

**GOING ON THE OFFENSIVE:
STRATEGIES FOR INVESTIGATING,
COMBATING, AND AFFIRMATIVELY
LITIGATING AGAINST FRAUD**

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GENERAL AREAS OF DISCUSSION

- I. Proactively Combating the Potential for Fraud
- II. Investigating Allegations of Fraud, Both Historical and Real-Time
- III. Litigating Allegations of Fraud by the Government
- IV. Examples of Recent Federal Cases (Civil & Criminal)

I. PROACTIVELY COMBATING THE POTENTIAL FOR FRAUD

- A. Create and Maintain a Legitimate, Enforceable Compliance Program
- B. Emphasize – REPEATEDLY – Appropriate Coding and Supporting Documentation
- C. Constantly Analyze and Review Data to Spot Trends Early On
- D. Constantly Review Existing and Proposed Relationships for Possible Anti-Kickback Statute Issues
- E. Develop Procedures for Returning Overpayments to the Government

**A. DEFENSE PERSPECTIVE:
CREATE AND MAINTAIN A LEGITIMATE, ENFORCEABLE
COMPLIANCE PROGRAM**

- i. If no compliance program exists, implement one immediately with competent assistance, be it a law firm or consultant.
- Gather information about compliance efforts to date (if any) and confirm what currently is in place, *i.e.* compliance report logs, auditing plans, Board resolutions related to the compliance program, training programs and records, etc.
- Identify what you hope to address, both short-term and long-term.
- Do not procrastinate because of cost concerns.

**A. DEFENSE AND DOJ PERSPECTIVE:
CREATE AND MAINTAIN A LEGITIMATE, ENFORCEABLE
COMPLIANCE PROGRAM**

- ii. Assuming written compliance program manual and policies are already in place, review against the OIG Model Compliance Programs and the Federal Sentencing Guidelines for Organizations to ensure an effective compliance program.
- USAM 9-28.000 - Principles of Federal Prosecution of Business Organizations
 - USAM 9-28.300 – Factors to Be Considered - "The Filip Factors"
 - "The existence and effectiveness of the corporation's pre-existing compliance program." See USAM 9-28.800 – Corporate Compliance Programs
- "While the Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees, the critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct to achieve business objectives. The Department has no formulaic requirements regarding corporate compliance programs.
- The fundamental questions any prosecutor should ask are:
 - Is the corporation's compliance program well designed?
 - Is the program being applied earnestly and in good faith?
 - Does the corporation's compliance program work?"

**B. DEFENSE PERSPECTIVE:
EMPHASIZE – REPEATEDLY – APPROPRIATE CODING AND
SUPPORTING DOCUMENTATION**

- i. Inappropriate coding
 - Not capturing all receivables.
 - Risk that actions could be interpreted by government as knowing or reckless upcoding.
 - If possible, consider using in-house coders/billers.

**B. DEFENSE PERSPECTIVE:
EMPHASIZE – REPEATEDLY – APPROPRIATE CODING
AND SUPPORTING DOCUMENTATION**

ii. Supporting documentation

- Standard request at outset of any CMS audit or DOJ investigation.
- The strength of supporting medical documentation is at the core of many cases, whether investigations of medical necessity, Medicare Advantage payments, or other issues.
- Particularly important if your claims data is aberrant.

**C. DEFENSE COUNSEL & DOJ PERSPECTIVE:
CONSTANTLY ANALYZE & REVIEW DATA TO SPOT TRENDS EARLY**

- i. Data Analysis is a crucial component of identifying and managing risks as part of an effective compliance program.
- What types of data has the company identified to help detect the types of misconduct most likely to occur in your line of business?
 - How often does the company collect and analyze such data?
 - Who performs the analysis?
 - Who reviews it?
 - How is the data used to enhance the compliance program?
 - How did you address/respond to red flags?

**C. DOJ PERSPECTIVE:
INCREASED USE OF DATA ANALYTICS IN CRIMINAL HCF CASES**

- ii. Significant Law Enforcement Investment in Data Analytics Resources, Tools and Personnel
- Newly-Formed Fraud Section Data Analytics Team
 - Supports Medicare Strike Force cities (Fraud Section and U.S. Attorneys' Offices)
 - Access to real-time billing data
 - Find investigative leads, identify trends and targets, corroborate fraud tips
 - HHS-OIG Consolidated Data Analytics Center (CDAC)
 - Supports HHS components/OIG investigations
- iii. Data Analytics Focus
- High-risk providers
 - Billing outliers (by geographic area, type of service, specialty/peers)

**C. DOJ PERSPECTIVE:
SOURCES OF CRIMINAL HCF CASES**

- Data analysis
- Referrals from law enforcement partners (HHS-OIG, FBI, FDA-OI, Medicaid Fraud Control Units, DCIS, IRS, Postal OIG)
- Cooperating defendants
- Cooperating witnesses
- HHS-OIG and FBI hotline complaints
- Zone Program Integrity Contractor (ZPIC) referrals
- Medicare Hotline Complaints from beneficiaries
- *Qui Tam* False Claims Act complaints/relators

