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False Claims Act and Qui Tam Update: The Times They Are a-Changin'

June 21, 2011

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TAB 1

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False Claims Act and Qui Tam Update: The Times They are a-Changin

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June 21, 2011

Discussion Agenda

- False Claims Act overview
- Recent U.S. Supreme Court and Federal Court decisions
- Recent settlements and impact on criminal and administrative actions
- Defense strategies to challenge investigations and litigation proceedings
- Compliance strategies to mitigate risk

Enforcement Landscape

- Sustained legislative anti-fraud agenda – 2009-2012
- FCA amendments part of seminal anti-fraud measures
- FCA is driver of recoveries as well as criminal and administrative prosecutions; qui tam provisions majority of cases; largely settlements, not litigation
- FCA recoveries since 1986 are $27 billion; $18.5 billion from the health industry
- FY 2010, $3 billion recovered, of which $2.5 billion in the health industry; skewed focus on one industry sector
- Other industry sectors ripe for focus

Enforcement Landscape

- Over 1000 qui tams reported under seal
- DOJ stats suggest uptick in filing after decline of filings
- Declination is approximately 75 to 80% of cases
- Relator recoveries higher in DOJ-intervened cases
- Pressure to process cases
- DOJ internal processing of new policies
- New relator strategies for litigation: Medline
  - $85 million relator settlement
  - Declined DOJ qui tam

Enforcement Landscape

- Trend to national initiatives and industry qui tams. Cardiac ICD investigation, Kyphoplasty investigation, Biliary Stent
- Fewer settlements and more litigation, even in parallel criminal and administrative proceedings?
- Judicial impatience with length of DOJ investigations under seal
- Defense advantage to one-sided investigations?

Enforcement Landscape

- FCA Amendments are under judicial review, DOJ implementation, and relator and defense evaluation
- Procedural changes impact investigation and litigation processes
- Substantive changes impact prosecution discretion, relator and defense strategies
- Substantive changes also impact corporate risk assessments, compliance activities, and legal obligations for certain matters, i.e. overpayments

Rise of State and Local FCAs

- Over 30 states, cities have own FCAs
- Most modeled almost exactly after Federal FCA
- Most have qui tam provisions
- Some limited to Medicaid fraud
- Enforcement and recoveries under State FCAs increasing
- More sophisticated attorneys, more aggressive, more willing to fight at state and local level

False Claims Act – It Is Still the One

- Civil War era statute with qui tam and disclosure provisions
  - Encourages tattle-telling and confession
  - Use a rogue to catch a rogue
  - Reduction in damages for voluntary disclosure
  - When should a company disclose? Money violations or regulatory violations?
- Intended to protect the treasury against "the hungry and unscrupulous host that encompass it on every side" … Provides qui tam remedy as the most effective method to detect fraud via private persons stimulated by ill will or hope of gain. *Marcus v. Hess*, 317 U.S. 537 (1943)
- Civil statute but is the origin of criminal and administrative fraud investigations and prosecutions under DOJ parallel proceeding policy

False Claims Act

- Civil preponderance of the evidence standard; 51% weight of evidence
- No specific intent requirement; reckless disregard or deliberate ignorance will due; smidge over negligence? Gross negligence?
- Mandatory treble damages and minimum $5500 to maximum $11,500 penalty per false claim
- Retaliation provisions
  - Expanded in 2009 amendment from employees to include non-employee agents and contractors
  - Protects lawful actions to stop violations or assist qui tam actions
- State False Claims Act statutes under the Deficit Reduction Act
  - Increases investigative and litigation complexity

False Claims Act – Who May Be Liable?

- FCA applies to any "persons" that violate the statute
  - Corporations, non-profit associations, professional societies, individuals
  - Local governments, but not States, for qui tam actions
- 2009 amendments expanded potential for third-party or downstream liability for manufacturers, vendors and suppliers, banks, investment firms, and consultants
- Entities and individuals that do not submit claims can be liable under the statute for causing the submission of a false claim
  - Significant battleground
- DOJ FCA suit against Guidant for defective devices used in hospital procedures
- Recent Blackstone decision for First Circuit

False Claims Act – Who Can Bring Action?

- Civil Fraud Section or U.S. Attorney's Office?
  - Often both
- U.S. Attorney Manual
  - Criteria and authority
- False Claims Act Guidance
  - Still good after all these years
- Parallel Proceeding with other domestic and international matters
  - Need to consider States, SEC, FCPA

False Claims Act – Who Can Bring Action?

- Private individuals under the private citizen qui tam provisions
  - 31 U.S.C. 3730, subject to jurisdictional requirements amended in 2010
- If allegations publicly disclosed in news media, federal hearing or proceeding, must be an original source and provided material information to the government prior to filing suit
  - Area of great challenge
  - Balance of reporting fraud v. parasitic and opportunistic suits
- Actions filed under seal in U.S. District Court
  - You have been sued
  - Defendant parties rights held in abeyance
  - Not served the summons
- DOJ – mandatory duty to investigate allegations under seal and decide to take over case
  - How far must they go? How many years can they take? When does defendant party get to protect its rights?

False Claims Act Violations

- Seven (7) types of misconduct create potential liability causes of action under the statute
  - Retaliation is a separate violation with different damages
- 3729(A). False Claims
  - Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval
  - Direct presentment to government is not required
- 3729(B). False Statement
  - Knowingly uses or causes to be used a false record or statement material to a false or fraudulent claims
  - Requires underlying false claim to be actionable

False Claims Act

- 3729(C). Conspiracy
  - Expanded in 2009 amendments. Separate liability like retaliation
- 3729(G). Knowingly makes, uses, or causes to be made or used, a false record or statement material to the obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property
- Expanded liability from 2009 amendments
  - Improper is not defined. Look to expanded definition of Obligation

False Claims Act-Key New Definitions

- Obligation-31 U.S.C. 3729(b)(3). Definition greatly expands scope of false statement and improper avoidance prongs of 3729(G)
- Obligation means: an established duty; whether fixed or not fixed, arising from:
  - an express or implied contractual, grantor-grantee or licensor-licensee relationship;
  - a fee-based or similar relationship
  - statute or regulation; or
  - the retention of an overpayment

False Claims Act-Key New Definitions

- Claim-3729(b)(2). 2009 amendments greatly expand concept of claim
  - Any request or demand for money or property to the government, contractor, grantee, or recipient IF the money or property is to be spent, or used on the government's behalf or to advance a government program or interest and the government has provided some or all of the funding
  - Advancing a government program or interest appears to have infinite application

FCA Theories of Liability –The Easy Stuff

- Billing for services not rendered
- Billing for services partially performed
- Inflated or upcoded requests for payment or contract vouchers
- Substandard product manufacturing, product substitution, quality deficiencies, failure to test
- False grant applications
- Bid or RFP documents that are false to get contract award
- Defective or manipulated pricing

FCA Theories of Liability –The Hard Stuff

- Regulatory violations: any will do?
- Conflicts of interest, industry codes of ethics, and corporate compliance program deficiencies
- Certifications of compliance
  - Is the certification a condition of payment or participation? Material to payment?
- False statements to get downstream stimulus or TARP money
- Determining whether alleged misconduct meets new definitions
  - Advancing or promoting a government program or interest?

Civil Investigative Demands
31 U.S.C. § 3733

- CIDs allow government to obtain broad False Claims Act discovery before a complaint is filed
  - Documents, sworn testimony, interrogatories
- Authority delegated to USAO
- Increases investigative complexity and cost
- Has some defense advantages
  - DOJ must disclose “False Claims Act Custodians”
  - Counsel permitted in depositions

Public Disclosure Bar

- 31 U.S.C. 3730(e)(4)(A):
  - The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed:
    - *i. in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;*
    - *ii. in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or*
    - *iii. from the news media . . .*
- Intended to avoid "parasitic" whistleblowers who offer no additional information about already-disclosed FCA violations

“Public”

- Wide dissemination of allegations not necessary
- 2010 amendment to FCA provided that disclosures made in state investigations, hearings, reports, and audits do not constitute public disclosures

“Substantially the Same”

- Formerly, qui tam suits were barred if the allegations were “based upon” publicly disclosed information
- FCA amended in 2010 to provide that allegations must be “substantially the same” as publicly disclosed allegations for bar to apply
- Need not precisely repeat public knowledge if allegations simply echo known facts
- Fraud need not be expressly alleged in the publicly disclosed information

Who Can Raise

- Formerly, public disclosure was jurisdictional issue that any party (both the government and the defendants) could raise at any time
- 2010 amendments to FCA abolished jurisdictional status, but did not prohibit defendants from raising public disclosure as an affirmative defense or via a Rule 12(b)(6) motion
- Government may oppose dismissal of qui tam
  - Gatekeeper of public interest, but criteria unclear
  - Parasitic suits should be disfavored

Specific Types of Disclosure

- Hearings
  - Government must be party; before 2010 amendments, disclosures in private litigation constituted public disclosure whether or not government was party to suit
  - Includes civil litigation, but courts split on whether disclosures in criminal proceedings operate as a bar
  - Filed material is publicly disclosed, but courts split on whether non-filed discovery material qualifies as public disclosure

Specific Types of Disclosure

- Federal reports, audits, hearings, or investigations
  - Includes responses to FOIA requests
  - State reports, hearings, and investigations eliminated in 2010 amendments
- News media
  - Courts split on whether online disclosures constitute “news media” for purposes of bar
  - Courts also split on whether foreign news media’s disclosures trigger bar
  - trade, scientific and medical journals are qualified disclosures

“Original Source” Exception

- Public disclosure bar does not bar qui tam suit if “the person bringing the action is an original source of the information”
- Original source defined in 31 U.S.C. 3730(e)(4)(B):
  - An individual who either
    - *i. prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or*
    - *ii. who 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.*

“Original Source” Exception

- Prior to 2010 amendments, qui tam relators had to have “direct and independent” knowledge of the “information on which the allegations are based”
- New provision requires only that the relator’s independent knowledge “materially add” to publicly disclosed information
- Significant arena for litigation

“Original Source” Exception

- Prior to 2010 amendments, exception was phrased as “and”
  - [A]n individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information
- Revised section permits “original source” status for relator who voluntarily disclosed the information prior to the public disclosure or who has additional knowledge
- Permits qui tam suit by relator with same information that was publicly disclosed, as long as the relator passed it to the government before the disclosure
  - Need not derive information independently
  - Could rely on secondhand information

Dominant Legal Issues

- Implied v. express certification
- Regulatory violations
- Downstream liability
- Causation generally
- Materiality
- Damages

FCA: Case Law Developments – Public Disclosure Bar

- Public Disclosure Bar
  - *Graham County Soil and Water Conservation Dist. V. US ex rel. Wilson* (S. Ct. March 2010) - The Court held that state and local sources, in addition to federal, can constitute public disclosures
  - Justice Stevens acknowledged the Healthcare Reform Law amended the definition of public disclosure to only encompass federal sources of information
  - The Court did not conduct an analysis under the amended FCA because there was no mention of retroactivity for the public disclosure definition as amended by FERA

FCA: Case Law Developments – Public Disclosure Bar *(cont'd)*

- *US ex rel. Baltazar v. Warden* (7th Cir. Feb. 2011)
  - Federal reports generally describing industry-wide fraud are not a public disclosure barring a qui tam action where the reports do not name any individual making a false claim or any particular false claim made
  - Additionally, in this case the relator provided specific facts particular to the defendant, supporting a conclusion that relator's claim was based on her own knowledge rather than the public reports
- *Schindler Elevator Corp. v. United States ex rel. Kirk* (S. Ct. May 2011)
  - The public disclosure bar of the FCA precludes plaintiffs from bringing claims under the FCA based on information obtained through Freedom of Information Act (FOIA) requests for public documents
  - The Court concluded that a FOIA response is a federal report or investigation, constituting a public disclosure, under the terms of the FCA
  - The decision reinforces the Court's opposition to opportunistic suits

FCA: Case Law Developments – Adequacy of Pleading

- *US ex rel. Underwood v. Genentech, Inc.* (E.D. PA June 2010)
  - Where relator alleges the indirect submission of a false claim, the identification of a specific false claim is not required to meet the Rule 9(b) requirements as long as the relator uses "an alternative means of injecting precision and some measure of substantiation into [the] allegations of fraud"
- *US ex rel. Ebeid v. Lungwitz* (9th Cir. August 2010)
  - The Court accepts that the implied false certification theory can support liability under the FCA, but finds that the relator failed to plead fraud with sufficient particularity under Rule 9(b)
  - Specifically, the Court notes that relator failed to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"

