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

Parent Company

Ownership Interest

Health Plan

Contractual Relationship

Members

Medical Group Practice

Employment Agreement

Physicians

Management Organization

Ownership Interest

Participating Provider Agreement

Participating Provider Agreement

Home Health Agency

Ownership Interest
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.*
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.*
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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