Maintaining Effective Compliance Under the ACA’s Evolving Reimbursement Rules

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Topics to Discuss

1) Payment and Service Delivery Models

2) Federal Laws Involved

3) Tools and Techniques for Compliance
Categories of Innovation Models

• Accountable Care Organizations (ACOs)
• Episode-based Payment Initiatives
• Primary Care Transformation
• Initiatives Focused on the Medicaid and CHIP Population
• Initiatives Focused on the Medicare-Medicaid Enrollees
• Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models
• Initiatives to Speed the Adoption of Best Practices

Source: https://innovation.cms.gov/initiatives/index.html#views=models
ACOs
Overview of ACOs

An ACO is a group of doctors, hospitals, and other providers who join together voluntarily to give coordinated care to their Medicare patients, and who can share in the savings achieved as a result of their coordination.

- The Medicare Shared Savings Program rewards ACOs that lower their health care costs while meeting quality of care performance standards.
- ACOs split the shared savings that they generate with Medicare.
Overview of ACO Structure

ACO

Participants
(Based on TIN)

Providers/Suppliers
(All Providers under a Participant’s TIN)
ACO Payment Models

• Although Medicare will continue to offer a Fee-for-Service program for patients, there are two types of payment models available to the ACOs.
  – One-sided model
  – Two-sided model
• The main differences between these two types of models are the degree of risk involved and the potential savings available.
• The one-sided model may only be used by an ACO during its initial agreement period. (NOTE: 12/2014 proposed rule to renew one-sided model for second three-year period)

See Methodology for Determining Shared Savings and Losses under the Medicare Shared Savings Program issued by CMS in November 2012.
Hospital ACO Structure

- Hospital
- ACO
- ACO Participants (e.g., Contracted Physicians)
- Medicare

Key:
- Green arrows: Shared Savings
- Dashed arrows: Contractual Relationship
- Solid line: Equity Interest

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Independent Physician ACO Structure

- Physicians
- Third-Party Investors
- ACO
- ACO Participants (e.g., Physicians)
- Medicare

Key:
- Green arrows: Shared Savings
- Dotted green arrow: MSSP Agreement
- Black dashed arrow: Contractual Relationship
- Black line: Equity Interest

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Next Generation ACOs

• Greater access to home health, telehealth and skilled nursing facilities

• Opportunities for beneficiaries to receive benefits for receiving services from the ACO and certain affiliated providers

• A process to allow beneficiaries to confirm their relationship with an ACO provider

• Compensation for attainment as well as improvement
Next Gen ACO Payment Models

• Normal FFS Payment
• Normal FFS Payment + Infrastructure Payment
• Population-Based Payments
• Capitation
Federal Fraud and Abuse Laws

- Physician Self-Referral Law (Stark Law)
- Federal Anti-Kickback Statute (AKS)
- Civil Monetary Penalties Law (CMPL)
- Enacted to protect patients from fraud, improper referral payments, and unnecessary utilization.
- Certain ACO specific waivers regarding these laws were granted by CMS and OIG.
- No federal waivers for commercial ACOs.
- Antitrust Implications remain.
ACO Waivers

1) ACO pre-participation waiver
2) ACO participation waiver
3) A “shared savings distributions” waiver
4) Compliance with the Stark Law Waiver for the AKS and Gainsharing CMP
5) A “patient incentive” waiver
6) SNF 3-day Rule (Eff. 1/1/17, for Track 3 ACOs only)
7) Billing and payment for telehealth services (anticipated 1/1/17)
8) Homebound requirement for home health benefit (proposed)
9) Post-acute care settings (proposed)
OTHER INNOVATION MODELS
Other Innovation Models

• **Episode-based Payment Initiatives** - health care providers held accountable for the cost and quality of care provided during an episode of care, which usually begins with a triggering health care event (e.g., hospitalization) and extends for a limited period of time thereafter.

• **Primary Care Transformation** - Strengthening and increasing access to primary care providers, who are key contact for patient needs, is critical to promoting health and reducing overall health care costs. For example, utilize a team-based approach, while emphasizing prevention, health information technology, care coordination, and shared decision making among patients and their providers.

Source: https://innovation.cms.gov/initiatives/index.html#views=models
Other Innovation Models – cont’d

• **Initiatives Focused on the Medicaid and CHIP Population** - Medicaid and CHIP are administered by the states but are jointly funded by the federal government and states. Initiatives in this category are administered by the participating states.

• **Initiatives Focused on the Medicare-Medicaid Enrollees** – Medicare/Medicaid programs were designed with distinct purposes. Individuals enrolled in both programs (the “dual eligibles”) account for a disproportionate share of the programs’ expenditures. A fully integrated, person-centered system of care that ensures that all their needs are met could better serve this population in a high quality, cost effective manner.

Source: [https://innovation.cms.gov/initiatives/index.html#views=models](https://innovation.cms.gov/initiatives/index.html#views=models)
Other Innovation Models – cont’d

• **Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models** – CMS looks to partner with local communities and health care leaders from across the entire country to help accelerate the testing of innovations developed on the local level to improve the health care system.

• **Initiatives to Speed the Adoption of Best Practices** - The CMS Innovation Center is partnering with a broad range of health care providers, federal agencies professional societies and other experts and stakeholders to test new models for disseminating evidence-based best practices and significantly increasing the speed of adoption.