FCA: Case Law Developments – Standard for Liability

- *US ex rel. Bahrain v. ConAgra, Inc.* (10th Cir. Oct. 2010)
  - Reversed judgment in favor of the relator because the jury specifically found that the relator had not proved that the defendant made a false record or statement **for the purpose of** concealing, decreasing, or avoiding an obligation to pay or transmit money or property to the government
- *US ex rel. Steury v. Cardinal Health, Inc.* (5th Cir. Nov. 2010)
  - A false certification, implicit or explicit, does not give rise to liability under the FCA unless certification is required as a prerequisite to payment

FCA: Case Law Developments – Standard for Liability *(cont'd)*

- *US ex rel. Vigil v. Nelnet, Inc.* (8th Cir. May 2011)
  - If certification of compliance with program terms is a condition of program participation, rather than payment, a false certification is not actionable under the FCA
- *US ex rel. Hutcheson v. Blackstone Medical, Inc.* (1st Cir. June 2011)
  - A suit against a party that did not submit any claims to the government survived a 12(b)(6) challenge where the non-submitting party is alleged to have caused the party submitting the claim to falsely certify compliance with a precondition of payment (compliance with the AKS)
- *US ex rel. Seal 1 v. Lockheed Martin Corp.* (11th Cir. June 2011)
  - Allegation that a product sold to the government is defective, without any specific facts regarding particular misrepresentations, claims presented or conditions for payment with regard to the defective product, is insufficient to support a claim under the FCA

FCA: Case Law Developments – Scienter

- *US v. Science Applications Int'l Corp.* (D.C. Cir. Dec. 2010)
  - District Court's instruction on collective knowledge (allowing the jury to find that the defendant acted with scienter even if no employee knew the company's claims were false) was legally deficient.
  - Recognized the implied certification theory of FCA liability, but the Court required strict enforcement of materiality and scienter requirements of the FCA.
  - Concludes that the proper measure of damages under the FCA takes into account the value of the goods and services.
- *US ex rel. Ubl v. IIF Data Solutions* (4th Cir. April 2011)
  - Evidence that the government knows about the facts underlying an allegedly false claim, can differentiate between an incorrect claim, which is generally not actionable, and a knowing false claim, submitted with the requisite scienter.

FCA: Case Law Developments – Reverse False Claims

- *US v. Caremark, Inc.* (5th Cir. Feb. 2011)
  - Caremark is alleged to have knowingly made false statements to the states that impaired their ability to fulfil an obligation to the federal government to recover monies paid by the federal government.
  - The court allowed the government to proceed with an theory that Caremark offered an alleged indirect reverse false claim, having caused the states to fail to solicit repayment to the federal government.

FCA: Case Law Developments – Seal Provisions

- *ACLU v. Holder* (4th Cir. Mar. 2011)
  - The FCA's seal provisions do not violate the separation of powers under the Constitution because it is a proper subject of congressional regulation (as an inherent power of the court reasonably useful to achieve justice) and does not so intrude on the judiciary as to prevent it from accomplishing its constitutionally assigned functions.
  - The ACLU also challenged the FCA's seal provisions as violative of the First Amendment. The Court held the plaintiffs lacked standing on their First Amendment claim because they failed to show any particular *qui tam* relator who would be willing to speak with plaintiffs, but was prevented from doing so by the FCA's seal provision.

FCA: Case Law Developments – Miscellaneous

- *US ex rel. Eisenstein v. City of New York* (S. Ct. 2009)
  - Where the US declines to intervene in privately initiated FCA action, it is not a "party" to the litigation, even though it is the real party in interest. As a result, the 30-day time limit pursuant to Fed. R. App. P. 4(a)(1)(A) applies.
- *Cell Therapeutics, Inc. v. Lash Group, Inc.* (9th Cir. 2009)
  - Plaintiff allegedly relied on representations made by defendant when seeking Medicare reimbursement for off-label use of its cancer drug.
  - Plaintiff settled with the government and a relator for alleged FCA violations and sued defendant for indemnification.
  - The Court held that a *qui tam* defendant can bring a third party claim under the statute and the Plaintiff could maintain an indemnity suit despite settlement because the settlement did not amount to a finding of FCA liability.

FCA: Case Law Developments – Miscellaneous

- *US ex rel. Radcliffe v. Purdue Pharma L.P.* (4th Cir. March 2010)
  - A pre-filing release is enforceable with respect to a subsequent *qui tam* action under the FCA when the government had knowledge of the alleged fraudulent conduct before the suit was filed.

Recent Settlements and Suits

- *U.S. V. GlaxoSmithKline-SB Pharmco* (2010)
  - $750 million global resolution, $600 million attributed to FCA qui tam
  - Relator share $80 million
  - GMP violations
  - Potential qui tam floodgate
- Quest Diagnostics (2011)
  - $241 million to resolve California FCA case
  - Overbilling state Medicaid for diagnostic testing
  - Relator is CEO of competitor
- Wheelabrator Technologies (2011)
  - $7 million. Municipal waste contract fraud
  - Massachussetts FCA recovery

Recent Settlements and Suits

- Deutsche Bank AG and MorgageIt, Inc. (SDNY 2011)
  - DOJ FCA action for $386 million for alleged mortgage fraud
- FedEx: $8 million (2011)
  - DOJ FCA related to allegations of delivery delay misrepresentations in wake of 9/11
- Education Management (2011)
  - FCA qui tam; DOJ intervention
  - Illegal compensation of student recruiters
  - Regulatory violation of Title V
- Ven-A-Care Medicaid Pricing Qui tams
  - Par Pharmaceuticals – $145 million

Recent Settlements and Suits

- Verizon: $93 million (2011)
  - Surcharges and overcharges to GSA invoices for government data communications
  - Charged for federal, state and local taxes
- BP Oil Platform FCA (2011)
  - Alleged false compliance certifications
  - DOJ intervened in qui tam
- *U.S. v. NYC* (2011)
  - Alleged verbilling Medicaid
  - DOJ intervened qui tam
- BMS
  - California Ins. Commission joins qui tam suit
  - Alleged AKS violations to promote drug

Individual Liability

- Virtually all of criminal and administrative prosecutions have emanated from FCA qui tam proceedings
- Federal and state agencies have exclusion and/or debarment authority
- DOJ and agency policy currently very chaotic
- Criminal and civil resolutions may not release individuals for administrative remedies
- Need to consider at inception of investigation; impact on strategy

Individual Liability

- Criminal liability may be direct or indirect
- Conduct-based liability: FDCA, false statements, obstruction, anti-kickback, or conspiracy allegations
- Indirect or strict liability based on corporate responsible officer doctrine (ROCD), otherwise known as Park doctrine
- Civil liability – False Claims Act for causing submission of false claim
- Administrative – mandatory exclusion or debarment based on conviction of specified offenses; permissive exclusion based on agency exercise of discretion of enumerated offenses, including RCOD

Responsible Corporate Officer Doctrine

- First recognized in 1943 in *U.S. v. Dotterweich* – permits criminal liability for any corporate employee responsible for legal violations that impact public welfare for life and health if:
  - statute intended to improve common good; and
  - no culpable intent requirement (strict liability)
- More recently, used in FDA-focused prosecutions; concept has broadly morphed to denote government perspective on individual accountability

Responsible Corporate Officer Doctrine *(cont'd)*

- 1975 – *U.S. v. Park* (Park Doctrine) affirms that individuals may be criminally liable for misdemeanor violations if in a position of corporate responsibility and failed to act to prevent violation that impacts public health.
  - Park: CEO misdemeanor violations of FDCA for exposing food to rodent-infested warehouse; repeated warnings
- Purdue Pharma prosecution (2007)
  - RCOD applied to senior managers and general counsel
- KV Pharma prosecution (2011)
  - RCOD applied to CEO
- No constitutional issue for strict liability public-welfare offenses if no *mens reas* requirement, penalties small, and no grave injury to individual's reputation
  - Is this true today?

FDA's Agency Position On Responsible Corporate Officer Doctrine

- FDA policy on application of the Park Doctrine
  - Special procedures for referral and recommendation
  - Misdemeanor prosecutions are valuable enforcement tool.
- Applies to corporate officials without proof of intent to deceive or defraud or proof of negligence
- Primary consideration is person's position in company and relationship to violation and whether person had authority to correct or prevent violation
- Other factors include actual or potential harm to public, violation is obvious, pattern of violations or unheeded warnings, violation is serious, and prudent use of agency resources
- FDA Commissioner Hamburg enforcement position on Park and FDA debarment

OIG Exclusion Authority

- OIG has permissive exclusion authority in approximately 15 instances, including false claims
  - *IG v. Dinkel* (2011)
    - *Announced agenda to use permissive exclusion authority to exclude individuals from federal healthcare programs*
- OIG has pursued exclusion in RCOD cases-Purdue and KV. Misdemeanor convictions related to public health offenses. (b)(3) exclusions
- (b)(15) exclusion of officer or manager of an entity convicted of health care offense (sanctioned entity); status-based exclusion
- Recently, applied RCOD exclusion theory regarding status, not conduct
  - Howard Solomon, CEO Forest Laboratories (2011)
    - *No conviction or allegation of wrongdoing*

Defense Strategies

- Goal #1: Manage company's credibility dividend in all communications and strategic actions from first call to government
- Define strategy early!
  - Goal is always DOJ declination and relator dismissal under seal-most FCA cases resolved that way. How to get there? What about criminal? What about exclusion and debarment?
- Assess corporate and individual liability issues early
- Assess opportunities for information and cooperation-blue books
- Determine what to fight about substantively on legal issues; never housekeeping on document production

Defense Strategies

- FCA Amendments confirm that proactive defense strategies are necessary preintervention
  - Routine processing is not a defense advantage
- Rethinking global approaches
  - Should states be dealt with first in multidistrict matters?
- CIDs and information sharing preintervention will require defense interaction with Court
  - How to position company?
  - Cost Sharing

Defense Strategies

- Extension of retaliation provisions to contractors and agents affects many industry sectors and requires focus on current process for handling whistleblower and other complaints
- Overpayment liability compels process check-up and disclosure strategies, particularly in health sector

Compliance Strategies to Mitigate Risk

- Robust compliance programs remain the best defense
  - What is an effective compliance program? Is it one strike and FCA liability?
- Trend to credit for good compliance programs?
- Effectiveness reviews must extend beyond 7 elements to program or contract review; training and auditing key
- Audit work plan should take into account contract or program requirements
- Encourage employees, agents, and contractors to use internal channels to address concerns or issues
- Disclosure Assessment – when to go to government?

Overpayments and FCA

- An overpayment retained beyond 60 days is considered an Obligation under the FCA. 31 USC 3729(b)(3)
- Overpayments are funds, not benefits; focus is on funds received and retained
- Regulatory violations that impact *right to funds* may form basis of overpayment liability: Stark, licensure for reimbursement of certain professional services, and conditions of payment generally
- Overpayment timely reported should not give rise to FCA liability even if not repaid in 60 days
  - Improper avoidance of "obligation" is key issue

Overpayments and FCA

- Retention of an overpayment beyond 60 days is a potential FCA violation; obligation under FCA
- Strategy for detection and processing refunds to government programs is critical compliance upgrade
- Not just Medicare; Medicaid and other federal programs
- PPACA requirements: report and return overpayments within 60 days of identity or date corresponding cost report is due
- May make repayment to contractor, carrier, intermediary

