Nashville Healthcare Fraud Conference

December 3, 2015

co-sponsored by:

THA
TENNESSEE HOSPITAL ASSOCIATION

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Year in Review:
Looking Back on Healthcare Fraud Issues in 2015


Compensation
Public
Individual
Adventist
Healthcare
Liability
Yatesates
Carolina
Physician
Tuomey
CIA
Parikh
settle
overpayment
Medicaid
violated
rel
District
LifeCare
FCA
Relators
summary
Stark
Sep
North
hospitals
60-day
Apr
disclosure
judgment
OCIG
9(b
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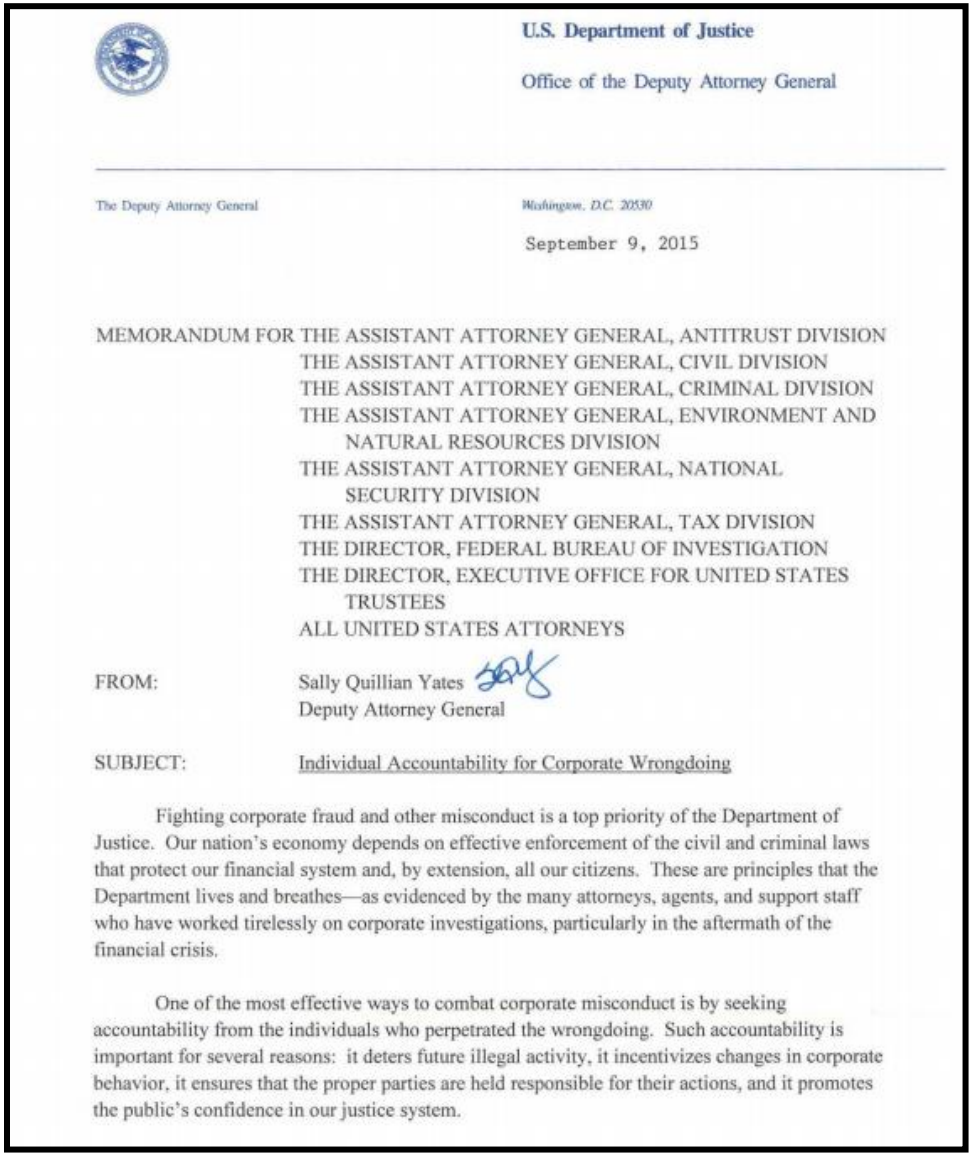
September
Schaengold
pay
Broward
Court
United
Law
Hospital
South
Citizens
States
Health
Treble
Medicare
U.S
agreed
Kane-Healthfirst
operates
physicians
Statute
Anti-Kickback
Aseracare

The Year That Was

- Individual Liability
- 60-day Overpayment Rule
- Medicaid Enforcement
- Using Statistical Sampling to Prove FCA Liability
- Physician Compensation
- Hot Enforcement Sectors
- Who is Driving the Bus on Development of Case Law?

Individual Liability

Yates Memo



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION
THE ASSISTANT ATTORNEY GENERAL, NATIONAL SECURITY DIVISION
THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION
THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES TRUSTEES
ALL UNITED STATES ATTORNEYS

FROM: Sally Quillian Yates
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate Wrongdoing

Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.

Yates Memorandum Key Points:

- DOJ instructed to focus on pursuit of parallel civil and criminal recovery
- DOJ to focus on individual liability:
  - Settlements with companies will not release civil or criminal claims against individuals
  - Factors beyond ability to pay will drive consideration of whether to pursue civil actions against individuals
- Cooperation credit in resolving a matter with DOJ will require disclosure of all relevant facts about conduct and individuals involved

Knowing Retention of Overpayments

- ***U.S. ex rel. Kane v. Healthfirst, Inc.***, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)
  - United States alleged that hospitals failed to make timely repayment of money overbilled to Medicaid as a result of MCO's software glitch
    - 2009: Overcharges began
    - 2010: Hospitals discovered overcharges and asked Kane to determine scope of affected claims
    - 2011: Kane fired four days after sending email attaching spreadsheet of claims noting 900+ claims (>$1M)
    - 2013: Hospitals eventually repaid all claims, but only after issuance of CID

.

From: Robert Kane
Sent: Friday, February 04, 2011 5:51 PM
To: Kathryn Dakis; Toni Jones; Allise Williams; Cristobal Barriuso; Howard Lindenauer
Subject: RE: AG's office on the Healthfirst/Medicaid Coins problem.
Attachments: HF ERA Analysis.xls

Adding Howard

Allise,
As we discussed at yesterday's meeting attached is the spreadsheet that used our available ERA files that dated back to May of '09 to report on the CAS CO 2 Segments that were problematic from HF. This does not replace the need for IS to continue their efforts to produce the complete report from the Remit Database.
Nothing on these sheets shows the effect the posting had on Eagle, but most likely was problematic. This gives some insight to the magnitude of the issue. The secondary FC was obtained by cross referencing to Eagle.

Robert Kane
Technical Director
Revenue Cycle Operation - Systems
Patient Accounting Dept.
Continuum Health Partners Inc.
Voice (212) 256-3028
FAX (212) 256-3595

Knowing Retention of Overpayments

- ***U.S. ex rel. Kane v. Healthfirst, Inc.***
  - Government: Kane's email and spreadsheet properly "identified" overpayments which matured into "obligations" when not reported and returned within sixty days
  - Defendants: Kane's email only provided notice of *potential* overpayments and did not identify actual overpayments so as to trigger sixty-day report and return clock.

Knowing Retention of Overpayments

- ***U.S. ex rel. Kane v. Healthfirst, Inc.***
  - Court: the sixty day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained
  - But . . . just because a claim might qualify as an obligation does not establish a violation of the FCA

State AGs – Recent Multi-State Healthcare Fraud Enforcement

- Amgen Inc., improper off-label marketing, $71 million, 48 state AGs
- Cancer Fund of America, fundraising fraud, lawsuit by 50 state AGs

.

Sources of AG Multistate Authority

- Broad array of powers
- Broad array of remedies
- Chief state law enforcement officer
- Independence and discretion
- Political benefits

The Urban Lawyer (Fall 2014)

"AGs have shifted from primarily pursuing local consumer protection issues and defending state agencies to exploring business practices on a national scale relating to industries heretofore untouched by state regulators."

B. Nash, A. Luciano & B. Mosca, *Recent Developments in State Attorneys General Enforcement*, 46 The Urban Lawyer 901, 901 (Fall 2014).

Consumer Protection

- Tennessee Consumer Protection Act (1977)
- AG authority:
  - Acts or practices “deceptive to the consumer”
  - Represents all consumers in state
  - Broad discovery powers
  - No statute of limitations
  - Injunction, restitution, civil penalties
- Compliance monitors

Medicaid Fraud and Abuse

- Federal False Claims Act (1863)
- Tennessee Medicaid False Claims Act (1993)
  - Treble Damages
  - Civil Penalties
  - Whistleblowers
- Federal/State cooperation

Medicaid Fraud and Abuse

News

FOR IMMEDIATE RELEASE
March 19, 2015

Contact: HHS Press Office
202-690-6343

Departments of Justice and Health and Human Services announce over $27.8 billion in returns from joint efforts to combat health care fraud

Administration recovers $7.70 for every dollar spent to fight health care-related fraud and abuse; third-highest on record

Proving Fraud Through Extrapolation

- Courts increasingly willing to allow government to argue that liability should be extrapolated across a universe of claims based on review of a sample
- ***U.S. ex rel. Martin v. Life Care Centers of America Inc.***, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014).
  - Court permitted DOJ to use random sample of 400 admissions from 82 SNFs to extrapolate findings across 54,000 patients
- ***U.S. v. Robinson*, 2015 WL 1479396 (E.D. Ky. Mar. 31, 2015).**
  - Physician: medical necessity of eye exams was a subjective determination established on a patient-by-patient basis. United States should not be able to extrapolate from 30 claims to 25,779, in order to establish *liability* under the FCA.
  - Court, citing *Life Care*, held that extrapolation in the Sixth Circuit was "reliable and acceptable evidence in determining facts related to FCA claims as well as other adjudicative facts"

Proving Fraud Through Extrapolation

- ***U.S. ex rel. Paradies v. Aseracare, Inc.***, *2:12-CV-245-KOB (N.D. Ala. June 25, 2015).*
  - "Statistical evidence is evidence."
  - Court bifurcated FCA trial into liability and damages phase and limited the scope of the "falsity phase to evidence that related in time and location to 124 patients"
- ***U.S. ex rel. Michaels v. Agape Senior Community, Inc.***, *2015 WL 3903675 (D.S.C. Jun. 25, 2015).*
  - Court disallowed statistical sampling and extrapolation because evidence.
  - "Distilled to its essence, each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary."
  - Certified for interlocutory appeal.

