BLUE CROSS BLUE SHIELD WEBINAR

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What Payors Need to Know About False Claims Act Liability

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False Claims Act

- 31 USC § 3719, the False Claims Act ("FCA" sets forth seven bases for liability. The most common ones are:

    1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment

    2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid

False Claims Act (cont'd.)

3. Conspiring to commit a violation of the False Claims Act
4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government

- Obligation defined as an established duty, whether or not fixed, arising… from retention of any overpayment

Elements of an FCA Offense

- The Defendant must:
  - Submit a claim or fail to return an overpayment (or cause it to be submitted)
  - To the "Government" or a Contractor
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal treasury
  - Damages (maybe)

Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - Had “actual knowledge of the information”; or
  - Person acted in “deliberate ignorance” of the truth or falsity of the information; or
  - Person acted in “reckless disregard” of the truth or falsity of the information

Penalties

- Civil penalty from $5,500 to $11,500 per false claim
- Three times the amount of damages which the Government sustained

Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claim Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- Relationship between Relator and Government
  - Collaborators in recovery of money

Department of Justice Investigative Guidelines

- Were false claims submitted by a provider with knowledge of their falsity?
  - Was there actual or constructive notice of the rule or policy on which a potential case would be based?
  - Was the rule or policy clear?
  - Does the size of the false claim support inference of knowledge or inference of mistake?
  - What plans did the provider make to adhere to the rules?
  - Are there any past remedial efforts?
  - Did the provider receive guidance by program agents on the issue?
  - Have there been previous audits to the provider of same or similar billing errors?

Types of FCA Cases

- Unbundling (billing single service as if one service)
- Services not rendered
- Billing for items or services that are not covered
- Upcoding
- Duplicate billing
- Submitting false or inflated cost reports

Types of FCA Cases (cont'd.)

- Quality of care ("standard of care claims" or "worthless claims")
- Research grant and clinical trial fraud
- Actions under the Food, Drug & Cosmetic Act
  - Misbranding and adulteration of drugs and promotion of off-label use
- False Claims Act cases based on violations of the Stark Law and/or the Anti-Kickback Statute ("Tainted Claims")

Health Care Reform (i.e. Affordable Care Act) and False claims Act Amendments

- Liability for overpayments and failure to return a known overpayment within 60 days from identification-return of known overpayment an affirmative and express obligation
- Claims for payment from government contractors, grantees or other recipients if money is spent on government's behalf or to advance a government program or interest
- Materiality requirement for False Claims Act liability
- A violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act

Health Care Reform and False Claims Act Amendments (cont'd.)

- Public disclosure ban no longer jurisdictional and does not require dismissal of a case if the government opposes dismissal
- State proceedings and private litigation do not qualify as public disclosure, but Federal proceedings and news media reports do qualify for public disclosure
- Original source no longer requires "direct and independent knowledge", but only independent of previously publicly disclosed information that materially adds to publicly disclosed information

FCA Statistics

- If the government intervenes and obtains recovery, the Relator can receive between 15% and 30% of the proceeds
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 25% (approximately 300-400 cases)
- Approximately $18.5 billion in health care FCA recoveries since 1986, with annual average recoveries of $1.9 billion
- Recoveries have increased (higher penalties and publicity) and FY 2010 was over $3 billion.
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action

Application of Fraud and Abuse Laws to Private Exchange Insurers

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse
- Federal payments to private insurance exchanges subject to False Claims Act

Anti-Kickback Statute

- Felony to knowingly and willfully offer, pay, solicit, or receive anything of value in return for a referral, or to induce generation of business reimbursable under a Federal health care program [42 U.S.C. § 1320a-7b(b)].
- No actual knowledge or specific intent to commit a violation of AKS in order to violate the law [Affordable Care Act § 6402(f)].

Anti-Kickback Statute (cont'd)

- Violation occurs when the person meets the mental state and engages in the conduct, not necessarily when they know they are violating the AKS.
- Certain statutory exceptions may apply [42 U.S.C. § 1320a-7b(b)(3)], or the matter may fit an applicable safe harbor [42 C.F.R. § 1001.952].

