The Medicare Shared Savings Program: Accountable Care Organizations

Agenda

1. Introductory Remarks & Speaker Introductions – Julie Allen
2. ACO Governance Structure – Matthew Amodeo
3. ACO Operational Requirements – Matthew Amodeo
5. ACO Interrelationships: Office of Inspector General Guidance and Fraud and Abuse Waivers – Douglas Swill
6. Analysis of Internal Revenue Service Guidance – T.J. Sullivan
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Matthew P. Amodeo is a partner in the Health Law Practice Group. His practice is focused primarily on hospital-physician integration transactions, health care joint ventures and managed care contracting. He also advises several national providers and practice management companies in structuring and negotiating managed care and other arrangements with hospitals and other providers in managed care networks. In these capacities, Matt has delivered and negotiated many highly complex risk-sharing and other arrangements.

Speakers

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Robert W. McCann is a partner in the Health Law Practice Group. Robert has practiced law in the health care field for more than 26 years, focusing on antitrust counseling, mergers and acquisitions, business transactions, capital financing and tax and Medicare compliance for hospitals, health care systems and provider-sponsored organizations. Robert currently represents more than 100 mergers and acquisitions, and in numerous federal antitrust investigations and litigation.

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Julie Scott Allen is a government relations director with the firm's Government & Regulatory Affairs Practice Group. For more than 15 years, Julie has focused on government relations, including advocating at the federal and state level and promoting legislation, regulatory and business agendas for nonprofit and for-profit clients and national organizations. Julie is skilled at navigating clients through the legislative and regulatory environments and working with clients to develop and advocate for legislative and regulatory positions.

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T. J. Sullivan is a health care transactional and tax partner with more than 20 years experience assisting health care organizations on complex regulatory and business issues. He has extensive experience advising managed care organizations, other health care providers and payers, health systems and hospital networks. He has advised on the development of strategies for managed care organizations to improve their financial health and profitability, developed executive compensation plans and executive incentive programs and advised on federal and state regulatory matters. T.J. has also represented clients in government proceedings and has assisted clients in structuring and negotiating complex transactions.

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Douglas B. Swill is a partner and chair of the Health Law Practice Group. His practice is concentrated in the representation of health systems, hospitals, physician groups, health care providers and other health care providers in structuring, implementing and enforcing compliance policies and programs. Douglas has assisted hospital systems and physician group practices in structuring transactions to minimize fraud and abuse risks, as well as complying with federal, state and local regulations and laws. He has represented health systems and hospitals in more than 100 merger, acquisition and other transactions.
Minimum Legal/Structural Requirements

1. Legal entity recognized under state law
2. Tax ID Number (TIN)*
3. Capable of receiving/distributing savings
4. Can ensure provider compliance with ACO laws/rules, QI policies, etc.
5. Capable of performing all other ACO functions under ACO rules/regulations

* May or may not be an enrolled Medicare provider/supplier

Permissible ACO Structures

> Physician Group Practice
> Network of Independent Physicians (IPA)
> Joint Ventures Between Hospitals and Physicians (PHO)
> Hospital with Employed Physicians (Integrated Delivery System)
> Method II Critical Access Hospitals (CAH)
> Others approved by CMS
> No FQHCs or RHCs, but shared savings incentive available for including in ACO network
Shared Governance

Composition:

> Separate legal entity (or part of a legal entity)
  - Board of Directors, Management Committee
  - No “management agreement” – type governance structures

> Appropriate and proportional control by ACO Participants
  - Example: ACO with 70% PCPs and 30% specialists:
    - Governing board: PCPs: 70% voting control
    - Specialists: 30% voting control

> Medicare Beneficiary Representative(s) with no conflicts of interest with ACO

> 75% ACO provider representation
  - Management companies, financing companies, etc. cannot exceed 25% of Board

> Single, financially/clinically integrated entities may use entity Board as ACO Board
  - Medicare beneficiary requirement may necessitate separate ACO entity

Group Practice ACO Governance

*Most state laws prohibit non-physicians as P.C. Board Members
IPA Governance Model

IPA ACO, LLC
- Proportional IPA Physicians on ACO Board
- Medicare Beneficiary on ACO Board

