

Medicare ACOs: Fraud and Abuse Perspectives

This webinar is brought to you by the Fraud & Abuse (Fraud) Practice Group and the Accountable Care Organization Task Force (ACO TF) (a joint endeavor of the Antitrust; Fraud and Abuse; Health Information and Technology; Healthcare Liability and Litigation; Hospitals and Health System; In-House Counsel; Labor and Employment; Life Sciences; Long Term Care, Senior Housing, In-Home Care, and Rehabilitation; Medical Staff, Credentialing, and Peer Review; Payors, Plans, and Managed Care; Physician Organizations; Regulation, Accreditation, and Payment; Tax and Finance; and Teaching Hospitals and Academic Medical Centers Practice Groups)

May 24, 2011 ...1:00-2:30 pm Eastern

Kathleen McDermott, Esquire
Morgan, Lewis & Bockius LLP
Washington, DC

Michael W. Paddock, Esquire
Crowell & Moring
Washington, DC

Discussion Agenda

Accountable Care Organization (ACO) Purpose.

ACO Compliance Provisions.

CMS/OIG Proposed Stark, AKS and CMP Waivers.

CMS/OIG Specific Requests for Comments on Further
Waivers.

ACO Compliance Perspectives.

ACO Purpose and Ambition

CMS intends wide variety of provider and supplier structures to meet fundamental mission of PPACA:

- “ Integrated and Coordinated Care by providers and suppliers
- “ Measurable improvements in quality of care
- “ Lower costs to the Medicare program
- “ Performance incentives to achieve goals.

There will be multiple ACO Models. One size not intended to fit all. Core principle: group of medical providers and suppliers that accepts responsibility for providing or arranging for group of patients under payment arrangement that allows for net profit payments for achieving reduced costs and improved or enhanced quality of care.

Substantial governance, compliance and accountability provisions.

CMS Proposed ACO Models

May 17, 2011 Press Release:

- “ Center for Medicare and Medicaid Innovation (Innovation Center). Initiatives for ACO Models.
- “ Pioneer ACO Model. Letter of intent due June 8th; Applications due July 18th; Open Door Forum, June 7th.
- “ Advance Payment ACO Initiatives. Comments due June 17th.
- “ Accelerated Development Learning Sessions. June, 2011.

Selected ACO Compliance Related Requirements

- Mandated Governance Structure
- ACO Professional Credentialing, Screening and Reporting
- Marketing Guidelines
- Program Integrity Requirements
- Compliance Plans and Program Requirements
- Conflicts of Interests
- Prohibition on Certain Referrals and Cost Shifting
- Processes to promote Patient Engagement, Evidence-based medicine, Coordination of Care and Quality Measures

