

# Health Care Fraud Investigations: *What to Do When the Government Knocks*

**August 17, 2016**

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# Presented by

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**Marcia Nusgart, R.Ph., *Moderator***

Executive Director, Alliance for Wound  
Care Stakeholders  
marcia@woundcarestakeholders.org  
301.530.7846



**David E. Matyas**

Member, Epstein Becker Green  
dmatyas@ebglaw.com  
202.861.1833



**George B. Breen**

Member, Epstein Becker Green  
gbreen@ebglaw.com  
202.861.1823



**Lynn Shapiro Snyder**

Member, Epstein Becker Green  
lsnyder@ebglaw.com  
202.861.1806

# ALLIANCE OF WOUND CARE STAKEHOLDERS

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## ➤ 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

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- 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

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- 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

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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



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# 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.

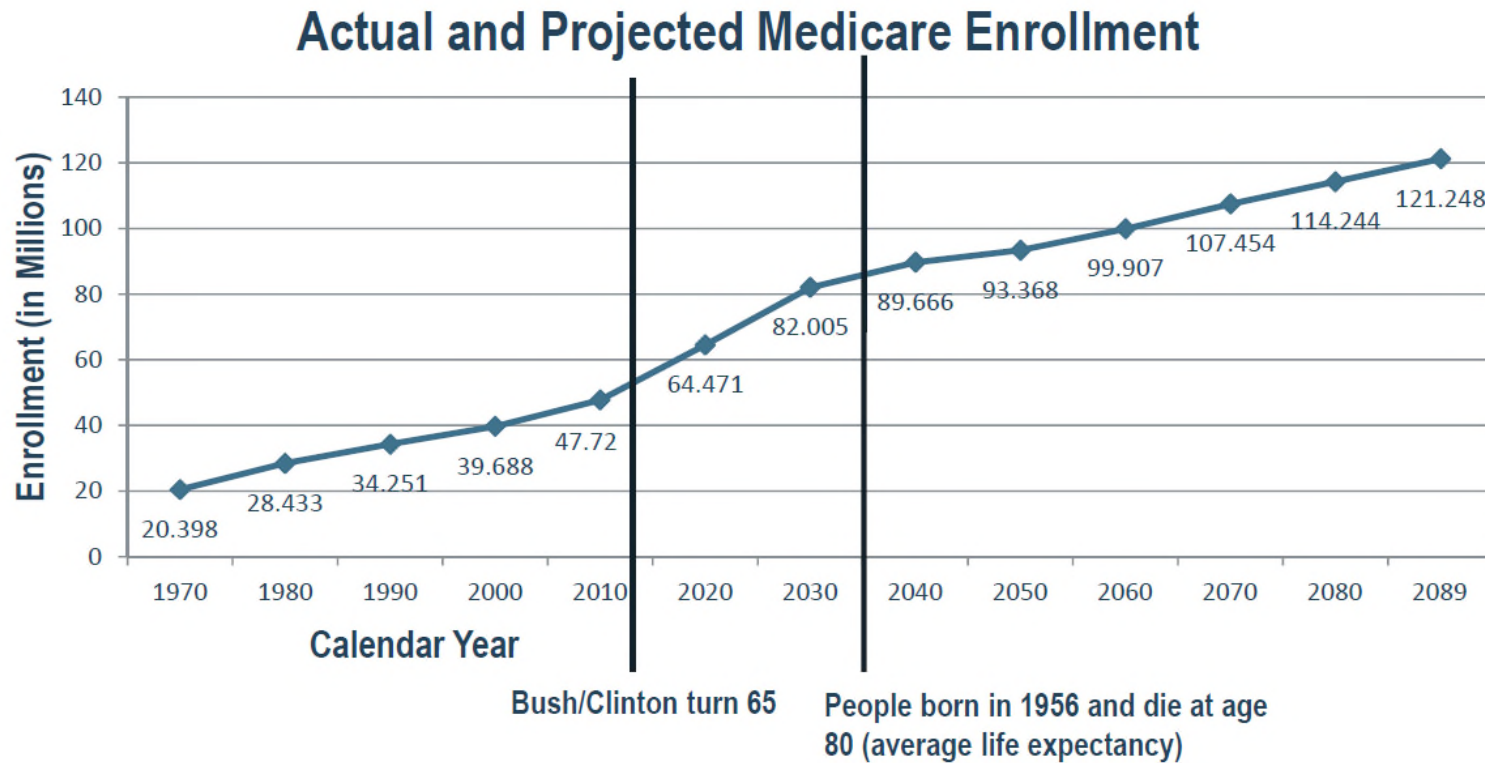


So . . .