IDS ACO, LLC
- IDS Mirror Board
- Medicare Beneficiary on ACO Board

*IDS charter may prohibit Medicare beneficiary on IDS Board

Integrated Delivery System Governance Model
Governance (Continued)

Powers:

> Authority to execute ACO functions:

- Administrative
  - Reporting
  - Patient engagement processes
- Fiduciary Functions
- Clinical Operations
  - Care coordination
  - Evidence-Based Medicine processes

Leadership/Management Structure

> CEO, Manager or General Partner
  - Character/competence-type review
  - Experienced in developing clinical practices which improve healthcare processes/outcomes

> Medical Director
  - Senior level
  - Full time
  - Board certified physician
  - Physically present

> QI/QA Committee
  - Physician directed
  - Internal performance standards
  - Providers held accountable
  - Identify and “rehab” outliers
ACO OPERATIONAL REQUIREMENTS

> Infrastructure
- Must be capable of collecting and evaluating data
- EHR technology certified to HHS standards
  - 50% PCP EHR compliance by Year 2
- Provides feedback to ACO providers
- Capable of influencing care decisions at point of care

> Care Guidelines
- ACO must operationalize evidence-based clinical care guidelines consistent with “triple-aims”
- Binding on all providers
- Performance evaluations, remedial action for outliers
- Process for provider expulsion for non-compliance
> **Compliance Plan**

- Designated compliance officer (not outside counsel)
- Compliance training
- Method for employee/contractor whistle-blowing
- Duty to report suspected legal violations to law enforcement

> **Savings Distribution Plan**

- Criteria for sharing savings/losses among ACO providers
- Consistent with goals of Medicare Shared Savings Program/triple aims

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> **Patient-Centered Care Focus**

> Individualized care based on patient’s unique needs, preferences, culture

> Access to own medical records and to relevant clinical information for informed decision making

> Active participation in decision making

> Routine assessment of patient satisfaction by caregivers

> Care integrated with community resources

> Coordinated care transitions among providers across care spectrum
ACO Tools/Functions Required to Assess Patient-Centered Care

1. Beneficiary care survey
2. Patient involvement in ACO governance
3. Process for evaluating ACO population health needs
4. System for identifying high-risk patients and developing individualized care plans
5. Mechanisms for coordination of care (e.g., telehealth, electronic exchange of health data among providers)
6. Process for communicating clinical information/evidence-based medicine to beneficiaries in a manner that is readily understandable
7. Written standards for patient access/communication, re: medical records
8. Internal process for measuring clinical performance by physicians across practices, and using results to improve care

Managing Changes in ACO Operations

“Participants” vs. “Providers/Suppliers”

> ACO Participant: A professional or facility/supplier that has a Tax ID number (TIN) and submits claims to CMS under its TIN
> ACO Provider/Supplier – A professional or facility/supplier that bills for services under reassignment, using a TIN of an ACO Participant. Identified by their TIN and/or NPI.
> ACO Participants can be removed, but not added to an ACO during 3-Year Agreement
  – Antitrust Concerns
> ACO Providers can be removed or added during 3-Year Agreement without notice to CMS
  > 30 days prior notice to CMS of “significant changes”:
  – Inability to comply with 3-Year Agreement due to:
    • Any deviations from original application (e.g., legal restructuring, changes in eligibility, changes in governing body composition)
    • Government required reorganization due to fraud or antitrust concerns
    • Any imposition of sanctions by governmental or accrediting agencies

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Managing Changes in ACO Operations

Upon receipt/review of ACO 30-day notice CMS may:

1. Allow ACO to continue with new structure with updated savings share
2. Allow ACO to continue but require new 3-year agreement and start over because revised entity is materially different from original applicant
3. Require antitrust review before being allowed to continue
4. Disqualify
5. Allow mutual agreement to terminate

Public Reporting Requirements

> Standardized Reporting Form/Format to be set by CMS:

- ACO Name, Location, Contact Person
- Participating Providers
- Members of Governing Body
- Committees and Committee Leaders
- Quality Performance Scores
- Shared Savings/Loss Information
- Shared Savings Distributed vs. Reinvested to Support “Triple Aims”
ACO Operations/Conduct Leading to Termination

> Cherry picking (avoidance of at-risk patients)
> Failure to meet quality standards (after opportunity to cure)
> Failure to submit timely/accurate reports
> Failure to meet eligibility requirements at any time
> Non-compliance with beneficiary notice requirements
> Violation of fraud & abuse laws or other Medicare laws/rules
> Failing to offer "opt-out" form to beneficiaries
> Using unapproved marketing materials
> Inability to repay losses
> Other
Antitrust Policy Statement

> The 2011 Policy Statement provides antitrust enforcement guidance only with respect to ACOs participating in the Medicare Shared Savings Program.

