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Health Care Industry

Emerging Legal

Issues Webinar Series

Emerging Fraud and Abuse Risks for 2015

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The webinar will begin shortly, please stand by. The materials and a recording will be sent to you after the event.

Overview

- Emerging Business Strategies in the Health Care Marketplace
- Emerging Fraud and Abuse Issues
  - False Claims Act
  - Anti-Kickback Statute
  - Stark Law
  - CMS Program Integrity
- Resultant Trouble Spots and How to Protect Yourself

Emerging Business Strategies Implicating Unique Fraud and Abuse Risks

Payor/Provider Clients Are Creating New Ventures

- Payors acquiring providers
- Providers creating their own insurance products
- Providers integrating with other providers to form care continuums
- Blurred lines from a regulatory perspective: What are we and how does this new business work?

Emerging Business Strategies Implicating Unique Fraud and Abuse Risks (cont'd)

- Health care payment and health care delivery models are rapidly changing
  - Affordable Care Act Impact
  - Other New Payment Models
  - Health Care Exchanges and ACOs
  - Increased Transparency
  - Big Data

Emerging Business Impact on Fraud and Abuse Risks

- As payment incentives change, new incentives and new methods of potentially "cheating" government evolve
- Government focus and enforcement of fraud and abuse laws slowly adapts to changing health care environment
- In turn, providers and payors must "learn the laws" sometimes from unique perspectives
- Important to keep attuned to emerging trends

The False Claims Act: Three Emerging Risk Areas

- Quality of Care Provider Prosecutions ("Worthless Services") Cases
- Focus on Medicare Advantage and Part D Plans
- For Providers and Plans More Active, Aggressive, and Sophisticated Whistleblowers and Less Favorable Case Law

False Claims Act

Theory of Providing Sub-par "Quality of Care" As Basis for False Claim

- Claim for payment is false if services do not meet payor standards/expectations
- Incentive is reverse of providing "not medically necessary" care
- Increased enforcement ties into strong focus on quality and changing economic incentives
  - Reimbursement (value-based purchasing)
  - Focus on efficacy of treatments
- Coordinated care
  - Use of innovative care models to increase quality
  - Government focus crosses provider types
  - Includes individual providers, hospitals, SNFs

False Claims Act (cont'd)

- Examples of Sub-par "Quality of Care" False Claims Actions
  - *United States, ex rel. Absher v. Momence Meadows Nursing Center Inc.*
    - Jury verdict in favor of relator based on difference between amount of claims submitted and value of services provided
    - Seventh Circuit overturns: "Worth less is not worthless."
    - Concerned with excessive involvement of regulatory apparatus
    - Implication: the FCA is not the proper tool for policing regulatory compliance

False Claims Act (cont'd)

- Extendicare settlement
  - $38 million for conduct at 33 facilities
  - Staffing, medication errors, and pressure wounds cited
  - Also cited medically unnecessary therapy care
- Other settlements:
  - Wound care
  - Overuse of antipsychotics to "stabilize" SNF situation
- Beyond FCA risk, note also 42 U.S.C. § 1320a-7a(b)

False Claims Act (cont'd)

- What can you do?
  - Avoid financial incentives that could encourage "under treating" or "sub-quality" care
  - Emphasize quality of care in compliance plans
  - Make sure that quality measures are a focus of protocols auditing and monitoring activities
  - Include measures to affirmatively improve quality, not just prevent errors

Emerging Payors, Plans, MCO False Claims Risk Areas

- Recent emergence of new economic incentives and government contract opportunities has raised level of FCA risk
- Any false claim, record, or statement resulting in the receipt of federal funds can expose a health plan to FCA liability. Records or data on which claims are based clearly within scope of FCA.
- **Examples of risk areas:**
  - Certification of community rate or, starting in 2013, accuracy of MLR data submission
  - Plan rate bid certs
  - Timeliness of claims payments, notices of claim denials, reconsiderations, and appeals, marketing, enrollment/disenrollment, under utilization, accessibility of services