Physician Compensation Cases

- *U.S. ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (settlement announced: Oct. 16, 2015)*
  - $72.4 million settlement (following $237 million judgment) to resolve FCA allegations involving part-time employment arrangements with specialist physicians
- *U.S. ex rel. Payne v.* ***Adventist*** *Health (Sep. 21, 2015)*
  - $118.7 Million settlement to resolve FCA allegations involving improper compensation arrangements with physicians, including bonuses that took into account value of physicians' referrals
- *U.S. ex rel. Reilly v.* ***North Broward*** *Hosp. Dist. (Sep. 15, 2015)*
  - $69.5 million settlement to resolve FCA allegations that physician employment arrangements were above FMV and not commercially reasonable due to internal tracking of contribution margins from referrals

Physician Compensation Cases

- "This case is troubling. It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."
  - *U.S ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015) (Wynn, J. *concurring*).

Physician Compensation Cases

- "Those complications were added by high-priced lawyers who tried to build loopholes for their clients. The original law was pretty simple."
  - Joe Carlson, "Pete Stark: Repeal the Stark Law," *Modern Healthcare* (Aug. 2, 2013).

Physician Compensation Cases

U.S. ex rel. Schaengold v. Memorial Health, Inc., *No. 4:11-cv-58 (S.D. Ga.)*

- Government intervention alleging that physician employment agreements exceeded fair market value, were not commercially reasonable, and took into account volume or value of referrals.
- Compensation paid to the physicians was not commercially reasonable in the absence of the projected contribution margin from downstream referrals

Physician Compensation Cases

U.S. ex rel. Schaengold v. Memorial Health, Inc., *No. 4:11-cv-58 (S.D. Ga.)*

- Apr 2008 presentation seeking approval of acquisition:
  - "High volume practice with large numbers of hospital admissions and referrals to specialists"
  - "estimated gross revenues (including downstream revenues from referrals) to St J/C" of
    - 2006: $57 million + $3.4 million radiology
    - 2007: $63 million + $3.7 million radiology
  - Projected contribution margin of $3.5 – $5M per year

Physician Compensation Cases

U.S. ex rel. Schaengold v. Memorial Health, Inc., No. 4:11-cv-58 (S.D. Ga.)

- Different version of slide deck deleted "referrals," "downstream revenue," and "projected contribution margin"
- Memorial projected acquisition would result in financial losses of $670k per year for five years
- Nevertheless, recommended doing the deal because of increase in "hospital revenue"

Physician Compensation Cases

	2008	2009	2010	2011
Bradley	$229,853.35	$612,782.98	$646,974.68	$137,628.04
Corse	$208,451.71	$501,388.75	$683,874.51	$133,661.78
Gaskin	$151,513.27	$418,109.81	$324,628.34	$ 87,081.76
Losses	$597,000.00	$1,100,000.00	$1,400,000.00	$392,000.00

Physician Compensation Cases

- Email from Sr VP of Physician Services:
  - "You have a unique compensation formula that no other Memorial physician has – the model is different."
  - "Your compensation is well above the 90th percentile. . . . Your compensation must be proportional to your wRVU productivity and your current compensation is not."
- Doctor's notes from meeting with Sr VP of Physician Services:
  - Memorial's "goal is to not appear that they are buying referrals."
- Board member email: "We all recognize we cannot continue to pay the salaries at the same level. However, we cannot afford to lose paying patient referrals to the hospital."

Debate over Medicare, Social Security, other federal benefits divides GOP

Republicans are openly feuding over whether to seek drastic changes to Medicare, Social Security and other entitlement programs, risking a potentially damaging intraparty battle ahead of the 2016 elections.

The rift was exemplified this week by the GOP stars of the moment. Newly installed House Speaker Paul D. Ryan (R-Wis.) said he plans to pursue a "bold alternative agenda" that would include major revisions in entitlements. At the same time, leading Republican presidential candidate Donald Trump railed against proposals to end or significantly change Medicare.

Debate over Medicare, Social Security, other federal benefits divides GOP

Trump: “You can’t get rid of Medicare. It’d be a horrible thing to get rid of. It actually works. You get rid of the ___, ___, and ___ - it works.”

Enforcement Focus in 2016?

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Preventing the Whistleblower

Panel Participants

Alana Sullivan	Senior Vice President and Chief Compliance Officer, Erlanger Health System
Steve Hinkle	Vice President and Chief Compliance Officer, Ardent Health Services

False Claims Act and Whistleblowers

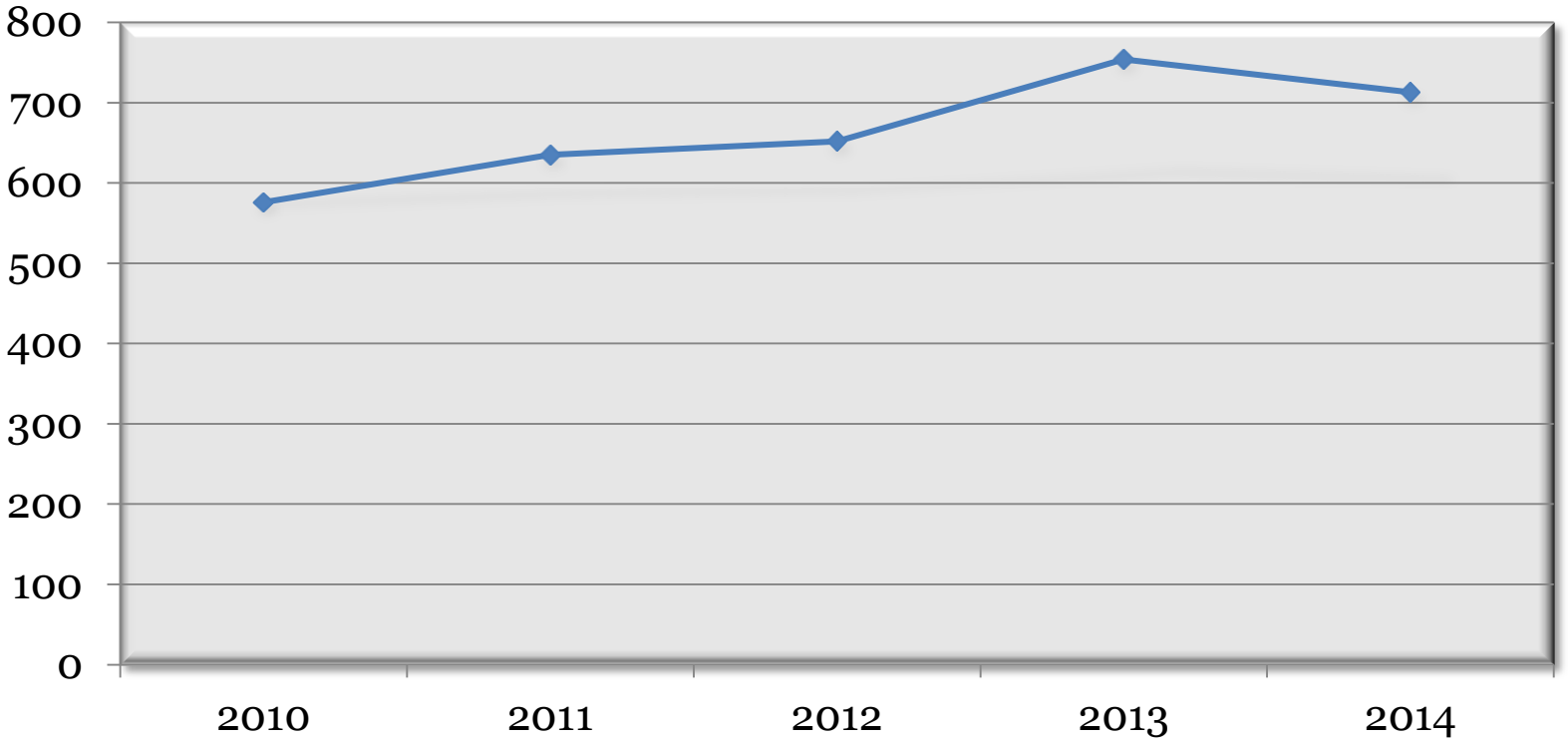
- Prohibits knowingly making or causing the submission of false claims for payment to the federal government
- Provides for **treble (3x)** damages and per claim penalty of between **$5,500** and **$11,000**
- Allows for private parties (*qui tam* relators) to bring suit on behalf of the government and participate in % of any recovery

False Claims Act and Whistleblowers

- Protects whistleblowers from discharge, suspension, demotion, threats, harassment or other discrimination in the terms or conditions of employment
- Provides for reinstatement with the same seniority, two times back pay, compensation for special damages, litigation costs, and attorneys' fees

New FCA Qui Tam Lawsuits

Number of New FCA Qui Tam Lawsuits Filed by Year (FY 2010 - 2014)



Over 3,300 new FCA qui tam lawsuits filed since 2010

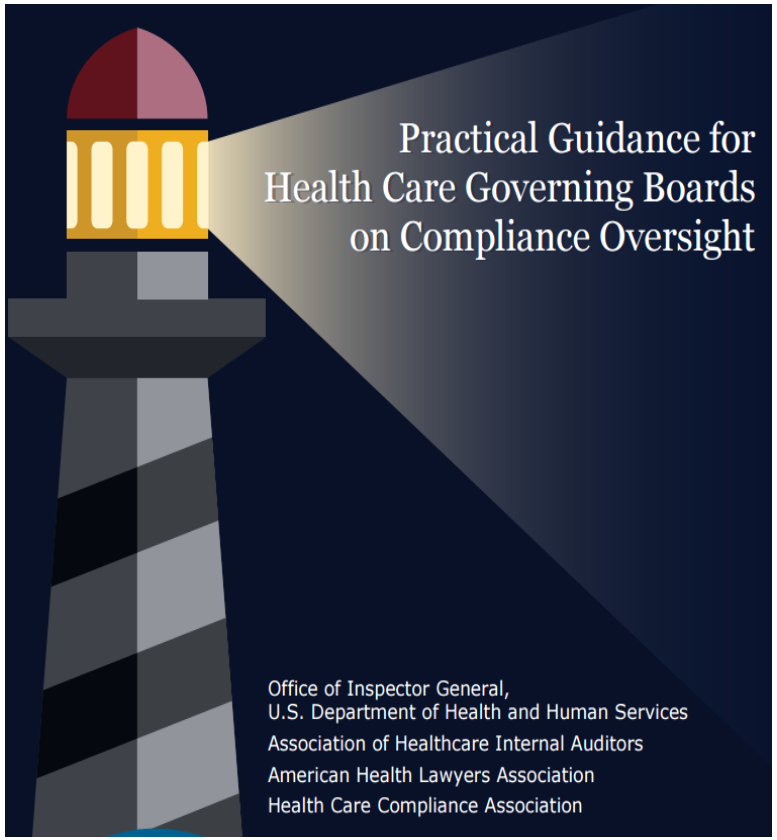
Assessing the Organization's Compliance Function