The Anti-Kickback Statute

- What it all means? – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program

- 42 states and D.C. have enacted their own anti-kickback statutes

Elements

- Remuneration
- Offered, paid, solicited, or received
- Knowingly and willfully
- To induce or in exchange for Federal program referrals

Remuneration

- Anything of value
- “In-cash or in-kind”
- Paid directly or indirectly
- Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations

To Induce Federal Program Referrals

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test and culpability can be established without a showing of specific intent to violate the statutory prohibitions

Fines and Penalties

- The Government may elect to proceed:

Criminally:

- Felony, imprisonment up to 5 years and a fine up to $25,000 or both
- Mandatory exclusion from participating in Federal health care programs
- Brought by the DOJ

Civilly:

- A violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the Civil False Claims Act
- Penalties are same as under False Claims Act (more later)
- Controversial, yet expanding use of the FCA

Fines and Penalties (cont'd.)

Administratively:

- Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved
- Discretionary exclusion from participating in Federal health care programs
- Brought by the OIG

Exceptions and Safe Harbors

- Many harmless business arrangements may be subject to the statute
- Approximately 24 exceptions ("Safe Harbors") have been created by the OIG
- Compliance is voluntary
- Must meet all conditions to qualify for Safe Harbor protection
- Is substantial compliance enough?

Guidance on the Anti-Kickback Statute

- Advisory Opinions from the OIG
  - A party may request advice on the law, concerning (1) remuneration within the meaning of the law, (2) whether they are meeting one of the law's exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - Advisory Opinions on numerous arrangements which involve the Anti-kickback Statute.

Guidance on the Anti-Kickback Statute (cont'd.)

- Fraud Alerts and Special Advisory Bulletins
- Preamble to the Safe Harbor Regulations
- Compliance Program Guidance's
- **www.oig.hhs.gov**

Physician Self-Referral ("Stark") Law

- Prohibits certain physician self-referrals:
  - physician requests for an item or service
  - establishing a plan of care that involves furnishing designated health services

    [42 U.S.C. § 1395nn; 42 C.F.R. § 411.350 et seq.].
- General exceptions:
  - ownership interests [42 U.S.C. § 1395nn(c)] and/or compensation arrangements [42 U.S.C. § 1395nn (e)].

The Stark Law

- A prohibition on physician self-referrals
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception

Penalties

- Nonpayment of claims to entity submitting claims
- Civil Money Penalties of $15,000 for each service rendered plus an assessment of three time the amount claims
- Penalty of up to $100,000 for “circumvention scheme”
- FCA liability for submission of false claims resulting from Stark prohibited referral.

Difference Between Anti-Kickback Statute and the Stark Law

- Physician referrals only
- No "knowingly and willfully standard" – strict liability
- Involves Designated Health Services ("DHS")

Types of Designated Health Care Service ("DHS")

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology and Imaging Services (MRI, CAT, scan, ultrasound)
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

What is a Financial Relationship?

- Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will quality as a financial arrangement under the Stark law

  Examples:

  - Stock ownership
  - Partnership interest
  - Rental contract
  - Personal service contract
  - Salary
- Compensation agreements can be direct or indirect
  - Exceptions for certain indirect compensation arrangements

Exceptions

- **C**ompliance is mandatory
- Types of exceptions:
  - In-office ancillary services
  - Personal physician services by member of group practice
  - Pre-paid health plan
  - Certain publicly traded securities
  - Rural provider (investment interests)
  - Hospital ownership (must be in the “whole” and not “specialty” hospital)
  - Rental of office space and equipment
  - Bona fide employment
  - Personal services arrangement
  - Physician recruitment

MANAGED CARE COMPLIANCE AND ENFORCEMENT: INDUSTRY TRENDS & KEY TOPICS

Health Reform Trends: The Affordable Care Act

- Insurance exchanges
  - State exchanges
  - Federal exchange
- Medical Loss Ratio (MLR) requirements
  - New formula for calculating MLR
  - Varying MLR requirements depending on plan type (e.g. 85% for Medicare Advantage Plans)
- Fraud and abuse provisions
  - Identified Medicare/Medicaid overpayments not repaid within 60-days are "obligations" for purposes of the False Claims Act
  - Lower intent standard necessary to prove a violation of the Anti-Kickback Statute (mere consciousness that conduct was "wrongful" or "unlawful"

Health Reform Trends: The Affordable Care Act (cont'd.)

