Mastering the Legal, Regulatory and Compliance Issues Associated with Laboratory Developed Tests

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- **Compliance Fundamentals**
- **Basic Fraud and Abuse Principles**
- **Lab-Specific Issues**
- **The June 25, 2014 OIG Special Fraud Alert and Subsequent Fallout**

- **Compliance Fundamentals**

Elements of an Effective Compliance Plan

OIG's Compliance Guidance lists seven elements of an effective compliance plan:

1) implementing written policies and procedures;
2) designating a compliance officer and compliance committee;
3) conducting effective training and education;
4) developing effective lines of communication;
5) conducting internal monitoring and auditing;
6) enforcing standards through well-publicized disciplinary guidelines; and
7) responding promptly to detected problems and undertaking corrective action.

- **Basic Fraud and Abuse Principles**

Fraud, Abuse, Kickbacks and Related Issues

- Anti-kickback statutes
- False Claims Act
- Stark Law
- Exclusion sanctions

Federal Anti-Kickback Statute

- The federal anti-kickback statute (AKS) makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursed by federal health care programs.
  - Payments, credits or other forms of remuneration provided to Medicare/Medicaid beneficiaries can implicate the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).
  - However, if no federal programs currently reimburse the test and you do not believe that any federal programs will pay for the test for an extended period of time, then the federal anti-kickback statute is probably not applicable to the test.

Federal Anti-Kickback Statute (cont.)

- Remuneration includes anything of value and can take many forms besides cash, such as over payment for services, free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.
- The statute covers the payers of kickbacks—those who offer or pay remuneration— as well as the recipients of kickbacks—those who solicit or receive remuneration. Each party's intent is a key element of their liability under the AKS.
- Generally, the difficulty in determining potential liability lies in distinguishing between remuneration intended to induce referrals and remuneration paid to the referral source in return for legitimate services and in appropriate amounts

Federal Anti-Kickback Statute (cont.)

- Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution.
  - To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements.
  - Safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to *bona fide* employees.

Violations of the Federal False Claims Act

- Courts allow both persons and states to bring civil lawsuits under the False Claims Act (FCA) based on alleged violation of the AKS.
- These are known as “Qui Tam” or “Whistleblower” cases
- A claim made pursuant to a kickback can itself be a false claim.

AKS and False Claims

- The case law in this regard was mixed, with some courts holding that there was an "implied certification" in some situations where participating in a program like Medicaid impliedly certified compliance with all laws, including the AKS.
  - A violation of the AKS would then result in a false statement that the hospital was complying with all laws, causing a potential violation of the FCA. Other courts rejected this idea.

Stark: What Is It and What Services Are Covered By It?

Stark prohibits certain physician referrals to entities they have an interest in:

- ***Clinical laboratories***
- Physical therapy
- Occupational therapy
- Certain radiology services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parental and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Federal Exclusion Statute

- OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances.
- OIG has discretion to exclude individuals and entities on several other grounds:
  - misdemeanor convictions related to health care fraud;
  - suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity;
  - provision of unnecessary or substandard services;
  - submission of false or fraudulent claims to a Federal health care program;
  - engaging in unlawful kickback arrangements; and
  - defaulting on health education loan or scholarship obligations.

- **Lab-Specific Issues**

Common Issues of Concern

- Lab investigations have been fairly common going back to the 1990s and initial OIG Guidance from 1998.
- OIG/DOJ investigations have looked at a variety of issues, not limited to sales:
  - Seeking reimbursement for tests not performed,
  - Tests performed but not ordered,
  - Tests ordered by a non-authorized individual
  - Payments to physicians for referrals
  - Physician markup
  - Inaccurate/inappropriate selection and reporting of diagnosis and procedure codes

A Classic Lab Fraud Example

Former Owner Of Wilkesboro Clinical Laboratory Pleads Guilty To Criminal Health Care Fraud And Tax Charges And Agrees To Pay $300,000 To Settle Civil Fraud Allegations

FOR IMMEDIATE RELEASE April 25, 2013

United States Attorney Anne M. Tompkins Western District of North Carolina

CHARLOTTE, N.C. – The former owner of Wilkesboro Clinical Laboratory ("WCL") pleaded guilty today in U.S. District Court for his involvement in a health care fraud scheme in which he and his company billed Medicare for services which were not rendered, announced Anne M. Tompkins, U.S. Attorney for the Western District of North Carolina. Louis Francis Curte, 49, also admitted he filed false tax returns from 2007 to 2010.

In a separate civil settlement with the U.S. Attorney's Office, Curte also agreed to pay $300,000 to resolve civil fraud allegations that he and his company violated the Physician Self-Referral Act or "Stark Law."