Effective Compliance Program Includes:

- Conducting internal monitoring and auditing
- Implementing compliance and practice standards
- Designating a compliance officer with appropriate reporting lines
- Conducting compliance training and education
- Responding appropriately to detected offenses and taking corrective action
- Developing open lines of communication
- Enforcing disciplinary standards

HHS-OIG Guidance for Boards

- OIG guidance on Board's oversight and review of compliance program functions:



- Stresses meaningful oversight and "asking the right questions"
- Working knowledge of regulations and the organization
- Promotion of robust communication with management
- Meaningful assessment of compliance program
- Identification and addressing of risks from emerging industry trends
- Engender compliance responsibility through incentives based on compliance and quality outcomes

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http://www.bassberry.com/services/practices/healthcare-regulatory/healthcare-fraud-and-abuse

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A Deeper Dive on Data Mining

Program Integrity in Tennessee:
TennCare Oversight – Activities - Coordination

DENNIS J. GARVEY, JD
DIRECTOR, OFFICE OF PROGRAM INTEGRITY
BUREAU OF TENNCARE

Use of Investigators

We have employees who perform investigations:

- Registered Nurses; and
- Certified Coders,
- Law Enforcement background

In addition, other educational credentials are held by this staff, such as Certified Fraud Examiner (CFE). We are also proud to have one of a very few individuals in the nation to have achieved status as a Certified Program Integrity Professional (CPIP).

Use of Data Mining

- We have a dedicated staff of data miners.
  Staff are well-educated, varying in educational levels from that of Ph.D. to Associate's Degree.

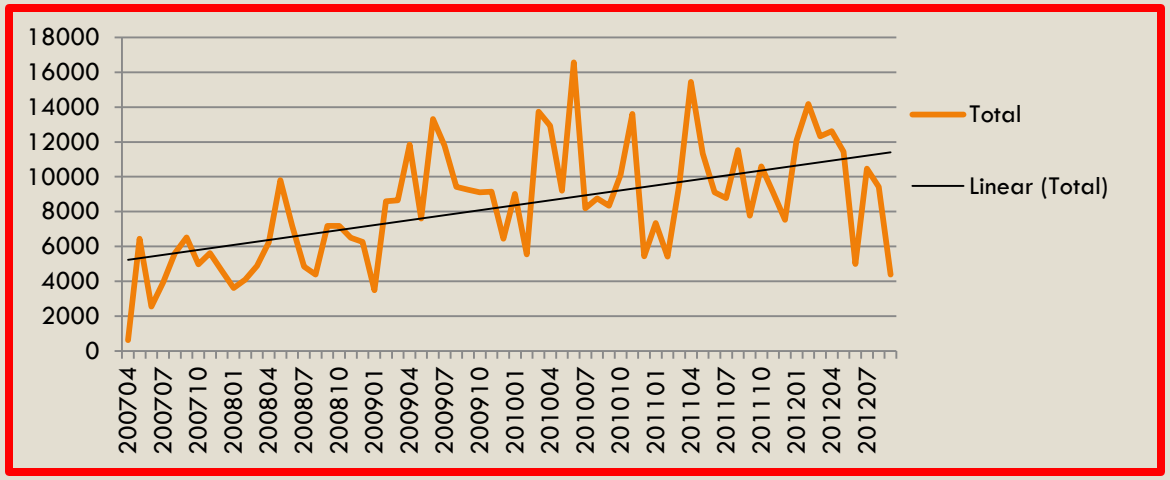
- Data Mining is performed on Encounter Data both:
  - As a matter of Routine, and
  - In response to a Tip or Allegation received.

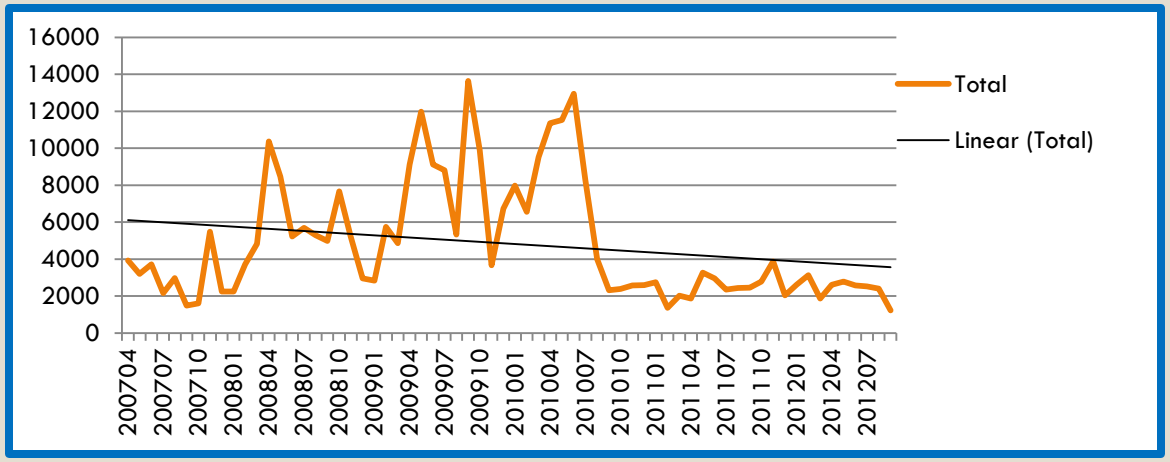
TennCare Uses Data to Detect Overpayments

We can routinely look at data for:

- Excluded persons
- Deceased enrollees/providers
- Peer comparison for all providers
- Outliers by taxonomy
- Percentage payment increase quarter by quarter
- Procedure count by provider
- Narcotic prescription count and Percentage of total

95165 Usage History by MCO





MCO A: 95165 use gradually trending upward

MCO B: 95165 use declined after August 2010 **(but trends upwards for all other codes)**

Medical Record Reviews

- Coding Reviews
  - Rules, Policies & Procedures
  - Coding Guidelines (CPT, ICD-9, HCPCS)
  - Medical Decision Making
  - Appropriate Level of service
  - Appropriate use of modifiers
  - Preventive Services
  - Ancillary Services (labs, testing)

- Nurse Reviews
  - Rules, Policies & Procedures
  - Legibility of Records
  - Cloning of records
  - Scope of practice
  - Medical Necessity
  - Evidenced Based Medicine
  - Appropriate Ordering, Documentation and Signatures
  - Standards of Care

Reporting Allegations To TennCare

PHONE

Fraud Hotline

1-800-433-3982

Fax: 615-256-3852

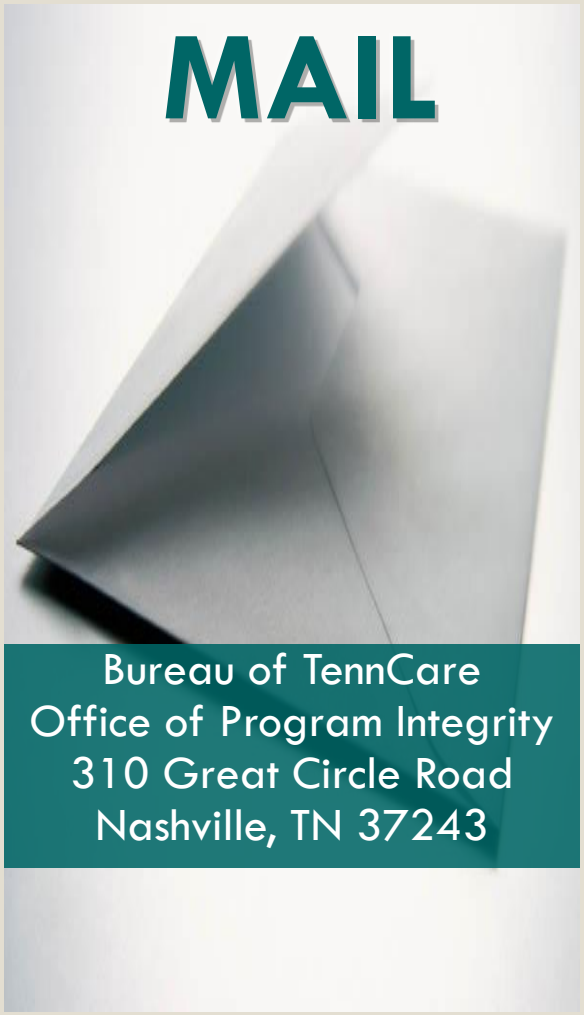
EMAIL

Go to:

www.tncarefraud.tennessee.gov

or email us at:

Programintegrity.TennCare@tn.gov



MAIL

Bureau of TennCare
Office of Program Integrity
310 Great Circle Road
Nashville, TN 37243

Enchanced Data Analysis Capabilities:
Medi-Medi Program

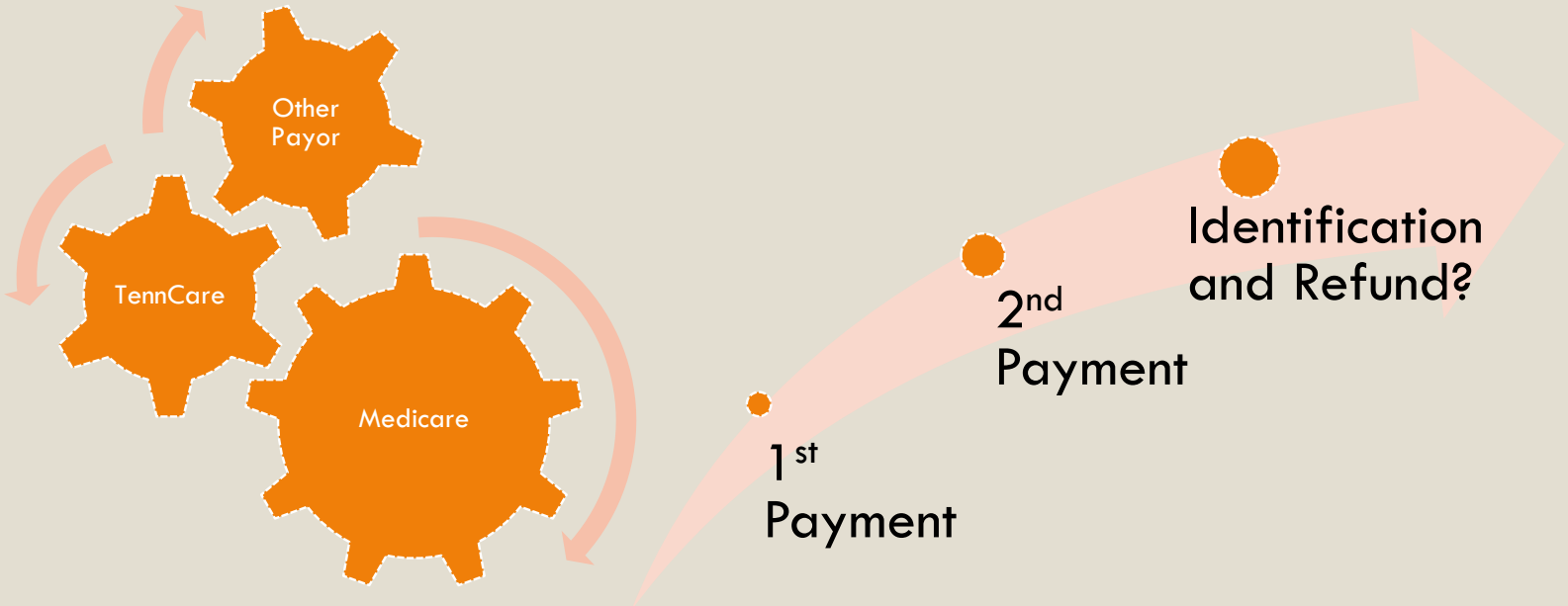
TIM BYRNES, MABA
PROGRAM MANAGER
ADVANCEMED

