ACO FORMATION, OPERATION AND COMPLIANCE

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OVERVIEW

• Affordable Care Act and ACOs
• Trends in Integration
• Role of Compliance
• ACO Formation and Operation
  Lessons Learned
• Transferring Skills

INTRODUCTION

THE PROGRAM AND INTEGRATION
PROGRAMS AND GOALS

- Affordable Care Act
- ACOs
- CMS Innovation Center
- Bundled Payments
- Insurance Exchanges
- Fraud and Abuse and Waste
- Three Aims
  - Better care for individuals
  - Better care for populations
  - Lower growth of expenses

TRENDS IN INTEGRATION

- You have to know where we have been to know where we are going . . .
  - Consolidation and movement in the market
  - Focus on primary care as gatekeepers
  - We do not want to make the same mistakes we made in the past

WHAT IS DIFFERENT THIS TIME AROUND?

- Increased focus on quality
- The need for IT solution
- Shifting of care settings away from the hospital to lower cost settings
- Focus on primary care but now also on specialists
- Both private and public payors
- Care coordination and population health
### COMMON THEMES

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Potential Pitfalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Improved outcomes</td>
<td>• Connectivity issues</td>
</tr>
<tr>
<td>• Cost efficiency</td>
<td>• Fraud and abuse issues</td>
</tr>
<tr>
<td>• Patient satisfaction</td>
<td>• Reimbursement</td>
</tr>
<tr>
<td>• Market advantage</td>
<td>• Remedial measures and credentialing</td>
</tr>
<tr>
<td>• Affiliation rather than consolidation</td>
<td>• HIPAA privacy and security</td>
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</tbody>
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### WHAT IS AN ACO?

Accountable Care Organization (ACO)

- Participate in Medicare
- ACO participants
- 5,000 beneficiaries
- Tax identification number (TIN)
- Legal entity and governance
- Shared savings/losses
- Quality measures
- Application and CMS Agreement

### KEY ACO DEADLINES FOR 2014

- Applications posted on CMS website: Coming Soon
- NOIs accepted: May 1, 2014 - May 30, 2014
- CMS User ID forms accepted: May 6, 2014 - June 9, 2014
- Applications accepted: July 1, 2014 - July 31, 2014
- Application approval or denial decision: Fall 2014
- Reconsideration review deadline: Fall 2014
TRAJECTORY OF PROGRAM

- 27 ACOs
  - 5 in Advance Payment Program
  - April 2012
- 89 ACOs
  - 15 in Advance Payment Program
  - October 2012
- 106 ACOs
  - 15 in Advance Payment Program
  - January 2013
- 123 ACOs
  - January 2014
- 32 ACOs in Pioneer ACO model when it began

CMS Innovation Center

LESSONS LEARNED

FORMATIONS, OPERATIONS AND COMPLIANCE

LEGAL ENTITY

- Form of legal entity – look to state law
  - Corporation
  - Partnership
  - Limited liability company
  - Foundation
LESSON: ACOs ARE NOT LIKE THE OTHERS
• ACO rules are a game changer for corporate and transactional principals
  • Governance
  • Tax exemption
  • Conflict of interest
• At the same time, remember your transaction basics:
  • Legal entity often is LLC, but look to state law Super majority powers
  • Voting rights, composition and quorum
  • Corporate practice of medicine may dictate structure

GOVERNANCE
• Governing bodies must have the following characteristics:
  • Oversight
  • Transparency
  • Fiduciary Duty
  • Conflict of Interest Policy
  • Composition and Control

GOVERNANCE
• ACO participants must have at least 75 percent control of the governing body
• ACO will remain provider-driven
• Medicare beneficiaries served by the ACO and representatives of entities that are not enrolled in Medicare constitute remaining 25 percent
  • Health plans
  • Investment companies
  • Others
LESSON: FOCUS ON GOVERNANCE SOONER THAN LATER

