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False Claims Act Enforcement on the Rise

Best Practices for Healthcare Providers to Avoid or Defend Investigations and Whistleblower Actions

THURSDAY, FEBRUARY 23, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

T. Jeffrey Fitzgerald, Partner, **Polsinelli Shughart**, Denver

Lisa M. Noller, Partner, **Foley & Lardner**, Chicago

Judith A. Waltz, Partner, **Foley & Lardner**, San Francisco

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February 23, 2012

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Noteworthy Settlements

- Big Pharma Pays Big … Again
  - AstraZeneca ($68.5M for deceptive marketing)
  - Serono ($44.3M for off-label marketing)
  - UCB SA ($34M for off-label marketing)
  - Novo Nordisk ($26.7M for off-label marketing)
  - Watson Pharm. ($79M for deceptive pricing)
  - Amgen ($780M for alleged kickbacks)
  - GlaxoSmithKline ($3 billion)

Noteworthy Settlements

- Pharma-Type Investigations, 2nd Generation (medical device and others)
  - Medline Industries (supplier, $85 million for improper rebates and sales conduct)
  - Guidant (medical device, $9.25 million for alleged pricing and sales conduct)
  - Define (medical device, $2.4 million for alleged kickbacks, sham customer surveys and sales conduct)
  - Medtronic (medical device, $23.5 million for alleged kickbacks and sales conduct)

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Noteworthy Settlements

- Stark and Anti-Kickback
  - San Joaquin Community Hospital ($734,000 for technical Stark violations)
  - Select Medical Corp. ($7.5 million for alleged kickbacks with medical directors)
  - Bristol Hospital and Bristol GI Assoc. ($158,000 for undocumented leases; MDs included in settlement)
  - Ohio Valley Health Services & Education Corp ($3.8 million for improper compensation agreements)

Department of Justice

United States Attorney William J. Ihlenfeld, II
Northern District of West Virginia

FOR IMMEDIATE RELEASE
MONDAY, SEPTEMBER 12, 2011
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OHIO VALLEY HOSPITALS TO PAY $3.8 MILLION TO RESOLVE ALLEGATIONS OF FALSE CLAIMS TO FEDERAL HEALTH CARE PROGRAMS

WHEELING, W.V. – Ohio Valley Health Education & Services Corporation (OVHS&E), Ohio Valley Medical Center (OVMC) and East Ohio Regional Hospital (EORH) have agreed to pay $3.8 million to the United States to settle allegations that they violated the Stark Act from January 2005 to August 2010, announced William J. Ihlenfeld II, U.S. Attorney for the Northern District of West Virginia. The agreement ends an investigation that OVHS&E, OVMC and EORH submitted false claims for payment to the Medicare program and the Medicaid program.

"The compensation arrangements that OVHS&E, OVMC and EORH had with local physicians were improper and were for significant sums, and thus the penalty assessed is severe. Illegal agreements like these drive up the cost of healthcare and in the end we all pay for it in the form of higher taxes," said U.S. Attorney Ihlenfeld. "OVHS&E, OVMC and EORH were cooperative during the investigation and provided our agents with the information necessary to bring the first phase of the investigation to a conclusion. Phase Two of the case involves pursuing the physicians involved and requiring that they return the prohibited payments and pay the statutory penalties."

"A physician who believes he is in violation of the Stark Act may come forward and self-report the noncompliance. While there are never any guarantees, self-reporting may lead to less formal and more lenient settlement proceedings depending upon the circumstances involved," continued U.S. Attorney Ihlenfeld.

Noteworthy Settlements

- Cayuga Medical Center ($3.6M) to resolve allegations of improper physician recruitment
  - 5/18/07: Hospital submits voluntary disclosure under OIG protocol
  - 11/14/07: Whistleblower files *qui tam* action
  - 1/25/12: United States pays relator $566,955.18 (~15% of settlement)

Ongoing Settlement Themes

- Gotcha Enforcement Continues
  - Rex Healthcare ($1.9 million for kyphoplasty procedures)
  - St. Mary Medical Center ($3.3 million one-day inpatient stays)
  - Lifepoint Hospitals ($1 million for outpatient observation services billed as inpatient)
  - UT Southwestern ($1.4 million for PATH-type issues)
  - Denver Health ($6.3 million for alleged observation billed as inpatient)

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Lessons from Others' Settlements

- Failure to Refund Overpayments
  - Catholic Healthcare West ($9.1 million to resolve allegations that it did not refund Medicare overpayments related to DSH reimbursement)
- Employed Physicians
  - Columbia University ($995,000 to resolve allegations of fraudulent overbilling by an employed physician)

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Court Decisions

- DOJ Has Good Year at the U.S. Courts of Appeals
  - *U.S. ex rel. Baltazar v. Warden*, 7th Cir.,
  - *U.S. ex rel. Ramadoss v. Caremark,* 5th Cir.
  - *U.S. ex rel. Wilkins v. United Health Group,* 3rd Cir.
  - *New York v. Amgen*, 1st Cir.
- Existing Case Law Extended
  - AKS violations actionable under False Claims Act
    - *U.S. ex rel. Wall v. Vista Hospice Care, (*N.D. Tex.)
  - AKS "one purpose" intent standard
    - *U.S. v Borrasi*, (7th Cir.)