Medi-Medi Matched Data Database

- Combines Medicare and Medicaid data to highlight providers that may appear normal in each program individually, but become aberrant when viewed together
- Allows TennCare to access matched Medicare/Medicaid data for enhanced fraud and abuse analysis
  - All claims for matched providers in the State
  - All claims for matched recipients in the State
- Creates common framework for analysis of Medicare/Medicaid data across multiple states

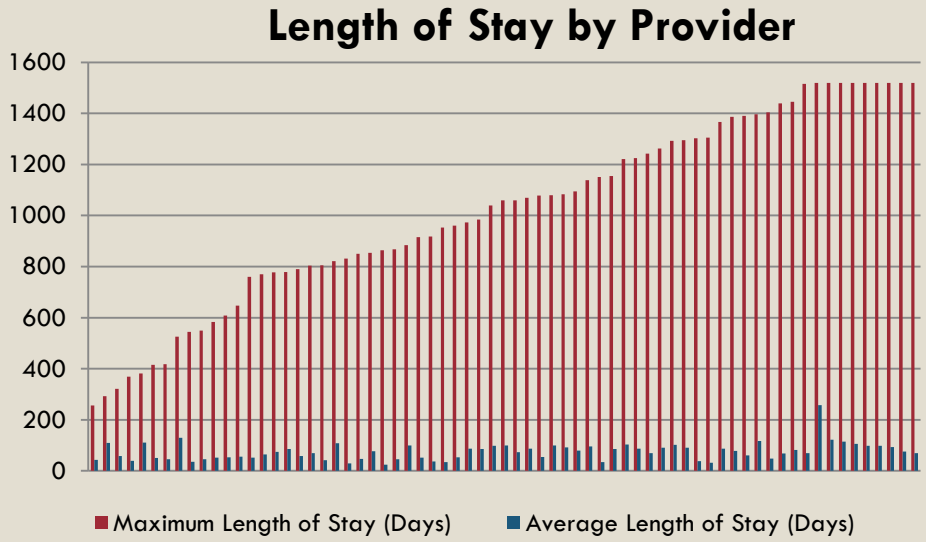
Medi-Medi Projects

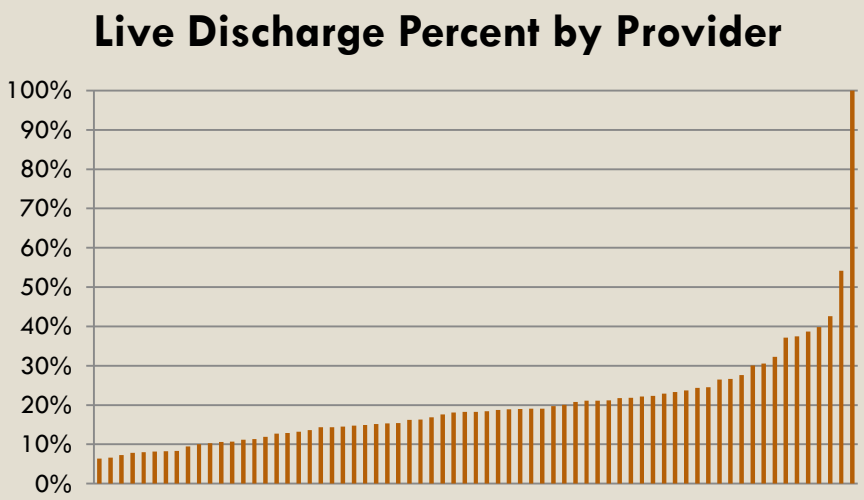
- Duplicate Payment Across Programs
  - Medicare – Primary Payor
  - TennCare – Payor of Last Resort
  - Other Medicaid – Inappropriate Multiple Medicaid Eligibility



Medi-Medi Projects

- Hospice
  - Length of Stay
  - Live Discharges
  - Suspicious Diagnoses

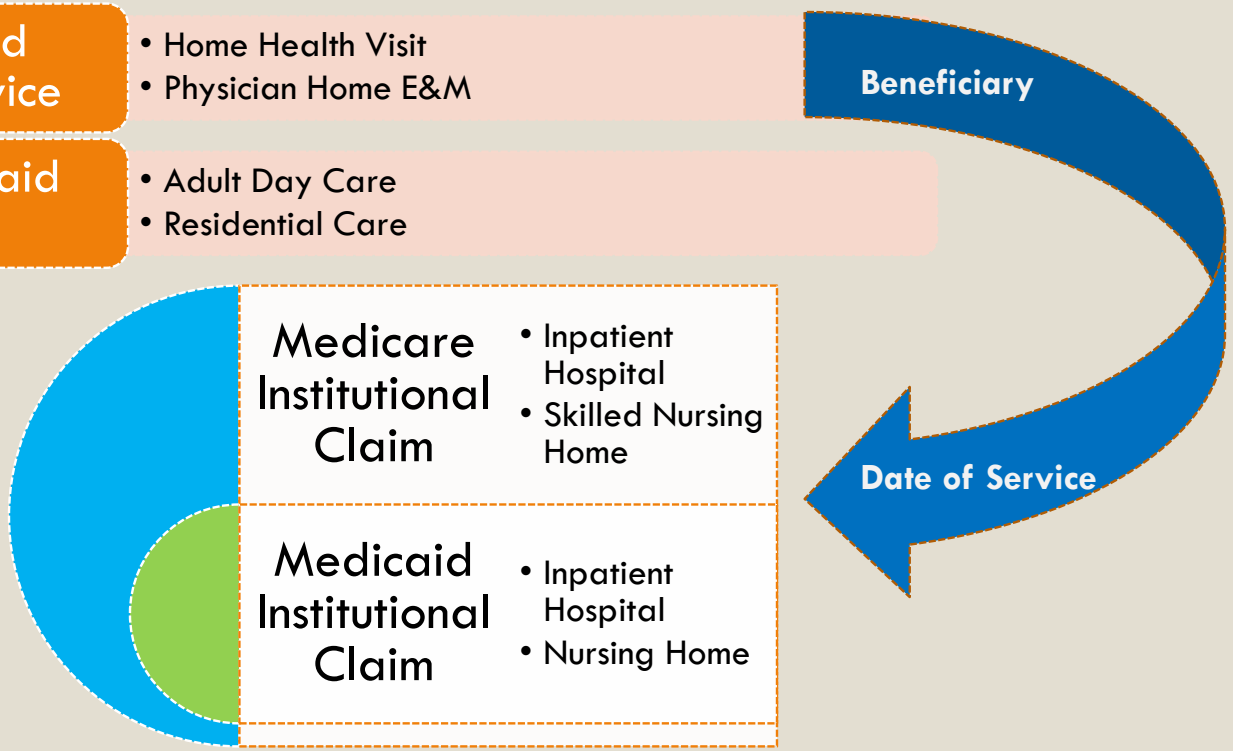




Medi-Medi Projects

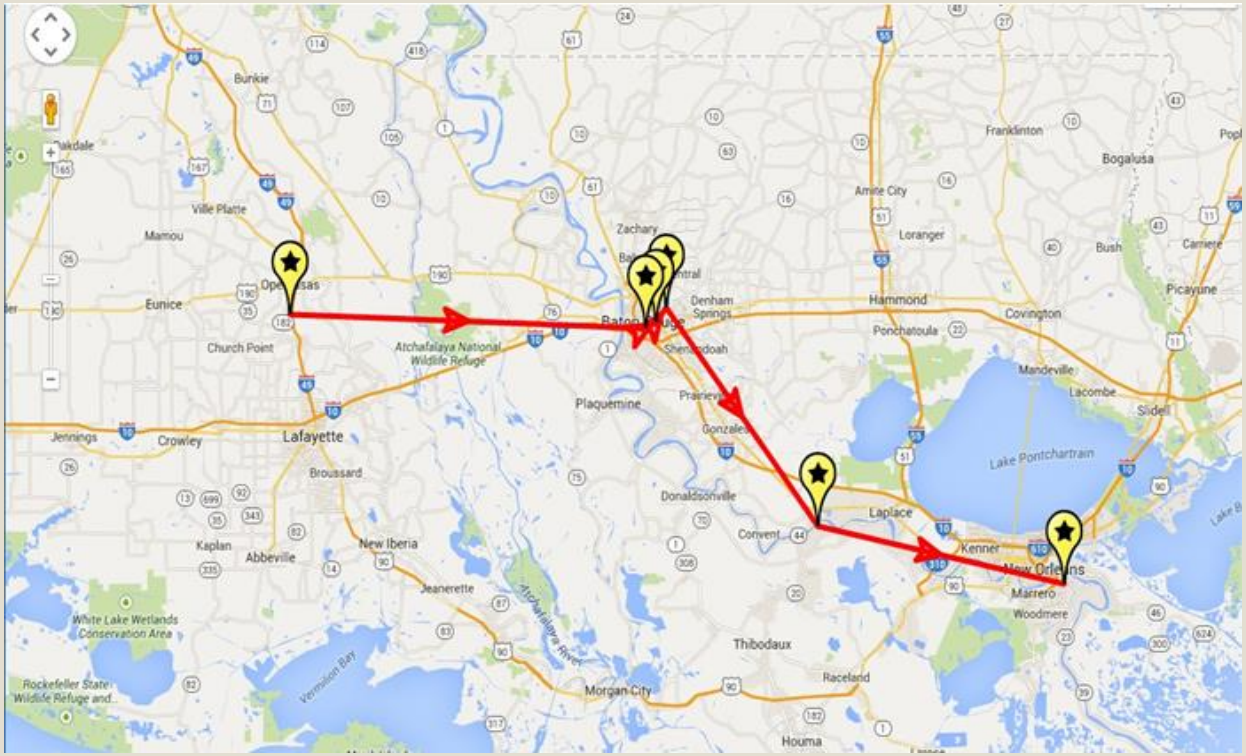
- Personal Care Services During Institutional Stay

