ACO Compliance Planning: Navigating the Briar Patch

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Erin Roberts, Partner, Smith Moore Leatherwood LLP
Barry Herrin, Partner, Smith Moore Leatherwood LLP
Greg Radinsky, VP, Chief Corporate Compliance Officer, Northwell Health

Disclaimer

- The materials and views expressed in this presentation are the views of the presenters and not necessarily the views of their organizations
Goals of the Presentation

• Keep you awake!
• Tips on ACO compliance implementation
• Discuss related ACO legal issues
• Answer your questions!

Accountable Care Organizations (ACOs)

• Why is it called an ACO?
• What is an ACO?
• Commercial ACO vs. Medicare ACO Model?
• What is the Medicare Shared Savings Program?
• Are ACO requirements different from similar government programs?
ACO Compliance Program

- No one size fits all
- Compliance coordination with ACO providers/suppliers
- Integration within a current compliance plan allowed
- Conduct a Compliance Gap Analysis/Assessment Early
- ACO maintains ultimate responsibility for ACO compliance

MSSP v. NYS SSL/Part 521 Compliance Program

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<th>MSSP – at least the following elements</th>
<th>NY SSL 363-d/Part 521</th>
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<tr>
<td>• Designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO’s governing body</td>
<td>• Written policies and procedures</td>
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<td>• Mechanisms for identifying and addressing compliance problems related to the ACO’s operations and performance</td>
<td>• Designated employed vested with the responsibility for the day-to-day operation of the compliance program</td>
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<td>• A method for employees or contractors of the ACO, the ACO participants, or the ACO providers/suppliers to reported suspected problems related to the ACO</td>
<td>• Training and education of all affected employees and persons associated with the provider</td>
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<td>• Compliance training for the ACO, the ACO participants, ACO providers/suppliers</td>
<td>• Communication lines to the responsible compliance position</td>
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<td>• Requirement for the ACO, its ACO participants, and other individuals or entities performing functions or services related to ACO activities to report probable violations of law to an appropriate law enforcement agency</td>
<td>• Disciplinary policies to encourage good faith participation in the compliance program</td>
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<td>• Regulation also requires periodic updates to reflect changes in law and regulations</td>
<td>• A system for routine identification of compliance risk areas specific to the provider type</td>
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<td>• A system for responding to compliance issues as they are raised</td>
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<td>• A policy of non-intimidation and non-retaliation for good faith participation in the compliance program</td>
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Potential Core ACO Compliance Policies/Plan

- General ACO Compliance Plan and/or Policy
- Code of Conduct
- Notice of Privacy Practices
- Conflicts of Interest
- Marketing Materials
- Patient Incentives
- Record Retention
- Reporting of Probable Violations of Law
- Prohibited Referrals /Ensuring Freedom of Choice
- Beneficiary Data Sharing Notification
- Data Access and Use
- Beneficiary Notification
- Exclusion Screening
- Compliance Training
- Compliance Risk Assessment and Work Plan
- Compliance Audit and Monitoring
- Responding to Government Audits, Inquiries and Investigations
- Investigations Process (including beneficiary and provider complaints)/Hotline
- ACO Management Compliance Committee Charter
- Disciplinary Policy/Guidelines

ACO False Claims Act Exposure

- False reports or certifications (e.g., quality, annual compliance and data certifications)
  - ACO certifying to the accuracy, completeness, and truthfulness of such information
  - Certification statement may state: “to the best of my knowledge or belief”
  - Incorrect information submitted during the performance year must be corrected before the recertification
- Violations of Stark law, Anti-Kickback statute, and Civil Monetary Penalties law
- Failure to return identified overpayments within 60 days
Select Compliance Considerations and Risks

- Conflicts of Interest
- Exclusion screening of ACO participants/providers/suppliers/contractors
- Avoidance of high-risk beneficiaries
- Record retention
- Beneficiary inducements
- Patient notification
- Marketing materials (avoidance of steering and inducements)
- Compliance with Data Use Agreement and HIPAA
- Updating of ACO website
- Limitation on beneficiary freedom of choice (e.g., beneficiary steering)
- Cherry picking (e.g., risk profile changes in assigned population)
- Antitrust (e.g., improper exchange of pricing or other sensitive data)

