Health Care Fraud Investigations:

*What to Do When the Government Knocks*

August 17, 2016
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ALLIANCE OF WOUND CARE STAKEHOLDERS

Who is the Alliance?

- A non-profit multidisciplinary trade association of physician specialty societies and clinical associations whose members treat patients with wounds
- Serves as an “umbrella” association for clinical organizations whose members treat patients with wounds

Mission of the Alliance:

- To promote quality care and access to wound care products and services for people with wounds.
- Focus on compelling issues of commonality to the organizations in the reimbursement, government and public affairs affecting wound care.
CLINICAL ASSOCIATION MEMBERS

- Academy of Nutrition and Dietetics
- American Association of Nurse Practitioners
- American College of Foot & Ankle Surgeons
- American College of Hyperbaric Medicine
- American College of Phlebology
- American College of Wound Healing and Tissue Repair
- American Diabetes Association® Interest Group on Foot Care
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Venous Forum
- Association for the Advancement of Wound Care
- Dermatology Nurses Association
- National Association for Home Care and Hospice
- National Lymphedema Network
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Visiting Nurses Association of America
FOUNDATIONS OF ALLIANCE WORKPLAN

- Wound Care Quality Measures
- Wound Care Research
  - Reimbursement Issues- (Coverage, Coding and Payment)- for both Fee for Service and Implementation of Medicare Access and CHIP Reauthorization (MACRA)
    - Submit Comments to Federal Agencies and their Contractors and Speak at Meetings
      - Centers for Medicare and Medicaid Services (CMS) and their contractors (DMEMACs, A/B MACs)
      - Agency for Healthcare Research and Quality (AHRQ)
      - Food and Drug Administration (FDA)
    - Serve as resource to CMS coverage, coding and payment staff for education about wound care
Have you already been involved in a government health care fraud investigation or audit?

Would you know what to do if an FBI agent were to visit you at home?
Agenda

I. Current Regulatory Environment for Fighting Health Care Fraud
II. Enforcement Trends, Recent Settlements and Decisions
III. Overview of the False Claims Act
IV. Types of Government Touches
V. Mitigating Risks
VI. Questions and Answers
I. Current Regulatory Environment for Fighting Health Care Fraud
The Federal Government is rapidly expanding its role as the dominant payer and dominant regulator of health care goods and services.
Timelines and Trends

MEDICARE PROGRAM ENROLLMENT

Actual and Projected Medicare Enrollment

Key fact: Former President George W. Bush’s birthday: July 6, 1946 & Former President Bill Clinton’s birthday: August 19, 1946

Note: Enrollment numbers are based on Part A enrollment only. Beneficiaries enrolled only in Part B are not included.
Source: CMS Office of the Actuary, 2014
Timelines and Trends
MEDICARE MANAGED CARE ENROLLMENT

Total Medicare Advantage Plan Enrollment

Timelines and Trends

MEDICAID AND MEDICAID MANAGED CARE ENROLLMENT

Medicaid Enrollment

- Total Enrollment
- Medicaid Managed Care
- Traditional Medicaid
- Medicaid Expansion

Medicaid expanded with 100% cost coverage (2014)

Calendar Year

Source: Centers for Medicare & Medicaid. 2013 Statistical Supplement, Table 13.4; AIS Medicare and Medicaid Market Data. 2015; Kaiser Family Foundation, Total Monthly Medicaid and CHIP Enrollment for May 2014 and May 2015; CMS, Medicaid Managed Care Penetration Rates as of December 31, 2010; CMS National Summary Of Medicaid Managed Care Programs And Enrollment as of July 1, 2010; CMS, Total Medicaid Enrolees-Villa Group Break Out Report, March 2015; Reported on the CMS-64: Coverage Gains Under Recent Section 1115 Waivers: A Data Update, S. Artiga and C. Mann, Kaiser Family Foundation, August 2005.