**D. DEFENSE PERSPECTIVE:
CONSTANTLY REVIEW EXISTING AND
PROPOSED RELATIONSHIPS FOR POSSIBLE
ANTI-KICKBACK STATUTE AND STARK ISSUES**

- AKS continues to be an area of focus for criminal HCF investigations and prosecutions, particularly where conduct:
 - causes overutilization of items or services
 - involves patient steering that interferes with or undermines patient choice
 - frustrates/impedes patient access to care
- If there is any doubt as to a relationship, seek legal advice.
- What are you really paying for?
 - If there is any doubt as to a relationship, perform a sincere cost-benefit analysis – Is it really that worth it?

**E. DEFENSE PERSPECTIVE:
DEVELOP PROCEDURES FOR RETURNING OVERPAYMENTS TO
THE GOVERNMENT WHEN IDENTIFIED**

- Medicare Advantage organizations: develop procedures for prompt return of overpayments that are identified through compliance programs and other channels
 - "60-day Rule": must use "reasonable diligence" to investigate credible information of overpayments
 - Timely, good-faith investigation not to exceed six months
 - If overpayment is identified, must look back six years
 - 60-day repayment clock begins when the overpayment is identified and quantified
- Knowing failure to return overpayments under these rules can lead to False Claims Act liability

**II. DEFENSE PERSPECTIVE:
INVESTIGATING ALLEGATIONS OF FRAUD,
BOTH HISTORICAL AND REAL-TIME**

- A. Tailor Data Mining to Specific Allegations of Misconduct
- B. Review Pertinent Bank Records, Corporate and Individual (if necessary)

**II. DEFENSE PERSPECTIVE:
INVESTIGATING ALLEGATIONS OF FRAUD,
BOTH HISTORICAL AND REAL-TIME**

- C. Review Pertinent Documentation
 - Emails, letters, and texts
 - Contracts, both draft and final
 - Compliance material
 - Marketing material
 - Previous legal advice
 - Misc.

**II. DEFENSE PERSPECTIVE:
INVESTIGATING ALLEGATIONS OF FRAUD,
BOTH HISTORICAL AND REAL-TIME**

- D. Conduct Necessary Interviews
- E. If Necessary, Retain Consultant – UNDER PRIVILEGE – to Perform Forensic Review
- F. If Appropriate, Implement Remedial Measures

**III. DEFENSE PERSPECTIVE:
LITIGATING ALLEGATIONS OF HCF FRAUD BY THE GOVERNMENT**

A. Establish Positive Dialogue with Government Attorneys and/or Agents

- How to build the reservoir of trust
 - Make contact as early as possible
 - Be as cooperative and forthcoming as possible

**III. DOJ PERSPECTIVE:
LITIGATING ALLEGATIONS OF HCF FRAUD BY
THE GOVERNMENT – COOPERATION**

- “To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct.”
 - Memo from Deputy Attorney General Sally Quillian Yates to DOJ, “Individual Accountability for Corporate Wrongdoing” (Sept. 5, 2015).
- “A company should not expect to receive cooperation credit for just producing documents in response to a grand jury subpoena. That has never been considered cooperation in any other context, and it will not be recognized as cooperation in the health care fraud context either. To the contrary, compliance with lawful process is a legal requirement, not voluntary cooperation.”
- “Cooperation means that a corporation has made an affirmative effort to investigate potential wrongdoing, and that it has turned over the facts uncovered during that investigation in a timely way to our prosecutors. In particular—and as I have said in other contexts over the last year—it is important that cooperating companies identify the culpable individuals. Prosecuting individuals for their criminal wrongdoing, including for health care fraud, is a top priority for the Criminal Division.”
 - Assistant Attorney General Leslie R. Caldwell’s Remarks at the American Bar Association’s 25th Annual National Institute on Health Care Fraud in Miami, Florida on May 14, 2015.

**B. DEFENSE PERSPECTIVE:
KNOW WHAT YOU ARE RESPONDING TO AND HOW TO RESPOND –
IS THE UNDERLYING INVESTIGATION CIVIL OR CRIMINAL OR
PARALLEL OR ADMINISTRATIVE?**

- Civil Investigative Demands (“CIDs”):
 - Request for Documents
 - Interrogatories
 - Deposition
- Document subpoenas
 - HHS-OIG subpoena
 - HIPAA subpoena a/k/a Authorized Investigative Demand (“AID”)
 - Grand Jury subpoena
- Interviews
 - Government request for informal interview
 - Law enforcement drop-in interview

**B. DEFENSE PERSPECTIVE:
KNOW WHAT YOU ARE RESPONDING TO AND HOW TO
RESPOND – IS THE UNDERLYING INVESTIGATION CIVIL OR
CRIMINAL OR PARALLEL OR ADMINISTRATIVE?**