*Source: [https://innovation.cms.gov/initiatives/index.html#views=models](https://innovation.cms.gov/initiatives/index.html#views=models)*
FURTHER EXAMPLES OF MODELS
(CINs and Narrow Networks)
Clinically Integrate Networks (CINs)

FTC Guidance

• Mechanisms to monitor and control healthcare services that are designed to control costs and ensure quality

• Choose CI network physicians who are likely to further these efficiency objectives

• Investment of capital – monetary and human – in the necessary infrastructure to realize the claimed efficiencies
CINs

**Figure 1: Overview of Clinical Integration**

- Lab
- Billing
- Electronic Medical Record (EMR)

- Claims
- Care Management
- Provider Network

- Physician Office
- Health Plan
- Hospital
- Patient Location

- Integrated Health System (IHS)
- Radiology
- Pharmacy
- Telemedicine
- Remote Monitoring
- Personal Health Record (PHR)

*Considerations of Clinical Integration*, Truven Health Analytics (Dec. 2011)
Narrow Networks

- Lower cost insurance plan option but with fewer options for choice of providers
- Not new concept; similar to HMOs
- Significant increase since Affordable Care Act took effect (close to 45% of ACA exchange plans are narrow network plans)
Narrow Networks, cont’d

• Considerable public backlash and negative media attention

• Lawsuits and state laws attempting to regulate

• AMA policy to address inadequate insurance networks and protect patient choice
TOOLS & TECHNIQUES FOR COMPLIANCE
# Enforcement Players

- **U.S. Dep’t of Justice (DOJ)**
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch’
  - Healthcare fraud coordinators within 94 U.S. Attorneys’ Offices
  - FBI
  - DEA
- **Local District Attorneys**
- **Medicaid Fraud Control Units**
- **Centers for Medicare and Medicaid Services (and Medicaid Agencies)**
- **Tricare Management Authority**
- **Federal/State contractors**
- **Commercial payor special investigative units**
- **Licensing boards**
- **Whistleblowers**
Criminal Statutes

- False Claims, 18 U.S.C. § 287
- Conspiracy, 18 U.S.C. §§ 371 or 1349
- False Statements, 18 U.S.C. §§ 1001 and 1035
- Mail/Wire Fraud, 18 U.S.C. §§ 1341 and 1343
- Failure to maintain clinical records, 21 U.S.C. §§ 331(e) and 355(i)
- Health Care Fraud, 18 U.S.C. § 1347
- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)

* CMS may suspend payments and/or revoke from Medicare at same time based on “credible allegations of fraud”
AKS

- Criminal statute, 42 U.S.C. 1320a-7(b)(b)
  - Remuneration is anything of value
- Recommend or arrange for items/services under federal programs
  - Includes non-clinicians
  - State analogs may limit kickbacks in cash/private plans
- Greater compliance with safe harbor generally means less risk
  - HHS-OIG Advisory Opinions
  - Remember One Purpose Test
- Forms basis for civil liability
AKS Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations
- Waiver of Beneficiary Coinsurance and Deductible Amounts
- Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
- Price Reductions Offered to Health Plans

- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- Referral Arrangements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations
- Ambulance Replenishing
- Health Centers
- Electronic Prescribing Items and Services
- Electronic Health Records Items and Services
Remember the ACA

- Enacted March 23, 2010
- Amendments to Anti-Kickback statute
  - Rejects stringent definition of knowledge - No longer must prove intent to violate the “AKA”
  - Violations result in falsity under the False Claims Act (FCA)
  - FCA violations can occur even if claim was submitted by an “innocent” third-party
- Clarification of sentencing guidelines
  - Presumption intended loss is value of claim, not actual payment
Compliance Tips

1) Compliance officer and program oversight
2) Policies and procedures
3) Education
4) Audit
5) Corrective actions to identified problems
6) Open communications
7) Enforce violations
Compliance Tips, cont’d

“The Third Line”
Independent Compliance Oversight and Internal Audit will provide independent oversight and monitoring.

“The Second Line”
Compliance will provide compliance management, framework and policies.

“The First Line”
Management is accountable for identification of risks, internal controls, and compliance activities and monitoring in order to be compliant with laws and regulations.
Compliance Tips, cont’d

• Do you know what your organization’s compliance risk profile looks like?
• Do employees know their compliance responsibilities?
• Are they held accountable for them regardless of title?
• Are your compliance efforts satisfactory?
• Could you attest that they are?
• Could your board?
• Could your executive leadership team?
• Could operational management?
• Has the compliance program ever been assessed?
Compliance Tips – cont’d

• Listen and investigate when an employee, contractor, agent, or anyone tells you that there is a “problem” at the company.
  ▪ RemEDIATE the identified problem promptly.
  ▪ Consider self-disclosure, repayment strategies, and obligations.
Compliance Self-Assessment

1) Can personnel describe compliance program?
   - How about key executives?

2) Are historical audits and assessments available for inspection or comparison?
   - Are reviews done at regular intervals or only compliant-driven?

3) Do you trend high-risk areas and/or require corrective action?
   - Or does corrective action = evidence of wrongdoing?

4) Is the hotline used for more than HR issues?
   - Is there a log of all calls with document responses?
Compliance Self-Assessment, cont’d

1) Has the program evolved with the organization?
2) Is there a culture of responsibility and accountability?
   - Or are “some more equal than others”?
3) Is the compliance team free to raise concerns?
   - Or has the board asked who is the compliance officer?
4) Is there a commitment to compliance?
   - Or is the budget less than optimal and the team housed in an offsite sub-basement?
5) Can you convince the government of any of the foregoing?
   - Could be difference between repayment v. civil penalties v. criminal charges.
Questions and Answers

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