In-Home Waiver Service	• Personal Care • Home Delivered Meal
Home-Based Medical Service	• Home Health Visit • Physician Home E&M
Other Medicaid Services	• Adult Day Care • Residential Care



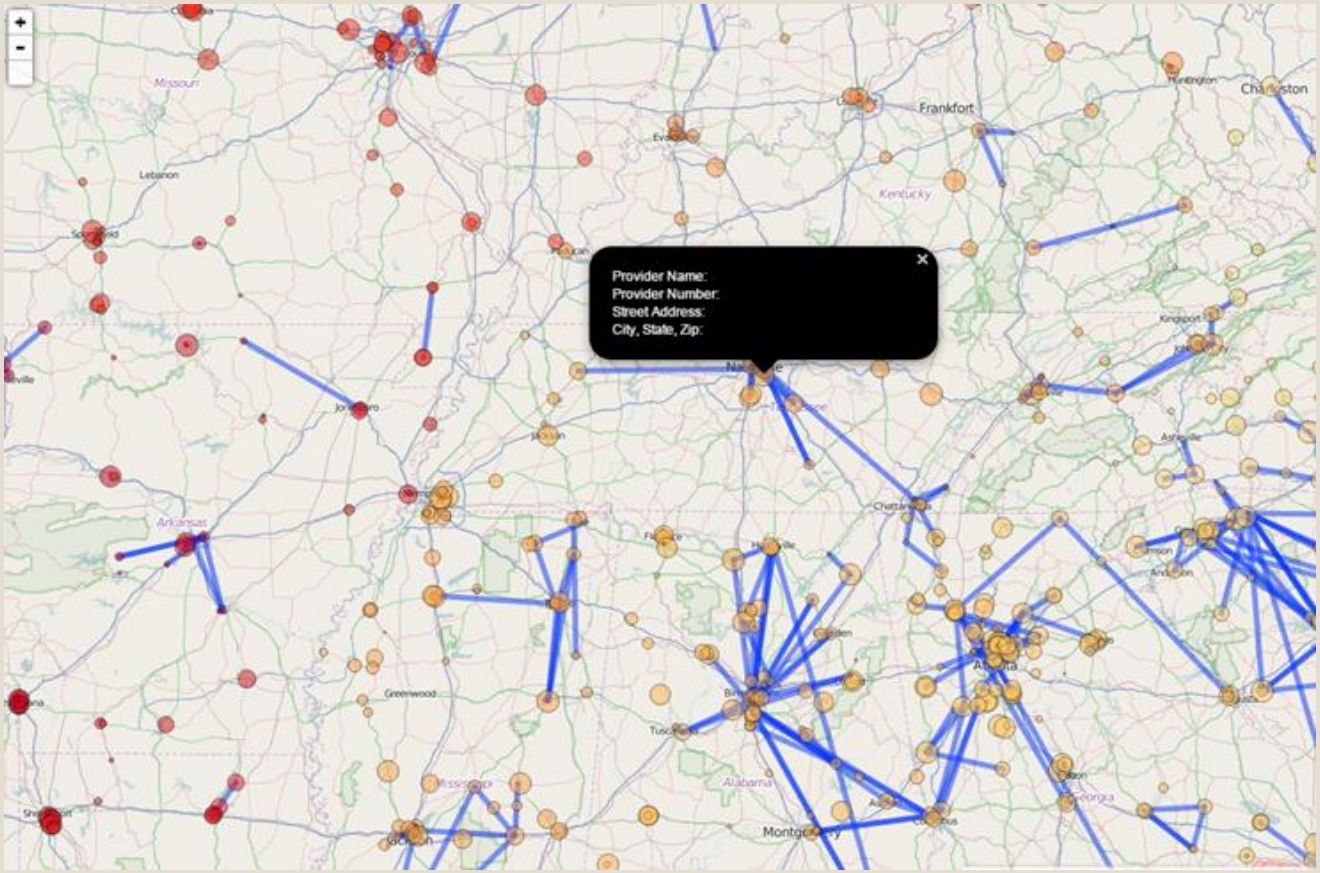
Interactive Mapping

- Mapping tool to evaluate physician's billing for home visits
- Procedure code time estimates from CMS
- Travel time estimates from Google maps
- Medicare and Medicaid claims
- Provides complete picture of one day's billing for physician in question



Interactive Mapping

- One of many interactive maps developed by AdvanceMed is used for the purpose of identifying beneficiary sharing among providers



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Overpayments and Self-Disclosure

Overview

- Origins of the Legal Obligation
- Identifying and Evaluating
- Time is of the Essence: the 60-Day Rule
  - Is Your 60-Day Clock Ticking?
  - Healthfirst
- Voluntary Repayment or Self-disclosure
- Disclosure Considerations
- Looking Ahead

Legal Obligations to Disclose

- Affordable Care Act (ACA), 42 U.S.C. § 1128J(d)
  - Providers must “report and return” overpayments within 60 days of identification of overpayment
  - Retention of overpayment after 60-days is an “obligation” under the False Claims Act (FCA)
- False Claims Act, 31 U.S.C. § 3129(a)(1)(G)
  - Violation of the FCA if a person “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government”
  - FCA violations subject to treble damages and penalties

Identifying and Evaluating

- How do potential overpayments arise:
  - Compliance Audits
  - Employee Complaints
  - Transaction Diligence
- How does one respond?
  - Take reasonable steps to ascertain scope/issue
    - What is a reasonable inquiry?
    - How far back?
    - How many claims?

The 60-Day Rule

- Proposed Rule for Medicare Parts A & B (Feb. 16, 2012)
  - Proposes that a person has **identified** an overpayment if the person has actual knowledge of the existence of the overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment.
  - "In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals overpayment, the provider then has 60 days to report and return the overpayment."
  - "Failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment."

The 60-Day Rule

- Final Rule for Medicare Parts C & D
  - Defines “identified” in the context of Medicare Parts C and D as when the Medicare Advantage organization or prescription drug plan sponsor “has determined or should have determined through the exercise of reasonable diligence that it has received an overpayment.” 42 C.F.R. §§ 422.326(c), 423.360(c).
  - Only applies to Medicare Parts C and D.

Is Your 60-Day Clock Ticking?

- *U.S. ex rel. Kane v. Healthfirst, Inc.* (S.D.N.Y.)
  - Allegations: Continuum failed to timely make refunds to Medicaid as a result of MCO's software glitch
  - 2009: Overcharges began
  - 2010: Continuum discovered overcharges and asked Kane to determine scope of affected claims
  - 2011: Kane fired four days after sending email attaching spreadsheet of claims noting 900+ claims (>$1M)
  - 2013: Continuum eventually repaid all claims, but only after issuance of Civil Investigative Demand

Is Your 60-Day Clock Ticking?

- *U.S. ex rel. Kane v. Healthfirst, Inc.* (S.D.N.Y.)
  - First judicial opinion interpreting 60-day overpayment rule (Aug. 3, 2015)
  - Court:
    - "Identification" of overpayments, which triggers the 60-day repayment obligation, occurs when a company is put "on notice" of potential overpayments, rejecting the Defendant's argument that "identified" means when the overpayment is "known with certainty."
    - A more lenient interpretation would "create a perverse incentive to delay learning the amount due."

Is Your 60-Day Clock Ticking?

- Implications and Concerns
  - Can you “identify” the unknown?
  - What to do if the complexity of the investigation and/or the lack of sufficient information makes repayment within 60 days impossible?
  - Do anonymous or vague reports to the compliance office that may or may not have an impact on claims or the receipt of overpayments start the 60 day report and repay clock?
  - What are the impacts of the “rolling” identification of overpayments based on separate samples or batches of claims/records under review?

Voluntary repayment or self-disclosure?

- What are the considerations?
  - Nature of the issue
  - Surrounding Circumstances
    - Whistleblower concerns
    - Transaction looming
  - Size of overpayment (dollar amount)
  - Do you want a release of potential claims?
    - Refunds alone cannot resolve potential liability for conduct arising in overpayment.
    - MACs may make referrals to OIG whenever there is a belief that circumstances warrant referral

Where Do You Disclose?

- Voluntary Refund - MACs
- OIG
- CMS
- DOJ

OIG Self-Disclosure Protocol

- 2013 Updated SDP :
  - Available for providers seeking to disclose potential violations of federal criminal, civil or administrative laws for which exclusion or CMPs are authorized
  - Not available for matters solely involving:
    - Overpayments or errors (defers to appropriate CMS contractor)
    - Stark law violations
- Requirements
  - Must “acknowledge conduct is a potential violation” and “explicitly identify the laws that were potentially violated”
  - Waive statute of limitations
  - Ensure that corrective actions are implemented and misconduct has stopped
  - Certification that it will complete internal investigation within 90 days of submission (no longer 90 days from acceptance)
- Benefits
  - Avoid CIA; and typical multiplier of 1.5 applied to single damages
  - Suspends repayment obligation as long as it is timely.

CMS Self-Disclosure Protocol

- Protocol issued on September 23, 2010
  - Under the SRDP, each disclosure must contain:
    - Description of actual or potential violations & legal analysis
    - Financial analysis
    - Certification
  - Submission of a disclosure suspends ACA obligation to return overpayment until settlement or withdrawal of disclosure
  - SRDP may not be used to obtain determination from CMS whether Stark violation occurred
- Practicalities: huge backlog, years behind.

Looking Ahead

- Final 60-Day Overpayment Rule is expected in early 2016
  - As of February 17, 2015, CMS extended by 1 year the timeline for publication of a final rule concerning policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII as outlined in the proposed rule published February 16, 2012, at 77 FR 9179.

Reggie Hill – *Chief Compliance Officer,* LifePoint Health

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Navigating Parallel Proceedings

“To be parallel, by definition, the separate investigations should be like side-by-side train tracks that never intersect.”