# Timelines and Trends

## MEDICARE PROGRAM ENROLLMENT



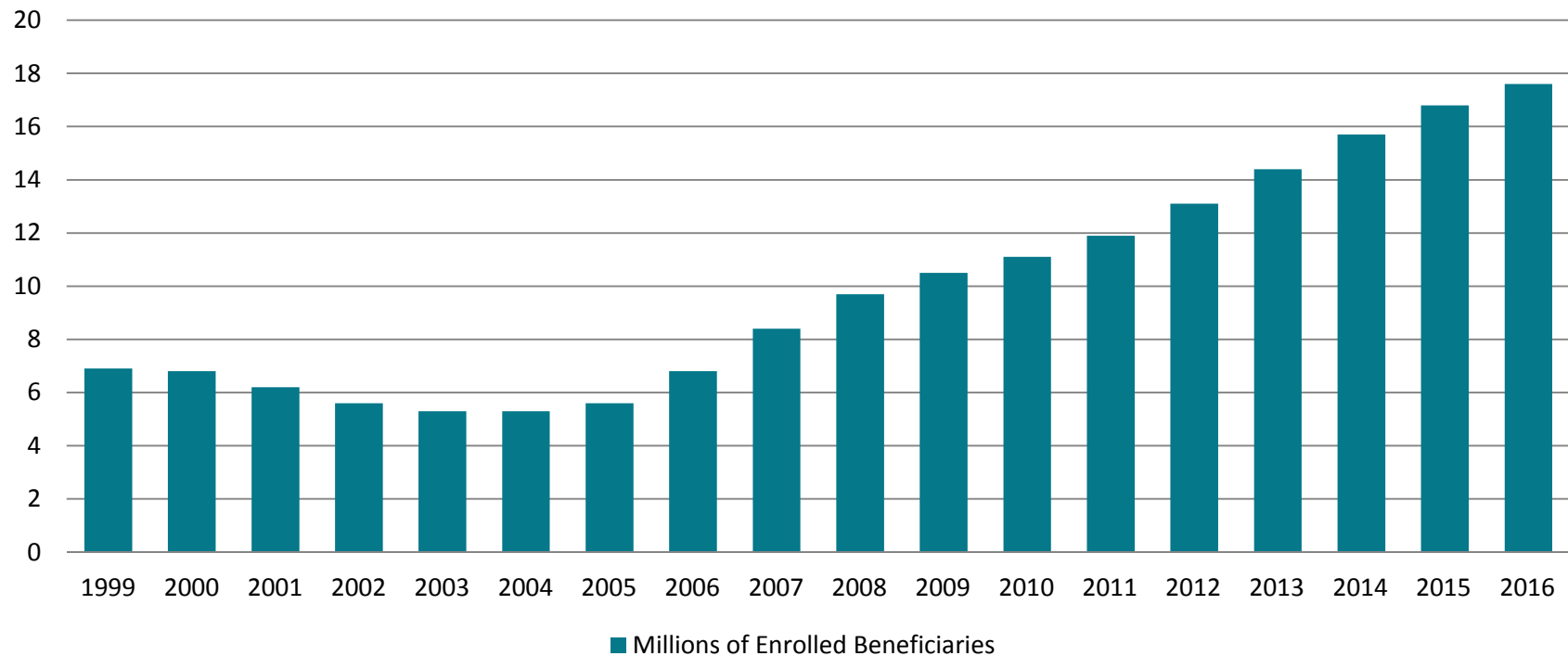
Key fact: Former President George W. Bush's birthday: July 6, 1946 & Former President Bill Clinton's birthday: August 19, 1946

