



**Buchanan
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ACOs: Compliance Considerations

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“May you live in interesting times.”

Old Chinese curse

Today's Presentation

- Background and overview on ACOs
- What is an ACO?
- Key regulatory requirements
- Compliance plan requirements
- Compliance issues and potential concerns
- Fraud & abuse “waivers”

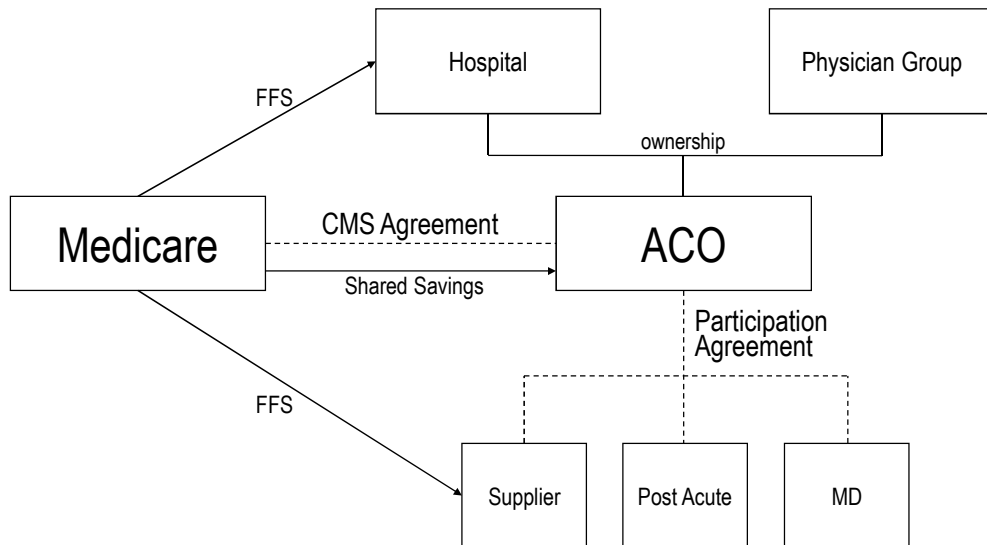
Background and Content

- “Triple aim”
- CMS demonstration programs
 - “Alternative payment models”
- Commercial ACOs
- Recent developments
- Future predictions?

What Is an ACO?

- A group of providers and practitioners who come together to coordinate care with goal of enhancing quality and containing costs.

ACO: One Example



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What Is an ACO?

- Creature of regulations (42 CFR Part 425)
- Creature of the CMS Agreement
- Goals/Objectives
- Services/Payment
 - FFS
 - Shared Savings
 - Distributions to participants

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Basic Elements/Components

- Separate legal entity (separate TIN)
- Entity must
 - Be capable of receiving shared savings
 - Repay shared losses
 - Ensure compliance with quality standards
- Governance
- Leadership and management
- Patient-centered processes
- Beneficiary attribution
- Shared savings and fee-for-service billing

Agreements with Participants and Providers/Suppliers

- Must include sufficient level of PCPs
 - 5000 beneficiaries
- “ACO Participant”
 - TINs used for reporting
- Other providers and suppliers
- Written agreement with all ACO participants and providers/suppliers required
- Post-Acute Providers
 - “Pay-to-play” arrangements?

Requirements of Participation Agreement

- Written agreement required
 - Signature required by authorized representative
- Must require participant to comply with all requirements of the MSSP and all applicable laws and regulations
- Rights and obligations set forth
 - Quality reporting
 - Notices
 - Exclusivity
- Description of shared savings
- Remedial action
- One year term (or longer)
- Close-out processes

Marketing Requirements

- Submission to CMS required
 - 5 days notice
- Template language
- Not used in discriminatory manner
- Not materially inaccurate or misleading
- Requirements regarding no beneficiary inducements

Program Integrity Requirements

- Compliance officer who reports to board
- Mechanisms to identify issues
- Method to report issues
- Training
- Requirement to report suspected violations
- Screening (exclusions)

Practical Considerations

- Existing resources may be utilized
 - Example: Hospital compliance office
 - “Rented” hotline

Specific Prohibitions and Requirements

- Compliance with laws
 - Anti-Kickback Statute (“AKS”), False Claims Act (“FCA”), Stark Law, Civil Monetary Penalties (“CMP”) Law
 - Should be included in all agreements
- Certification of data and information
- Beneficiary inducements prohibited
- Prohibitions regarding required referrals

Compliance Issues

- Avoidance of at-risk beneficiaries
- Quality metrics
- Marketing requirements/restrictions
- Accuracy of data (FCA)
- Beneficiary inducements
- Patient notices
- Patient Opt-Out
- Privacy/data security

Fraud and Abuse Waivers

- AKS
- Stark Law
- CMP Law

“Waivers”

- What are they?: Specific “safe harbors” applicable to ACOs
- 5 waivers
 - Pre-participation waiver
 - Participation waiver
 - Shared savings distribution waiver
 - Stark waiver
 - Patient incentive waiver

Effect and Limitation of Waivers

- Broad exemption from otherwise very limiting, draconian laws (that have serious penalties)
- Only applicable to MSSP
 - Will not protect arrangements outside of MSSP
- Waivers not difficult to meet
 - Unlike other safe harbors there are few requirements
 - But: must “dot I’s and cross T’s”

Pre-Participation Waiver

- Start-up arrangements
- Good faith intent
- Diligent steps to develop ACO
- “Reasonably related to MSSP purposes”
- Documentation
- Public disclosure

Participation Waiver

- ACO actually participating in MSSP
- 6 month close-out period
- ACO satisfies various requirements
- “Reasonably related to purposes of MSSP”
 - Board approval
- Documentation
- Public disclosure

Shared Savings Distribution Waiver

- Protects distribution of shared savings by ACO to participants, providers and suppliers
- Does not cover commercial ACO distributions

Compliance with Stark Law Waiver

- Provides AKS protection if arrangement satisfies Stark exception
- Limited value

Patient Incentive Waiver

- Covers free or below FMV items or services
 - But not cash
- ACO participation in MSSP
- Reasonable connection
- Items and services
 - For preventive care
 - Advance adherence to treatment, drug regime, care plan or chronic care management

Other Program Waivers

- BPCI (BPCI 1 to 4 and BPCI Advanced)
- ESCO
- Joint replacement (CJR Program)

RECOMMENDATIONS?

QUESTIONS?

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