

# **The Fraud Enforcement and Recovery Act and Healthcare Reform: Implications for Compliance Initiatives and Fraud Investigations**

**Presented by:**

**Robert Threlkeld, Esq.**

**Holly Pierson, Esq.**

**Paul F. Danello, Esq.**





# Overview

- Background
- Significant modifications to the following statutes:
  - False Claims Act (“FCA”)
  - Anti-Kickback Statute (“AKS”)
  - Civil Monetary Penalties (“CMP”) Law
  - Criminal Healthcare Fraud Statute
  - Physician Self-Referral Law (“Stark”)
- Enhanced Compliance Programs and Enrollment Screening Protections
- Expansion of RACs
- Continued Increases in Funding to Combat Fraud



# Background

- Increased emphasis on compliance by healthcare providers and curtailing fraud and abuse as a method to pay for federal healthcare programs.
- Recent changes to significant healthcare laws greatly expand the likelihood of investigations and whistleblower complaints.
- Devotion of significant additional resources to the investigation and prosecution of fraud.



# Modifications to the False Claims Act

- Significant changes to FCA by recent legislation, including the Fraud Enforcement and Recovery Act of 2009 (“FERA”) and the Patient Protection and Affordable Care Act (“PPACA” or the “Healthcare Reform Law”).
- In general, the changes broaden potential liability and reduce available defenses to defeat whistleblowers and government suits.
- Expansion of FCA and increased funding for fraud enforcement increases the likelihood of investigations and lawsuits.



# Modifications to False Claims Act By FERA

- **FRAUD ENFORCEMENT AND RECOVERY ACT (“FERA”)**
  - signed by President Obama on May 20, 2009
  - significant changes to FCA
- **Elimination of Presentment Clause**
  - No longer necessary to prove that provider “presented” the claim to “the government”
  - Now simply have to show that the claim was made to a *recipient* of federal funds and the funds were
    - 1) Spent or used on the government’s behalf; or
    - 2) Used to advance a government program or interest, any portion of which was or will be reimbursed by the government



# Modifications to False Claims Act By FERA (cont.)

- **Elimination of the Specific Intent Requirement**
  - Reversed Supreme Court decision in *Allison Engine v. United States*, 128 S. Ct. 2123 (2008)
    - Removed language from the FCA that required the government/whistleblower to prove that the defendant specifically intend that the government pay the allegedly false claim
  - False statement must now only be “*material to*” a government payment of a claim (*i.e.*, the false claim had a “*material tendency to influence*” or was “*capable of influencing*” the payment of a claim.)



# Modifications to False Claims Act By FERA (cont.)

- **Inclusion of Reverse False Claims In FCA Liability**
  - Expanded FCA to cover any person who “*knowingly conceals*” or “*knowingly and improperly avoids or decreases*” an “*obligation to pay or transmit money or property to the Government.*”
- Did not define or clarify the meaning of “obligation”



# Modifications to False Claims Act By FERA (cont.)

- **Civil Investigative Demands (CIDs)**
  - Previously only issued by Main Justice only; now authority to issue delegated to the individual U.S. Attorneys
  - Allow government to compel document production and sworn testimony in civil investigations.
  - Allows civil investigators and prosecutors to share results with whistleblowers' counsel and with criminal investigators/AUSAs



# Changes to the FCA By the Patient Protection and Affordable Care Act

- **PPACA** directly linked the retention of overpayments to FCA liability.
- Defines the term “overpayments” as *“any funds that a person receives or retains [from a federal payor] to which the person, after applicable reconciliation it not entitled. . . .”*
- Provides that all overpayments must be reported and refunded **within 60 days** after the identification of the overpayment or the date any corresponding report is due.
- Clarifies that a repayment retained after the deadline for reporting and repaying it is an “obligation” for FCA purposes (*i.e.*, a failure to return any overpayments by the deadline may result in false claim liability)



## Changes to the FCA By the Patient Protection and Affordable Care Act (cont.)

- **Expansion of “Original Source” Rule.**
  - A qui tam relator must be the "original source" of the underlying information as defined by the statute
- Before PPACA, the FCA defined “original source” as “an individual who has *direct and independent* knowledge of the information upon which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section.