- Criminal Indictment
- Civil Complaint
- Be Aware of Potential Collateral Consequences: Administrative remedies, including potential impact on government program participation

**B. DEFENSE PERSPECTIVE:
KNOW WHAT YOU ARE RESPONDING TO AND HOW TO
RESPOND – IS THE UNDERLYING INVESTIGATION CIVIL OR
CRIMINAL OR PARALLEL OR ADMINISTRATIVE?**



**C. DEFENSE PERSPECTIVE:
MACRO CONCEPTS TO ALWAYS KEEP IN MIND**

- Be aware of applicable privileges (attorney/client, 5th Amendment, etc.)
- Be precise, but not unnecessarily pugilistic
- Be aggressive if and when appropriate
- Document communications in writing only when necessary

IV. EXAMPLES OF RECENT FEDERAL CASES

A. Civil Settlements

B. Criminal Prosecutions

CIVIL SETTLEMENTS

THE UNITED STATES ATTORNEY'S OFFICE
CENTRAL DISTRICT OF CALIFORNIA

SEARCH THE ARCHIVE

URGENTIVE

Long Beach-Based Health Plan Pays Nearly \$320 Million to Settle Allegations that it Received Overpayments for Medi-Cal Patients

FOR IMMEDIATE RELEASE August 23, 2012

SCAN Health Plan Pays Another \$2.82 Billion to Resolve Claims of Inflated Risk Adjustment Scores that Increased Reimbursements from Medicare Part C

LOS ANGELES – In the largest recovery ever obtained from a single Medi-Cal provider, a Long Beach-based managed care health plan has paid \$319.85 million to resolve allegations that it received overpayments from Medi-Cal.

On August 16, 2012, SCAN Health, the State of California to resolve care patients.

On August 16, 2012, SCAN also paid an additional \$2.82 million to the federal government – bringing the total settlement in this matter to \$322,670,650 – to settle a whistleblower lawsuit's allegations that the company unlawfully caused an inflation of some of its patients' "risk adjustment scores," which then inflated Medicare payments to the company.

Under Medicare Part C's managed care system, physicians for patients enrolled in a Medicare Advantage health plan report patients' diagnosis codes to the plan, which then reports the codes to the federal Centers for Medicare and Medicaid Services (CMS), which then uses the codes to develop risk adjustment scores for the patients. Risk adjustment scores measure the health of patients and are used by Medicare Part C to determine how much to pay the plan as a monthly capitated rate for each patient.

CRIMINAL PROSECUTIONS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, June 22, 2016

National Health Care Fraud Takedown Results in Charges against 301 Individuals for Approximately \$900 Million in False Billing

Most Defendants Charged and Largest Alleged Loss Amount in Strike Force History

Attorney General Loretta E. Lynch and Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell announced today an unprecedented nationwide sweep led by the Medicare Fraud Strike Force in 36 federal districts, resulting in criminal and civil charges against 301 individuals, including 64 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$900 million in false billings. Twenty-three state Medicaid Fraud Control Units also participated in today's arrests. In addition, the HHS Centers for Medicare & Medicaid Services (CMS) is suspending payment to a number of providers using its suspension authority provided in the Affordable Care Act. This coordinated takedown is the largest in history, both in terms of the number of defendants charged and loss amount.

For the Strike Force locations, in the Southern District of Florida, a total of 100 defendants were charged with offenses relating to their participation in various fraud schemes involving approximately \$220 million in false billings for home health care, mental health services and pharmacy fraud. In one case, nine defendants have been charged with operating six different Miami-area home health companies for the purpose of submitting false and fraudulent claims to Medicare, including for services that were not medically necessary and that were based on bribes and kickbacks. In total, Medicare paid the six companies over \$24 million as a result of the scheme.

CRIMINAL PROSECUTIONS

Department of Justice
Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Friday, July 23, 2016

Three Individuals Charged in \$1 Billion Medicare Fraud and Money Laundering Scheme

The owner of more than 30 Miami-area skilled nursing and assisted living facilities, a hospital administrator and a physician's assistant were charged with conspiracy, obstruction, money laundering and health care fraud in connection with a \$1 billion scheme involving numerous Miami-based health care providers.

Assistant Attorney General Leslie E. Caldwell of the Justice Department's Criminal Division, U.S. Attorney Wilfredo A. Ferrer of the Southern District of Florida, Special Agent in Charge George L. Piro of the FBI's Miami Field Office and Special Agent in Charge Skimone E. Richmond of the U.S. Department of Health and Human Services Office of Inspector General (OIG) Miami Regional Office made the announcement.

"This is the largest single criminal health care fraud case ever brought against individuals by the Department of Justice, and this is further evidence of how successful data-driven law enforcement has been as a tool in the ongoing fight against health care fraud," said Assistant Attorney General Caldwell.

ONE BILLION DOLLAR
HEALTHCARE FRAUD SCHEME

ESFORMES
NETWORK