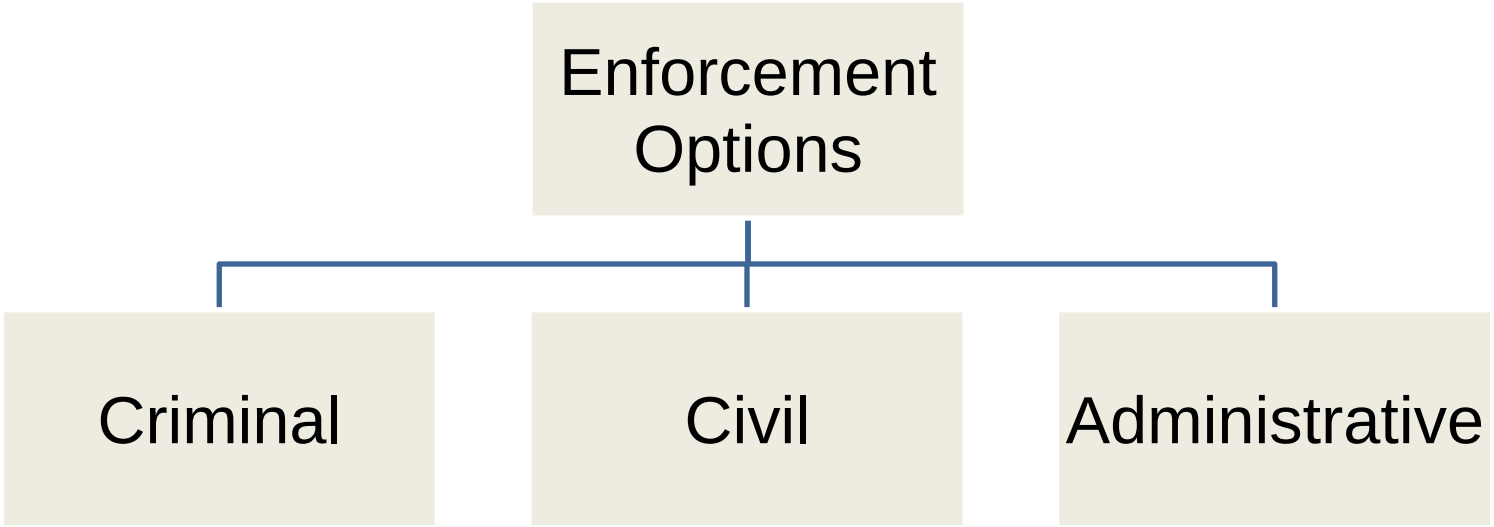
United States v. Scrushy, 366 F. Supp. 2d 1134, 1139 (N.D. Ala. 2005)

“There is nothing improper about the government undertaking simultaneous criminal and civil investigations . . .”

United States v. Stringer, 535 F.3d 929 (9th Cir. 2008)

Parallel Proceedings

- Government need not bind itself to a single remedy at the outset of an investigation
- Rather, it may proceed criminally, civilly, administratively or on parallel tracks



Office of the Attorney General
Washington, D. C. 20530

January 30, 2012

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS
DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
ALL ASSISTANT UNITED STATES ATTORNEYS
ALL LITIGATING DIVISIONS
ALL TRIAL ATTORNEYS

FROM: THE ATTORNEY GENERAL

SUBJECT: Coordination of Parallel Criminal, Civil, Regulatory, and Administrative Proceedings

The Department has placed a high priority on combating white collar crime. This includes the fight against fraud, waste, and abuse, whether it is in connection with health care, procurement, or other financial fraud, as well as consumer protection, the environment, antitrust, tax, commodities and securities fraud. The Department and the Financial Fraud Enforcement Task Force and its members are committed to using all of the remedies available — criminal, civil, regulatory, and administrative. To facilitate that goal, I am issuing this policy statement to update and further strengthen the Department's longstanding policy that ensures that Department prosecutors and civil attorneys coordinate together and with agency attorneys in a manner that adequately takes into account the government's criminal, civil, regulatory and administrative remedies.

Department policy is that criminal prosecutors and civil trial counsel should timely communicate, coordinate, and cooperate with one another and agency attorneys to the fullest extent appropriate to the case and permissible by law, whenever an alleged offense or violation of federal law gives rise to the potential for criminal, civil, regulatory, and/or agency administrative parallel (simultaneous or successive) proceedings. By working together in this way, the Department can better protect the government's interests (including deterrence of future misconduct and restoration of program integrity) and secure the full range of the government's remedies (including incarceration, fines, penalties, damages, restitution to victims, asset seizure, civil and criminal forfeiture, and exclusion and debarment).

The potential for parallel proceedings arises in many of the Department's white collar enforcement priorities, and it is essential that an effective and successful response involve an evaluation of criminal, civil, regulatory, and administrative remedies. Although some matters

"[I]t is important that criminal [and civil … attorneys coordinate in a timely fashion, discuss common issues that may impact each matter, and proceed in a manner that allows information to be shared to the fullest extent appropriate to the case and permissible by law."

U.S. Attorney's Manual 1-12.000

1-12.000
Coordination of Parallel Criminal, Civil, and Administrative Proceedings

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The Attorney General issued a Memorandum on July 28, 1997,* requiring a system for coordinating the criminal, civil and administrative aspects of all white-collar crime matters within every United States Attorney's office and each Department Litigating Division. The system should contain management procedures to address issues of parallel proceedings including:

- **timely assessment of the civil and administrative potential in all criminal case referrals, indictments, and declinations;**
- **timely assessment of the criminal potential in all civil case referrals and complaints;**
- **effective and timely communication with cognizant agency officials, including suspension and debarment authorities, to enable agencies to pursue available remedies;**
- **early and regular communication between civil and criminal attorneys regarding *qui tam* and other civil referrals, especially when the civil case is developing ahead of the criminal prosecution; and**
- **coordination, when appropriate, with state and local authorities.**

The Attorney General has further directed that appropriate staff in each office receive comprehensive training regarding parallel proceedings utilizing a course of instruction and training materials to be developed by the Council on White-Collar Crime and the Office of Legal Education.

*** The full text of this Memorandum is at DOJ Organization and Functions Manual 27.* * The 1997 Memorandum has been superseded by a 2012 Memorandum. The 2012 Memorandum has replaced the 1997 Memorandum at DOJ Organization and Functions Manual 27, and USAM 1-12.000 is currently being revised.**

Why Pursue Parallel Proceedings?

Parallel proceedings maximize the government's available tools and remedies against those committing fraud in a variety of ways, including:

- **Criminal penalties**: prison sentence, fines, restitution and asset forfeiture on the criminal side
- **Additional tools available in criminal matters:** search warrants, HIPAA subpoenas, undercover operations, faster recovery.
- **Different statutes of limitations:** The statute of limitations for civil actions may be as long as six to ten years. *See, e.g.,* 28 U.S.C. §§ 2415(a); 31 U.S.C. § 3731(b). As a result, civil cases may have a much larger "liability window" than criminal cases.
- **Larger damages and penalties:** Certain civil statutes, such as the False Claims Act, allow for the government to recover treble damages and certain penalties.
- **Lower burden of proof:** In civil cases, the burden typically is only a preponderance of the evidence. Also, reckless or willful disregard for the truth may result in liability in a civil case.
- **Different constitutional considerations:** In civil cases, the right to invoke the Fifth Amendment privilege against self-incrimination may carry consequences, and the court may draw adverse inferences if Fifth Amendment privileges are invoked.
- **Creative civil remedies are available:** In the civil context, the government may obtain asset freezes or injunctions under 18 U.S.C. § 1345 or otherwise (discussed further below); garnishments; suspension and debarment from participation in regulated activity or government programs; or pre-indictment restraint of assets through civil forfeiture actions.

Court Approval of Parallel Proceedings

- "It would stultify enforcement of federal law to require a government agency . . . to choose either to forego recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the outcome of a criminal trial." *U.S. v. Kordel*, 397 U.S. 1, 10 (1970).
- "In the absence of substantial prejudice to the rights of the parties involved, such ***parallel proceedings are unobjectionable*** under our jurisprudence." *SEC v. Dresser Industries, Inc.*, 628 F.2d 1368, 1375 (D.C. Cir. 1980) (*en banc*).

Court Approval of Parallel Proceedings

"There is no general federal constitutional, statutory, or common law rule barring the simultaneous prosecution of separate civil and criminal actions by different federal agencies against the same defendant involving the same transactions.

Parallel civil and criminal proceedings instituted by different federal agencies are not uncommon occurrences because of the overlapping nature of federal civil and penal laws.

The simultaneous prosecution of civil and criminal actions is generally unobjectionable because the federal government is entitled to vindicate the different interests promoted by different regulatory provisions even though it attempts to vindicate several interests simultaneously in different forums."

United States v. Simcho, 326 Fed. Appx. 791 (5th Cir. 2009)

Parallel Proceedings Hypothetical

Criminal AUSA reads WSJ article that the SEC is investigating insider trading allegations by executives at NuDrugz, Inc., related to insider trades surrounding the announcement of new cholesterol lowering medication Nupitor

NuDrugz's share price skyrocketed following FDA approval of Nupitor and announcement of its estimated market share for this drug

Criminal AUSA receives anonymous phone call from sales rep at NuDrugz, who claims that:

(1) Clinical studies have shown that Nupitor is also effective at re-growing hair for balding men;

(2) NuDrugz management is pressuring sales reps to promote Nupitor to physicians for off-label uses; and

(3) Sales of Nupitor have tripled since management began requiring sales reps to promote the drug off-label

Parallel Proceedings Hypothetical

Criminal AUSA decides to open a criminal investigation of NuDrugz

- *What techniques does Criminal AUSA have available to obtain information about NuDrugz and Nupitor?*
- *What considerations are informing the manner in which the investigation is conducted?*

Civil AUSA reports that a new *qui tam* action has been filed against NuDrugz concerning the off-label promotion of Nupitor. Civil AUSA conducts the interview of the relator and decides to send a Civil Investigative Demand for testimony to the NuDrugz CFO.

- *What considerations should Civil AUSA keep in mind with their CID for testimony of the NuDrugz CFO?*
- *The CFO makes a number of harmful admissions during the CID. Can these admissions be used in furtherance of the criminal investigation?*

Parallel Proceedings Hypothetical

SEC informs Criminal AUSA that it will be taking the deposition of the NuDrugz CFO and CEO. After reviewing the CID transcript, there are a handful of follow up questions that the Criminal AUSA wished the Civil AUSA had asked during the CID deposition.