Payors, Plans, MCO Risk Areas

- **Examples of Risk Areas (continued)**
  - False data or certifications regarding encounter data, quality-of-care review, enrollee health status reports, or data required to be submitted to the government
  - Red-lining (e.g., improperly discourage enrollment by persons deemed to be "sicker" or at higher risk for serious illness to decrease risk and enhance revenue; and failure to provide appropriate level of services)
  - In operating/overseeing provider network, failure to properly monitor for fraud
- **What to Do**
  - Recognize broad sweep of FCA to underlying documents and data
  - Be wary of incentives and ways to "game" system and shut down opportunities
  - Establish proper procedures, audit protocols, etc. to assure accuracy

False Claims Act – Whistleblowers Abound

Continued Emergence of an Aggressive, Knowledgeable Relator's Bar

- Extremely active in the health care space
- DOJ has indicated that it will increasingly rely on relator's bar to prosecute cases — fewer interventions, but no diminution in returns
  - Did not intervene in *Absher*
  - Other high-profile cases

False Claims Act – Whistleblowers Abound (cont'd)

- Relators sometimes more difficult to deal with than the government
- Case law not helping – e.g., recent Pennsylvania case permitting relator to bring claims for post-employment period

What to Do:

- Compliance and responsiveness to complaints
- In qui tam litigation, early aggressive defenses and efforts to disengage relator and government
- Be alert to possible overpayments and repay.

Anti-Kickback Statute (AKS)

- In a Risk-based World, Adjustments to AKS are Representative of New Health Care Economy
- Emerging Risks Related to New Provider Payment Models
- Continued Emphasis on Enforcement Against Individuals

Anti-Kickback Statute (AKS)