*Enrollment was above zero but under 500,000, thus was rounded down.
Federal Government Agencies

COOPERATIVE EFFORTS AND POOLING RESOURCES

Federal Departments:

- Department of Justice (DOJ)
  - Offices of the United States Attorneys (USAO)
- Federal Bureau of Investigation (FBI)
- Department of Health and Human Services (DHHS)
  - Office of Inspector General (OIG)
    - Office of Audit Services (OAS)
    - Office of Evaluations and Inspections (OEI)
  - Office for Civil Rights (OCR)
  - Center for Medicare and Medicaid Services (CMS)
    - Center for Program Integrity (CPI)
Federal Government Agencies

COOPERATIVE EFFORTS AND POOLING RESOURCES

Task Forces:

- Health Care Fraud Prevention & Enforcement Action Team (HEAT)
- Medicare Fraud Strike Force (Strike Force)

<table>
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<tr>
<th>Date</th>
<th># of People Charged</th>
<th>Amount of Loss</th>
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<tbody>
<tr>
<td>July 2010</td>
<td>94</td>
<td>$251 million</td>
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<td>February 2011</td>
<td>111</td>
<td>$225 million</td>
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<td>September 2011</td>
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<td>May 2012</td>
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<td>October 2012</td>
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<td>$430 million</td>
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<td>May 2013</td>
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<td>May 2014</td>
<td>90</td>
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<td>June 2015</td>
<td>243</td>
<td>$712 million</td>
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<tr>
<td>June 2016</td>
<td>~275</td>
<td>~$800 million</td>
</tr>
<tr>
<td>Total</td>
<td>App. 1,200</td>
<td>Over $3.5 billion</td>
</tr>
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Federal Efforts Against Fraud

FY 2015 HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM (“HCFAC”)

Federal Government won or negotiated over $1.98B in judgments and settlements

U.S. Attorneys Offices opened over 900 new criminal health care fraud cases

More than 600 defendants were convicted for health care fraud related crimes

Over 4,000 individuals and entities were excluded from participation in the federal health care programs
Government’s Perspective: FRAUD ENFORCEMENT IS PROFITABLE

Profitability is now a driving force behind the continued increase in investigations and prosecutions.

HCFAC not only pays for itself, but it produces an unequaled return on investments ("ROI") for a Government program.

The average ROI over the last three years is $6.10.
Enforcement Environment

GOVERNMENT INVESTMENTS IN FRAUD ENFORCEMENT ACTIVITIES

Investments to Increase Collaboration

- HEAT
- Strike Force
- Healthcare Fraud Prevention Partnership (HFPP)
- Unified Program Integrity Contractors (UPIC)

Investments in State-of-the-Art Technologies

- Predictive Analytics
- $1 Billion+ savings (2014 & 2015)
- $11.60 for every dollar return-on-investment (2015)

Individual Liability

The Yate’s Memo (Sept. 9, 2015)

1. To be eligible for **any** cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.

2. Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.

3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

“One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.” *The Yate’s Memo (Sept. 9, 2015).*
Individual Liability

The Yate’s Memo (Sept. 9, 2015)

4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for individuals.

5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.

6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.

“By focusing on building cases against individual wrongdoers * * * we maximize our ability to ferret out the full extent of corporate misconduct.” The Yate’s Memo (Sept. 9, 2015).
DOJ’s First Compliance Counsel Expert

Areas of Inquiry When Evaluating Company’s Compliance Program

- Whether the design of the program takes into account the company’s complexity and highest risk areas;
- Whether the program’s monitoring and auditing are effective;
- Whether stakeholders throughout all levels of company are knowledgeable about the program and understand the risks relevant to their duties; and
- Whether the company has demonstrated its seriousness in compliance by investing into the program.