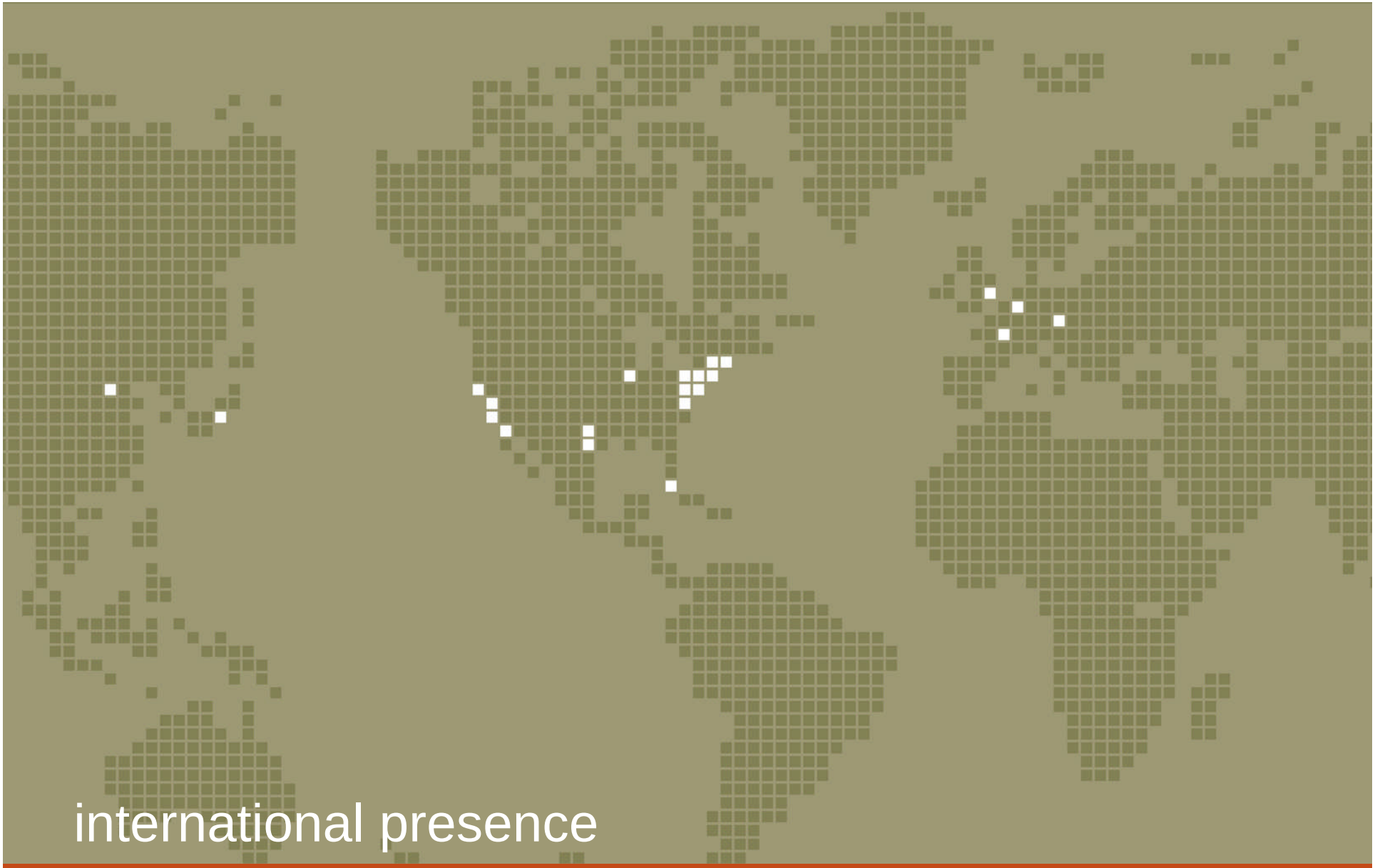
Overpayments and FCA

- When is overpayment identified?
  - Government's view is when fact of overpayment, not amount, is identified
  - Disclosure or reporting of overpayment may need to occur before repayment for large non-routine situations
  - Judgment call but better to err on side of disclosure
  - Premature disclosures can be chaotic and result in incomplete or incorrect information to government
  - Nature of overpayment may compel disclosure to DOJ or OIG and not to contractor

Overpayments and FCA

- Strategies to stop the clock?
  - Implement and update a standard corporate process to take into account FCA and PPACA new provisions
  - Continuous audits and assessment
  - On detection of overpayment, credible documentation of key information
    - *Expect look back obligation*
  - Letter notice to contractor of identified overpayment with investigation or audit continuing
  - Immediate processing of known overpayment and schedule of continuing audit and repayment for “look-back” period
  - Verbal and written disclosure to local US Attorney that voluntary refund situation exists and schedule preliminary disclosure; generally not for routine overpayments

Questions



international presence

Beijing Boston Brussels Chicago Dallas Frankfurt Harrisburg Houston Irvine
London Los Angeles Miami New York Palo Alto Paris Philadelphia Pittsburgh
Princeton San Francisco Tokyo Washington Wilmington

TAB 2

FALSE CLAIMS ACT
31 U.S.C. §§ 3729-3733

As amended by S. 386, Fraud Enforcement and Recovery Act of 2009 and by H.R. 3590, the Patient Protection and Affordable Care Act of 2010

§ 3729. False claims

(a) LIABILITY FOR CERTAIN ACTS.—

(1) IN GENERAL.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil

Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) REDUCED DAMAGES.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information,

(B) such person fully cooperated with any Government investigation of

(C) such violation; and

(D) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) COSTS OF CIVIL ACTIONS.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) DEFINITIONS.—For purposes of this section—

(1) the terms “knowing” and “knowingly”—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term “claim”—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) EXEMPTION FROM DISCLOSURE.—Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) EXCLUSION.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

§ 3730. Civil actions for false claims

(a) RESPONSIBILITIES OF THE ATTORNEY GENERAL.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) ACTIONS BY PRIVATE PERSONS.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) RIGHTS OF THE PARTIES TO QUI TAM ACTIONS.—

(1) If the Government proceeds with the action, t shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2) (A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the

court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable

diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) AWARD TO QUI TAM PLAINTIFF.—

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus

reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) CERTAIN ACTIONS BARRED.—

(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2) (A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4) (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that it 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.

(f) GOVERNMENT NOT LIABLE FOR CERTAIN EXPENSES.—The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) FEES AND EXPENSES TO PREVAILING DEFENDANT.—In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) RELIEF FROM RETALIATORY ACTIONS.—

(1) IN GENERAL—Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor, or agent or associated others in furtherance of other efforts to stop I or more violations of this subchapter.

(2) RELIEF.—Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys'

fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

§ 3731. False claims procedure

(a) A subpena [subpoena] requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought—

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

(c) If the Government elects to intervene and proceed with an action brought under 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

(d) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(e) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

§ 3732. False claims jurisdiction

(a) ACTIONS UNDER SECTION 3730.—Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) CLAIMS UNDER STATE LAW.—The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

(c) SERVICE ON STATE OF LOCAL AUTHORITIES.—With respect to any State or local government that is named as a co-plaintiff with the United States in an action brought under subsection (b), a seal on the action ordered by the court under section 3730(b) shall not preclude the Government or the person bringing the action from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence and information possessed by the person bringing the action on the law enforcement authorities that are authorized under the law of that State or local government to investigate and prosecute such actions on behalf of such governments, except that such seal applies to the law enforcement authorities so served to the same extent as the seal applies to other parties in the action.

§ 3733. Civil investigative demands

(a) IN GENERAL.—

(1) ISSUANCE AND SERVICE.—Whenever the Attorney General, or a designee (for purposes of this section), has reason to believe that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation, the Attorney General, or a designee, may, before commencing a civil proceeding under section 3730(a) or other false claims law, or making an election under section 3730(b), issue in writing and cause to be served upon such person, a civil investigative demand requiring such person—

(A) to produce such documentary material for inspection and copying,

(B) to answer in writing written interrogatories with respect to such documentary material or information,

(C) to give oral testimony concerning such documentary material or information, or

(D) to furnish any combination of such material, answers, or testimony.

The Attorney General may delegate the authority to issue civil investigative demands under this subsection. Whenever a civil investigative demand is an express demand for any product of discovery, the Attorney General, the Deputy Attorney General, or an Assistant Attorney General shall cause to be served, in any manner authorized by this section, a copy of such demand upon the person from whom the discovery was obtained and shall notify the person to whom such demand is issued of the date on which such copy was served. Any information obtained by the Attorney General or a designee of the Attorney General under this section may be shared with any qui tam relator if the Attorney

General or designee determine it is necessary as part of any false claims act investigation.

(2) CONTENTS AND DEADLINES.—

(A) Each civil investigative demand issued under paragraph (1) shall state the nature of the conduct constituting the alleged violation of a false claims law which is under investigation, and the applicable provision of law alleged to be violated.

(B) If such demand is for the production of documentary material, the demand shall—

(i) describe each class of documentary material to be produced with such definiteness and certainty as to permit such material to be fairly identified;

(ii) prescribe a return date for each such class which will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying; and

(iii) identify the false claims law investigator to whom such material shall be made available.

(C) If such demand is for answers to written interrogatories, the demand shall—

(i) set forth with specificity the written interrogatories to be answered;

(ii) prescribe dates at which time answers to written interrogatories shall be submitted; and

(iii) identify the false claims law investigator to whom such answers shall be submitted.

(D) If such demand is for the giving of oral testimony, the demand shall—

(i) prescribe a date, time, and place at which oral testimony shall be commenced;

(ii) identify a false claims law investigator who shall conduct the examination and the custodian to whom the transcript of such examination shall be submitted;

(iii) specify that such attendance and testimony are necessary to the conduct of the investigation;

(iv) notify the person receiving the demand of the right to be accompanied by an attorney and any other representative; and

(v) describe the general purpose for which the demand is being issued and the general nature of the testimony, including the primary areas of inquiry, which will be taken pursuant to the demand.

(E) Any civil investigative demand issued under this section which is an express demand for any product of discovery shall not be returned or returnable until 20 days after a copy of such demand has been served upon the person from whom the discovery was obtained.

(F) The date prescribed for the commencement of oral testimony pursuant to a civil investigative demand issued under this section shall be a date which is not less than seven days after the date on which demand is received, unless the Attorney General or an Assistant Attorney General designated by the Attorney General determines that exceptional circumstances are present which warrant the commencement of such testimony within a lesser period of time.

(G) The Attorney General shall not authorize the issuance under this section of more than one civil investigative demand for oral testimony by the same person unless the person requests otherwise or unless the Attorney General, after investigation, notifies that person in writing that an additional demand for oral testimony is necessary.

(b) PROTECTED MATERIAL OR INFORMATION.—

(1) IN GENERAL.—A civil investigative demand issued under subsection (a) may not require the production of any documentary material, the submission of any answers to written interrogatories, or the giving of any oral testimony if such material, answers, or testimony would be protected from disclosure under—

(A) the standards applicable to subpoenas or subpoenas duces tecum issued by a court of the United States to aid in a grand jury investigation; or

(B) the standards applicable to discovery requests under the Federal Rules of Civil Procedure, to the extent that the application of such

standards to any such demand is appropriate and consistent with the provisions and purposes of this section.

(2) EFFECT ON OTHER ORDERS, RULES, AND LAWS.—Any such demand which is an express demand for any product of discovery supersedes any inconsistent order, rule, or provision of law (other than this section) preventing or restraining disclosure of such product of discovery to any person. Disclosure of any product of discovery pursuant to any such express demand does not constitute a waiver of any right or privilege which the person making such disclosure may be entitled to invoke to resist discovery of trial preparation materials.

(c) SERVICE; JURISDICTION.—

(1) BY WHOM SERVED.—Any civil investigative demand issued under subsection (a) may be served by a false claims law investigator, or by a United States marshal or a deputy marshal, at any place within the territorial jurisdiction of any court of the United States.

(2) SERVICE IN FOREIGN COUNTRIES.—Any such demand or any petition filed under subsection (j) may be served upon any person who is not found within the territorial jurisdiction of any court of the United States in such manner as the Federal Rules of Civil Procedure prescribe for service in a foreign country. To the extent that the courts of the United States can assert jurisdiction over any such person consistent with due process, the United States District Court for the District of Columbia shall have the same jurisdiction to take any action respecting compliance with this section by any such person that such court would have if such person were personally within the jurisdiction of such court.

(d) SERVICE UPON LEGAL ENTITIES AND NATURAL PERSONS.—

(1) LEGAL ENTITIES.—Service of any civil investigative demand issued under subsection (a) or of any petition filed under subsection (j) may be made upon a partnership, corporation, association, or other legal entity by—

(A) delivering an executed copy of such demand or petition to any partner, executive officer, managing agent, or general agent of the partnership, corporation, association, or entity, or to any agent authorized by appointment or by law to receive service of process on behalf of such partnership, corporation. association, or entity;

(B) delivering an executed copy of such demand or petition to the principal office or place of business of the partnership, corporation, association, or entity; or

(C) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return

receipt requested, addressed to such partnership, corporation, association, or entity at its principal office or place of business.

(2) NATURAL PERSONS.—Service of any such demand or petition may be made upon any natural person by—

(A) delivering an executed copy of such demand or petition to the person; or

(B) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to the person at the person's residence or principal office or place of business.

(e) PROOF OF SERVICE.—A verified return by the individual serving any civil investigative demand issued under subsection (a) or any petition filed under subsection (j) setting forth the manner of such service shall be proof of such service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such demand.

(f) DOCUMENTARY MATERIAL.—

(1) SWORN CERTIFICATES.—The production of documentary material in response to a civil investigative demand served under this section shall be made under a sworn certificate, in such form as the demand designates, by—

(A) in the case of a natural person, the person to whom the demand is directed, or

(B) in the case of a person other than a natural person, a person having knowledge of the facts and circumstances relating to such production and authorized to act on behalf of such person.

The certificate shall state that all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the false claims law investigator identified in the demand.