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

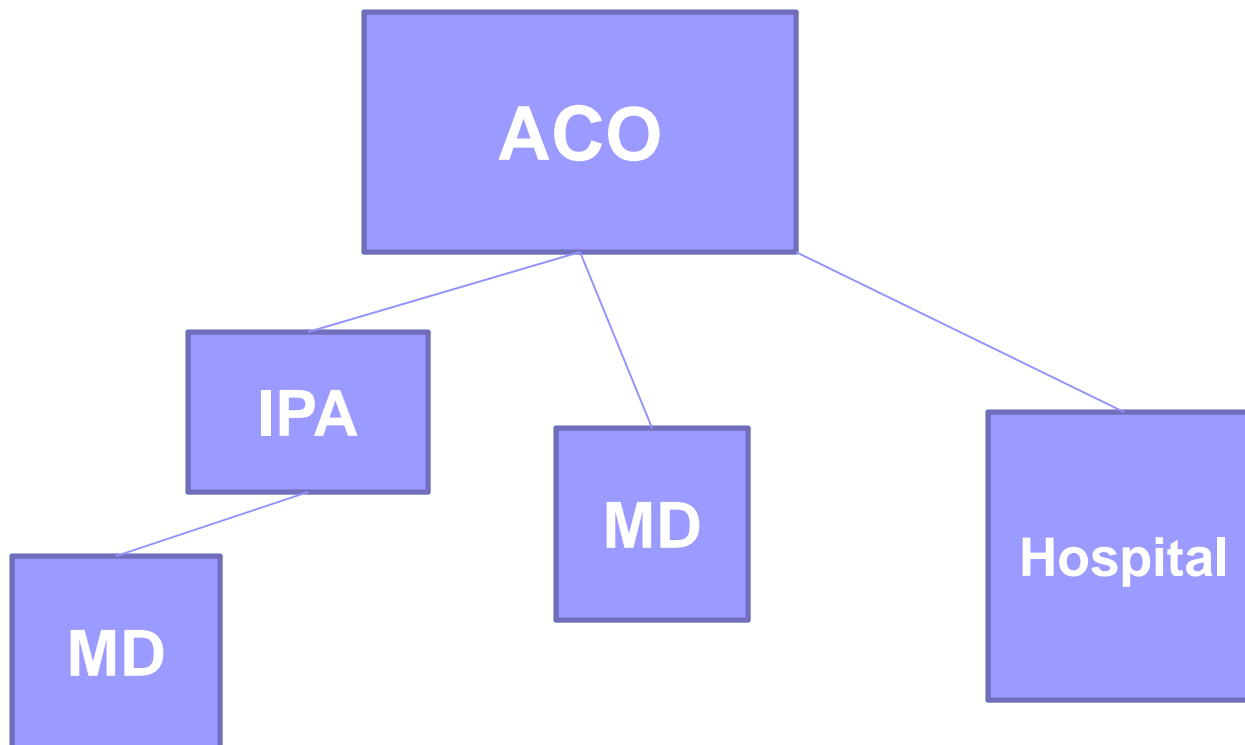
The Stark Law and ACOs



- 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

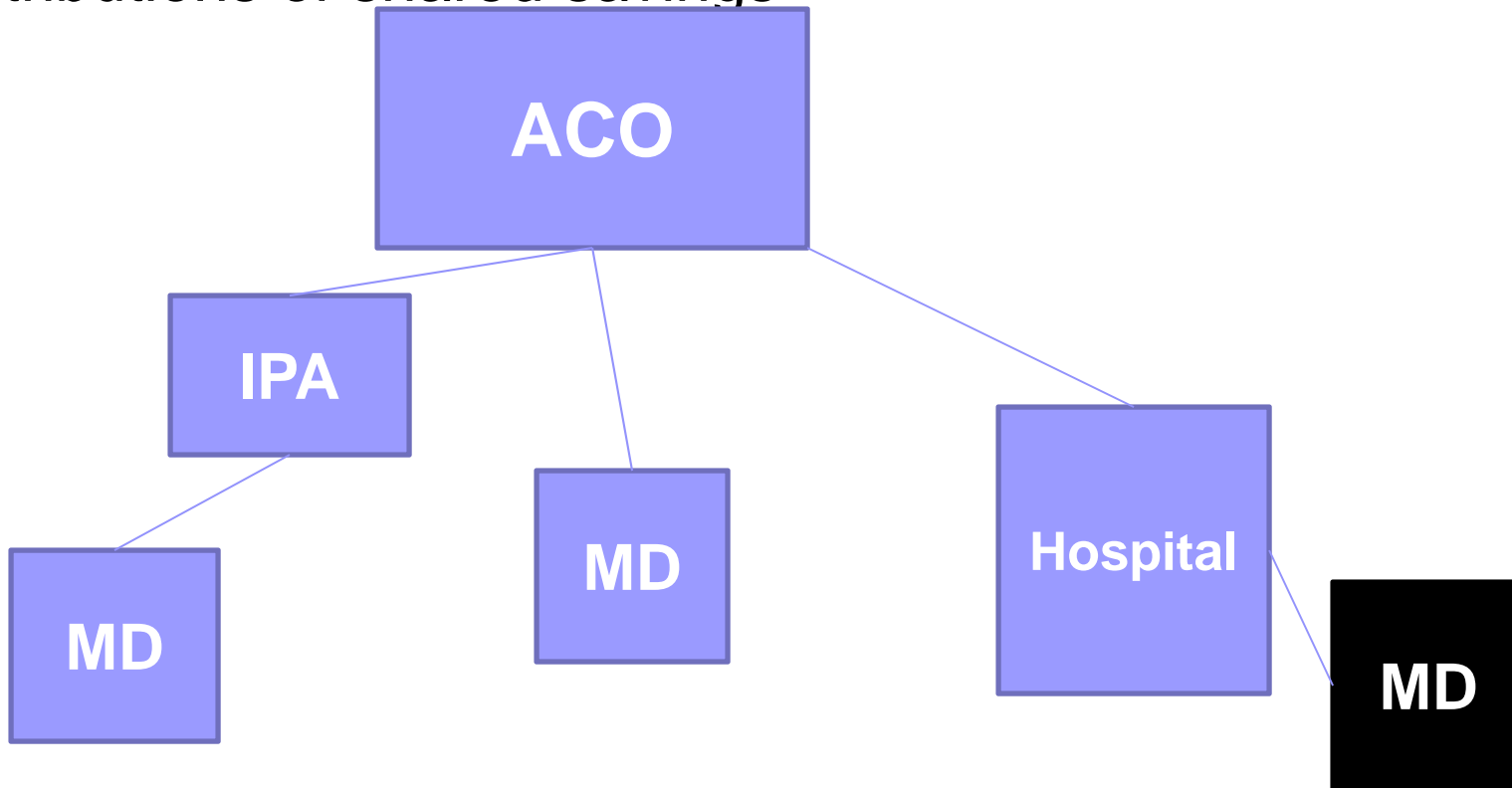


- If so, the indirect compensation arrangement could either:
 - “ satisfy the indirect compensation arrangement exception (411.357(p))
 - FMV, set out in writing, signed by parties, specifies the services subject to the arrangement, does not violate the anti-kickback statute; **OR**
 - “ be subject to 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?

CMS/OIG Solicit Comments On...

- Substantial request for comments. Due June 6, 2011 by 5:00pm. Are waivers necessary to effectuate ACO purpose and operations for the following:
 - ACO Establishment-are waivers necessary for actions related to: 1. forming ACO; 2. ACO governance; 3. building technological and administrative capability. Investment funding to finance ACO.
 - ACO Arrangements. Financial arrangements beyond distribution of shared savings.
 - Distribution of shared savings from private payors.

CMS/OIG Solicit Comments On...

- Other financial arrangements not yet proposed.
- Duration of waivers.
- Additional Safeguards.
- Scope of waivers.
- Two-sided risk model.
- Use of existing exception and safe harbor for electronic health records.
- Beneficiary inducements.
- Timing of the waivers.

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?

Other Agency Considerations

- Fraud and abuse perspectives inherently impacted by other considerations. IRS and Anti-Trust.
- IRS. April 18, 2011 Bulletin Notice. Participation in MSSPs through ACOs by Tax-Exempt Organizations.
 - “ Potential for adverse tax consequences if not structured properly.
 - “ IRS may determine if prohibited remuneration or private benefit has occurred.
 - “ Presumption of no impermissible private benefit or inurement if CMS and IRS factors are met.

