, and, though not clearly articulated in the Enforcement Policy, contracting on an exclusive basis with a large proportion of a market area's PCPs unless demonstrably necessary to successful ACO operation;
  - Do not restrict contracting payers' ability to make quality and cost information available to enrollees if it is similar to performance measures under the SSP.
  - Avoid sharing competitively sensitive information among ACO provider participants if it could depress competition among the providers for contracting outside the ACO.

Public Comments Requested

- The antitrust agencies have requested public comment on the proposed Enforcement Policy both on substantive aspects as well as any technical corrections or adjustments that may be needed. Comments are due May 31, 2011.

Issues/Ambiguities for Comment

- How will CMS and the antitrust agencies handle applications from entities seeking to participate in the SSP that were formed prior to March 23, 2010, if they surpass the 50% PSA share threshold?
  - Will mandatory antitrust review process apply?
- How does one tell if an ACO was "formed" prior to March 23, 2010?
- Is it sound policy to base decision whether to enter into government contract on law enforcement intentions of antitrust agency?
  - Judicial review? CMS says ACO whose SSP application has been denied or whose agreement is terminated due to a determination made by a reviewing antitrust agency may not contest the merits of the antitrust agency's determination through the proposed CMS reconsideration review process
- Is the PSA screening filter for the safety zone and the mandatory review a good tool?
  - PSA mechanism as filter in lieu of reference to product and geographic "market"
  - Too many false positives or false negatives?
  - How burdensome and complex will new tests be for ACOs with many individual participating providers?

Big Picture Message for Payors and Providers

- Providers demanded more guidance. They got it!
  - They may not like it.
  - Unprecedented linkage of CMS policy to antitrust policy
- Antitrust agencies not prepared to radically change the antitrust rules of the road
- Market and new Medicare reimbursement rules are enhancing opportunities for collaboration between payors and providers
  - Watch out for collaborations that create blockades to competition
  - Watch out for collaborations that are window dressing for price fixing schemes
  - Watch out for ACO activity that freezes out Medicare Advantage plans
  - Watch out for creating “bad documents”
- Details, details, details

Questions?

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Reminder—The slides and a link to a recording of the webinar will be sent to attendees.