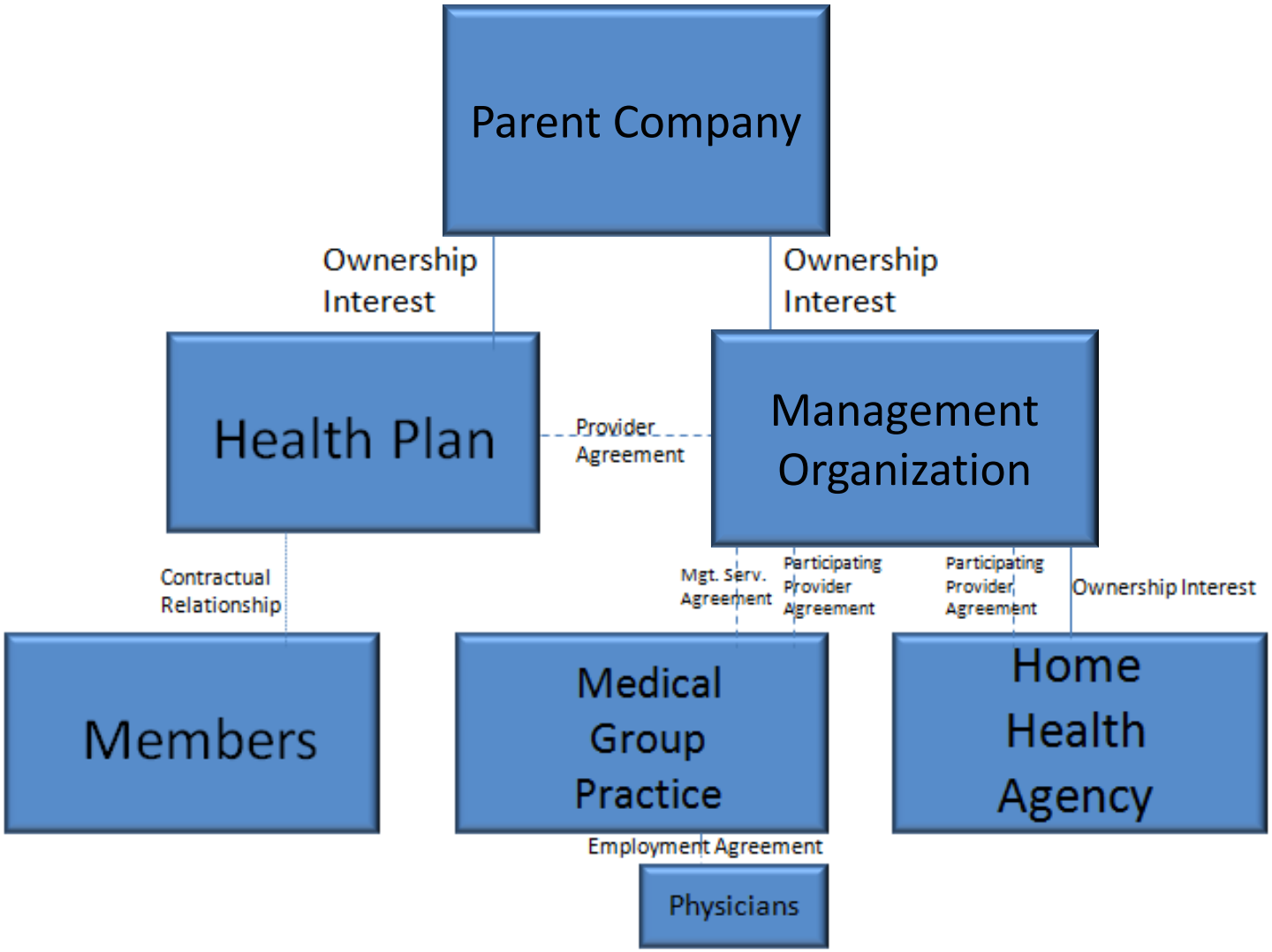
Adjustments to AKS in New World

- New Proposed Safe Harbors
  - For Beneficiaries
    - Copayment waivers
    - Certain ambulance services
    - First fill of a generic drug (MA and Part D plans)
  - Free or discounted transportation
- Revision of Definition of "Remuneration" Under CMP Statute
  - Excludes items that promote access and present a low risk of harm
  - Protects rewards programs (i.e., coupon programs)
  - Allows for providing certain items to patients in financial need

How Common Business Arrangements May Implicate Fraud and Abuse Laws

- For plans/providers
  - Managed care safe harbor protects traditional plan-provider arrangements, e.g., provider discounts, risk sharing arrangements
- Some provider relationships create unique kickback-type issues:
  - Referrals to or from owned-providers
  - "Swapping" opportunities to maximize revenue (e.g., fee for service revenue from sicker patients and MA revenue associated with healthier patients)
  - Upstream provider income to related party
  - Incentives to over/under-utilize health care services
  - Beneficiary inducements
  - Risks in complex arrangements

Complex Arrangement Example



Anti-Kickback Statute

- Heightened focus on prosecuting individual actors within corporate structure (Directors, CEOs, CFOs, etc.)
- Government philosophy
  - New ACA exclusion authorities allow for increased focus on managing employees
  - No change in culture if upper echelons of management not pursued
  - Corporate owners and managers are focus of Corporate Integrity Agreements as well
  - Examples:
    - Hollywood Pavilion: CEO and 4 high-ranking employees sentenced
    - Premier Hospice and Palliative Care—former owners liable after new owner self-disclosed company's prior fraud

Stark Law Enforcement Trends

- If Waivers Missed, New Payment and Payor Models Present Hidden Stark Issues
- Partial Integration
- Group Practice/IOAS
- Exception Preservation
- Creation of Financial/Referral Relationships Impacting Stark

Stark Law (cont'd)

Helpful Trend: Innovative Payment Provider Models May Avoid Stark Completely

- Waivers
  - Extension of waivers of fraud and abuse laws to ACOs
  - Application of fraud and abuse waivers to other programs (Bundled Payment)
  - "Partially Integrated" Systems at Most Risk
  - Consolidations may disrupt existing Stark exceptions

Stark Law (cont'd)