- Start with governance
- Ownership does not have to tie to governance rights
- Put thought into your Medicare Beneficiary
- You can use existing structures but governance is a good reason to start clean with a new entity
- Prepare for the first meeting of the governing body after your start date
- Set up a structure you can grow into

LEADERSHIP

- Manager
- Medical Director
- Compliance Officer

THE ROLE OF COMPLIANCE

- Compliance officer a required position for an ACO
  - Reports directly to governing body
  - Can be a lawyer but not the lawyer
  - May be a current compliance officer
  - Responsible for compliance plan (or program)
  - Certification requirements by leadership
LESSON: YOU HAVE CHOSEN WISELY

- Leadership is key to an ACO’s success and ACOs will need the attention of the leadership selected
- Leadership is often “contributed” or paid by contractual arrangement
- Must include a compliance officer that is not the attorney and a compliance plan
- Stepping away from cookie cutter approach is okay, but you need a plan that will be detailed in the application
- Rarely find employees in early adopter ACO, but some are moving in that direction

LESSON: COMPLIANCE

- Report suspected violations to law enforcement (part of policies)
  - Compliance Program (can leverage existing programs)
  - Compliance Policies and Procedures (NPP; access to PHI; patient complaints, retention/disposal of PHI/records; COI; licensure and verification; training/education; patient incentive waivers for in kind - preventive care/advance clinical goal, e.g., blood pressure monitor)
  - Monitor CMS claims to ensure opt-outs’ data not flowing?
  - FISMA Considerations

COMPLIANCE

- Compliance Training (Centralized? At Participant Level?)
- Code of Conduct
- Compliance officer
- Mechanism for reporting issues (Hotline?)
LESSON: ORGANIZATIONAL STRUCTURE

• Entity formation documents/amendments (own EIN, shared governance, distribute shared savings, etc.)
• State licensing (if necessary, e.g., risk bearing)
• Org charts with position descriptions/reporting (Background checks? Exclusion screening? COI?)

LESSON: ORGANIZATIONAL STRUCTURE

• Compliance Officer – independent; reporting relationship – direct access to the top; COI
• Patient/Consumer Advocate
• Network participation agreements
• Clinical/administrative systems to: promote evidence-based medicine and patient engagement; quality measures reporting; care coordination across continuum; patient-centeredness (e.g., individual care plans)
• Senior level medical director (board certified) – clinical oversight, part of ACO

LESSON: BENEFICIARY OPT OUT/DATA SHARING/MARKETING

• Initial opt out notice; subsequent notice at time of visit
• Signage and written notices to explain data sharing and opt out right
• All subject to CMS’ marketing requirements – approval process
• CMS approval process – guard against coercion, misleading information
• Marketing materials defined broadly – when in doubt, submit for CMS approval
• ACO information publicly available on its website (Update regularly)
• If provider leaves – need to opt out or get patient consent, even though still aligned
LESSON: ACO PARTICIPANTS AND PROVIDERS / SUPPLIERS

- Medicare provider/supplier bills under ACO participant TIN (i.e., physician in large group practice which practice is in ACO as participant)
- Agreements in place – mandate compliance with ACO program compliance, but ACO ultimately responsible – distribute copy of agreement
- TIN/NPI list – correct? Notify CMS within 30 days of changes?
- Notify providers/suppliers 30 days prior to submission?
- Process to ensure not on exclusion list
- Termination issues/process? (consider: must maintain 5,000 beneficiaries)
- Business plan for selection of new participants and/or providers/suppliers?