Prohibition on Certain Required Referrals and Cost Shifting

- Concerns over overutilization of services for Medicare or other federal health programs with respect to care of individuals who are not assigned to the ACO
- Prohibition of an ACO from conditioning participation in the ACO on referrals of non-ACO business
- Increased scrutiny of claims data to detect patterns of cost shifting, including patterns of shifting drug costs
- Prohibition on limiting or restricting referrals of beneficiaries to ACO participants/providers/suppliers within the same ACO, except in limited circumstances
  - Beneficiary retains freedom of choice
Avoidance of At-Risk Patients

• CMS will monitor the assignment of beneficiaries from the prior year to the current year.
• May result in oversight through a corrective action plan or termination

Patient Notification

• ACO participants to post signs in their facilities indicating participation in the Shared Savings Program
• ACO participants make available standardized written information developed by CMS to beneficiaries whom they serve
  – Required in setting in which beneficiaries are receiving primary care services
• Not required to notify beneficiaries in the event that it terminates participation in the MSSP
Beneficiary Inducements

- In general, the ACO prohibited from providing gifts, cash, or other remuneration as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO
- Flexibility to offer beneficiary inducements for healthy behavior
  - Must be a reasonable connection between the item or services and the medical care of the beneficiary
  - Covers free or below FMV items or services (not cash or cost sharing waivers)
    - Blood pressure cuff for a patient with a history of high blood pressure so that the patient can provide ongoing self-monitoring
  - The items or services are in-kind and either are preventative care items or services to advance one or more of the prescribed clinical goals

Marketing Materials

- Include those materials and activities used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program
- ACOs may use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all marketing requirements
- ACO must use template language where available
- Materials must be provided in “plain” language
- Materials may not be used in a discriminatory manner or for discriminatory purpose, and must not be inaccurate or misleading
- Applies to social media and websites
CMS ACO Audit

• Potential CMS ACO audits
  – Analysis of financial and quality measurement data reported by ACO
  – Site visits
  – Beneficiary and provider complaints
  – Claims analysis, chart reviews, beneficiary surveys, and coding audits

Documentation Check List

• Documentation of waiver compliance
• Organizational charts
• Background checks
• Compliance training
• Minutes and agendas of committee/leadership meetings
• Provider/supplier lists including removals
• Updated policies and procedures
• TIN/NPI lists
• Conflict of interest reviews and disclosure statements
Documentation Check List (cont.)

- Shared savings/loss distribution methodologies and changes
- Approved marketing materials/CMS submissions
- ACO website updates
- Copies of all provider/supplier agreements
- Root cause analysis to address identified compliance issues (CMS likes data!)
- Corrective action plans including disciplinary documentation
- Beneficiary forms and signs (e.g., data opt-out, beneficiary notification requirement)
- Evidence of a culture of compliance (e.g., posters, compliance week, email alerts)

Final Pre-Planning Tips

- Leverage existing efforts
- Involve Compliance early
- Developing a culture of compliance immediately
- Build a strong governance model
- Establish a certification trail
- Develop a robust annual work plan
- Launch effective marketing of compliance program
Compliance & Avoiding Waiver Pitfalls

- Waiver Compliance starts with Board Compliance
  - Imperative to the know the requirements of each waiver
  - Think in terms of “what are the purposes of the MSSP?”
  - Know the legal thresholds that may protect Board’s decision
  - DOCUMENT decision making
- MSSP waivers do not apply to commercial ACOs (more on this later)

Commercial ACO Issues

- Imperative to know applicable State insurance laws and incorporate critical language into Participation Agreement signed by all ACO Participants
  - Adherence to credentialing standards
  - Cooperation with payor grievance procedures
  - Verification of Member eligibility

- Common management and incentives are critical and important for harmonization across the ACO
Compliance with Governance Requirements