(2) PRODUCTION OF MATERIALS.—Any person upon whom any civil investigative demand for the production of documentary material has been served under this section shall make such material available for inspection and copying to the false claims law investigator identified in such demand at the principal place of business of such person, or at such other place as the false claims law investigator and the person thereafter may agree and prescribe in writing, or as the court may direct under subsection (j)(1). Such material shall be made so available on the return date specified in such demand, or on such later date as the false claims law investigator

may prescribe in writing. Such person may, upon written agreement between the person and the false claims law investigator, substitute copies for originals of all or any part of such material.

(g) INTERROGATORIES.—Each interrogatory in a civil investigative demand served under this section shall be answered separately and fully in writing under oath and shall be submitted under a sworn certificate, in such form as the demand designates, by—

(1) in the case of a natural person, the person to whom the demand is directed, or

(2) in the case of a person other than a natural person, the person or persons responsible for answering each interrogatory.

If any interrogatory is objected to, the reasons for the objection shall be stated in the certificate instead of an answer. The certificate shall state that all information required by the demand and in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted. To the extent that any information is not furnished, the information shall be identified and reasons set forth with particularity regarding the reasons why the information was not furnished.

(h) ORAL EXAMINATIONS.—

(1) PROCEDURES.—The examination of any person pursuant to a civil investigative demand for oral testimony served under this section shall be taken before an officer authorized to administer oaths and affirmations by the laws of the United States or of the place where the examination is held. The officer before whom the testimony is to be taken shall put the witness on oath or affirmation and shall, personally or by someone acting under the direction of the officer and in the officer's presence, record the testimony of the witness. The testimony shall be taken stenographically and shall be transcribed. When the testimony is fully transcribed, the officer before whom the testimony is taken shall promptly transmit a copy of the transcript of the testimony to the custodian. This subsection shall not preclude the taking of testimony by any means authorized by, and in a manner consistent with, the Federal Rules of Civil Procedure.

(2) PERSONS PRESENT.—The false claims law investigator conducting the examination shall exclude from the place where the examination is held all persons except the person giving the testimony, the attorney, for and any other representative of the person giving the testimony, the attorney for the Government, any person who may be agreed upon by the attorney for the Government and the person giving the testimony, the officer before whom the testimony is to be taken, and any stenographer taking such testimony.

(3) WHERE TESTIMONY TAKEN.—The oral testimony of any person taken pursuant to a civil investigative demand served under this section shall be taken in the judicial district of the United States within which such person

resides, is found, or transacts business, or in such other place as may be agreed upon by the false claims law investigator conducting the examination and such person.

(4) TRANSCRIPT OF TESTIMONY.—When the testimony is fully transcribed, the false claims law investigator or the officer before whom the testimony is taken shall afford the witness, who may be accompanied by counsel, a reasonable opportunity to examine and read the transcript, unless such examination and reading are waived by the witness. Any changes in form or substance which the witness desires to make shall be entered and identified upon the transcript by the officer or the false claims law investigator, with a statement of the reasons given by the witness for making such changes. The transcript shall then be signed by the witness, unless the witness in writing waives the signing, is ill, cannot be found, or refuses to sign. If the transcript is not signed by the witness within 30 days after being afforded a reasonable opportunity to examine it, the officer or the false claims law investigator shall sign it and state on the record the fact of the waiver, illness, absence of the witness, or the refusal to sign, together with the reasons, if any, given therefor.

(5) CERTIFICATION AND DELIVERY TO CUSTODIAN.—The officer before whom the testimony is taken shall certify on the transcript that the witness was sworn by the officer and that the transcript is a true record of the testimony given by the witness, and the officer or false claims law investigator shall promptly deliver the transcript, or send the transcript by registered or certified mail, to the custodian.

(6) FURNISHING OR INSPECTION OF TRANSCRIPT BY WITNESS.—Upon payment of reasonable charges therefor, the false claims law investigator shall furnish a copy of the transcript to the witness only, except that the Attorney General, the Deputy Attorney General, or an Assistant Attorney General may, for good cause, limit such witness to inspection of the official transcript of the witness' testimony.

(7) CONDUCT OF ORAL TESTIMONY.—

(A) Any person compelled to appear for oral testimony under a civil investigative demand issued under subsection (a) may be accompanied, represented, and advised by counsel. Counsel may advise such person, in confidence, with respect to any question asked of such person. Such person or counsel may object on the record to any question, in whole or in part, and shall briefly state for the record the reason for the objection. An objection may be made, received, and entered upon the record when it is claimed that such person is entitled to refuse to answer the question on the grounds of any constitutional or other legal right or privilege, including the privilege against self-incrimination. Such person

may not otherwise object to or refuse to answer any question, and may not directly or through counsel otherwise interrupt the oral examination. If such person refuses to answer any question, a petition may be filed in the district court of the United States under subsection (j)(1) for an order compelling such person to answer such question.

(B) If such person refuses to answer any question on the grounds of the privilege against self-incrimination, the testimony of such person may be compelled in accordance with the provisions of part V of title 18 [18 USCS §§ 6001 et seq.].

(8) WITNESS FEES AND ALLOWANCES.—Any person appearing for oral testimony under a civil investigative demand issued under subsection (a) shall be entitled to the same fees and allowances which are paid to witnesses in the district courts of the United States.

(i) CUSTODIANS OF DOCUMENTS, ANSWERS, AND TRANSCRIPTS.—

(1) DESIGNATION.—The Attorney General shall designate a false claims law investigator to serve as custodian of documentary material, answers to interrogatories, and transcripts of oral testimony received under this section, and shall designate such additional false claims law investigators as the Attorney General determines from time to time to be necessary to serve as deputies to the custodian.

(2) RESPONSIBILITY FOR MATERIALS; DISCLOSURE.—

(A) A false claims law investigator who receives any documentary material, answers to interrogatories, or transcripts of oral testimony under this section shall transmit them to the custodian. The custodian shall take physical possession of such material, answers, or transcripts and shall be responsible for the use made of them and for the return of documentary material under paragraph (4).

(B) The custodian may cause the preparation of such copies of such documentary material, answers to interrogatories, or transcripts of oral testimony as may be required for official use by any false claims law investigator, or other officer or employee of the Department of Justice. Such material, answers, and transcripts may be used by any such authorized false claims law investigator or other officer or employee in connection with the taking of oral testimony under this section.

(C) Except as otherwise provided in this subsection, no documentary material, answers to interrogatories, or transcripts of oral testimony, or copies thereof, while in the possession of the custodian, shall be available for examination by any individual

other than a false claims law investigator or other officer or employee of the Department of Justice authorized under subparagraph (B). The prohibition in the preceding sentence on the availability of material, answers, or transcripts shall not apply if consent is given by the person who produced such material, answers, or transcripts, or, in the case of any product of discovery produced pursuant to an express demand for such material, consent is given by the person from whom the discovery was obtained. Nothing in this subparagraph is intended to prevent disclosure to the Congress, including any committee or subcommittee of the Congress, or to any other agency of the United States for use by such agency in furtherance of its statutory responsibilities.

(D) While in the possession of the custodian and under such reasonable terms and conditions as the Attorney General shall prescribe—

(i) documentary material and answers to interrogatories shall be available for examination by the person who produced such material or answers, or by a representative of that person authorized by that person to examine such material and answers; and

(ii) transcripts of oral testimony shall be available for examination by the person who produced such testimony, or by a representative of that person authorized by that person to examine such transcripts.

(3) USE OF MATERIAL, ANSWERS, OR TRANSCRIPTS IN OTHER PROCEEDINGS.—Whenever any attorney of the Department of Justice has been designated to appear before any court, grand jury, or Federal agency in any case or proceeding, the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony received under this section may deliver to such attorney such material, answers, or transcripts for official use in connection with any such case or proceeding as such attorney determines to be required. Upon the completion of any such case or proceeding, such attorney shall return to the custodian any such material. answers, or transcripts so delivered which have not passed into the control of such court, grand jury, or agency through introduction into the record of such case or proceeding.

(4) CONDITIONS FOR RETURN OF MATERIAL.—If any documentary material has been produced by any person in the course of any false claims law investigation pursuant to a civil investigative demand under this section, and—

(A) any case or proceeding before the court or grand jury arising out of such investigation, or any proceeding before any Federal agency involving such material, has been completed, or

(B) no case or proceeding in which such material may be used has been commenced within a reasonable time after completion of the examination and analysis of all documentary material and other information assembled in the course of such investigation,

the custodian shall, upon written request of the person who produced such material, return to such person any such material (other than copies furnished to the false claims law investigator under subsection (f)(2) or made for the Department of Justice under paragraph (2)(B)) which has not passed into the control of any court, grand jury, or agency through introduction into the record of such case or proceeding.

(5) APPOINTMENT OF SUCCESSOR CUSTODIANS.—In the event of the death, disability, or separation from service in the Department of Justice of the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony produced pursuant to a civil investigative demand under this section, or in the event of the official relief of such custodian from responsibility for the custody and control of such material, answers, or transcripts, the Attorney General shall promptly—

(A) designate another false claims law investigator to serve as custodian of such material, answers, or transcripts, and

(B) transmit in writing to the person who produced such material, answers, or testimony notice of the identity and address of the successor so designated.

Any person who is designated to be a successor under this paragraph shall have, with regard to such material, answers, or transcripts, the same duties and responsibilities as were imposed by this section upon that person's predecessor in office, except that the successor shall not be held responsible for any default or dereliction which occurred before that designation.

(j) JUDICIAL PROCEEDINGS.—

(1) PETITION FOR ENFORCEMENT.—Whenever any person fails to comply with any civil investigative demand issued under subsection (a), or whenever satisfactory copying or reproduction of any material requested in such demand cannot be done and such person refuses to surrender such material, the Attorney General may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person a petition for an order of such court for the enforcement of the civil investigative demand.

(2) PETITION TO MODIFY OR SET ASIDE DEMAND.—

(A) Any person who has received a civil investigative demand issued under subsection (a) may file, in the district court of the United States for the judicial district within which such person resides, is found, or transacts business, and serve upon the false claims law investigator identified in such demand a petition for an order of the court to modify or set aside such demand. In the case of a petition addressed to an express demand for any product of discovery, a petition to modify or set aside such demand may be brought only in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending. Any petition under this subparagraph must be filed—

(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the demand to comply with the provisions of this section or upon any constitutional or other legal right or privilege of such person. During the pendency of the petition in the court, the court may stay, as it deems proper, the running of the time allowed for compliance with the demand, in whole or in part, except that the person filing the petition shall comply with any portions of the demand not sought to be modified or set aside.

(3) PETITION TO MODIFY OR SET ASIDE DEMAND FOR PRODUCT OF DISCOVERY.—

(A) In the case of any civil investigative demand issued under subsection (a) which is an express demand for any product of discovery, the person from whom such discovery was obtained may file, in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending, and serve upon any false claims law investigator identified in the demand and upon the recipient of the demand, a petition for an order of such court to modify or set aside those portions of the demand requiring production of any such product of discovery. Any petition under this subparagraph must be filed—

(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the portions of the demand from which relief is sought to comply with the provisions of this section, or upon any constitutional or other legal right or privilege of the petitioner. During the pendency of the petition, the court may stay, as it deems proper, compliance with the demand and the running of the time allowed for compliance with the demand.

(4) PETITION TO REQUIRE PERFORMANCE BY CUSTODIAN OF DUTIES.—At any time during which any custodian is in custody or control of any documentary material or answers to interrogatories produced, or transcripts of oral testimony given, by any person in compliance with any civil investigative demand issued under subsection (a), such person, and in the case of an express demand for any product of discovery, the person from whom such discovery was obtained, may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian, a petition for an order of such court to require the performance by the custodian of any duty imposed upon the custodian by this section.

(5) JURISDICTION.—Whenever any petition is filed in any district court of the United States under this subsection, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry out the provisions of this section. Any final order so entered shall be subject to appeal under section 1291 of title 28. Any disobedience of any final order entered under this section by any court shall be punished as a contempt of the court.

(6) APPLICABILITY OF FEDERAL RULES OF CIVIL PROCEDURE.—The Federal Rules of Civil Procedure shall apply to any petition under this subsection, to the extent that such rules are not inconsistent with the provisions of this section.

(k) DISCLOSURE EXEMPTION.—Any documentary material, answers to written interrogatories, or oral testimony provided under any civil investigative demand issued under subsection (a) shall be exempt from disclosure under section 552 of title 5.