Compliance Perspectives

- Fraud and abuse risks for ACOs go way beyond the proposed waivers which may much ado about nothing?
- Proposed waivers reflect ambition to sustain existing fraud and abuse laws to the fullest extent possible. DO not supplant current law. Waiver for AKS and CMP for Stark compliance relationships is technical and largely insubstantial.
- Real fraud and abuse risk is in material non-compliance with structure and processes requirements and data reporting.
- Process for certification and accountability safeguards will be critical.

Compliance Perspectives

ACOs will be subject to recognized fraud and abuse vulnerabilities similar to Medicare managed care programs: cherry picking healthy patients, provider and supplier credentialing, enrollment and marketing practices, documentation of bona fide clinical outcomes, incentive payments for quality outcomes with subcontractors.

ACO requirements for governance structure, complying with state licensure and validating quality assurance and improvement process require substantial technology and administrative commitment.

Compliance Perspectives

- Current provider and supplier staff models insufficient to meet full ACO regulatory obligations.
- ACO structure will require substantial investment or other financing, creation of additional compliance, clinical, accounting and audit functions.
- ROI for ACOs is unclear and may lead to traditional fraud and abuse vulnerabilities if expectations are not realistic.
- Are fraud and abuse laws worthy of greater waiver or reform effort to support overall goal of health reform?

Speaker Contact Information

- Kathleen McDermott, Partner, Morgan Lewis & Bockius, LLP, Washington, DC. 202-739-5458; kmcdermott@morganlewis.com
- Michael Paddock, Partner, Crowell & Moring, Washington, DC. 202-624-2519. mpaddock@crowell.com
- Mark Bonanno, Law Offices of Mark Bonanno, Portland, OR. 503-493-3330; mlb@healthlawoffice.com