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Court Decisions

- Amendments to the False Claims Act not Applied Retroactively
  - *U.S. ex rel. Stone v. Omnicare Inc., (*N.D. Ill.)
- Court Dismissed a Third-Party Complaint Seeking Contribution from Coding and Billing Experts
  - *U.S. ex rel. Ryan v. Staten Island University Hospital*, (E.D.N.Y.)
- FCA Penalties of $11 Million (8-1 ratio) not Excessive Under Excessive Fines Clause
  - *U.S. ex rel. Hobbs v. MedQuest Assoc.* (M.D. Tenn.)

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Court Decisions

- Medicare Enrollment Conditions Do Not Create Private Right of Action
  - *Baum v. Northern Dutchess Hospital, (*N.D.N.Y.)
- State Statute of Limitations Does Not Bar Claim Based Upon Fraudulently Unnecessary Surgery
  - *Bonham v. Weinraub*, (4th Cir.)
- Administrative Claims Suspension Does Not Violate Due Process Rights
  - *Personal Care Products Inc. v. Hawkins,* (5th Cir.)

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Court Decisions

- Medicare Enrollment Deficiencies Create False Claims Liability
  - *U.S. v Carell* (M.D. Tenn.) (denying motion to dismiss; failure to identify owners of home health in Medicare enrollment process made all claims false because CMS would not have enrolled provider if know of certain owners)
- Truce Between States and Feds over splitting of Medicaid Recoveries
  - *West Virginia v. Sebelius* (4th Cir.)
  - *Alabama v. CMS* (11th Cir.)

Court Decisions

- Physician has a claim for unjust enrichment where physician provided services to hospital without a contract and without violating Stark Law
  - *Braum v. Promise Regional Medical Center* (D. Kan.)

CMS Enforcement

- CMS Stark Disclosure Protocol
  - Required by PPACA, guidance issued 9/23/10
  - CMS will report/publish outcomes
  - Two settlements in 2011
    - A “critical access hospital in Mississippi” … failed “to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital and emergency room physicians” [paid $130,000]
    - A “general acute care hospital in Massachusetts” … failed “to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital department chiefs and the medical staff for leadership services, and (2) failed to satisfy the requirements of the personal services arrangements exception for arrangements with certain physician groups for on-site overnight coverage for patients at the Hospital” [paid $579,000]

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State False Claims Act

- Deficit Reduction Act of 2005
  - Requires providers with $5+ million in annual Medicaid payments of to educate employees about the False Claims Act through written policies
  - Gives states a 10% increase in share of fraud recoveries if state has a false claims law like the FCA
- OIG Determined That 17 States Do Not Have a Medicaid False Claims Act That Meets the Standards Required to Receive a 10% Increased Share of FCA Recoveries

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Individual Liability

- OIG guidance on exclusion of owners and managers (10/19/10)
  - Owner of excluded entity may be excluded
  - Manager of excluded entity may be excluded if knew or should have known of conduct
- Park doctrine becomes topic of discussion
  - *U.S. v Park*, 421 U.S. 658 (1974) (responsible corporate officer criminally liable based upon authority to prevent or correct a public health offence)

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Individual Liability

- Former in-house counsel of GSK, acquitted (May 2011)
- InterMune founder convicted of wire fraud for issuing off-label press release about Actimmune—sentenced to 6 months home detention and $20,000 fine (04/2011)
  - DOJ requested 10 years prison and $1 fine
- KV Pharmaceutical CEO sentenced to 30 days in jail plus $1.9M in fine after plea of guilty to FDA misbranding (03/2011)

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False Claims Act Enforcement on the Rise

