

O B E R | K A L E R
Attorneys at Law

**Beyond the Cover Story: A Focused Overview of
the Key Provisions of the ACO Regulations**

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***SPEAKERS ARE BOLDED**

Agenda

- Welcome – *Julie Kass*
- Application and Agreement with CMS – *Sarah Swank*
- Eligibility, Governance and Leadership – *Sarah Swank and Bob Clark*
- Antitrust – *Bill Berlin*
- Fraud and Abuse – *Julie Kass*
- Assignment of Beneficiaries – *Julie Kass*
- Shared Savings Determination – *Leslie Goldsmith*
- Quality Monitoring and Reporting – *Kristin Carter*
- Privacy – *Jim Wieland*
- Tax Exempt Organizations – *Alan Arville*

Comments: Dates and Deadlines

- To be assured consideration, comments must be received no later than
 - CMS Proposed ACO Rule: June 6, 2011
 - DOJ / FTC Antitrust Guidance: May 31, 2011
 - CMS / OIG Fraud and Abuse Guidance: June 6, 2011
 - IRS Tax Guidance: May 31, 2011

Application

- Eligible providers and suppliers
- Contents
- Documents required
- Timing of filing

Agreement

- Term
- Effective date/Performance period
- Parties
- Major terms
- Amendments
 - Significant changes
 - New program standards
- Termination

Legal Entity

- Form of legal entity
- TINs
- Existing entities
- Paying for formation costs

Governance

- Composition
- Shared governance
- Patient-centered governance
- Conflict of Interest

Leadership

- Manager
- Medical director
- Compliance
 - Compliance officer
 - Compliance plan
- Quality assurance

The Antitrust ACO Policy Statement

What Providers Need to Know To
Decide Whether To Participate

To Which ACOs Does The Statement Apply?

- Competing providers
- Criteria for Shared Savings Program
- Contracting with commercial insurers
- Clinical integration

Streamlined Analysis Based on ACO's Share

- How to calculate the PSA shares necessary to make threshold determinations
- Safety zone – 30%
 - Rural exception – can exceed 30%
 - Dominant provider limitation – single provider can exceed 50%
- Mandatory review for ACO's exceeding 50%

How To Reduce Risk Of Investigation Or Mitigate Antitrust Concern

- Same factors used for ACOs with shares between 30-50% and over 50%. Don't:
 - Prevent payor steering
 - Tie ACO services to services of providers outside of ACO (including participants)
 - Make ACO providers exclusive to the ACO (except PCPs)
 - Restrict payors ability to provide info to enrollees to select NW providers
 - Share price info among ACO participants

Agency Review Process

- Documents and information required
- 90 day review period
- Agency approval required for ACOs exceeding 50%

Fraud and Abuse Waivers

- What do the fraud and abuse waivers cover?
 - Why are the waivers narrow?
- What are the general criteria to meet the waiver requirements?
- How do the Stark, Anti-Kickback and CMP waivers differ?

Fraud and Abuse Waivers

- How do you protect ACO arrangements that don't involve distribution of the shared savings?
 - How are arrangements concerning the formation of an ACO protected?
 - How are other compensation arrangements, such as medical director arrangements with the ACO, protected?
 - Are there protections for arrangements among ACO participants?

Fraud and Abuse Waivers

- Request for comments on other waivers:
 - Formation costs, technology expenses, training
 - Arrangements among providers involved in the ACO
 - Distribution of savings from private payers
 - Additional waivers for Track II model
 - EHR exception/safe harbor extension
 - Waivers for beneficiary inducement

Assignment of Beneficiaries

- Why is the assignment of beneficiaries significant?
 - How does the assignment of beneficiaries drive other ACO benchmarks?
- How are beneficiaries assigned? CMS addresses these issues:
 - operational definition of ACO in order to distinguish among ACOs
 - Can a provider/supplier be in more than one ACO?
 - definition of *primary care services*
 - determination of whether to assign beneficiaries prospectively or retrospectively
 - determination of the proportion of primary care services necessary for a beneficiary to be assigned to a particular ACO
 - Does assignment by primary care physician make sense?
- What if patients don't want to be part of an ACO?