New York University, Corporate Compliance and Enforcement Round Table discussion (Nov. 13, 2015), available at http://www.law.nyu.edu/corporatecompliance/events/roundtable-discussion.
II. Enforcement Trends, Recent Settlements and Decisions
Wound Care Enforcement

HHS-OIG PRIORITIES

OIG 2016 Work Plan –
Selected inpatient and outpatient billing requirements

- Will review Medicare payments to acute care hospitals to determine hospitals’ compliance with selected billing requirements and recommend recovery of overpayments
- Prior OIG audits, investigations, and inspections identified areas of risk for noncompliance with Medicare billing requirements
Recent Settlements and Decisions

IN THE NEWS

- **08/2013:** Whistleblower alleged that HBOT providers falsely submitted claims to the government certifying that they had “provided direct supervision” and were “immediately available” even though they were not present on-site during the HBOT session.

- **12/2013:** Lymphedema & Wound Care Institute paid a $4.3M FCA settlement for allegations that they had billed Medicare for providing manual lymphatic drainage therapy using massage therapists as opposed to physical therapists as required under the rules and regulations governing the Medicare program.

- **05/2016:** Whistleblower alleged that provider upcoded “selective debridement” to “surgical/excisional debridement” resulting in pricier claims. Allegations also included that providers were providing medically unnecessary HBOT sessions by falsely misdiagnosing pressure ulcers as diabetic ulcers.
III. Overview of the False Claims Act
The False Claims Act

- The False Claims Act ("FCA") prohibits any person who:
  - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
  - Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .
  - Is liable to the U.S. Government for civil penalty of $5,500 to $11,000, plus 3 times the amount of damages Government incurred because of the violation.
  

- Materiality: the falsehood was material to decision to pay the claim

- Scienter: “knew or should have known”; “deliberate ignorance” of truth of falsity; “reckless disregard” of the truth or falsity of the claim

No specific intent needed
**Qui Tam Relators**

- The federal FCA is a *qui tam* statute, providing private citizens ("relators") with the opportunity to file complaints alleging violations of the FCA on behalf of the U.S. Government
  - Relators may receive 15% - 30% of amount recovered
- Once a whistleblower files a suit, the Department of Justice must decide whether to "intervene"

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**Department of Justice**

**Office of Public Affairs**

**FOR IMMEDIATE RELEASE**

**Thursday, December 3, 2015**

**Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015**

Recoveries Exceed $3.5 Billion for Fourth Consecutive Year
The False Claims Act

EXAMPLES AND TYPES OF FALSE CLAIMS ACT ALLEGATIONS

- Inadequate documentation of services performed
- Billing for services that are of such poor quality they are deemed “worthless.”
- False Certifications
- Billing for Goods or Services not Provided
- Medically Unnecessary
- Upcoding
Wound Care Enforcement

KEY RISK AREAS

Hyperbaric Oxygen Therapy

- Certifying attendance or direct supervision by physician, when actually not
- Falsely diagnosing to qualify for HBOT coverage

Debridement

- Upcoding
- Inadequate documentation of services performed
The OIG Provided Reports on Areas of Concern A Decade Ago

Top Compliance issues for the OIG on Debridement

1. Billing the debridement at a higher level than actually provided (or inconsistent with the documented wound)
2. Billing a non debridement service as surgical debridement (e.g. callous paring)
3. Insufficient documentation to know what was done

Top Compliance Issues for the OIG on Hyperbaric Oxygen Therapy

1. Billing Medicare for a non-covered condition
2. Inadequate documentation to support the medical necessity of HBOT
3. Giving patients more hyperbaric treatments than medically necessary
4. Failing to perform the appropriate tests or treatment before instituting HBOT
5. Not having a physician in attendance during the hyperbaric treatment

Recent DOJ investigations have targeted the areas in these 2 reports
IV. Types of Government ‘Touches’
Types of Government

FORMAL GOVERNMENT NOTICES

- OIG Subpoenas
- Grand Jury Subpoenas
- Civil Investigative Demand (CID)
- Search Warrant
- DOJ Contact Letters
- Informal Notices