Lisa M. Noller

February 23, 2012

HHS/DOJ Health Care Fraud and Abuse Program Report, February 2012

Total Transfers/Deposits by Recipient FY 2011	
Department of the Treasury	
Deposits to the Medicare Trust Funds, as required by HIPPA	
Gifts and Bequests	
Amount Equal to Criminal Fines	$5,399
Civil Monetary Penalties	$1,195,736,432
Asset Forfeiture	$16,495,458
Penalties and Multiple Damages	$22,401,515
Subtotal	$578,413,099
	$1,813,051,909
Centers for Medicare & Medicaid Services	
HHS/OIG Audit Disallowances – Recovered – Medicare	$74,057,438
Restitution/Compensatory Damages	$660,522,078
Subtotal*	**$734,579,516**
Grand total of Amounts Transferred to the Medicare Trust Funds	**$2,547,631,425**
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	$74,423,629
Veteran's Administration	$20,238,404
HHS/OIG Cost of Audits, Investigations and Compliance Monitoring	$8,949,927
Office of Personnel Management	$53,035,272
Other Agencies	$11,276,161
Federal Share of Medicaid	$599,911,275
HHS/OIG Audit Disallowances – Recovered – Medicaid	$354,092,195
Subtotal	**$1,121,926,863**
Realtors' Payments**	**$419,484,976**
TOTAL * **	**$4,089,043,264**

Enforcement Actions in FY 2011

- Opened 1,110 new criminal HCF investigations
  - 2,561 potential defendants
- 1,873 health care fraud prosecutions pending
  - 3,118 potential defendants
- Filed criminal charges in 489 cases
  - 1,430 named defendants
- In FY 2011, 743 defendants were convicted of HCF-related crimes (AKS, wire/mail/health care fraud)