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

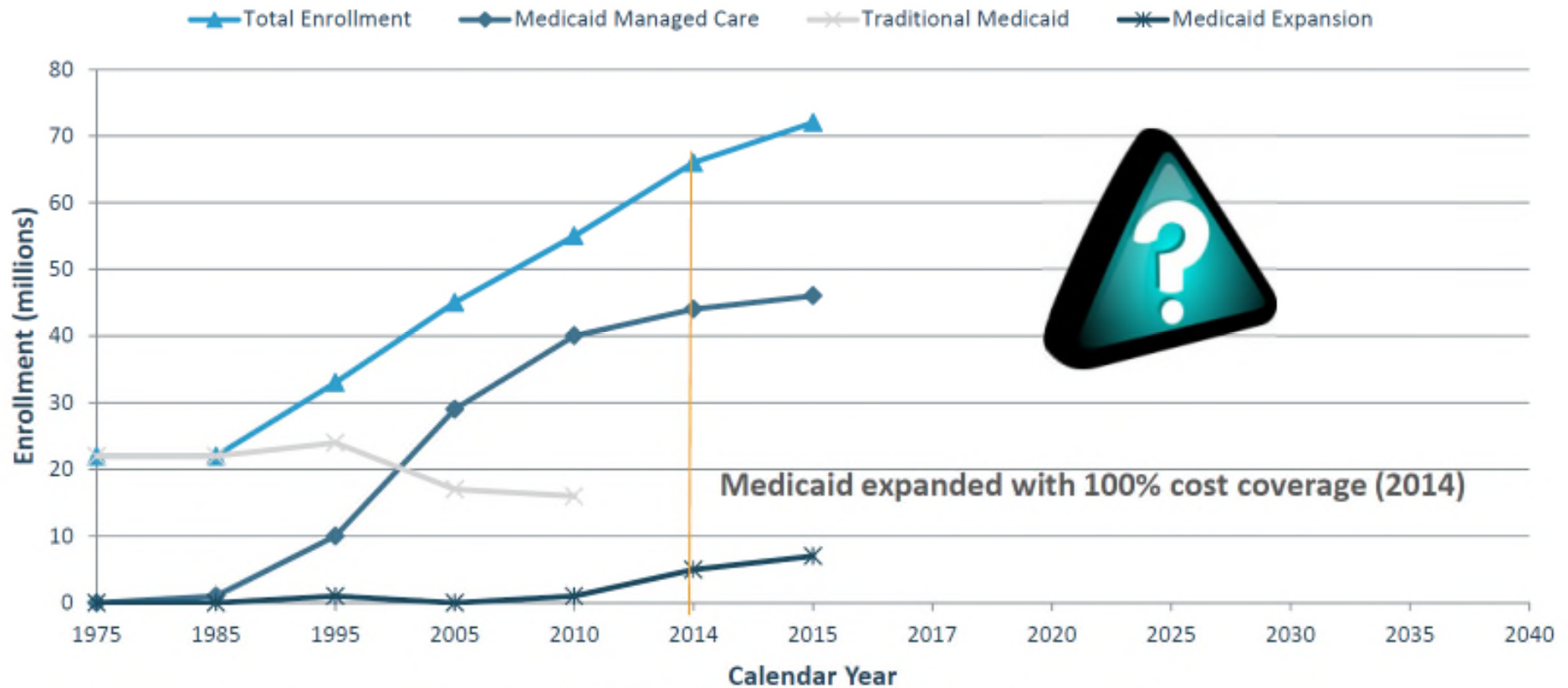


Source: Kaiser Family Foundation, <http://kff.org/medicare/fact-sheet/medicare-advantage/>

# Timelines and Trends

## MEDICAID AND MEDICAID MANAGED CARE ENROLLMENT

### Medicaid Enrollment



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 Enrollees - VIII Group Break Out Report, March 2015, Reported on the CMS-64. Coverage Gains Under Recent Section 1115 Waivers: A Data Update, S. Ariga 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)