> However, Medicare-approved ACOs receive a “halo” benefit for their commercial ACO activities.

> All other types of “integration” are evaluated under the 1996 Statements of Antitrust Enforcement Policy in Health Care.

Antitrust Policy Statement

> The main factors in the Agencies’ assessment of ACOs are:
  – Market share
  – Provider exclusivity
  – Contracting behavior

> Market share is evaluated using:
  – Primary (75%) service area as a proxy for a geographic market
  – MDC and MSC codes as proxies for product markets.
Antitrust Policy Statement – Approach

> ACOs that meet Safety Zone requirements need do nothing

> ACOs that exceed 50% market share in any service line must obtain federal antitrust clearance in order to participate in Medicare Shared Savings Program (MSSP):
  – Expedited review process
  – Mandatory time frame (90 days before CMS cutoff)

> ACOs in the middle may seek Agency review voluntarily (but cannot participate in MSSP if receive negative response from the reviewing Agency).

Antitrust Policy Statement – Safety Zone

> To fall within the Safety Zone:
  – Must have no greater than 30% share in any service line in the PSA of any participating provider
    ▪ Limited rural hospital/physician exception
  – No hospital or Ambulatory Surgical Center can be exclusive to the ACO
  – ACOs with “dominant” (50%+) provider cannot require exclusivity from the dominant provider or from any commercial payor
Antitrust Policy Statement – Contracting Issues

1. Preventing payors (contractually) from implementing limited panel or tiered networks (etc.)
2. Tying and bundling of services
3. Exclusive contracts (de jure or de facto) with physician specialists, hospitals, or ambulatory surgical centers
4. Preventing payors from providing information on provider cost, quality, and performance to enrollees
5. Sharing (or facilitating the exchange) of provider pricing or other competitively sensitive information
Fraud and Abuse Waivers

> ACO providers will continue to be paid on a Fee-For-Service basis and traditional fraud and abuse principles will apply

> ACO model contemplates shared savings based on certain quality benchmarks and reduced costs; implication of Stark, Anti-Kickback and Civil Monetary Penalties

> PPACA authorizes HHS Secretary to waive certain fraud and abuse laws to carry out Medicare Shared Savings Program (MSSP)

> Publication of ACO proposed regulations and CMS/OIG Notice (with consent period) of proposed waiver of fraud and abuse laws for ACOs – April 7, 2011. Comments due June 6, 2011

Fraud and Abuse Waivers

> Waivers would not apply to any other provisions of Federal or State law

> Intend to apply waivers uniformly to all qualified ACOs, ACO participants, and ACO providers/suppliers participating in ACO MSSP

> CMS and OIG require two threshold qualifications for ACO Waiver:

- Agreement with CMS to participate in MSSP
- ACO and its providers/suppliers comply with agreement and regulations (i.e., all transparency, reporting, and monitoring requirements)
Fraud and Abuse Waivers

> Stark Law (42 U.S.C. 1395nn)

- A physician may not refer Medicare patients for certain designated health services to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies.
- An entity receiving a prohibited referral may not bill the Medicare program for the resulting items and services.

Fraud and Abuse Waivers

> Stark Waiver

- Waiver for distribution of the shared savings received from CMS
  - To all participants and providers/suppliers who participated during the year the savings were earned; or
  - To others for activities necessary for and directly related to ACO’s participation in MSSP

- Other financial relationships, either with referring physicians or their immediate family members participating in the MSSP and implicating Stark need to satisfy an existing exception (i.e., FMV, Personal Services, Employment, Indirect Compensation)
Fraud and Abuse Waivers

> Anti-Kickback Statute (42 U.S.C. 1320a-7b(b)(1)-(2))

- Persons may not knowingly offer, solicit or receive, directly or indirectly, overtly or covertly, in cash or in kind, any remuneration to induce or influence the furnishing, arrangement, purchase, leasing, or ordering of items or services for which payment may be made in whole or in part under a federal healthcare program.