## Original Source Expansion (cont.)

- After amendment, the “*original source*” includes an individual who has either:
  - voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based prior to a public disclosure, OR
  - has knowledge that is *independent of and materially adds to the publicly disclosed allegations* or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.
- Eliminates the requirement for *direct knowledge* by the whistleblower.
- Allows individuals to still be considered whistleblowers *after the public disclosure* of allegations or transactions if the whistleblower’s information is *independent of and materially adds to* the already-disclosed information.



## Narrows “Public Disclosure” Bar

- Prior to amendment by PPACA, the “public disclosure” bar to FCA lawsuits was considered *jurisdictional* and applied more broadly to bar suits when the allegations had been publicly disclosed to the news media or in a state, local or federal criminal, civil, administrative or congressional investigation, proceeding, hearing, audit or report.
- Under the amended law, the jurisdictional nature of the public disclosure provision is eliminated and
  - The government has the right to oppose dismissal even if there has been a public disclosure.
  - The public disclosure definition is limited only to disclosures in the news media and in *federal*, not state or local, proceedings.

**Anti-Kickback Statute, Healthcare Fraud  
Statute, Stark Law, and Civil Monetary  
Penalty Law Changes**



# Changes to Anti-Kickback Statute

- Eliminates specific intent requirement
- Clarifies that claims that include items or services resulting from a violation of the Anti-Kickback Statute constitute “false or fraudulent claims” under the False Claims Act
- Provides that a violation of the Anti-Kickback Statute is a “federal health care offense.”
  - Federal health care offenses are subject to certain procedures for investigation, freezing of assets, injunctions and sentencing of parties suspected of committing such an offense.



# Additional Penalties Under CMP Law

- Knowingly making false statements in an application, bid, or contract to participate/enroll in a federal health care program (up to \$50,000 per violation)
- Knowingly making or using a false record or statement material to a false or fraudulent claim for payment by a federal health care program (up to \$50,000 per violation)
- Failing to grant OIG timely access for audits, investigations, evaluations, etc. upon reasonable request (up to \$15,000 per day delayed)
- Ordering or prescribing a medical or other item or service while excluded from a Federal health care program (up to \$50,000 per prohibited order or prescription)
- Failing to report and return a known overpayment within statutory time limits.



# Civil Monetary Penalties Law: Exceptions

**PPACA provides for certain exceptions that will not violate the law:**

- (1)** *remuneration* that promotes access to care and poses low risk of harm to patients and federal health care programs;
- (2)** the offer or transfer of coupons, rebates, or rewards from a retailer for free or less than fair market value if the coupons, rebates, or rewards are offered on equal terms and available to the general public regardless of health care status, and are not tied to the provision of items or services reimbursable by a governmental health care program;
- (3)** the offer or transfer of items or services for free or less than fair market value to individuals determined to be in financial need if there is a reasonable connection with the medical care of the individual and the items or services are not tied to the provision of any health care service and are not offered as part of any advertisement or solicitation; and
- (4)** the waiver of co-payments for the first fill of a covered Part D drug that is a generic drug for individuals by a prescription drug plan under Medicare Part C or D (to be effective on a date specified by the Secretary).



# Changes to Healthcare Criminal Fraud Statute

- Eliminates specific intent requirement in 18 U.S.C. § 1347
- Amends definition of “healthcare offense” under 18. U.S.C. § 24(a) to specifically include violations of the AKS and the Food, Drug and Cosmetic Act.