- *Should Criminal AUSA call the SEC attorney and propose a list of questions to be asked during the SEC deposition?*

SEC informs Criminal AUSA that SEC is closing its investigation and will be cancelling a number of depositions of high level managers at NuDrugz scheduled for the upcoming weeks. Criminal AUSA believes that those depositions would have yielded significant information for the criminal investigation.

- *Should Criminal AUSA ask the SEC attorney to conduct the depositions before the SEC closes its investigation?*

- *Can Criminal AUSA ask Civil AUSA to conduct CID depositions of those managers if the SEC closes its investigations?*

Parallel Proceedings Hypothetical

Civil AUSA believes that the FCA allegations regarding NuDrugz off-label promotion of Nupitor can be resolved through settlement. Civil AUSA has a good faith belief that Criminal AUSA will not pursue the criminal investigation if the FCA allegations are resolved.

- *May Civil AUSA discuss resolution of the FCA allegations with NuDrugz counsel without including Criminal AUSA?*

- *May Civil AUSA suggest to NuDrugz counsel that if the FCA allegations are resolved through settlement that the criminal investigation likely will be closed?*

NuDrugz informs its outside counsel that it wishes to attempt to resolve all investigations related to Nupitor.

- *How does the NuDrugz outside counsel negotiate the resolution of the civil and criminal investigation with the government?*

Potential Landmines

What is the Purpose of the Investigation?

There must be a valid, independent objective at the commencement of a civil investigation or civil litigation.

A civil investigation or litigation should never be used solely to obtain evidence for criminal prosecution (or vice versa).

What Has the Government Told the Defendant/Target About the Status of the Investigation?

The government cannot induce individuals or parties to civil proceedings to take action, or to supply information based on misleading assurances that no criminal case is contemplated. *See, e.g., United States v. Rodman*, 519 F.2d 1058, 1059 (1st Cir. 1979); *United States v. Hrdlicka*, 520 F. Supp. 403 (W.D. Wisc. 1981); *United States v. Rand*, 308 F. Supp. 1231, 1234 (N.D. Ohio 1970).

Issues about the proper conduct of parallel proceedings are most likely to arise when the ultimate targets of the criminal prosecution can claim either that they were wholly ignorant of the criminal investigation or ignorant as to its scope.

If the criminal investigation is open and overt, this will greatly minimize a defendant's ability to complain they were misled. *See, e.g.*, *United States v. Luce*, 2006 WL 2850478 (N.D. Ill. Sept. 29, 2006).

How Are Covert Investigations Handled?

If the criminal investigation is covert and must remain that way (as is often the case), the government must exercise care in not making statements to defendants that can be construed as calculated to lull prospective targets into not asserting their Fifth Amendment rights.

Typically, this will require the government to provide a defendant adequate warnings to protect the defendant's constitutional rights.

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Kerry Harvey

United States Attorney for the Eastern District of Kentucky

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HealthCare Appraisers INCORPORATED

Addressing Physician Compensation Issues in Due Diligence

Legal Foundation for Physician Compensation

- Anti-Kickback Statute (Criminal Statute – Felony)
  - Prohibited – Intentional payment for referrals (past, present or future)
  - Safe Harbors offer protection - Key ones require FMV
  - OIG Advisory Opinions – frequently require FMV
- Stark Statute (Civil Law - not criminal)
  - Prohibited – Financial relationships between physicians and "DHS" entities to which they refer UNLESS the arrangement fits into a Stark exception.
  - Stark exceptions typically require the 3 Tenets of Defensibility: Fair market value, commercial reasonableness and not taking into account DHS referrals
  - Governance, internal controls and documentation processes should enhance defensibility

Legal Foundation for Physician Compensation

- IRS Private Inurement Guidance (for non-profit entities)
  - Prohibited - Use of public funds to benefit private individuals or for-profit entities.
  - What is legitimate compensation?
  - Payments for items or services needed to ensure the non-profit mission
  - Payments must not exceed FMV for the items or services provided
  - Penalties: Loss of non-profits status (back taxes owed) or “intermediate sanctions”

Key Concept – FMV

- Stark Statute – FMV:
  - The value in arm's length transactions, consistent with the general market value… (1877 (h)(3) of the Social Security Act)
- Narrower regulatory definition of FMV (42 CFR §411.351):
  - The value in arm's-length transactions, consistent with the general market value.
  - General market value means the compensation that would be included in a service agreement as the result of bona fide bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party.
  - Compensation does not take into account the volume or value of anticipated or actual DHS referrals

Key Concept – FMV

- Burden of establishing FMV rests with the parties
- Appropriate valuation methods
  - CMS will not provide “bright-line” standards
  - Based on facts and circumstances
  - Look to nature of the transaction, location and other factors
- Limited guidance from CMS
  - External valuations may be relevant to intent but will not ensure FMV
    - BUT: while internal valuations are okay, they are susceptible to manipulation, do not have strong evidentiary value and are subject to more intensive scrutiny (i.e., external valuations are preferred).
  - Use of multiple, objective, independently published surveys is prudent
- Documentation sufficient to support FMV will vary – no rule of thumb
  - FMV for administrative services may differ from FMV of clinical services
  - Definition is “qualified in ways that do not necessarily comport with the usage in standard valuation techniques and methodologies. For example, the methodology must exclude valuations where the parties to the transactions are at arm’s length but in a position to refer to one another.” [emphasis added]

Key Concept – FMV

- Safe harbor regulations require FMV, but the AKS does not define it.
- OIG Guidance
  - Special Fraud Alert – Clinical Laboratory Services (October 1994):
    - Presumption that compensation outside of FMV is in exchange for referrals.
    - "By 'fair market value' we mean value for general commercial purposes. However, 'fair market value' must reflect an arms-length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them."
- OIG Compliance Guidance for Individual and Small Group Practices (October 2000):
  - "The OIG's definition of 'fair market value' excludes any value attributable to referrals of Federal program business or the ability to influence the flow of business. Adhering to the rule of keeping business arrangements at fair market value is not a guarantee of legality, but is a highly useful general rule."
- OIG Supplemental Guidance for Hospitals (January 2005):
  - Hospitals should have appropriate processes for making and documenting reasonable, consistent, and objective determinations of FMV.
  - Is the determination of FMV based upon a reasonable methodology that is uniformly applied and documented?
  - If FMV is based in comparables, the hospital should ensure the market rate for the comparable services is not distorted.

Key Concept – Commercial Reasonableness

- Commercial Reasonableness
  - Not officially defined in Stark, but commentary defines it
    - Subjective Concept (Phase I): Sensible, prudent business agreement from the perspective of the parties
    - Objective Concept (Phase II): Would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential for DHS referrals
- Examples of Commercially Unreasonable Conduct:
  - Too many medical directors
  - Purchase of an EMR system, with no intention to ever use it
  - Complex arrangements with illogical components
  - No chance to earn a profit – is this okay?
  - Paying for early termination rights
  - Overbroad non-compete

Recent Enforcement Actions Involving Physician Compensation

- *U.S. ex rel. Payne, et al. v. Adventist Health (Sept. 21, 2015)*
  - $118 Million settlement to resolve allegations that Adventist violated the False Claims Act by maintaining improper compensation arrangements with referring physicians and by miscoding claims
- *U.S. ex rel. Reilly v. North Broward Hosp. Dist. (Sept. 15, 2015)*
  - $69.5 million settlement to resolve FCA allegations related to physician compensation arrangements that were above FMV and not commercially reasonable due to internal tracking of contribution margins from referrals
- *U.S. ex rel. Barker v. Columbia Regional Healthcare System Inc. (Sept. 4, 2015)*
  - $35 Million settlement to resolve former executive's False Claims Act suits accusing the Georgia Hospital chain of overpaying referring oncologist

Recent Enforcement Actions Involving Physician Compensation

- *U.S. ex rel. Schaengold v. Memorial Health, Inc. (S.D. Ga.)*
  - Allegations: Hospital entered into employment arrangements with three physicians as part of physicians' practice purchase that exceeded FMV, took into account the volume or value of referrals, and were not commercially reasonable.
  - Allegations: Hospital considered referrals to the hospital, pointing to projected and actual substantial losses related to physicians.
  - Hospital Board projected acquisition would result in financial losses of $670k per year for five years
  - BUT the Board recommended doing the deal because of increase in "hospital revenue."

Recent Enforcement Actions Involving Physician Compensation

- *Devender Batra, M.D. and Belmont Cardiology, Inc. (N.D. W. Va.)*
  - **$1 million settlement** to resolve allegations of improper compensation between Dr. Batra and two hospitals
  - Investigation into alleged Stark and FCA violations involving Dr. Batra followed a 2011 settlement with the hospitals after the hospitals self-disclosed noncompliant compensation arrangements with Dr. Batra and Belmont Cardiology
  - Hospitals cooperated in investigation against Dr. Batra and Belmont Cardiology

Common Valuation Pitfalls in Transactions

- Problems in Healthcare Valuation
  - Stark regulations suggest that traditional approaches may not always be possible to utilize
  - Data between parties in a position to refer cannot be utilized (does that leave anything?)
  - Valuation of healthcare service arrangements is still a relatively new area within the valuation profession
  - Many arrangements must also be commercially reasonable (different from FMV)
  - Independent appraisals not required, but are preferred
  - Some debate among lawyers and appraisers – e.g., intangible value

Common Valuation Pitfalls in Transactions

- Practical Problems for Parties
  - Parties' expectations are oftentimes difficult to counter
    - Changes to current agreements may be met with resistance by physicians
  - Rigorous, arm's-length negotiation may not result in a FMV outcome
  - Certain market data is simply not reliable
  - Risk tolerance of buyer and seller may differ

Roles in Transactions

- Role of Seller
  - Bears burden of establishing FMV and CR for past relationships
  - Assembles documentation to support all arrangements prior to due diligence
    - Considers pre-diligence audit of all arrangements
  - Works with counsel to address problematic relationships prior to due diligence
    - Considers whether disclosures are appropriate
    - Considers outside valuations to support retrospective compensation

Roles in Transactions

- Role of Buyer
  - Bears burden of establishing FMV and CR for future relationships
  - Obtains sufficient information needed to analyze all documented and undocumented physician relationships
  - Considers valuation analysis for future compensation
  - Determines how to address noncompliant relationships
  - Develops and implements internal governance and documentation processes
    - Stark's technical requirements
    - Stark's key tenets of defensibility (i.e., FMV, CR and the prohibition on TIA DHS referrals)
    - No one-size-fits all strategy for demonstrating compliance

Roles in Transactions

- Role of the Valuation Consultant
  - Recommends compensation parameters and provide expertise
  - Issues an objective third-party opinion on FMV and CR
- Role of Legal Counsel
  - Manages due diligence process
  - Analyzes past arrangements to determine appropriate response
  - Develops compensation plans and governance processes that support the valuator's FMV/CR parameters
  - Careful examination of any valuation opinions to enhance defensibility
  - Not to opine on FMV and CR

“Hot Button” Valuation Questions to Consider in Transactions

- How do you value and pay for quality, and who is entitled to the payment?
- When would a valuator’s opinion “take into account” referrals?
- What factors should (and should not) be looked at when determining commercial reasonableness?
- Can a hospital ever pay a doctor more in compensation than the profit the doctor generates from professional fees?
- How long is the “shelf-life” of a valuation? What are the implications of relying on an expired opinion?
- How do you value services in co-management agreement? What is the rationale?
- In valuing compensation, can you stack compensation for different tasks performed by the doctor?
- Is a doctor's practice worth anything beyond the depreciated value of its equipment?
- How do you prepare a medical group for the realities of valuation in a hospital transaction?
- Does compensation in a physician group practice even need to be FMV?
- Can you value mid-level supervision?