Yes . . . even the parking lot or the home
Responding

- Every communication from the government or its agents need to be treated seriously
- One person should be responsible for “opening the mail”
- Incorrect replies or not responding at all could be interpreted as abuse
- Read carefully and plan your response strategy at the beginning (who, what, why)
- Conduct the fire drill
- The role of legal counsel
- Anticipate landmines
- Respond
- Post-response follow-up
- Build a positive relationship with your FI’s Customer Service Manager
V. Mitigating Risks
Tip # 1

Be Sure All of Your Employees Know How To Respond To All Types of Government Inquiries
Government Inquiries

Practical Issues

- Maximize use of folding, wallet-size employee hotline cards
- Card should include appropriate protocol
  - Get identification
  - Find out what the inquiry is about
  - Explain your rights
  - Discuss contact with employer

Effectiveness and Added Value

- Improves the organization’s control of government investigations
- Improves employee morale because they are prepared and know their organization will support them
Tip # 2

Invest in Quality Training of Employees on the Concepts of Compliance
Training

PRACTICAL ISSUES

- Train at the level of the audience
- Train frequently
  - Short v. Long sessions
  - Frequent changes in government regulations
- Demonstrate that attendance is a priority by example (i.e., management participation)
Training

PRACTICAL ISSUES

- Use a variety of training methods
  - Video
  - Interactive sessions
  - Computer-based training
  - One-on-one
  - “Coffee break” training
  - Quizzes
Training

EFFECTIVENESS & ADDED VALUE

- Decreases likelihood of whistleblowers
- Creates frequent opportunity for face-to-face compliance discussions resulting in questions being raised
- Maximizes the employees understanding of compliance
- Ensures program remains current
- Improves employee confidence of right vs. wrong
Tip # 3

Coordinate Compliance with Human Resource Activities
HR

PRACTICAL ISSUES

- HR is not a surrogate for compliance
- HR should refer all disgruntled employee complaints to compliance officer for review
- Exit interviews should be conducted for all employees and HR needs to be educated to inquire about compliance issues/questions
- Disciplinary action by HR should be filed in Compliance files as well
- HR and Compliance need to be seen as places that are discreet
Tip # 4

Develop and Track a Budget for Compliance Activities
Budget

Be Practical

- Create a realistic budget that takes into account both new resources needed and the extent to which compliance activities can rely on existing operations (e.g., training)

Effectiveness and Added Value

- Demonstrates fiscal responsibility
- Ensures compliance officer accountability
- Assists in complying with CIAs
- Serves as a quantifiable benchmark of effectiveness
Tip # 5

Consider the Impact That Compensation Methodologies Have on Promoting or Discouraging Compliant Business Behavior
Compensation

Practical Issues

- Beware of employee commission-based compensation generally

- When paying commissions, consider including factors that improve and benefit the organization as a whole
  - QA checks
  - Consumer retention and satisfaction

- Examine the compliance officer’s compensation
  - Consider whether the compensation methodology promotes compliance decision-making for the benefit of the entire organization
  - Volume of hotline activity
  - Number/availability of training sessions
  - Adequacy of documentation of effectiveness benchmarks

Effectiveness and Added Value

- Written Policies and Procedures are not the sole source of compliance

- Money and Behavior should promote the same compliant goals established in written policies and procedures
AN EFFECTIVE COMPLIANCE PROGRAM THAT ADDS VALUE TO THE ORGANIZATION REQUIRES WRITTEN POLICIES AND WELL-INFORMED PEOPLE NOT ONE OR THE OTHER
Mitigation Summary

1. Train your employees on how to respond to all types of government inquiries
2. Invest in your compliance program
3. Compliance coordination with HR
4. Budget for compliance activities
5. Consider how your compensation methodologies impact complaint business behavior
6. Develop and maintain written compliance policies and train your employees
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Deep Roots in Health Policy, Regulation, Payment

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Thank You.