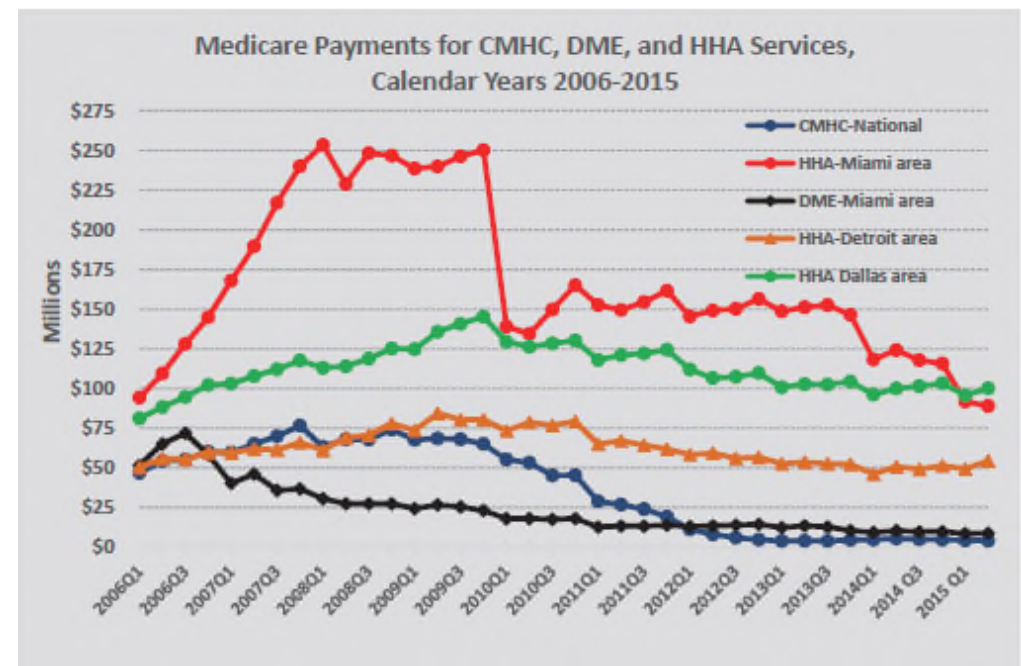
# Federal Government Agencies

## COOPERATIVE EFFORTS AND POOLING RESOURCES

### Task Forces:

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

NATIONAL HEALTH CARE FRAUD TAKEDOWNS		
Date	# of People Charged	Amount of Loss
July 2010	94	\$251 million
February 2011	111	\$225 million
September 2011	91	\$295 million
May 2012	107	\$452 million
October 2012	91	\$430 million
May 2013	89	\$223 million
May 2014	90	\$260 million
June 2015	243	\$712 million
June 2016	~275	~ \$800 million
<b>Total</b>	<b>App. 1,200</b>	<b>Over \$3.5 billion</b>



The Dept. of Health and Human Services & Dept. of Justice, Health Care Fraud and Abuse Control Program Annual Report for Fiscal year 2015 (Feb. 2016), available at <https://oig.hhs.gov/reports-and-publications/hcfac/index.asp>; OIG, Media Materials: National health Care Fraud Takedown 2016, available at <https://oig.hhs.gov/newsroom/media-materials/2016/takedown.asp>.

# Federal Efforts Against Fraud

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

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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)



Shantanu Agrawal et al., *Medicare's "Big Data" tools Fight & Prevent Fraud to Yield Over \$1.5 Billion in Savings* THE CMS BLOG (July 11, 2016), <https://blog.cms.gov/2016/05/27/medicares-big-data-tools-fight-prevent-fraud-to-yield-over-1-5-billion-in-savings/>.

# 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.



*Hui Chen, Compliance Counsel Expert at U.S. Department of Justice*

New York University , Corporate Compliance and Enforcement Round Table discussion (Nov. 13, 2015), available at <http://www.law.nyu.edu/corporatecompliance/events/roundtable-discussion>.

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## II. Enforcement Trends, Recent Settlements and Decisions

# Wound Care Enforcement

## HHS-OIG PRIORITIES

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### OIG 2016 Work Plan – Selected inpatient and outpatient billing requirements

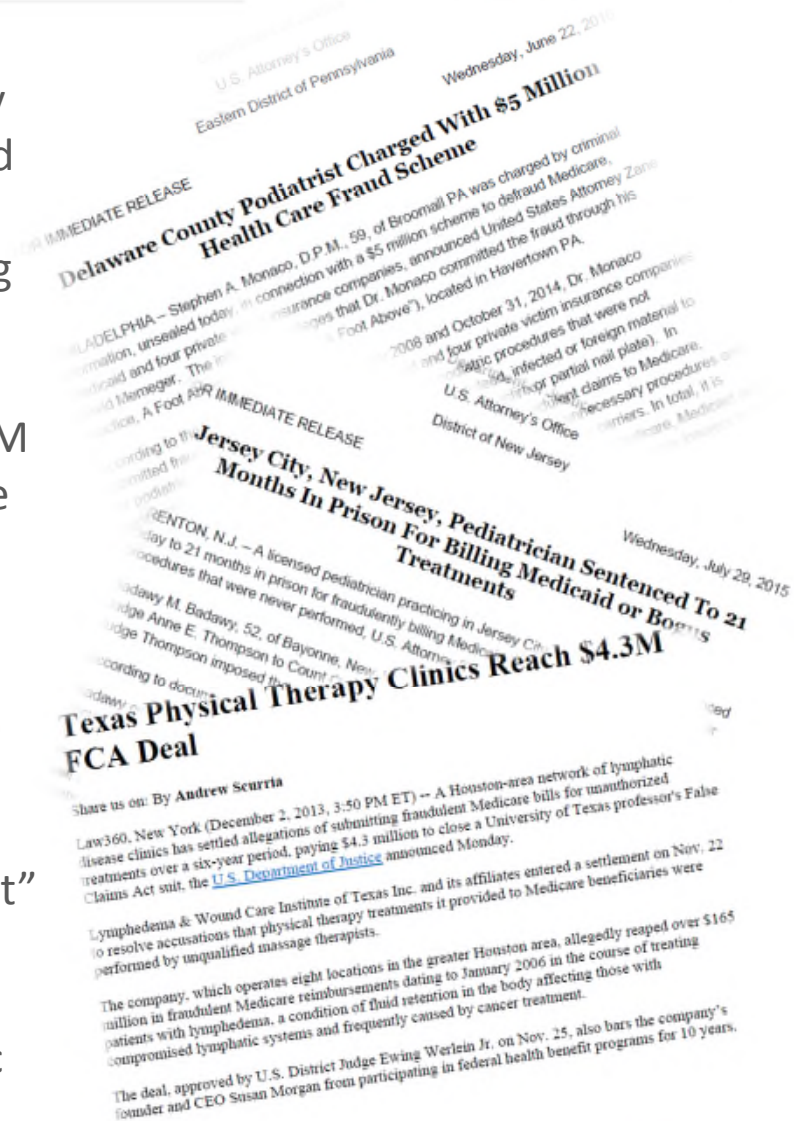
- Will review Medicare payments to acute care hospitals to determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments
- Prior OIG audits, investigations, and inspections identified areas of risk for noncompliance with Medicare billing requirements