(l) DEFINITIONS.—For purposes of this section—

(1) the term “false claims law” means—

(A) this section and sections 3729 through 3732; and

(B) any Act of Congress enacted after the date of the enactment of this section [enacted Oct, 27, 1986] which prohibits, or makes available to the United States in any court of the United States any civil remedy with respect to, any false claim against, bribery of, or corruption of any officer or employee of the United States;

(2) the term “false claims law investigation” means any inquiry conducted by any false claims law investigator for the purpose of ascertaining whether any person is or has been engaged in any violation of a false claims law;

(3) the term “false claims law investigator” means any attorney or investigator employed by the Department of Justice who is charged with the duty of enforcing or carrying into effect any false claims law, or any officer or employee of the United States acting under the direction and supervision of such attorney or investigator in connection with a false claims law investigation;

(4) the term “person” means any natural person, partnership, corporation, association, or other legal entity, including any State or political subdivision of a State;

(5) the term “documentary material” includes the original or any copy of any book, record, report, memorandum, paper, communication, tabulation, chart, or other document, or data compilations stored in or accessible through computer or other information retrieval systems, together with instructions and all other materials necessary to use or interpret such data compilations, and any product of discovery;

(6) the term “custodian” means the custodian, or any deputy custodian, designated by the Attorney General under subsection (i)(1);

(7) the term “product of discovery” includes—

(A) the original or duplicate of any deposition, interrogatory, document, thing, result of the inspection of land or other property, examination, or admission, which is obtained by any method of discovery in any judicial or administrative proceeding of an adversarial nature;

(B) any digest, analysis, selection, compilation, or derivation of any item listed in subparagraph (A); and

(C) any index or other manner of access to any item listed in subparagraph (A); and

(8) the term "official use" means any use that is consistent with the law, and the regulations and policies of the Department of Justice, including use in connection with internal Department of Justice memoranda and reports; communications between the Department of Justice and a Federal, State, or local government agency, or a contractor of a Federal, State, or local government agency, undertaken in furtherance of a Department of Justice investigation or prosecution of a case; interviews of any qui tam relator or other witness; oral examinations; depositions; preparation for and response to civil discovery requests; introduction into the record of a case or proceeding; applications, motions, memoranda and briefs submitted to a court or other tribunal; and communications with Government investigators, auditors, consultants and experts, the counsel of other parties, arbitrators and mediators, concerning an investigation, case or proceeding.

TAB 3

Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act

SUMMARY: This notice sets forth nonbinding factors the Office of Inspector General (OIG) will consider in deciding whether to impose permissive exclusion in accordance with section 1128(b)(15)(A)(ii) of the Social Security Act (the Act), which authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses.

SUPPLEMENTARY INFORMATION

I. Purpose and Rationale

Section 1128(b)(15) of the Act authorizes the Secretary, and by delegation the Inspector General, to exclude an individual owner, officer, or managing employee of a sanctioned entity, as defined in section 1128(b)(15)(B) (i.e., an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs). Exclusions under section 1128(b)(15) of the Act are derivative in nature and are based upon the individual's role or interest in a company that is excluded or is convicted of certain offenses. Exclusions under section 1128(b)(15) are permissive, that is, the Secretary has the discretion whether to exclude or not to exclude. OIG's exercise of this discretion is not subject to administrative or judicial review.

Section 1128(b)(15) of the Act provides two different bases for exclusion. Individuals who have an ownership or a control interest in a sanctioned entity may be excluded under section 1128(b)(15)(A)(i) if they knew or should have known of the conduct that led to the sanction. Officers and managing employees, as defined in section 1126(b) of the Act, may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity.

Because the elements of these two provisions are so different, our exclusion analysis differs depending on whether the individual in question is: (1) an owner or (2) an officer or a managing employee.

The statute sets a higher standard for exclusion of an owner, requiring evidence that the owner knew or should have known of the conduct that formed the basis for the sanction. In general, if the evidence supports a finding that an owner knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. This presumption may be overcome when OIG finds that significant factors weigh against exclusion.

With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity. A "managing employee" is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. While OIG does not intend to exclude all officers and managing employees, when there is evidence that an officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion. As with the presumption relating to owners, the presumption may be overcome when OIG finds that significant factors weigh against exclusion.

OIG will consider the factors set forth below in deciding whether to exclude an officer or a managing employee in the absence of evidence that the person knew or should have known of the misconduct. We believe that these factors will serve a number of useful purposes: (1) they will allow for the development of effective investigations and investigative plans by OIG and its law enforcement partners, (2) they will establish and publicize a framework that will serve as a basis for OIG's permissive exclusion decisions, (3) they will allow for the appropriate allocation of OIG's finite resources to actions that have the most remedial and deterrent effect, and (4) they will positively influence individuals' future behavior and compliance with Federal health care program requirements by holding individuals accountable for misconduct within entities in which they are in positions of responsibility.

These factors are internal agency guidelines that may be subject to modification at any time. They are not intended to limit OIG's discretionary authority to exclude individuals or entities that pose a risk to Medicare and other Federal health care programs or program beneficiaries, nor do they create any rights or privileges in favor of any party. Further, these factors do not supplant or modify, in any way, the OIG regulations, codified at 42 CFR part 1001, governing program exclusions.

These factors were derived from multiple sources, including: (1) the regulations governing exclusions under sections 1128(b)(15) and 1128A of the Act (42 CFR parts 1001 and 1003); (2) the factors for implementation of permissive exclusion under section 1128(b)(7) (62 Fed. Reg. 67392 (Dec. 17, 1997)); (3) the responsible corporate official doctrine established in case law, including *U.S. v. Park*, 421 U.S. 658 (1975); and (4) decisions of the Departmental Appeals Board in exclusion matters.

II. Factors To Be Considered in Implementing OIG's Permissive Exclusion Authority Under Section 1128(b)(15)(A)(ii)

OIG may use the following factors to determine whether to impose a permissive exclusion under section 1128(b)(15)(A)(ii) of the Act in a particular case. They are

informal and nonbinding. The presence or absence of any or all of these factors does not constitute the sole grounds for determining whether OIG will pursue exclusion.

When considering whether to exclude an individual under section 1128(b)(15), OIG will consider the basis for the criminal conviction and/or exclusion of the entity, as well as any other conduct that formed the basis for criminal, civil, or administrative investigations, cases, charges, or resolutions. In addition, OIG will consider matters that involve entities that are or were related to the convicted or excluded entity. For example, OIG will consider the conduct alleged by the Government in a civil False Claims Act settlement with a corporate parent of the convicted or excluded entity. As used in the following factors, the term "misconduct" includes the factual basis for the criminal conviction or exclusion that underlies the potential 1128(b)(15) exclusion as well as any other conduct OIG considers relevant, including allegations in criminal, civil, and administrative matters involving the convicted or excluded entity or any related entity.

A. Circumstances of the Misconduct and Seriousness of the Offense

1. What were the nature and scope of the misconduct for which the entity was sanctioned? What were the nature and scope of any other relevant misconduct? At what level of the entity did the misconduct occur (e.g., violation by one field employee of company policy versus headquarters' involvement and/or direction)?

2. What was the criminal sanction imposed against the entity (or related entities) or any individuals? What was the amount of any criminal fine, forfeiture, or penalty imposed? What was the amount of any civil or administrative payment regarding related or similar issues? What was the length of any period of exclusion imposed?

3. Was there evidence that the misconduct resulted in (1) actual or potential harm to beneficiaries or other individuals or (2) financial harm to any Federal health care program or any other entity? If financial loss to the programs or other persons occurred, what was the extent?

4. Was the misconduct an isolated incident or part of a pattern of wrongdoing over a significant period of time? Has the entity previously had similar problems with OIG, the Centers for Medicare & Medicaid Services or its contractors, or any other Federal or State regulatory agency? What was the nature of these problems?

B. Individual's Role in Sanctioned Entity

1. What is the individual's current position? What positions has the individual held with the entity throughout his or her tenure, particularly at the time of the

underlying misconduct? What degree of managerial control or authority is involved in the individual's position?

2. What was the relation of the individual's position to the underlying misconduct? Did the misconduct occur within the individual's chain of command?

C. Individual's Actions in Response to the Misconduct

1. Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)? Did these actions take place before or after the individual had reason to know of an investigation? If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.

2. Did the individual disclose the misconduct to the appropriate Federal or State authorities? Did the individual cooperate with investigators and prosecutors and respond in a timely manner to lawful requests for documents and evidence regarding the involvement of other individuals in a particular scheme?

D. Information About the Entity

1. Has the sanctioned entity or a related entity previously been convicted of a crime or found liable, civilly or administratively, or resolved a civil or administrative case with the Federal or State Government or a government entity? If so, what was the prior conduct that formed the basis for these actions?

2. What is the size of the entity (e.g., how many employees does the entity have, what are the revenues, how many product lines/divisions are there within the entity)? What is the corporate structure of the entity (e.g., how many subsidiaries (operating and nonoperating) are there, what are the sizes of the subsidiaries, and what are the reporting relationships between the subsidiaries)?

TAB 4

Morgan Lewis
COUNSELORS AT LAW

Healthcare Reform Law

Fraud and Abuse and Program Integrity Provisions

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
FRAUD AND ABUSE			
1	**Overpayments** Sec. 6402 (42 U.S.C. § 1301 et. seq.)	• Overpayments must be reported *and returned* within 60 days of identity or the date a corresponding cost report is due, which ever is later. Repayments may be made to the carrier, contractor or intermediary. • Any overpayment retained after the 60-day deadline is considered an obligation for purposes of the False Claims Act**.** • 2009 False Claims Act amendments provided an expanded definition of obligation. 31 U.S.C. 3729(b)(3).	March 23, 2010

2	**Medicare Self-Referral Disclosure Protocol**
	Sec. 6409
		• Establishes a self-referral disclosure protocol (''SRDP'') for health care providers and suppliers to disclose an actual or potential violation of the Federal Physician Self-Referral Law (Stark Law).
		• Authorizes HHS discretion to reduce the amount due and owing for all violations under the Stark Law to an amount less than that specified in the statute. In establishing the amount due, the following factors may be considered:
		  • Nature and extent of the improper or illegal practice;
		  • Timeliness of such self-disclosure;
		  • Cooperation in providing additional information related to the disclosure; and
		  • Such other factors as the Secretary considers appropriate.
			SRDP procedures to be established no more than six months from the date of enactment, March 23, 2010
			Procedures to be established in consultation with the OIG.

3	**Medicare/ Medicaid Anti-Kickback Statute (AKS) Amendments.** Sec. 6402 (42 U.S.C. § 1320a-7b)	• A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. • A person need not have actual knowledge of the AKS nor specific intent to commit an AKS violation.	March 23, 2010
4	**AKS CMP Remuneration Definition**	Relevant to the beneficiary inducement provisions, remuneration *does not* include: • Any remuneration which promotes access to care and	March 23, 2010

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	Amended Sec. 6402 (42 U.S.C. § 1320a-7a(i)(6))	poses a low risk of harm to patients and Federal health care programs. • Offer or transfer by a retailer of coupons, rebates or other rewards if certain conditions are met. • Offer or transfer of items or services for free or less than fair market value by a person to an individual in financial need if certain conditions are met. • After January 1, 2011, the waiver by a PDP sponsor MA organization of any copayment for an enrollee's first fill of a covered part D generic drug.	
5	**Expansion of Recovery Audit Contractor (RAC) Program** Sec. 6411 (42 U.S.C. § 1396a(a)(42))	Mandates the expansion of the RAC program into Medicaid by requiring states to contract by December 31, 2010 with one or more RACs to identify underpayments and overpayments and recoup overpayments for Medicaid services.	March 23, 2010
	Sec. 6411 (42 U.S.C. § 1395ddd(h))	Mandates the expansion of the RAC program to Medicare Parts C and D by requiring HHS Secretary to contract with RACs to, among other things, ensure that each Part C MA plan and each Part D prescription drug plan has an anti-fraud plan in effect and to review the effectiveness of such anti-fraud plan.	
	Sec. 6411	Requires CMS to submit an annual report to Congress regarding the effectiveness of the RAC program under Medicare and Medicaid.	
6	**Medicaid State Plans – Additional Requirements** Sec. 6501 (42 U.S.C. § 1396a(a)(39))	Mandatory Medicaid termination if an individual or entity is terminated by Medicare or another Medicaid program.	January 1, 2011, unless state legislation is required.
	Sec. 6502 (42 U.S.C. § 1396a(a))	Mandatory Medicaid exclusion of individuals or entities that own, control or manage an entity that has unpaid overpayments determined to be delinquent; is suspended, excluded, or terminated from participation; or is affiliated with a suspended, excluded, or terminated individual or entity.	REPEALED December 15, 2010 as part of the Medicare and Medicaid Extenders Act of 2010 (P.L. 111-309). Pending legislation, the Strengthening Medicare Anti-Fraud Measures Act of 2011