- Accountable Care Organizations (ACOs)
  - ACOs promoted as part of Medicare shared savings program
  - FTC and DOJ policy statement create "safety zone" for experimentation with new ACOs
- Medicaid Funding
  - Starting in 2014, in states that choose to implement the ACA's expansion, individuals under 65 with income below 133% of the federal poverty level will be eligible for Medicaid
  - ACA increases the Medicaid payments for primary care doctors in fee-for-service and managed care plans

Compliance Trends: Medicare Managed Care Manual

Seven elements of an Effective Compliance Program

1. Written policies, procedures and standards of conduct
2. Compliance Officer, Compliance Committee and High Level Oversight
3. Effective training and education
4. Effective lines of communication
5. Well-publicized disciplinary standards
6. Effective system for routine monitoring, auditing and identification of compliance risks
7. Procedures and system for prompt response to compliance issues

Compliance Trends: Medicare Managed Care Manual (cont'd.)

Compliance Program Minimum Standards

- "Sponsors must establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements"

Special Investigation Units

- "An effective program to control [Fraud, Waste and Abuse (FWA)] includes policies and procedures to identify and address FWA at both the sponsor and downstream or related entity levels in the delivery of Parts C and D benefits"

Compliance Trends: Look to Your Certifications

Medicare Advantage Annual Attestation (42 C.F.R. § 422.504(1))

- MA organization must certify that risk adjustment data is accurate, complete and truthful (based on best knowledge, information and belief)

New York State Model Managed Care Contract

- "Covered services provided by the Contractor under this Contract shall comply with all standards of the New York State Medicaid Plan established pursuant to Section 363-a of the State Social Services Law and satisfy all other applicable requirements of State Social Services and Public Health Law"

Enforcement Trends: Recent Cases

- **WellCare**
  - A civil and criminal investigation into alleged overbilling of Medicare and Medicaid by WellCare, a Medicaid managed care plan
  - In April 2012, Wellcare agreed to pay $137.5M to the U.S. and nine states to settle FCA allegations.
  - Four executives convicted in May 2013.
- **Janke**
  - Allegations that the defendants submitted codes for MA reimbursement that were not supported and failed to look for erroneous diagnoses or delete codes upon learning that they were inaccurate
  - $22.6M settlement in November 2010

Enforcement Trends: Recent Cases (cont'd.)

- **SCAN**
  - Qui tam relator alleged that SCAN inflated risk scores to increase its Medicare premiums
  - $320M settlement in August 2012 (with $4M related to MA allegations)
- **UnitedHealth**
  - *Qui tam* case involving alleged violations of AKS and MA marketing regulations
  - DOJ declined to intervene and the case was dismissed after the parties reached a settlement agreement in principle

Enforcement Trends: Duty to Investigate Providers

- **CMS Medicare Managed Care Manual**
  - "Sponsors are required to investigate potential FWA [Fraud, Waste, Abuse] activity to make a determination whether potential FWA has occurred.
  - Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered."
- **Texas, 1 T.A.C. §§ 353.501 – 353.505**
  - Each managed care organization (MCO) subject to this section must develop a plan to prevent and reduce waste, abuse, and fraud Commission (HHSC),Office of Inspector General (OIG) for approval.
  - The MCO is responsible for investigating possible acts of waste, abuse, or fraud for all services, including those that the MCO subcontracts to outside entities.

Topic No. 1: RISK ADJUSTMENT

Risk Adjustment: Background

- Risk adjustment is based on demographic factors and health risk
- For purposes of the MA program, diagnoses submitted for payment must be documented in a medical record that was based on a face-to-face encounter between a patient and a healthcare provider
- RADV Audits
- Fee-For-Service Adjuster
- Other RADV audit protocol changes
- Beyond the MA program: The ACA expands risk adjustment to the commercial insurance market
- State Medicaid managed care programs.