Fraud and Abuse Waivers

> Anti-Kickback Statute (AKS) Waiver

- Identical waiver for distribution of shared savings
  - To all participants and providers/suppliers who participated during the year the savings were earned; or
  - To others for activities necessary for and directly related to ACO’s participation in MSSP

- Other financial relationships among ACO, participants and providers/suppliers necessary for and directly related to ACO’s participation in MSSP if it implicates the Stark Law and meets a Stark Law exception

- Failure to qualify for one of the proposed waivers under AKS would not mean automatically illegal under AKS
Fraud and Abuse Waivers

> Civil Monetary Penalties (42 U.S.C. 1320a-7a(b))

- A hospital or critical access hospital may not knowingly make a payment, directly or indirectly to a physician as an inducement to reduce or limit services provided to a Medicare or Medicaid beneficiary under the direct care of the physician.

ACO Fraud and Abuse Proposed Waivers

> Civil Monetary Penalty (CMP) Waiver

- Applies to two scenarios:
  - Distributions of CMS shared savings from hospital to physician if:
    - Both are ACO participants or providers/suppliers
    - Not made knowingly to induce physician to limit medically necessary items or services
  - Other financial relationships that comply with Stark law and regulations – similar to Anti-Kickback Statute waiver
ACO Fraud and Abuse
Proposed Waivers

> CMS and OIG recognized not all possible financial arrangements are covered in the proposed waivers. The agencies request comments on the following:

- ACO development costs
- ACO operating costs
- Financial arrangements between the ACO, ACO participants, ACO providers/suppliers and outside individuals or entities
- Distribution of shared savings and similar incentive payments from private payors
- Need for a waiver of CMP’s prohibition on patient inducements
- Duration of waivers
- Additional safeguards
- Two-sided risk model
IRS Issues ACO Guidance

> Notice 2011-20 (Mar. 31, 2011)
> Issued in concert with HHS proposed regulations
> Addresses Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program
> Not clear what form ACOs are going to take or governance structure but all participants must have “appropriate proportionate control”
> Issues: Does EO participation in ACO give rise to private benefit or inurement? UBTI?

Private Benefit/Inurement Analysis

> IRS “expects” to not find impermissible private benefit or inurement where:
  - EO’s participation in Shared Savings Program through ACO is set forth in a written agreement negotiated at arm’s length
  - CMS has accepted ACO into Shared Savings Program
  - EO’s share of economic benefits is proportional to benefits or contributions EO provides to ACO
Private Benefit/Inurement Analysis

> IRS “expects” to not find impermissible private benefit or inurement if:

- EO has ownership interest, capital contributions - ownership interests, allocations, and distributions must be proportional
- EO’s share of losses does not exceed share of benefits
- All contracts between EO and ACO or ACO participants are fair market value

ACO UBTI Analysis

> Key IRS point: Will analyze under “lessening the burdens of government” theory of exemption

- Government considers provision of Medicare to be its burden
- Medicare Shared Savings Program is established to lessen that burden
- Hospital/EO participation can help

> May escape some constraints of community benefit analysis
ACO UBTI Analysis

> Not a complete pass

> ACO participation in Shared Savings Programs other than Medicare/Medicaid might not further a charitable purpose or might involve too much private benefit

> Other issues remain

IRS ACO Issues

> Can nonprofit ACO itself be a (c)(3)?

> Will physician ownership/control prevent exemption?

> Will IRS ignore joint venture control test?

> IRS seeks comments on what additional guidance is needed (by May 31, 2011)
Practical Advice

> IRS had trouble approving HMOs, IPAs, PSROs, PHOs, RHIOs; ACOs will be no different

> Absent physician ownership, exemption should be available to nfp corporations controlled by EOs

> Carefully structured joint ventures should be OK (watch control issue)

> Must carefully manage private benefit to physicians, insurers, and taxable organizations

Conclusion

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> To find a recording and/or to download materials from our April 13 webinar, please go to: www.drinkerbiddle.com/acowebinarpart1