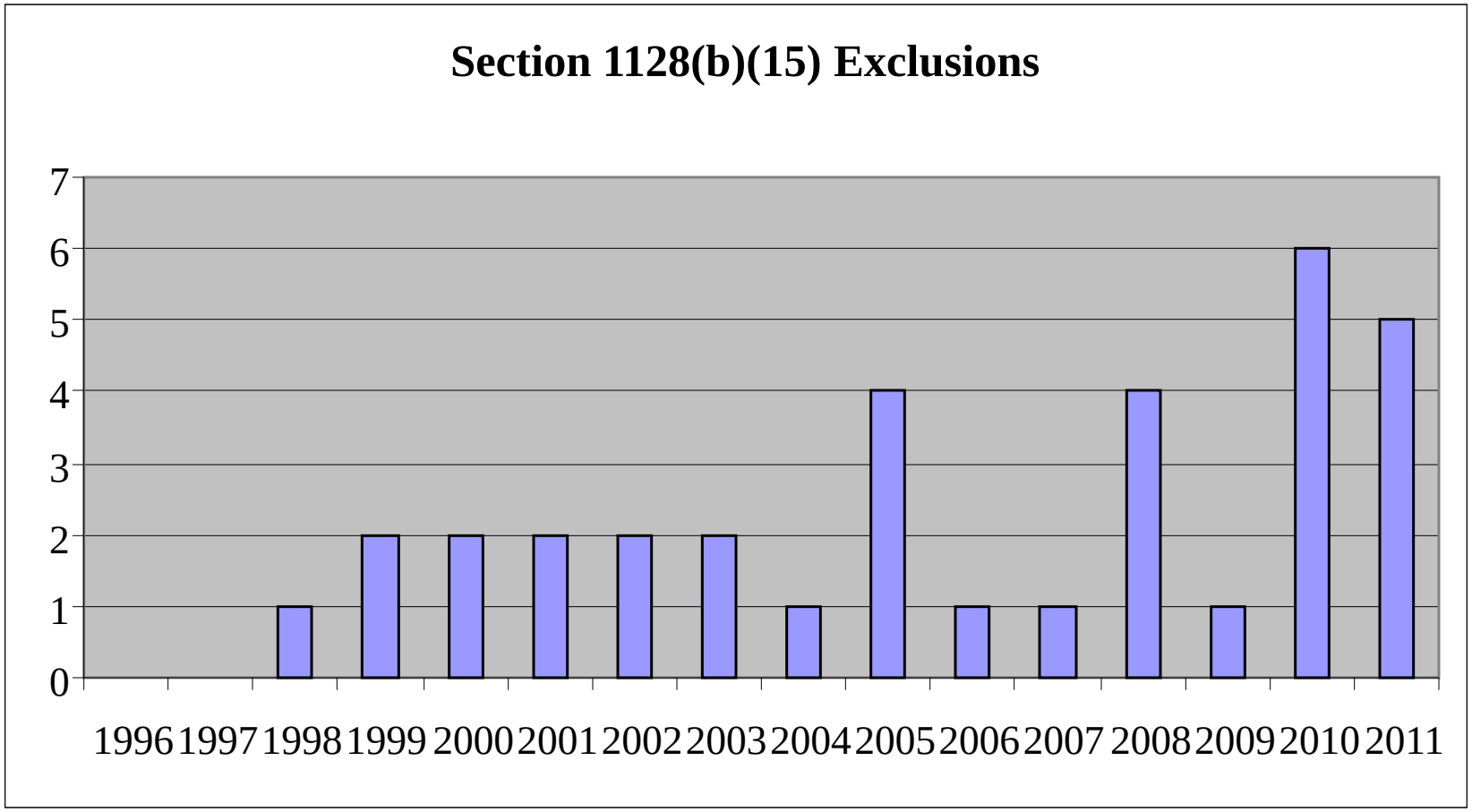
Enforcement Actions in FY 2011

- Many criminal cases include parallel civil investigations
  - Include FCA, *qui tams*
- DOJ opened 977 new civil health care fraud investigations
- 1,069 pending matters

Enforcement Actions in FY 2011

- HHS/OIG exercises exclusionary authority in connection with these matters
- Excluded 2,662 individuals and entities
- Based on:
  - Criminal convictions for Medicare/Medicaid fraud: 1,015
  - Fraud to other health care programs: 233
  - Patient abuse or neglect: 206
  - License revocations: 897

OIG's Use of Section 1128(b)(15)



The HEAT Is On

- Announced on May 20, 2009
- Mission:
  - To marshal significant resources across government to prevent waste, fraud and abuse in the Medicare and Medicaid programs
  - To reduce skyrocketing health care costs and improve the quality of care
  - To highlight best practices by providers and public sector employees
  - To build upon existing relationships between DOJ and HHS, such as Medicare Strike Force Teams
- Use “advanced data analysis techniques to identify high-billing levels in health care fraud hot spots”

HEAT Strike Force Locations

- 9 cities with Strike Force teams:
  Miami, FL
  Los Angeles, CA
  Detroit, MI
  Houston, TX
  Brooklyn, NY
  Baton Rouge, LA
  Tampa, FL
  Chicago, IL*
  Dallas, TX*

*(added in 2011)

Strike Force Results in FY 2011

- Charged 323 defendants
- Defendants billed Medicare >$1 billion
- 172 guilty pleas
- 26 defendants convicted following trial
- 175 defendants sentenced to prison terms
- Average prison sentence = 47 months

Civil Results in Parallel Cases

- Recovered $2.4 billion in FY 2011
  - Unlawful pharma pricing
  - Off-label marketing of medical devices and pharma products
  - Stark violations

Return on Investment

- Since 1997: $5.1 to $1.0
- 2009-2011: $7.2 to $1.0

Lessons Learned

- Government is more coordinated
- Prosecutors are more educated
- Strike Forces pursue “low-hanging fruit”

Be Proactive

- Annually review and revise compliance programs
- Take immediate remedial measures when uncover issues
- Ensure management personnel are on board, understand, appreciate and follow the company's compliance efforts
- Conduct routine internal data sampling, and address issues immediately

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Thank You!

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False Claims Act Enforcement on the Rise: Best Practices for Minimizing Liability Exposure

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Thursday, February 23, 2012

False Claims Backdrop for Compliance Programs

- Intent: Actual fraud, deliberate ignorance, or reckless disregard
- Available against those who submit false claims, or those who *cause* false claims to be submitted
- Includes whistleblower provisions

Compliance Programs

- Importance is greater than ever
  - Risks of noncompliance are increasing
  - More government resources than ever
- Soon to be mandatory as a condition of enrollment (required by PPACA ; no regs yet)
- Separate provisions require compliance program for SNFs

Involvement of Board and Officers in Compliance Program

- Risks are increasing for individuals
  - Responsible Corporate Officer cases
  - OIG exclusions against officers, controlling employees
- Recent CIAs include training requirements for Board members; attestations from Board and/or certain personnel functions as to the effectiveness of the compliance program and other responsibilities

Personnel Training, cont.

- Training of course should be a regular element of any compliance program (Sentencing Guidelines element)
- May be used to prove an element of intent for FCA (deliberate ignorance or reckless disregard for the truth or falsity of a claim)
- Check new guidance from CMS and OIG
  - CMS Quarterly Provider Compliance Newsletter, https://www.cms.gov/MLNProducts/Downloads/ProvCmpl_Products.pdf
  - OIG: A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse (CMS has a similar one on its website), various Compliance Guidances, Training Videos, CIAs
  - Fraud Prevention Toolkit, http://www.cms.gov/Partnerships/04_FraudPreventionToolkit.asp
  - RAC-identified issues for audit