- "Volume and Value of Referrals" Issues
- Compensation to Physicians Based on "Volume or Value of Referrals" Will Trigger Stark Problems
- Makes Little Sense in Managed Care Models Government (DOJ) Takes Strict View of What V/V of Referrals means
  - Tuomey
  - Halifax
  - Citizen's Medical Center
  - King's Daughters

Stark Law (cont'd)

- Moving in on Medicaid
  - *U.S. ex rel Baklid-Kunz v. Halifax Medical Center*
  - *U.S. ex rel Schubert v. All Children's Health System, Inc. et al.*

Medicaid.gov
Keeping America Healthy

Stark Law (cont'd)

- What to do?
  - Stark Law violations can lead to FCA violations
  - All new relationships must be analyzed for Stark and state law self-referral purposes
    - All compensation relationships with physicians
    - All equity relationships with physicians
    - All referral relationships with physicians
    - Draw the boxes and the flow charts
  - Strive to meet waivers and/or exceptions
  - Legal opinions helpful

CMS Program Integrity Priorities

60-day Overpayment Rule

- Overpayment rule will work hand-in-hand with FCA "reverse false claims" prohibition
- Along with the FCA, ACA provides a 60-day deadline for **reporting and returning** overpayments
- The deadline is the later of:
  - (A) the date which is 60 days after the date on which the overpayment was identified
    OR
  - (B) the date any corresponding cost report is due, if applicable
- Effective for overpayments "identified" as of the March 23, 2010 PPACA enactment date

CMS Program Integrity

60-day Overpayment Rules

- Proposed rule issued in 2012
  - Defined when an overpayment had been "identified"
  - Established 10-year look-back period
- February 2015: No Final Rule This Year
  - Requirement still effective
  - Courts are examining when an overpayment has been "identified"
- Medicare Advantage and Part D
  - Rules finalized in June 2014
  - 6-year lookback
  - Overpayment exists when after "applicable reconciliation," the plan retains funds to which it is not entitled

CMS Program Integrity (cont'd)

60-day Overpayment Rule Under the FCA

- Courts are reviewing the statutory requirement
  - *United States v. Continuum Health Partners, Inc. et al.*
  - *State of New York, ex rel. Robert P. Kane v. Healthfirst, Inc. et al.*

CMS Program Integrity (cont'd)

- What should you do?
  - Conduct a careful, well-documented investigation of all steps of the investigation
    - Develop plan for investigation at outset
    - Document progress of plan, noting completion of identified steps
  - Promptly return any identified overpayment
    - Through MACs where possible
    - If necessary, through self-disclosure protocols
  - Review audit policies
    - Failure to look back sufficiently where an overpayment has been prospectively identified could lead to liability
    - Ensure efficiency is emphasized

CMS Program Integrity (cont'd)

- New Enrollment Criteria
  - Denial of enrollment for unpaid Medicare debt
  - Link provider status to felony conviction for managing employee
  - Allow revocation of enrollment for a "pattern or practice" of improper billing
  - Eliminate enrollment retroactivity for certain provider/supplier types

The Year Ahead

- Increased Enforcement Risks
  - Government and Whistle Blowers
- Transparency and new reporting obligations will encourage enforcement actions
- Will Congress give enforcement agencies more or different tools to reflect changing health care landscape?
  - Grassley hearings

Final Takeaway

- In all new business relationships, careful assessment of all financial and referral relationships for fraud and abuse risk
- Accuracy of Reporting and Underlying Records and Data
- Quality of Care Cannot be Sacrificed for Efficiency
- Protect Your Directors (and yourselves), etc., with Strong Education/Training
- Compliance
  - Strong plan
  - Thorough implementation

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Health Care Industry Emerging Legal Issues Webinar Series

- *Antitrust Issues Facing the Health Care Industry:* May 13 - Katie Funk, Art Lerner
- *Advertising and Marketing Issues in the Health Care Industry:* September 29 - Chris Cole, David Ervin
- *How to Survive a Subpoena/CID:* November 17 - John Brennan, David O'Brien