Shared Savings

- Is the shared savings money worth the cost?
 - Cost considerations
 - Shared Savings considerations

Shared Savings

Track 1 versus Track 2

- 1-sided versus 2-sided models
- Increased risk provides greater potential shared savings
- Differences in the calculations
- Unknowns in the calculations

Shared Savings

- Minimum Savings Rate
- Shared Savings
- Shared Savings Rate
- Loss issues
- Payment Performance Limit

Appeals

- No review of any kind for most determinations related to ACOs and shared savings
- Limited reconsideration review by CMS of denials of an ACO application and termination for other than failure to meet quality performance standards

Quality Monitoring & Reporting

- What are the Proposed Quality Measures?
 - 65 Measures/5 Domains:
 - Patient Caregiver Care Experience (7 Measures)
 - Care Coordination (16 Measures)
 - Patient Safety (2 Measures)
 - Preventative Health (9 Measures)
 - At-Risk/Frail Populations (31 Measures)
- How Will Data Be Collected & Submitted?

Quality Monitoring & Reporting

- How Will CMS Score Quality Performance?
 - Year 1 – Pay-for-Reporting
 - Years 2 & 3 – Option 1 v. Option 2
- What Are The Consequences Of Failing To Meet Quality Performance Standards?
- Will There Be Any Public Reporting?

HIPAA

- Protected health information will be disclosed to and used within an ACO.
- Medicare fee-for service is a “payer” and a “covered entity” under HIPAA.
- ACO will either be a covered entity under HIPAA or a “business associate” of covered entity participants.

HIPAA

- Proposed Rule Covers HIPAA and disclosures By CMS.
- Our discussion will focus on HIPAA from the perspective of the ACO and its participants as well as HIPAA related provisions of the Proposed Rule.

HIPAA

- HIPAA Privacy Rule permits a covered entity to share PHI with another covered entity or with a business associate acting on behalf of a covered entity for the following purposes, without individual authorization or other special circumstances (such as a disclosure required by law), for:
 - Treatment,
 - Payment,
 - Health Care Operations in two (of six) specific categories:
 - Population based activities for improving health or reducing health care costs, protocol development, case management and care coordination, or
 - Reviewing the competence or qualifications of health care professionals or evaluating their performance.

HIPAA

- Effect of HIPAA on an ACO
 - ACO Participants will need to disclose PHI within the ACO for operational purposes
 - Will the treatment, payment and specified provisions of the HIPAA Privacy Rule definition of Health Care Operations cover uses and disclosures within the ACO?
 - PHI obtained from CMS
 - PHI generated by covered entities participating in the ACO relating to individuals assigned to the ACO

HIPAA

- The Organized Health Care Arrangement may be an option for appropriately structured ACO's
 - HIPAA permits broader sharing of PHI for OCHA Health Care Operations

HIPAA

- Minimum necessary provisions of HIPAA Privacy Rule apply to non-treatment disclosures of PHI
 - Proposed rule specifies the minimum necessary for requests for data from CMS
- Population based health care operations covers Medicare disclosures to ACO
- Proposed Rule modifies the HIPAA Marketing exception for ACOs

HIPAA

- In order to obtain PHI (subject to exception for initial data set), ACO must:
 - Certify that data will be
 - used only for patients assigned to the ACO, by a covered entity or a business associate of a covered entity participant
 - used only for activities falling into the “population based” portion of the definition of health care operations
 - Enter into a “Data Use Agreement” with CMS
 - Provide individuals with a “meaningful opportunity” to “opt-out” of having claims level information provided to the ACO

Tax Exempt Organizations

- ACO Participation
 - Private Inurement and Private Benefit
 - Unrelated Business Taxable Income
- IRS Notice 2011-20 Provides Criteria to Protect Shared Savings
- Concerns with “other” ACO activities

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