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
			(H.R. 675), proposes *permissive* exclusion from all federal health programs for individuals or entities affiliated with a suspended, excluded, or terminated individual or entity.
	Sec. 6503 (42 U.S.C. § 1396a(a))	Mandatory registration by agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers with the state and the HHS Secretary.	January 1, 2011, unless state legislation is required.
	Sec. 6505 (42 U.S.C. § 1396b(a))	Bars Medicaid payments for items or services to any financial institution or entity located outside the U.S.	
7	**False Claims Act-Public Disclosure Bar to *Qui Tam* Actions** Sec. 10104(j) (31 U.S.C. § 3730(e)(4))	• Public disclosure no longer an issue of jurisdiction but amendments do subject declined qui tam to dismissal if allegations publicly disclosed and relator is not original source. • DOJ may oppose dismissal of action where allegations publicly disclosed and relator is not original source. • Limits public disclosures to federal criminal, civil or administrative hearings in which the government is a party, and federal reports, hearings, audits or investigations. State proceedings and private litigation are not qualifying disclosures. • News media reports remain a qualifying disclosure to bar *qui tam* suits • Expands definition of "original source" to include (i) an individual who discloses to the government the information on which the claims are based prior to the public disclosure and (ii) an individual who provides independent knowledge that adds *materially* to the publicly disclosed information to the government before filing an action.	March 23, 2010
8	**Health Care Fraud Offense** **Sec. 10606** (18 U.S.C. §	• Amends 18 U.S.C. § 1347 criminal health care fraud statute to reduce intent required to establish a health care fraud offense violation. Knowing and willful standard does not require proof of actual knowledge of health care fraud	

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	1347; 18 U.S.C. § 24(a))	statute or specific intent to violate the statute. Similar amendment to anti-kickback statute. Sec. 6402 (42 U.S.C. § 1320a-7b). • Changes definition of health care fraud offense in 18 U.S.C. 24(a) to include violations of the anti-kickback statute, FDCA and certain ERISA provisions.	
9	**CMS Civil Monetary Penalties (CMP)** Sec. 6402, Sec. 6408 (42 U.S.C. § 1320a-7a(a))	Expands CMS liability for the following activities: • Ordering or prescribing a medical or other item or service during a period in which the person was excluded from a Federal health care program, if the person knows or should have know that a claim for such medical or other item or service will be made. • Knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any Federal health care program application, bid or contract (Penalty: $50,000 penalty and 3 times total amount claimed). • Knowing retention of an overpayment and not reporting and returning such overpayment. • Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program (Penalty: $50,000, for each false record or statement). • Failing to grant timely access, upon reasonable request, to the HHS Inspector General for audits, investigations, evaluations, or other statutory functions of the HHS Inspector General (Penalty: $15,000 per day).	March 23, 2010
10	**Beneficiary Fraud** Sec. 6402 (42 U.S.C. § 1301 et. seq.)	Imposes appropriate administrative penalties on those beneficiaries who knowingly participate in a Federal health care fraud offense or a conspiracy to commit a Federal health care fraud offense.	March 23, 2010
11	**Expanded HHS-OIG Subpoena Authority** Sec. 6402 (42 U.S.C. § 1320a-7(f))	Extends HHS testimonial subpoena authority to program exclusion investigations and authorizes HHS Secretary to delegate such subpoena authority to the HHS Inspector General.	March 23, 2010
12	**Obstruction of Program Audits**	Authorizes permissive exclusion for obstructing an investigation or audit. Prior provision applied only to	January 1, 2010

	PROVISION (Section of Healthcare Reform Law and Related Laws)	SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	Sec. 6408 (42 U.S.C. § 1320a-7(b)(2))	obstructing criminal investigations.	
13	**Evidentiary Privilege of Inter-Agency Correspondence Related to Any Investigation** Sec. 6607 (29 U.S.C. § 1134(d))	Secretary of Labor may promulgate a regulation that provides an evidentiary privilege for, and provides for the confidentiality of communications between or among, certain federal and state agencies (including State AG, DOJ, DHHS). Any privilege that is established must apply to communications related to any investigation, audit, examination, or inquiry conducted or coordinated by any of the agencies.	Corresponding regulations must be promulgated before privilege becomes effective.
14	**Data Sharing** Sec. 6403 (42 U.S.C. § 1320a-7e; 42 U.S.C. § 1396r-2)	• Mandates a national health care fraud and abuse data collection program for the reporting of certain final adverse actions and to furnish the information collected to the National Practitioner Data Bank. • Mandates states have in effect a system for reporting information with respect to formal licensing proceedings or final adverse actions. • Mandates termination of the Healthcare Integrity and Protection Data Bank and mandates transfer of all data collected therein to the National Practitioner Data Bank. Transition period is from date of enactment to the later of one year after enactment or the effective date of regulations related to this requirement. • Authorizes the Department of Veteran Affairs to have access to the National Practitioner Data Bank.	First day after the final day of the transition period.
	Sec. 6402 (42 U.S.C. § 1301 et. seq.)	• Mandates The Integrated Data Repository of the Centers for Medicare & Medicaid Services include claims and payment data from a variety of programs, including Medicare, Medicaid, Veterans Affairs, and the Indian Health Service, so that data from such programs can be matched with data in the HHS system for the purpose of identifying potential Medicare and Medicaid fraud, waste and abuse. • Mandates access by the HHS Inspector General and the Attorney General to claims and payment databases for purposes of conducting law enforcement and oversight activities.	March 23, 2010
	Sec. 6402 (42 U.S.C. § 1396b(i))	Prohibits federal matching payments to states for medical assistance to those individuals for whom the state does not report enrollee encounter data to Medicaid Management Information Systems (MMIS) in a timely manner.	March 23, 2010
	Sec. 6504 (42 U.S.C. §	• Mandates states submit expanded data elements under	Applies to data submitted, and

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	1396b(r)(1)(F) and 42 U.S.C. § 1396b(m)(2)(A)(xi))	MMIS as necessary for program integrity, program oversight, and administration. • Mandates state contracts with Medicaid managed care organizations provide for the provision of patient encounter data to the state.	contract years beginning, on or after January 1, 2010.
15	**Uniform Fraud and Abuse Referral Format** Sec. 6603 (42 U.S.C. § 300gg-93)	Mandates HHS request that the National Association of Insurance Commissioners develop: • A model uniform report form for private health insurance issuer seeking to refer suspected fraud and abuse to responsible state agencies for investigation; and • Recommendations for uniform reporting standards for such referrals.	March 23, 2010
16	**U.S. Sentencing Guidelines (USSG)** Sec. 10606 (Federal Sentencing Guidelines)	Amends Federal Sentencing Guidelines to provide an increase of between two and four levels for Federal health care offenses involving $1 million or more.	March 23, 2010
17	**Transparency Requirements for Health Industry Sectors**	There are significant transparency requirements for applicable manufacturers of covered devices, drugs, biologics and medical supplies, pharmacy benefit managers, hospitals, physicians, and skilled nursing facilities. These transparency requirements are contained in the Morgan Lewis March 29, 2010 Law Flash Healthcare Reform Legislation Delivers New Transparency Requirement to the Health Industry. Sec. 6001 (Physician and Hospital Disclosures on Physician Ownership and Investment) Sec. 6002 (Manufacturer and Group Purchasing Organization Reporting of Physician Ownership and Investment) Sec. 6003 (Physician Disclosure Requirements for In-Office Ancillary Services) Sec. 6004 (Manufacturer and Distributor Reporting on Prescription Drug Samples) Sec. 6005 (Pharmacy Benefit Manager Transparency Requirements) Sec. 6101 (Nursing Facility and Skilled Nursing Facility Disclosure of Ownership and Additional Information) Sec. 6104 (Nursing Facility Staffing Information)	
18	**Suspension of Payments Pending Investigation** Sec. 6402 (42	Medicare and Medicaid payments may be suspended pending investigation of a credible allegation of fraud, unless HHS determines there is good cause not to suspend payments.	March 23, 2010

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	U.S.C. § 1395y; 42 U.S.C. § 1396b(i)(2))		
19	**Fraud and Abuse Enforcement Funding** Sec. 6402 and Reconciliation Sec. 1303 (42 U.S.C. § 1395i(k))	The Healthcare Reform Law appropriates to the Health Care Fraud and Abuse Control Account an additional $100 million for FY 2011 through 2020 and the Reconciliation Law appropriates $250 million for FY 2011 through 2016 to cover the costs of the administration and operation of the health care fraud and abuse control program and the Medicare Integrity Program.	March 23, 2010
PROGRAM INTEGRITY			
20	**Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid and Children's Health Insurance Program (CHIP)** Sec. 6401 (42 U.S.C. § 1395cc(j); 42 U.S.C. § 1396a(a))	• Mandates establishment for new Medicare, Medicaid and CHIP providers, screening procedures, which must include licensure checks and may include criminal background checks, fingerprinting, database inquiries and site visits • Screening must occur within one year of enactment for new providers and suppliers and within two years of enactment for current providers and suppliers. • Mandates establishment of procedures to provide for a period (greater than 30 days and up to one year) of enhanced oversight (e.g., prepayment review and payment caps) for new providers and suppliers • New providers and suppliers must disclose current or past affiliations with any provider or supplier with uncollected debt, suspended payments or exclusion from a federal health care program, or revoked billing privileges. HHS may deny enrollment if such affiliations pose undue risk of fraud, waste, or abuse. • HHS may satisfy past due obligations of a provider or supplier by adjusting payments to providers or suppliers with the same tax identification number as the provider or supplier with the past due obligation. • HHS may impose a moratorium on enrollment of new providers or suppliers if necessary to combat fraud, waste, or abuse and provided that there would be no adverse impact on beneficiaries. • Establishment of a compliance program with core elements determined by HHS, in consultation with HHS OIG, is a condition of enrollment. • CMS must establish a process for making available to each state agency responsible for administering a State	March 23, 2010, unless otherwise noted.

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
		Medicaid plan or a CHIP plan the name, national provider identifier, and other identifying information for any Medicare or CHIP provider or supplier who is terminated from participation within 30 days of termination.	
21	**OIG Authority to Obtain Information From Providers and Suppliers** Sec. 6402 (42 U.S.C. § 1301 et. seq.)	HHS Inspector General may obtain information from any individual (including beneficiaries) or provider, supplier, grant recipient, contractor, manufacturer, distributor, or other entity, for purposes of protecting the integrity of Medicare and Medicaid, including supporting documentation necessary to validate Medicare and Medicaid payments.	March 23, 2010
22	**National Provider Identifier** Sec. 6402 (42 U.S.C. § 1301 et. seq.)	All Medicare and Medicaid providers and suppliers must include their national provider identifier on all program applications and claims.	January 1, 2011
23	**Physician Ownership** Sec. 6001 (42 U.S.C. § 1395nn)	Section 6001 places new restrictions on the physician self-referral law's (Stark Law) whole hospital exception as well as requiring additional transparency. Among other things, Section 6001: • Prohibits physician-owned hospitals that do not have a provider agreement from participating in Medicare. Physician-owned hospitals with a provider agreement could participate under prescribed conditions. • Requires hospitals to submit annual reports to HHS containing a detailed description of each physician owner or investor (and any other owners or investors) of the hospital and the nature and extent of all ownership and investment interests. HHS will publish such information on the CMS website. • Requires hospitals to implement procedures requiring physician owners and investors to disclose to patients referred to the hospital the physician's ownership or investment interest. • Requires hospitals to disclose the fact that the hospital is partially owned or invested in by physicians on the hospital's public website and in any public advertising by the hospital.	
24	**DME and Home Health Services** Sec. 6405 (42 U.S.C. § 1395m(a)(11)(B))	Limits ordering of DME or home health services for Medicare beneficiaries to Medicare enrolled physicians or eligible professionals. Authorizes HHS to extend these requirements to other Medicare items and services.	Applies to written orders and certifications made on or after July 1, 2010.
	Sec. 6406 (42 U.S.C. § 1395u(h) , 42	Authorizes HHS to revoke enrollment, for not more than one year for each act, of a Medicare physician, supplier, or provider who fails to maintain and provide access to	Applies to orders, certifications,