Auditing and Monitoring

- Think about your data “footprint”
  - Data mining – increasingly sophisticated and contemporaneous government tools
  - More information now submitted as to provider performance – e.g., quality indicators
  - Transparency – more information available to the public (think whistleblowers)
- Identify your specific risk factors
  - RAC and other audit reports
  - OIG Workplan and OIG Audits

Auditing and Monitoring

- Reverse false claims – improper retention of overpayments can be grounds for false claims (FCA changes in FERA, plus PPACA)
- Need to show process/project management to be able to demonstrate due care (i.e., no intent to retain improperly received funds)
- Auditing and monitoring and how you deal with results – use your “footprint” to determine compliance challenges

Voluntary Disclosure to Government Are Expected

- OIG Self-Disclosure Protocol
- CMS Stark Self-Referral Disclosure Protocol
- 60-Day Rule – “Self-Reported Overpayment Refund Process” (Proposed Rule issued 2/16/2012)

60 Day Refund Rule

- PPACA Section 6402(a); Section 1128J of the Social Security Act
- Requires that identified overpayments be refunded within 60 days of identification, or 60 days after cost report is reconciled
- Consequences: CMPs and FCA liability

60 Day Refund Rule (cont.)

- Proposed Rule – 77 Fed. Reg. 9170 (Feb. 16, 2012) – comments 60 days
  - "Reasonable Inquiry" – 60 day clock starts running after the provider has chance to undertake "reasonable inquiry"
  - 10 year look back period – cf. current 3-4 years after final determination (reopening)

60 Day Refund Rule (cont.)

- Other important points about the Proposed Rule:
  - Statute is in effect now, not after regs are finalized
  - Medicare Parts A and B only are addressed in the Proposed Rule; Statute covers MA, Part D, MCOs
  - If an overpayment is claims related, the 60 days generally does not extend until after the cost report is reconciled

Provider Enrollment

- Why include this topic when discussing FCA compliance?
  - OIG and CMS both stress the importance they are placing on proper provider enrollment in their fraud, waste and abuse control efforts
  - PPACA enhancements for both Medicare and Medicaid enrollment screening
  - Goes to fundamental elements of payment: who is furnishing, ordering, referring or prescribing the item or service for which a claim is submitted
  - Administrative enforcement

Physician Relationships

- For providers, probably currently the highest area of risk of enforcement
- "Avoiding Medicare Fraud and Abuse: A Roadmap for Physicians" (Oct. 2011), available at http://www.cms.gov/MLNProducts/downloads/
  - Physician relationships with payers
  - Physician relationships with fellow providers
  - Physician relationships with vendors

Suspensions Pending Investigations of Credible Allegations of Fraud

- Medicare and Medicaid statutory provisions and regulations allow a suspension of payments on the basis that the provider/supplier is under investigation for a credible allegation of fraud:
  - Medicare: 42 C.F.R. Part 405, Subpart C (42 C.F.R. § 405.370)
  - Medicaid: 42 C.F.R. § 447.90; Part 455

"Credible Allegation of Fraud" (Medicare and Medicaid)

- Not defined in ACA
- Medicare Regulation: A credible allegation of fraud is an allegation from any source, including but not limited to the following:
  - Fraud hotline complaints;
  - Claims data mining;
  - Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.
- Allegations are considered to be credible when they have indicia of reliability.
- Medicaid definition also includes requirement for State verification

42 C.F.R. § 405.370(a); cf 42 C.F.R. § 455.2 ("which has been verified by the State")

Medicare Suspensions

- 18 months maximum duration, beyond which suspension cannot continue absent special circumstances
  - If case has been referred to, and is being considered by OIG; OR DOJ submits written request to CMS to continue suspension
- Suspension for recovery of an overpayment might follow/extend one for investigation
- CMS consults with OIG but ultimate authority will be retained by CMS
- Applies to Parts A and B; separate authorities for Parts C and D

Medicaid Suspensions

- May be implemented without prior notice; 30 days plus 2 additional 30 days (after that they would expect provider to notice!)
- Deference to States in further defining "credible allegations" but recognition that standard will likely be lower than now existing
- No retroactive application, but upon effective date CMS expects States to suspend payments to those against whom there exist pending investigations of fraud
- Medicare's 180 day limit for suspensions not adopted for Medicaid

Medicaid Suspensions, cont.

- State can decide that suspension is not in best interests of the Medicaid program
- Good cause exception if provider submits written evidence that persuades the State not to pursue suspension
- No additional due process provisions, but notice of suspension should include existing appeal rights
- CMS promises close scrutiny of State performance - including documenting good cause determinations

Conclusions

- FCA Enforcement is Trending UP!
- Compliance Programs must run faster to stay in place!
- Risks for individuals have increased dramatically.

Questions?

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