Questions

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Conducting Effective Witness Interviews

Panel Participants

Bob Anderson, Former Assistant U.S. Attorney and Civil/Criminal Health Care Fraud Coordinator, U.S. Attorney's Office for the Middle District of Alabama

Tony Maffei, Special Agent, U.S. Department of Health and Human Services, Office of Inspector General

Agenda

- Types of Witness Interviews
  - Formal Witness Testimony
  - Informal Witness Interviews
- Parallel Proceedings
- Internal Investigations
- Strategies and Tips for an Effective Witness Interview

Conducting Effective Witness Interviews

- Two primary information-gathering tools:
  - Requests for Documents
  - Witness Interviews
- Threshold Questions:
  - Whom to interview?
  - When to interview?
  - Role of documents?

Conducting Effective Witness Interviews

- Formal Witness Testimony
  - For example:
    - Civil Investigative Demand ("CID") Testimony
    - Authorized Investigative Demand ("AID")/ HIPPA subpoena
    - Grand Jury Subpoena
  - Timing/ Approach
  - Recording and transcript of interview
  - Note: CIDs are becoming much more widely used for testimony, especially since the FCA amendments delegating authority to use them down to the U.S. Attorney level. Expect to see CIDs for testimony in many more cases.

Conducting Effective Witness Interviews

- Informal Witness Testimony
  - When used/ approach
  - Voluntary
    - Witnesses free to terminate interview at any time
  - Proffer Session
    - “Queen for a Day”
  - Memorialization of interview
  - How different than formal witness testimony?

Conducting Effective Witness Interviews

- Parallel proceedings:
  - Simultaneous criminal, civil and administrative actions
  - Often used in healthcare fraud matters
- Considerations:
  - Information sharing and collaboration amongst government attorneys
  - DOJ Approach
    - Criminal
    - Civil
  - OIG Approach

Conducting Effective Witness Interviews

- Internal Investigation:
  - Conducted by Company – often involving outside counsel – during the course of a healthcare fraud investigation
  - As with government investigation, documents and interviews are the primary information-gathering tools

Conducting Effective Witness Interviews

- Internal Investigation: *Witness Interviews*
  - Determining list of witness interviews
  - Order of interviews
  - Inform witness of purpose of interview
    - Existence of a Government investigation
    - Nature of issue/ problem being investigated
    - Counsel retained to advise organization
  - *Upjohn* Warnings
  - Purpose and approach of interview
  - Memorandum of interview

Conducting Effective Witness Interviews

- Internal Investigation: *Preparation for Government Interviews*
  - Counsel for Company v. Counsel for Individuals
  - Discussions with Government in advance of interview:
    - Designation (target, subject, witness)
    - Scope of interview?
    - Able to share documents to be used in connection with interview?
  - Preparation should include:
    - Counsel on the government interview, CID or grand jury process
    - Counsel regarding:
      - Credibility Concerns
      - Perjury Concerns
      - False Statements Liability

Conducting Effective Witness Interviews

- Tips and Strategies
  - Preparation is key
  - Knowledge of the subject matter is expected by the Government
  - If counsel is going to severely restrict what the witness can discuss, careful thought should be given about whether to offer the witness up for an interview at all
  - In the context of voluntary interviews, witnesses (and counsel) need to remember that they are always free to terminate the interview at any time.
  - Prepare for increased use of CID Testimony

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Anatomy of a Healthcare Fraud Investigation
An Interactive Case Study

Panel Participants

Chris Sabis	***Assistant U.S. Attorney – Civil Division***
	(Assistant United States Attorney, U.S. Attorney's Office for the Middle District of Tennessee)
Elizabeth Young	***Assistant U.S. Attorney – Criminal Division***
	(Trial Attorney, Fraud Section, Criminal Division, U.S. Department of Justice)
Steve Petrovich	***General Counsel of City Medical Center***
	(Senior Vice President and General Counsel, Ardent Health Services)
Brian Roark	***City Medical Center Outside Counsel***
	(Bass, Berry & Sims PLC)
Matt Curley	***Moderator***
	(Bass, Berry & Sims PLC)

Hypothetical Facts*

City Medical Center ("CMC") is a large, acute-care hospital based in Nashville, Tennessee.

Heart Group is a group of private-practice cardiologists whose physicians have privileges at CMC.

CMC's compliance hotline recently received an anonymous complaint regarding a Heart Group cardiologist named **Dr. Ticker**. Dr. Ticker has practiced at CMC for almost 10 years and is one of the busiest cardiologists at CMC.

The **anonymous caller** stated that the caller believed that Dr. Ticker regularly inserted stents into patients who did not need the procedure. The caller said that this problem was widely-known among the nurses in CMC's cath lab and that several had complained to the head of the cath lab, **Sandra Corazon**.

*All facts in this presentation are hypothetical and any resemblance to actual events or individuals is purely coincidental. The contents of this presentation do not reflect the views of the U.S. Department of Justice.

According to the caller, nothing had been done about the problem because CMC wanted to maintain Dr. Ticker's high referral volume to CMC.

In response to the hotline call, CMC's Director of Compliance directed staff to investigate the allegations. The compliance staff reviewed records and talked to several employees in the cath lab.

Some nurses said that there were no issues with Dr. Ticker's stenting procedures. Others stated that Dr. Ticker sometimes performed angioplasties and inserted stents on patients with less than 70% occlusion, including some patients with less than 50% occlusion.

The nurses said that many doctors believed that stenting is not indicated unless arteries show at least 70% occlusion on an angiogram study.

One nurse stated that she believed that some patients had suffered adverse effects as a result of the stent procedures, such as strokes.

In addition to those concerns, certain nurses and cath lab employees expressed concerns about rumors that Dr. Ticker had “sweetheart” deals with CMC, but had no further factual information about those rumors.

Sandra Corazon, who has recently been promoted to Director of Clinical Services at CMC, was interviewed and stated that she believes that all of Dr. Ticker’s stent procedures had been performed in appropriate circumstances and that she is aware of no other issues concerning Dr. Ticker.

The Director of Compliance contacts CMC's General Counsel to update him on the status of the compliance investigation.

During the compliance investigation, CMC receives an OIG subpoena requesting:

(1) Records relating to the hospital's performance of angioplasty and stenting procedures from 2005 to present; and

(2) Medical records relating to certain patients who received stents from Dr. Ticker.

The OIG subpoena directs that any communications regarding this matter be directed to AUSA Chris Sabis at the U.S. Attorney's Office.

Soon thereafter, CMC receives an Authorized Investigative Demand (AID) requesting all documents concerning:

(1) Dr. Ticker's relationship with Stentco, Inc., one of the world's largest cardiac stent manufacturers and the maker of the stents used by Dr. Ticker in procedures he performs at the CMC;

(2) Cath Lab Medical Directorship Agreement between CMC and Dr. Ticker, pursuant to which Dr. Ticker serves as Medical Director of CMC's cath lab; and

(3) Any other financial relationships between CMC and Dr. Ticker.

CMC’s General Counsel receives phone calls from two cath lab employees that they have been approached by someone claiming to be an agent from the federal government.

One employee spoke with the agent for an hour and the other has scheduled a time to talk with the agent later in the week.

Ms. Carazon receives a Civil Investigative Demand (CID) to appear at the U.S. Attorney's Office to provide testimony regarding:

(1) the procedures Dr. Ticker performs at CMC;

(2) Dr. Ticker's Cath Lab Medical Directorship Agreement; and

(3) research and support services that Ms. Carazon has performed for Dr. Ticker in connection with certain clinical trials in which Dr. Ticker has been involved over the past two years.

CMC's board of directors calls a board meeting seeking an update and report regarding the status of the internal investigation undertaken by CMC.

The U.S. Attorney's Office initiated its investigation of CMC as a result of the filing of a *qui tam* complaint by an employee of CMC, who still works as a staff member in CMC's Office of Compliance.

The complaint includes allegations that CMC and Dr. Ticker violated the False Claims Act based on violations of Stark and the Anti-Kickback Statute related to various agreements and "side-deals" with Dr. Ticker and claims that CMC presented false claims resulting from the performance of unnecessary medical procedures.

Ms. Carazon receives a grand jury subpoena to appear and testify before the grand jury regarding the same topics on which she provided testimony in connection with the CID.

The General Counsel receives a call from Ms. Carazon prior to her testimony before the grand jury and she informs the General Counsel that she has destroyed notes and other documents regarding CMC's relationship with Dr. Ticker.

CMC's outside counsel recommends to CMC that it should consider engaging in discussions with the government to globally resolve the outstanding criminal and civil issues facing CMC.

AUSA Chris Sabis recommends to the U.S. Attorney that the United States should intervene in the *qui tam* action with respect to the False Claims Act violations premised on a violation of the Anti-kickback Statute concerning Dr. Ticker's Cath Lab Medical Directorship Agreement.

AUSA Beth Young recommends to the U.S. Attorney that the United States should seek an indictment of Dr. Ticker concerning financial kickbacks related to his relationship with Stentco.

AUSA Young has not determined whether to recommend that CMC or any of its employees should be indicted.

The Board of Directors asks the General Counsel and CMC's outside counsel to discuss the range of possible outcomes and what a global resolution of these matters might look like.

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Managing Compliance Issues from the Client's Perspective

Jennifer Peters
Vice President and Chief Operations Counsel
LifePoint Health, Inc.

Charity Elmer
Senior Vice President and General Counsel
Cox Health

Cheryl Mason
Vice President Litigation
HCA Inc.

**Remarks of panelists reflect their own views and are not intended as an expression of the views of any organization or entity.*

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