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	U.S.C. 1395cc, 42 U.S.C. § 1320a-7(b)(11))	documentation relating to written orders or requests for payment for DME, certifications for home health services or referrals for other items and services.	and referrals made on or after January 1, 2010.
	Sec. 6407 (42 U.S.C. § 1395f(a)(2)(c); 42 U.S.C. § 1395m(a)(11)(B))	• Requires physician or other permitted professional to have a face-to-face encounter with a patient prior to issuing a certification for home health services or written order for DME. • Applies to Medicare and Medicaid. • Permits HHS to apply this requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of fraud, waste, or abuse.	• Applies to home health certification, after January 1, 2010. • Applies to written orders for DME upon enactment.
25	**Surety Bonds** Sec. 6402 (42 U.S.C. 1395m(a)(16)(B); 42 U.S.C. §1395x(o)(7)(C); 42 U.S.C. 1395y)	Surety bonds for DME and home health agencies must be commensurate with volume of billing.	March 23, 2010
26	**Application of Fraud and Abuse Laws to Private Exchange Insurers** Sec. 1313 (31 U.S.C. § 3729 et seq.) See also Sec. 10104 (striking § 1313(a)(6)(B))	• Requires HHS to provide for the efficient and non-discriminatory administration of Exchange activities and implement any measure or procedure appropriate to reduce fraud and abuse. • Subjects payments made by, through, or in connection with an Exchange to the False Claims Act if those payments include any Federal funds.	January 1, 2014
27	**Medicare Advantage (MA) or Part D Plan** Sec. 6408 (42 U.S.C. § 1395w-27(g)(2)(A); 42 U.S.C. § 1395w-27(g)(1))	• Establish penalties for Medicare Advantage and Medicare Part D plans that misrepresent or falsify information of up to the amount claimed by the plan or plan sponsor in connection with the misrepresentation or falsified information. • Authorizes sanctions and penalties for MA and Part D plans that enroll individuals in a plan without their consent; transfer an individual from one plan to another to generate commissions or fees; fail to comply with marketing restrictions related to approval of marketing materials and prohibited marketing activities; or employ or contract with an individual or entity who engages in	January 1, 2010

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
		conduct for which intermediate sanctions may be imposed.	
28	**Multiple Employer Welfare Arrangements (MEWAs) under ERISA** Sec. 6601 (29 U.S.C. § 1149)	Provides criminal penalties for any person, in connection with a MEWA, that knowingly makes a false statement or false representation of fact in connection with the marketing or sale of the MEWA in regard to the: • Financial condition of the MEWA; • Benefits provided by the MEWA; • Regulatory status of the MEWA under any Federal or State law governing collective bargaining, labor management relations, or internal union affairs; or • Regulatory status of the MEWA regarding exemption from state regulatory authority under ERISA.	March 23, 2010
	Sec. 6604 (29 U.S.C. § 1150)	Authorizes Secretary of Labor, for the purpose of identifying, preventing, or prosecuting fraud and abuse, to adopt regulations that would prevent MEWAs from claiming federal preemption as a defense under State law and would subject MEWAs to the laws of the States in which the MEWA operates.	Corresponding regulations must be promulgated before preemption change becomes effective.
	Sec. 6605 (29 U.S.C. § 1151)	Allows Secretary of Labor to issue a "cease and desist" order if it appears that the alleged conduct of a MEWA is (i) fraudulent, (ii) creates an immediate danger to the public safety or welfare, or (iii) is causing or can be reasonably expected to cause significant, imminent, and irreparable public injury. Authorizes the seizure of MEWA assets if it appears that the MEWA is in a financially hazardous condition.	March 23, 2010
	Sec. 6606 (29 U.S.C. § 1021(g))	Mandates MEWAs register with the Secretary and make annual reports regarding their operations.	March 23, 2010
29	**Section 340B Program Integrity Measures** Sec. 7102 (42 U.S.C. § 256b(d); 42 U.S.C.	• Requires Manufacturers to submit quarterly reports of 340B ceiling prices and the components used to calculate them to the Secretary. • Requires the Secretary to provide certain improvements in 340B compliance by manufacturers in order to prevent overcharges and other violations of the 340B discounted pricing requirements.	March 23, 2010

PROVISION (Section of Healthcare Reform Law and Related Laws)		SUMMARY OF REQUIREMENT	EFFECTIVE DATE
	256b(a))	• Establishes civil monetary penalties not to exceed $5,000 for each instance of overcharging a covered entity. • Requires the Secretary to provide certain improvements in 340B compliance by covered entities in order to prevent diversion and violations of the duplicate discount provision and other 340B requirements. • Requires the Secretary to promulgate regulations, within 180 days of the effective date, to establish and implement an administrative process for the resolution of (i) claims by covered entities that they have been overcharged for drugs purchased under 340B and (ii) claims by manufacturers after an audit has been conducted.	
30	**Medicare and Medicaid Integrity Programs** Sec. 6402 (42 U.S.C. § 1395ddd; 42 U.S.C. § 1396u-6(c)(2))	• Entities contracting with the Medicare Integrity Program and Medicaid Integrity Program must agree to provide performance statistics to HHS and HHS Inspector General. • HHS must conduct evaluations of contracting entities every 3 years and must submit an annual report to Congress.	March 23, 2010
31	**Time Period to Submit Medicare Claims** Sec. 6404 (42 U.S.C. § 1395f(a)(1); 42 U.S.C. § 1395u (b)(3)(B); 42 U.S.C. § 1395n(a))	• Reduces the period of submission of Medicare claims from three calendar years following the year in which services were furnished to one calendar year after the date of service. • Applies to services furnished on or after January 1, 2010. For services furnished before January 1, 2010, a bill or request for payment must be filed not later than December 31, 2010.	January 1, 2010
32	**Medicaid Coding** Sec. 6507 (42 U.S.C. § 1396b(r))	Mandates states use compatible methodologies of the National Correct Coding Initiative for Medicaid claims.	Effective for claims filed on or after October 1, 2010.

TAB 5

Inspections, Compliance, Enforcement, and Criminal Investigations

6-5 - PROSECUTION

6-5 - PROSECUTION

6-5-1 - Purpose

This section establishes guidelines for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. A number of different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.

As described below, all criminal referrals, whether initiated by the District, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with Section 6-5-2 and 6-5-3. If OCI declines the referral, the Center or District may pursue the matter through the preparation of a Summary and Recommendation in accordance with Section 6-5-5 et seq.

6-5-2 - Referral of Criminal Matters to the Office of Criminal Investigations

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with the local OCI office before pursuing any criminal matter. Designated center and ORA and FDA Headquarters points of contact must communicate with their respective OCI Senior Operations Manager (SOM). This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases.

During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. In accordance with SMG 9111, district management should notify the local Special Agent in Charge, Assistant Special Agent in Charge, or Resident Agent in Charge of the referral via telephone. For referrals of Park Doctrine prosecutions, see the procedures below.

For all criminal referrals, OCI will decide promptly whether or not to pursue the case. OCI will communicate its decision back to the referring Office. If OCI declines to pursue a referral, OCI will promptly convey its decision to the referring office, which may then proceed with the case and submit a formal summary and recommendation for prosecution in accordance with sections 6-5-5 and 6-5-13 of this chapter.

6-5-3 - Special Procedures and Considerations for Park Doctrine Prosecutions

Recommending Park Doctrine Prosecutions

The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A Park Doctrine prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to the Department of Justice. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead. Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

Other factors to consider include but are not limited to:

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread;
5. Whether the violation is serious;

6. The quality of the legal and factual support for the proposed prosecution; and
7. Whether the proposed prosecution is a prudent use of agency resources.

As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act. In addition, these factors are intended solely for the guidance of FDA personnel, do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evident.

When a district office is considering initiating a referral for a Park Doctrine prosecution, the district is required to consult with the appropriate center to ensure that the referral will align with agency priorities and that the center will support the referral and provide expert witnesses or other litigation support when necessary. Centers and district offices are also encouraged to consult with OCC and OCI HQ Special Agent in Charge (SAIC) and/or the Assistant Special Agent in Charge (ASAIC) Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If the district or center is seeking a misdemeanor prosecution under the Park Doctrine, the initial referral to OCI should clearly indicate that a Park Doctrine prosecution is being sought and the reasons that a Park Doctrine prosecution would be beneficial. At the same time that the district refers a Park Doctrine prosecution to an OCI Field Office, notice of the referral also should be sent to the SAIC and/or the ASAIC OCI HQ IOD, and the applicable center. Notice of all Park Doctrine referrals, whether initiated by the district office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in the Office of Chief Counsel (OCC), and the director of the Office of Enforcement.

Upon receipt of a Park Doctrine referral, OCI will promptly review the referral and will communicate with OCC and the referring office to obtain any information or assistance needed to present the matter for prosecution. In appropriate cases, the assigned OCC attorney and/or a representative from the Office of Enforcement or other component should participate in the initial presentation of the Park Doctrine matter.

6-5-4 - Communication Between OCI and Other FDA Components

The following Staff Manual Guides (SMGs) provide additional information on communications between OCI and other FDA components:

1. SMG 9111 Sharing of Information Related to Criminal Violations - http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212504.htm [1] – This SMG requires that OCI be notified of potential criminal activity immediately if there is an imminent threat to public health and within 10 business days in all other cases and that OCI evaluate the information within 10 business days and notify the district office of its initial assessment. It also addresses information sharing between OCI and other FDA components.
2. SMG 9110 Enhanced Communications with the Office of Criminal Investigations (OCI) and Improved Alignment of Criminal/Regulatory Priorities and Activities – http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212503.htm [2] - This SMG provides general procedures for the establishment of regularly scheduled meetings between OCI and center, ORA and other FDA components.

Notify OCI if you receive a request from a law enforcement agency (federal, state/local, or foreign) for non-public information related to a criminal case. Notification should be provided to the SAIC and/or the ASAIC, OCI HQ IOD. This is particularly important if the request relates to grand jury information, judicial proceedings under the Federal Food, Drug, and Cosmetic Act, or joint investigations with OCI and other law enforcement agencies about violations of the Federal Food, Drug, and Cosmetic Act. When OCI seeks non-public information on its own initiative or in response to a request described above, provide the information to the SAIC and/or the ASAIC OCI HQ IOD for their review and determination of appropriate written confidentiality assurances prior to disclosure. Indicate what information is non-public.

6-5-5 - Processing a Summary and Recommendation

In cases where OCI has declined to pursue a referral, the recommendation for prosecution or for investigation with a view of possible criminal charges will be prepared in the format of a Summary and Recommendation (S&R). This document is a memorandum containing all information that would permit review and evaluation of the district's recommendation, including the reasons for not including samples or individuals cited in the Section 305 notice (when such a notice is issued) and information concerning any potential weaknesses in the case, anticipated defenses, or reasons why discretion may be exercised not to prosecute a person (such as, extreme age or very poor health).

It is important for the S&R to contain all facts pertaining to the recommendation, since it will be relied upon to determine whether a case is prosecutable and worthy of forwarding to the Department of Justice (DOJ). In prosecution cases in which FDA forwards counts in an Information or Indictment (as opposed to referrals for criminal investigation), the S&R should present the evidence of **each element** of the offense to be charged.

Where a district submitted the original referral or where the referral relates to an inspectional process, each recommendation must be accompanied by the written concurrence of the District Director (DD) and the Regional Food and Drug Director (RFDD). The DD's approval must state why prosecution is the action of choice, and the RFDD must concur. This concurrence will appear on the last page of the S&R. Where a center submitted the original referral and the referral relates to a center process, each recommendation must be accompanied by the written concurrence of the director of the center's office of compliance.

See section 6-5-13 for detailed guidance for preparing an S&R.

6-5-6 - Criminal Prosecution after Section 305 Notice

Criminal referrals for which the agency has provided a notice and opportunity to respond, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act (the Act), should follow the procedures described below:

1. When a district does not have direct reference authority to issue a Section 305 notice, the district will submit a citation recommendation to the appropriate center(s) for review, after contacting OCI (as described in "Office of Criminal Investigations" above. Generally, the citation recommendation includes:
    a. the names and responsibilities of each individual and the charges to be presented in the notice;
    b. the full background history of notification of the persons to receive a notice; and,
    c. facts supporting the proposed charges, including assurance of interstate documentation. All pertinent evidence, such as work sheets, labels, and inspection reports, should be submitted with the recommendation. The center may request the interstate documentation if a special need to review it exists.
2. If the district or the center identifies an issue requiring consultation with the Office of Enforcement (OE), OCI, Office of the Chief Counsel (OCC), or an ad hoc committee, the component identifying the issue will obtain prompt resolution as early in the review process as possible.
3. If, following the meeting held in response to the Section 305 notice, there is no significant change in the facts, as set forth in the district's citation recommendation, the district will notify the center, which will promptly forward the district's citation recommendation package to the Division of Compliance Management and Operations (DCMO), in OE. Concurrently, a final S&R will be sent by the district to DCMO with copies to the center.

    If there is a significant change in the facts or strength of the proposed case, the district will submit the prosecution recommendation package to the appropriate center solely to determine whether prosecution remains warranted in view of the new information. If prosecution is warranted, the center will promptly forward to DCMO the prosecution S&R and the center's approval memo presenting the basis for its decision in light of the new information.