## Changes to Stark Law: Limitations on Physician-Owned Hospitals

- Limits Whole Hospital and Rural Provider Exception
- Available only for hospitals with Medicare provider agreement as of Dec. 31, 2010
- Existing physician-owned hospitals will not be able to increase capacity or percentage of physician ownership or investment after March 23, 2010
- Additional disclosure requirements
- Date confusion for hospitals that take advantage of the Dec. 31, 2010 deadline but had no physician owners as of March 23, 2010



# Changes In Stark Law: Disclosure Requirements For In-Office Ancillary Services Exception

- Imposes a new requirement for solo practitioners and physician group practices that qualify to use the in-office ancillary services exception with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services in the “radiology services” category that the Secretary of HHS determines appropriate, the referring physician must
  - Inform the patient in writing at the time of the referral that the patient may obtain the services for which the individual is being referred from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice, and
  - Provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.
- The change is effective for services furnished on or after January 1, 2010



# Stark Law: Self Disclosure Protocol

- Requires HHS to establish a Self-Referral Disclosure Protocol within 6 months
- Clarifies that the agency has discretion to compromise the amount for Stark violations (an ability that had not been clear prior to amendment), considering these factors:
  - Nature and extent of the improper practice
  - Timeliness of the disclosure
  - Cooperation in providing additional information related to the disclosure
  - Other factors which the Secretary considers appropriate

# **Enhanced Compliance Programs and Enrollment Screening Protections**



# Mandatory Compliance Program

- Requires providers and suppliers to establish compliance programs that satisfy requirements which will be established by the Secretary of Health and Human Services
- Applies to *all* providers and suppliers as a condition of enrollment in Medicare, Medicaid, and CHIP



# Enhanced Screening

- The Secretary of HHS (in consultation with the OIG) will establish new enrollment screening procedures within 180 days of enactment.
- Screening will include license checks and possibly fingerprinting, criminal background checks, multi-state database inquiries, random or un-announced site visits, etc.
- The Secretary has authority to subject certain providers/suppliers to temporary “provisional period” (30 days to one year) or grant an enrollment moratoria on enrollment of certain providers or suppliers
- Enhanced CMPs for false statements in enrollment process



# Expansion of RACs

- RAC program will be *expanded* to Medicaid, and Medicare Parts C and D.
- **Medicaid**
  - Requires all states to contract with at least one RAC by December 31, 2010. Medicaid RACs will also be paid on a contingency fee basis.
- **Medicare Parts C and D- RACs** must do the following:
  - ensure that Medicare Advantage and prescription drug plans under Parts C and D have anti-fraud plans in effect
  - examine claims for reinsurance payments to determine whether plans submitting those claims incurred costs in excess of the allowable reinsurance costs.
  - review estimates submitted by prescription drug plans with respect to the enrollment of “high cost beneficiaries” and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans
- Secretary of HHS must submit an *annual report* to Congress outlining the effectiveness of the RAC Program



## Increased Funding To Combat Fraud

- FERA allocated \$165 million to the DOJ in fiscal years 2010 and 2011 to hire fraud prosecutors and investigators and dedicated \$140 million to the FBI, \$50 million to the U.S. Attorney's Offices, and over \$80 million to other federal agencies for the specific purpose of investigating fraud.
- PPACA includes additional \$250 million over six years to fund fraud and abuse enforcement
  - Additional \$95 million for FY 2011
- In FY 2010, the all agency enforcement budget is over \$311 million



# Practical Tips

1. When creating your business plan and entering into regulated relationships, keep firmly in mind that the current environment is high risk and potential liability under FCA, AKS, and the Healthcare Fraud Statutes has been greatly expanded.
2. Be vigilant and proactive about implementing and/or updating your compliance program.
3. Be cognizant of the new “downstream” liability under FCA and how that may affect your risks of a whistleblower suit or government investigation.
4. Review and update current processes to identify and return overpayments.
5. Be aware of new restrictions on Physician-Owned Hospitals and the pending deadline for licensure of impacted hospitals.
6. Be on the look out for the forthcoming self-disclosure protocol on Stark violations. In the interim, there seems to be no downside to self-disclosing without the written protocol.
7. Review and update your RAC response plan to account for the expansion into Medicaid and Medicare Parts C and D.



# Thank you



Robert Threlkeld  
404-504-7757  
[rthrelkeld@mmmlaw.com](mailto:rthrelkeld@mmmlaw.com)



Paul F. Danello  
202-216-4819  
[pdanello@mmmlaw.com](mailto:pdanello@mmmlaw.com)



Holly Pierson  
404-504-7665  
[hpierson@mmmlaw.com](mailto:hpierson@mmmlaw.com)

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