U.S. Attorney Tompkins is joined in making today's announcement by Derrick Jackson, Special Agent in Charge, Department of Health and Human Services, Office of the Inspector General (HHS-OIG), Office of Investigations, Atlanta Region; Jeannine A. Hammett, Special Agent in Charge of the Internal Revenue Service, Criminal Investigation Division (IRS-CI); and John A. Strong, Special Agent in Charge of the Federal Bureau of Investigation (FBI), Charlotte Division.

Evolving Lab Compliance Issues

- There has been explosive growth in molecular and genomic testing over the past decade.
- These tests raise new potential issues for consideration:
  - No CPT codes assigned
  - Methodology is research use only (RUO) or investigational use only (IUO)
  - Lack of LCDs / NCDs
  - Providing costly tests during a period when carrier probably views test as investigational
  - Commercial insurer non-coverage policies
  - Potentially high cost to patients

Private Insurer Bringing Action for Overbilling

Blue Cross & Blue Shield of Mass., Inc., et al. v. Chan, et al.

- Blue Cross and Blue Shield of Massachusetts is suing Alfredo Chan, a doctor with a psychiatry practice , over a scheme in which Blue Cross was allegedly overbilled for laboratory services provided to Chan's patients.
- According to the complaint, Chan entered into an agreement with United Esoterics under which UE provided all laboratory services to Chan's patients.
- UE was not properly certified (under CLIA) to provide such services, and Chan's provider agreement with BCBSMA.

Private Insurers Bringing Action for Overbilling (cont.)

25. Upon information and belief, UE advertised itself as a turnkey laboratory service that would provide *profits* to physicians at no cost to them.

- Through Chan, UE then billed Blue Cross at higher out-of-network provider rates for laboratory services, resulting in Blue Cross overpaying UE compared to the in-network rates to which Chan contracted.
- UE also allegedly "unbundled" its services to increase payments from Blue Cross and charged for services that were never authorized by a physician, which charges were passed on by Chan. Chan allegedly split the profits with UE or received a referral fee from UE.
- Blue Cross is seeking damages in the amount of $255,104 it has overpaid, as well as attorney's fees and the costs of its investigation.

- **The June 25, 2014 OIG Special Fraud Alert and Subsequent Fallout**

Don’t Say We Didn’t Warn You!

Blood Draw Remuneration

- HHS Office of Inspector General has addressed payment for blood draws in the physician office (2005):
  - There is a substantial risk that the Lab would be offering the blood draw remuneration to the physicians in exchange for referrals to the Lab. Under the Proposed Arrangement, the physicians could receive up to twice the $3 amount Medicare pays for blood specimen collection, plus any necessary blood-drawing supplies free of charge.
  - Particularly when viewed in the aggregate, this compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab.
  - Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory, particularly in the circumstances presented here.

OIG Advisory Opinion No. 05-08, June 2005

Key Elements of the June 25, 2014 OIG Fraud Alert

- What does it cover?

  "compensation paid by laboratories to referring physicians and physician group practices (collectively, physicians) for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database"

Key Elements of the June 25, 2014 OIG Fraud Alert (cont.)

- What is the concern?

  "The anti-kickback statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of the statute occurs depends on the intent of the parties.... **This is true regardless of whether the payment is fair market value for services rendered.** The probability that a payment is for an illegitimate purpose is increased, however, if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare."

Key Elements of the June 25, 2014 OIG Fraud Alert (cont.)

- What is OIG looking for?
  - Payment exceeds fair market value for services actually rendered by the party receiving the payment.
  - Payment is for services for which payment is also made by a third party, such as Medicare.
  - Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.
  - Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
  - Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.
  - Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

Related Lab Investigations

- Wall Street Journal, September 8, 2014:
  - Until late June, Health Diagnostic Laboratory Inc. (HDL) paid $20 per blood sample to most doctors ordering its tests—more than other such labs paid. For some physician practices, payments totaled several thousand dollars a week….
  - HDL says it stopped the payments after the June 25, 2014 Special Fraud Alert was issued.
  - The fraud alert is part of an investigation the health agency's Office of Inspector General is conducting with the Justice Department into doctor payments by HDL and several other labs specializing in cardiac-biomarker testing.
  - HDL began offering tests in 2009, promising doctors a fee for each sample. In a May 1, 2010 memo, [HDL] distinguished between a venipuncture—drawing blood—and other aspects of processing and handling a sample, such as vial labeling, cooling and shipment coordination. HDL called those aspects "P&H."

Related Lab Investigations (cont.)

- Wall Street Journal, September 8, 2014:
  - "Fyi To all I want to refocus that this is an [sic] ph fee not a draw fee. One word makes it legal the other illegal."
  - A manager emailed back: "Can you explain the difference between a draw fee and a P&H fee?“
- Poll: How have those in the room responded?
- What should you do now?

Thank you.

- For follow-up, please contact:

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