LESSON: ACO PARTICIPANTS AND PROVIDERS/SUPPLIERS

- Compliance with beneficiary notification? Marketing?
- Quality reporting – accurate? Timely? Meeting targets? Performance improvement plan?
- Follow care management policies and procedures of ACO? Local policies with ACO reporting/oversight?
- ACO EHR access – for data analytics, quality improvement

SHARING SAVINGS TRACKS

- Two Tracks (participants choose):
  - **Track 1**: ACOs achieving a specified minimum savings rate can share in up to 50 percent of savings based on quality performance, and there is no downside risk for the full three-year agreement period
  - **Track 2**: ACOs that achieve a specified minimum savings rate can share in up to 60 percent of savings, but this model includes downside risk. ACOs not meeting the minimum savings rate will share in losses (not exceeding 60 percent)
SHARING SAVINGS TRACKS

One-sided Model
- No downside risk
- Share in up to 50% of savings
- Performance payment limit of 10% of benchmark expenditures

Two-sided Model
- Downside risk
- Share in up to 60% of savings
- Performance payment limit of 15% of benchmark expenditures

SELECTING A TRACK

- **NOW:** Pick a track and either no downside risk or risk in later years of the agreement
- **FUTURE:** After three year agreement, ACOs likely to be required to go at risk

QUALITY

- Quality Assurance Program
  - Committee not required
  - Still physician led
  - Include method in application
  - Must meet the Quality Performance Standards to be eligible for shared savings program
  - Must completely and accurately report data on all program measures
  - Possible sanctions or termination for failure to comply
QUALITY

Year 1: pay-for-reporting
- Complete and accurate data reporting on all program measures

Year 2: mix
- 8 measures pay-for-reporting
- 25 measures pay-for-performance
- Except survey results

Year 3: pay-for-performance

LESSON: DON’T JUST GO WITH THE FLOW

- Quality can change throughout the program, but not each performance year
- New focus on high quality and population management
- You may want to select or incentivize other quality measures
- “Meaningful use” of EHR double counted quality measure not a requirement, but likely need one
- Quality committee not required, but still physician led

DATA COLLECTING, SHARING & REPORTING

- Data reporting to CMS
  - Financial data
  - Quality data (including patient/caregiver experience)
- Data from CMS
  - “De-identified” data
  - Identifiable beneficiary data
- Data sharing among ACO Participants
  - Quality driven based on incentives
  - Now setting their own clinical protocols and measures
LESSON: DATA IS KING, BUT HIPAA RULES

- Beneficiary opt out may affect data received
- HIPAA applies
- ACOs are likely business associates of ACO participants, rather than covered entities themselves
- If set up as a physician group or health system that is billing Medicare could be a covered entity
- The HIPAA rules changed and they affect your ACO
  - Downstream contractors as business associates
  - Breach reporting

REMEMBER YOU HAVE SEVERAL AGENCIES TO NAVIGATE

- CMS
  - ACO Final Rule – establishes program requirements
- CMS and OIG
  - Fraud and abuse interim final rule – 5 waivers
  - Waivers apply to the MSSP and ACOs participating in it
  - No waiver, even for MSSP participants, for analogous state fraud and abuse laws
- FTC and DOJ
  - Antitrust statement – movement onto the commercial market
- IRS
  - Tax exempt hospital and health care organization notice – 5 factor test but many still look to FMV for comfort

5 CMS AND OIG FRAUD AND ABUSE WAIVERS – LAWS WAIVED

- Stark Law (Physician self-referral)
- Federal Anti-Kickback Statute (criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business)
- Gainsharing CMP (prohibits hospital payments to physician to reduce/limit care to Medicare beneficiary under his/her direct care)
- Beneficiary Inducements CMP (prohibits inducements to Medicare beneficiary likely to influence choice of provider/practitioner/supplier)
- Need to post on website (redact economic terms)
**FIRST WAIVER: PRE-PARTICIPATION WAIVER**

- ACO or its participants/providers/suppliers can fund ACO development services for benefit of all (i.e., hospital or referring physician); must be able to unwind; protects outside parties
- Does NOT include agreements for funding with home health agencies, DME suppliers, drug or device manufacturers
- Governing body must approve – reasonably related to CMS program purposes (i.e., triple aim)
- Prepare documentation of waived relationships at time of transaction; retain for 10 years; make available to CMS upon request