Risk Adjustment: Discussion Topics

- **Relationships with Providers**
  - Compensation
  - Health plan reports to providers
  - Education & training
  - Quality of care
- **Encounter Processing**
  - Health plan processing systems
  - Filtering
  - Deletions
- **Retrospective Chart Reviews**
  - Chart selection
  - Scope of review
  - Coding standards

Topic No. 2: Kickbacks

Kickbacks: Discussion Topics

- **Provider Contracting**
  - Anti-kickback safe harbor
  - Fair market value
  - Exclusivity
  - Other payments
- **Marketing Efforts**
  - Co-marketing
  - Provider involvement in enrollment

TOPIC NO. 3: MEDICAL LOSS RATIO

Medical Loss Ration: Background

ACA MLR=

Medical care claims + Quality improvement expenses

Premiums - Federal and state taxes, licensing, and regulatory fees

- **The Affordable Care Act**
  - Beginning in 2014, MA plans that fail to meet the minimum MLR of 85% will be required to remit partial payments to the Secretary of Health and Human Services.
  - If the MLR is less than 85% for three consecutive years, the Secretary will suspend plan enrollment for two years; and if the medical loss ratio is less than 85% for five consecutive years, the Secretary will terminate the plan contract.
  - Quality improvement expenses, include: Activities that, for example, improve (i) patient outcomes, safety, or wellness, or (ii) quality, transparency, or outcomes through enhanced health information technology. Excluded expenses would include: administrative expenses, such as insurance broker and agent compensation or fraud prevention activities.

Medical Loss Ration: Discussion Topics

- **Classifying Expenses**
  - Quality improvement expenses vs. Administrative expenses
  - Anti-fraud efforts
- **Recent Allegations**
  - *MRI Scan Center, LLC v. Nat'l Imaging Assocs., Inc.*: January 2013 complaint alleging that CIGNA and an imaging service manipulated Explanations of Benefits and Remittance Advices so that CIGNA could report a MLR which allowed it to avoid paying rebates

Medical Loss Ration: Discussion Topics (cont'd.)

- ***Wellcare*: Analogous Prosecutions?**
  - Wellcare's financial reporting to Florida Medicaid program allegedly concealed violations of the state's 80/20 rule (requiring 80% of premiums to be paid out to health care providers)
  - Several *qui tam* actions were filed resulting in a $137.5 million FCA settlement
  - Four former WellCare executives accused of defrauding the Medicaid program of more than $30 million were convicted after a jury trial in May of this year.

Examples of Risk Areas for Health Plans

- Contractual arrangements that involve government funds
  - Federal Employee Health Benefits program
  - Medicare Advantage plan
  - Medicare Part D plan
  - Medicaid managed care programs
- Areas of Vulnerability
  - Pricing – "non-interference clause"
  - PDP / Sponsor
  - PBM
  - Beneficiary

Examples of Risk Areas for Health Plans (cont'd.)

- Plan operations
  - Anti-Kickback and Sales and Marketing
  - Bait and Switch (Medicaid)
  - TrOOP Manipulation
  - Claim handling (payment accuracy, processing timeliness, correspondence, denials and appeals/grievances)
  - Complaint handling
  - Enrollment/disenrollment
  - SIU/Anti-Fraud
  - Oversight of downstream entities
  - Retention of known overpayments.

Examples of Risk Areas for Health Plans (cont'd.)

- Certifications / Reporting
  - Community rate certification (FEHB)
  - Bid certification (MA)
  - Reporting of member encounter data and health status data
  - Medical loss ratios calculations and premium rebating
  - Other data submission and certifications to the government.

Compliance Tips

- Inventory your plan's potential triggers of FCA exposure and the personnel/department involved
- Develop and deliver training on expanded FCA liability and potential triggers
- Ensure employees and third parties are aware of the health plan's expectation of ethical conduct and obligation to report concerns and issues
- Establish processes to prevent, identify, monitor and resolve overpayments due to federal and state programs

Compliance Tips (cont'd.)

- Reinforce knowledge of ethics hotline and protections to employees and third parties
- Investigate concerns reported to the compliance function and ethics hotline by employees and third parties
- Update the executive compliance committee and board of directors on the plan's identification of FCA risk areas and risk mitigation steps
- Follow publicized enforcement activity involving health plans; incorporate into compliance program functions as appropriate.

Internal Investigation Considerations

- Treat reported concerns seriously, investigate appropriately and keep C-suite informed (i.e., in-house counsel)
- Retain outside advisors as needed to facilitate the investigations, exposure quantification and possible disclosure
- Take appropriate corrective action – processes as well as personnel
- Don't be surprised if your independent auditor gets involved, especially if the allegations relate to senior management.
- Be prepared for Voluntary Disclosure (Ex. OIG Self-Disclosure Protocol).

THE END

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