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

BENTON CURTIS
SENIOR COUNSEL, BROAD & CASSEL

JONATHAN M. PHILLIPS
GIBSON, DUNN & CRUTCHER

PATRICE SULLIVAN
DEPUTY CHIEF, CRIMINAL DIVISION, U.S. ATTORNEY’S
OFFICE FOR THE EASTERN DISTRICT OF LOUISIANA)

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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 9-28.300 – 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)

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

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."


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

CRIMINAL PROSECUTIONS
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Department of Justice
Office of Public Affairs

IMMEDIATE RELEASE

Three Individuals Charged in Billing Medicare Fraud and Money Laundering Scheme

The arrest of more than 70 Medicare fraud suspects, including six individuals and two Medicare billing agencies, is the largest Medicare fraud enforcement action to date. The defendants are alleged to have bill

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