**FIRST WAIVER: PRE-PARTICIPATION WAIVER**

- ACO must be likely to participate by next application date
- Use once; waiver applies to pre-participation period only
- Waiver of Stark, Anti-Kickback, Gainsharing CMP
- Examples: Funding for IT, legal/consulting, staff hiring, capital contributions

**SECOND WAIVER: PARTICIPATION WAIVER**

- Starts when agreement with CMS begins
- Protects all parties to the arrangement (must involve participant/providers/and/or suppliers; protects outside parties)
- Governing body approval – see pre-participation
- Document preparation – see pre-participation
- Generally ends when program participation ends
- Waiver of Stark, Anti-Kickback, Gainsharing CMP
THIRD WAIVER:  
STARK LAW WAIVER  
• Antikickback and Gainsharing CMP are waived for financial relationships among ACO/participants/providers and suppliers that implicate Stark Law  
• Eligible if in good standing under ACO program; financial relationship is reasonable related to the ACO program; and financial relationship complies with Stark Law DHS, ownership/investment or compensation exceptions  
• Generally ends when program participation ends

FOURTH WAIVER:  
SHARED SAVINGS DISTRIBUTION WAIVER  
• Protects shared savings distribution methods (EXCEPT: hospital distribution to physician knowingly made to reduce/limit medically necessary services/items HOWEVER protects incentives for alternative evidence-based care that is medically necessary)  
• No particular requirements must be met  
• No particular duration

FIFTH WAIVER:  
PATIENT INCENTIVE WAIVER  
• Waives Beneficiary inducements CMP and Kickback Law  
• Applies to free/reduced items or services to beneficiaries  
• Must be preventive care items or services or advance clinical goal (i.e., adherence to treatment/drug regime)
AUDIT CONSIDERATIONS

- CMS audit – review the slides on Final Rule requirements for general scope. Address gaps now
- Keep documentation (marketing materials, beneficiary forms, etc.)
- Update agreements as relationships change – maintain current documentation
- Ask for extension if needed – meet deadlines and communicate
- Project lead to ensure organized process – compliance/legal review suggested

TRANSFERRING SKILLS

TRANSFERRING THE ACO EXPERIENCE

- Commercial Payors
- Patient Center Medical Home (PCMH)
- State Programs
- Regulation of Provider Risk
COMMERCIAL PAYORS

- Some start with the MSSP ACO Program and move into commercial while others start with commercial
- Skill set can be transferred
  - Number crunching for cost savings
  - Population management and quality assurance
  - Leverage existing resources
  - Shifting care settings
  - Movement toward point of care solutions

COMMERCIAL PAYORS

- Fraud and abuse issues related to risk sharing, whether in the form of:
  - Incentives and bonuses
  - Capitation and taking on risk
- State insurance laws
  - Risk sharing laws
  - Managed care contracting requirements
- Driven by data
  - Look at HIPAA provisions although often allowed for “health care operations” and “payment” of the covered entity
  - Look for data provisions and who owns the data
TRANSFERABLE SKILLS TO COMMERCIAL MARKET

- Leveraging population health management across continuum – beyond PCMH and traditional insurer disease management programs; challenge: pay ACO PMPM to cover operations
- Quality metrics – leverage CMS and identify commercial metrics (not all CMS metrics are applicable)
- Low hanging fruit – easy to tackle – need long term, sustainable plan to manage population and get paid for services; policies and procedures to manage population – NCQA? Segment patient population by disease state?
- Physician compensation – new payment models to reward value (shared savings not long term solution)
- Data warehouses; predictive modeling; dashboards

LEGAL CONSIDERATIONS FOR COMMERCIAL ARRANGEMENTS

- Do not share pricing information among participants; joint contracting for risk arrangements with shared savings/loss vs. negotiating fee for service
- Read the commercial contracts – understand cost targets, trend, minimum risk corridor, minimum savings rate, upside/downside caps, etc. Engage outside experts for assistance
- No mandatory antitrust review under CMS program – keep on radar for commercial lines (focus on shared savings/loss contracts to mitigate)

QUESTIONS?

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