# 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.





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## III. Overview of the False Claims Act

# The False Claims Act

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- 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.

31 U.S.C. §3729, *et seq.*

- 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

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- 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”

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

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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

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### 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

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## 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

<http://oig.hhs.gov/oei/reports/oei-02-05-00390.pdf>

Recent DOJ investigations have targeted  
the areas in these 2 reports

## 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

<http://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf>

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## IV. Types of Government 'Touches'

# Types of Government

## FORMAL GOVERNMENT NOTICES

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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

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- 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



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## V. Mitigating Risks

# TIP # 1

BE SURE ALL OF YOUR EMPLOYEES  
KNOW HOW TO RESPOND  
TO ALL TYPES OF  
GOVERNMENT INQUIRIES

# Government Inquiries

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## 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

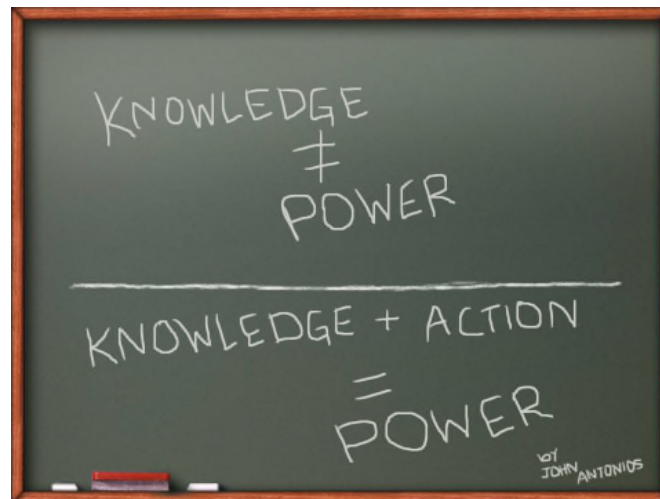
INVEST IN QUALITY TRAINING OF  
EMPLOYEES ON THE CONCEPTS OF  
COMPLIANCE

# Training

## PRACTICAL ISSUES

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- 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

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



# Training

## EFFECTIVENESS & ADDED VALUE

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- 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

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- 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

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## 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

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## 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

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## TIP # 6

AN **EFFECTIVE** COMPLIANCE PROGRAM  
THAT ADDS VALUE TO THE  
ORGANIZATION REQUIRES WRITTEN  
POLICIES AND WELL-INFORMED PEOPLE  
NOT ONE OR THE OTHER

# Mitigation Summary

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1. Train your employees on how to respond to all types of government inquires
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







# RESOURCES

- Epstein Becker Green has served as a thought leader in the health care industry for more than 40 years. Our attorneys regularly issue news advisories on cutting edge topics, host webinars on industry focused issues, and share informative videos.
- To join our mailing list, visit <http://www.ebglaw.com/subscribe/>
- Subscribe to our blogs:
  - [www.HealthLawAdvisor.com](http://www.HealthLawAdvisor.com)
  - [www.TechHealthPerspectives.com](http://www.TechHealthPerspectives.com)
- We invite you to view [\*Employment Law This Week\*](#)<sup>®</sup> - our 5-minute rundown of the latest labor and employment law news.



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Member, Epstein Becker Green

[lsnyder@ebglaw.com](mailto:lsnyder@ebglaw.com)

202.861.1806

**Thank You.**