• The ACO must provide for meaningful participation in the composition and control of the ACO’s governing body for ACO participants or their designated representatives

• At least 75 percent control of the ACO’s governing body must be held by ACO participants

• Ensure addressed not only in the planning phase, but also when there is a change of control or member substitution

Compliance with Participation Requirements

• Beware of inappropriate purchases of interest in an ACO by organizations that are not qualified to serve as ACO participants

• The following are qualified participants:
  – ACO professionals in group practice arrangements.
  – Networks of individual practices of ACO professionals.
  – Partnerships or joint venture arrangements between hospitals and ACO professionals.
  – Hospitals employing ACO professionals.
  – Critical access hospitals.
  – Rural health Clinics.
  – Federally qualified health centers.
Commercial ACO Risks

- MSSP waivers do not apply to commercial ACOs

- Ensure Common Management and Measurement
  - Largely different populations
  - Different regulatory requirements
  - MSSP/Commercial Leakage - Avoid Playing Plans Against Each Other

- State insurance laws
  - Risk sharing
  - Managed care contracting requirements

Tax Exemption Issues

- March 2011 IRS Guidance for tax-exempt organizations participating in MSSP
  - A hospital or health system's participation in an ACO can generally be linked to the charitable purpose of "lessening the burdens of government."
  - Under this premise, the IRS has said participation in the MSSP should not result in unrelated business taxable income (UBTI) for tax-exempt organizations.
Tax Exemption Issues

• March 2011 IRS Guidance for tax-exempt organizations participating in MSSP
  — All transactions among participants must be fair market value and the tax-exempt organization's share of economic benefits from the ACO should be proportional to its contributions to the ACO.

Tax Exemption Issues

• Although the IRS has said MSSP participation can be interpreted as a charitable purpose, the agency did not provide examples of charitable and non-charitable activities.
  — Especially significant for ACOs negotiating with commercial payors.
  — The IRS is still seeking comment to further define this exemption, so what specific activities unrelated to MSSP are considered “charitable” remains unclear.
**Antitrust Issues**

- The FTC and the Antitrust Division of the Department of Justice established guidelines in October 2011 for both MSSP participants and commercial ACOs.
  - The guidelines established a safety zone for participants in the MSSP and indicated other ACO providers would be evaluated under the rule of reason.
  - The rule of reason evaluates whether the ACO's potential pro-competitive effects are likely to outweigh those anti-competitive effects.

**Antitrust Issues**

- The agencies also outlined anticompetitive concerns for ACOs that fall outside of the antitrust safety zone.
  - One of those concerns is if an ACO improperly shares competitively sensitive information.
  - This is problematic regardless of the ACO's primary service area or market power, as it can lead participants to price-fix or otherwise collude in their provision of healthcare services outside the ACO.
Antitrust Issues

- Four other circumstances likely to raise concerns of anticompetitive behavior relate to provider-payor relationships.
  - Preventing or discouraging private payors from incentivizing patients to choose certain providers, including providers not participating in the ACO.
  - Linking the sales of ACO services to the private payor's purchase of other services from providers outside the ACO. For example, an ACO should not require a payor to contract with all of the hospitals under the same system of the hospital participating in the ACO.
  - Contracting exclusively with ACO physicians, hospitals, ambulatory surgery centers and other providers to prevent those providers from contracting with payors outside the ACO.
  - Restricting a private payor's ability to share enrollees information on its health plan cost, quality, efficiency and performance to help enrollee choose providers – if that information is similar to the cost, quality, efficiency and performance measures used in MSSP.

Questions

Greg Radinsky, Vice President & Chief Corporate Compliance Officer
Northwell Health
(p) (516) 465-8327 (e) gradinsk@nshs.edu

Erin Roberts, Partner, Smith Moore Leatherwood LLP
(p) (919) 755-8793 (e) erin.roberts@smithmoorelaw.com

Barry Herrin, Partner, Smith Moore Leatherwood LLP
(p) (404) 962-1027 (e) barry.herrin@smithmoorelaw.com