    NOTE: When a district has evidence sufficient to meet the requirements for direct reference authority to issue a Section 305 notice ("direct reference cite authority"), the procedures in # 1 above do not apply. (Except that OCI must be contacted, as described in "Office of Criminal Investigations" above.) After the Section 305 process has been completed and, if no new information is presented that affects the basis for the direct reference authority, the district should promptly submit its prosecution S&R directly to DCMO for a limited review. The district should concurrently send a copy of the S&R to the center.

If the response to the Section 305 notice reveals new information affecting the basis for the direct reference cite authority, the district must obtain center review and concurrence concerning that aspect of the recommendation before submitting it to DCMO.

4. DCMO will perform a limited review to determine whether the proposed prosecution conforms to agency policy and enforcement strategies and objectives. If DCMO concurs in the prosecution recommendation, it will forward all relevant materials to OCC, along with a memo concerning the issues it has considered and that DCMO believes OCC should review.
5. OCC will review the recommendation and, if it agrees that prosecution is supportable, prepare a referral letter and form of Information or Indictment.

6-5-7 - Criminal Prosecution without Section 305 Notice

Those instances in which the agency need not issue a Section 305 notice under the Act are codified in 21 CFR 7.84. No Section 305 notice is required in cases brought under Title 18 of the United States Code - as opposed to cases brought under the Act - or in cases exempt under 21 CFR 7.84(a)(2) and (3), based on the agency's belief that the notice might result in alteration or destruction of evidence or flight to avoid prosecution. Nor is a Section 305 notice usually provided when the agency is recommending further investigation.

Criminal referrals not preceded by a Section 305 notice should follow the procedures described below. OCI must be contacted early on in this process, in accordance with the procedures described in “Office of Criminal Investigations” above.

1. The district is to consult with DCMO, which will consult with OCC, to determine whether to issue a Section 305 notice or whether an ad hoc committee is needed to decide the issue. If DCMO and OCC agree that no Section 305 notice should be issued, DCMO will so notify the district. The district will then prepare an S&R and obtain approval from the Region before submitting the S&R to DCMO, with concurrent copies to the center and OCC for review. The district will explain under the heading "No Section 305 Notice" why such notice is not required. (Should DCMO and OCC decide that a Section 305 notice should be issued, DCMO will so notify the district who will then follow the procedure under RPM, "Prosecution after 305 Notice".)
2. If the center and DCMO concur in the recommendation, each will prepare a memo reflecting its views on the relevant issues. The center will forward its memo to DCMO.
3. DCMO will forward all relevant materials and memos to OCC and, if OCC agrees that prosecution is supportable, OCC will prepare a referral letter and form of Information or Indictment.

6-5-8 - Contempt Of Court; Violation of Probation

The district will prepare an S&R outlining the facts that establish the violative conduct and send it and a copy of the pertinent court order electronically via CMS to DCMO. Because DCMO and the relevant center are expected to conduct concurrent reviews, the S&R should include a request that DCMO send a task referral pursuant to CMS procedures to the center requesting its review.

Both the center and DCMO will have 10 working days to review the proposed action and upload their comments into CMS.

If no adverse comment is provided by either the center or DCMO, or if adverse comment was provided but a consensus to proceed is reached, the district will forward its S&R and supporting evidence to DCMO via CMS for prompt forwarding to OCC for review. If OCC agrees that the action is supportable, it will prepare a referral letter.

6-5-9 - Development of Felony Violation

Some investigations may reveal facts supporting potential felony charges under either Title 18 of the United States Code or 333(a)(2) of Title 21. A primary problem associated with these cases is determining the investigational end-point. When such situations are encountered, an ad hoc committee should be considered. This is because some potential cases should be referred at an early stage for a grand jury investigation, while FDA can carry others to investigational completion, prior to referral.

The following matters, among others, should be considered in these situations:

1. scope of the investigation;
2. status of current investigation, including identification of targets and of potential cooperating individuals;
3. strategy and timing in completing the investigation;
4. agency compliance policy in the area at issue;
5. preliminary evidence that violations are intentional;
6. identification of inspectional or investigational problems;
7. use of criminal search warrants;
8. need for or wisdom of a Section 305 notice citation; and,
9. recommendation for grand jury investigation (see RPM "Grand Jury Investigations").

For investigations subject to ad hoc committee oversight, the compliance branch in the managing organizational unit will prepare a status report whenever significant progress is made on an investigation or at least every 90 calendar days, whichever occurs first, and distribute it to DCMO, OCC, appropriate center, and affected regional/district offices.

6-5-10 - Referrals for Criminal Investigation

A referral from a district or center to DOJ for further criminal investigation, including an investigative grand jury, should follow the process described below:

1. The initiating unit, district or center, will notify OCI in accordance with the RPM section "Office of Criminal Investigations." If OCI elects not to pursue the case, then the district or center may notify DCMO and request an ad hoc committee meeting, and provide a Summary and Recommendation Document (S&R) of the existing evidence. Relevant, organized, and tabbed background material will be assembled by the initiating unit and uploaded with the S&R into CMS. The district should transfer the case to DCMO by changing the current owner to DCMO pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DCMO designated to receive notification when ownership of a case has changed to that office. Information should cross reference and cite specific pages of the background material.
2. Prior to scheduling the meeting, DCMO will review the background package and ensure that it is in a form that will facilitate review and identification of issues.
3. DCMO will promptly notify the committee via e-mail of the availability of the background package in CMS and in the body of the e-mail provide a time and place for the meeting, and identify the principal issues to be decided. With very rare exception, a minimum of 10 working days will be provided for members to review the background package; center review will be given high priority and the meeting will not be scheduled until the center is ready to participate. A copy of this e-mail should be uploaded into CMS.
4. The committee members should be prepared to make agency decisions on the issues, including whether referral should be made on the basis of the evidence in hand, whether additional assignments should first be issued, completed, and reviewed by the committee, or whether a noncriminal disposition should be considered in lieu of or in addition to a prosecution.
    a. Should the committee members concur in the recommendation for referral and believe that there is no need to gather further evidence or for a

further meeting, DCMO will promptly prepare a memorandum of the decision, upload it into CMS and forward a hardcopy to OCC as the agency's recommendation. DCMO will maintain ownership of the case. OCC will revise the district's draft of the referral letter, as necessary. DCMO should upload this draft into CMS.

b. Should the committee believe that additional investigation is needed, the committee will issue the appropriate assignments, record them in a memo that is uploaded in CMS and set a tentative date to reconvene. Offices performing the additional work will be responsible for providing written summaries of the results and, when appropriate, recommendations to the committee in advance of the next meeting. These associated documents should be uploaded into CMS. DCMO will monitor the status of the assignments and schedule via e-mail the follow-up meeting. A minimum of 5 working days will be provided for members to review new information prior to the meeting. DCMO will prepare a memorandum of any subsequent meeting and upload it into CMS.

5. If the committee decides, either on the basis of its initial review or on the basis of additional data discussed at a subsequent meeting, that a request for criminal investigation should be referred, DCMO will promptly forward to OCC any relevant materials that may not have previously been provided along with a written request that OCC refer the matter to DOJ.

   NOTE: When FDA participates in investigations in which another Federal agency has the lead and intends to request a criminal investigation, the district will work directly with the lead agency in developing evidence and in assisting in the investigation. In such cases, the district will promptly notify the relevant centers, DCMO, OCI, and OCC of the investigation, the district's role in it, and whether a grand jury investigation is contemplated.

   As soon as the district determines that it would like to seek the prosecution of Title 21 or Title 18 charges based upon violations involving FDA regulated articles in an investigation where another Federal agency has the lead, it will notify DCMO, for an FDC number, the centers, and OCC of its intent to do so and will promptly forward a recommendation to DCMO, the center or, if appropriate, directly to OCC, to obtain approval to proceed with the case.

   In some cases, an ad hoc meeting may be appropriate. If special time constraints are applicable because of the participation of other agencies, the recommendation should so state. Except for possible time constraints, joint investigations should be processed in the same manner as other FDA cases.

6-5-11 - Information And Indictments

These documents will usually be prepared by Office of Chief Counsel.

An Information is the formal legal document that is usually used to allege misdemeanor violations. An Indictment is the document in which felony violations are alleged, following presentation to the grand jury. This document is also referred to as a True Bill of Indictment. With the consent of a defendant, an Information may be presented to a grand jury, even though only misdemeanor violations are alleged.

6-5-12 - Grand Jury Investigations And Secrecy

Grand jury investigations are subject to Rule 6 of the Federal Rules of Criminal Procedure (see Exhibit 6-29). The fact of grand jury investigations and the actions of a Federal grand jury are secret. Only persons whose names have been filed with the court pursuant to Rule 6(e) may know about the grand jury's activities, such as whether the grand jury has issued a subpoena to someone. **For this reason, transcripts of testimony given before a grand jury can be read by or discussed only with persons who have been designated under Rule 6(e). Neither FDA colleagues nor supervisors may be advised of the substance of grand jury activities unless they have been designated under Rule 6(e).**

As with any pending investigation, there should be no comment whatsoever to the media or to the general public about the existence or activities of a grand jury. Even if there has already been speculation in the press about a grand jury or reports about it from witnesses called to testify before the grand jury (who are not bound by the rule of grand jury secrecy), no confirmation or other comment on the grand jury should be made.

Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation and the validity of any indictment the grand jury might return, but the rights of the persons accused.

Compromising the 6(e) rule is a very serious matter and could result in dismissal of the charges, the suppression of valuable information, and/or a contempt citation against persons violating Rule 6(e).

DOJ and the U.S. Attorney may request FDA to provide investigative support to conduct interviews, accompany U.S. Marshals to seize evidence, and so on. Any person who is involved in this type of investigation will be given a 6(e) designation where these actions involve matters occurring before the grand jury.

6-5-13 - Preparation of Summary and Recommendation

See Exhibit 6-25 for a model format for the summary and recommendation memorandum and Exhibit 6-26 for an example of a food sanitation case. The Sample Index is an outline of the support samples related to the prosecution.

1. ***Sample Number, Product, Date Shipped***
   The order of the counts in an Information or Indictment is variable, but should be determined by the significance or seriousness of the violations, rather than the sequential order of the sample numbers or the date of sample collection. However, where all samples or schemes have the same degree of seriousness, list in descending chronological order (most recent offense in Count I, next most recent offense in Count II, and so forth. The column headings may be changed to provide whatever information the district feels is significant. Beneath the sample number indicate the proposed count number. In cases where supporting samples are unnecessary, describe the scheme or violation and outline the elements of the offenses.
2. ***Citation Under Section 305 Of The FD&C Act***
   List complete names and addresses of all persons issued Section 305 notices. Prepare brief, concise paragraphs explaining significant new evidence obtained since the Recommendation for Citation was submitted. Also include any changes in the status of responsible individuals or the firm that have occurred since the center approved the issuance of 305 notices or, in the case of direct reference cite authority, since the Section 305 notice issued. See the RPM section "Criminal Prosecution after Section 305 Notice".) If this is a recommendation without a Section 305 notice, prepare a brief paragraph explaining the facts, including identifying the basis of concurrence with this approach, for example, "**Ad Hoc** meeting."
3. ***Legal Status***
   Prepare a brief paragraph describing the legal status of the firm as of the date of the S&R and at the time of the violations. If there has been a change in the legal status in the interim, furnish complete information concerning the change. As soon as the decision is made to recommend prosecution of a corporation, request certified copies of the Articles of Incorporation and the most recent Annual Corporate Registration. The annual corporate registration may list the current corporate officers at the date of filing. This request may be made in writing as shown in Exhibit 6-27 or in person so that the records are received in a form suitable for introduction into evidence (see Exhibit 6-28). If the Articles of Incorporation have been received before the recommendation has been submitted, so state in this section and enclose photocopies of the Articles with the recommendation. If they have not been received, include a statement that the Articles of Incorporation have been requested and photocopies will be submitted upon receipt.

   When preparing photocopies of certified copies, the removal of any staples nullifies the certification. -- Caution the Legal Secretary/Technician about this.

   If a corporation is dissolved, in most states it still legally exists for a period of time specified by the state in which it is incorporated and may be prosecuted during that period. In case of dissolution, submit copies of any notices thereof filed with the state and reports of any actions by the state on such dissolution.

4. ***Alleged Violation***
   Prepare a summary of what the case is about. Include a statement on how the problem came to the attention of the agency. List the violations under this heading. In the event the proposed counts are numerous and the violations involve several different sections of a statute, you may use an outline or tabular form. Adulteration and misbranding charges should be charged in separate counts. In cases involving fraud, a detailed statement of all pertinent data (who, what, when, where, why, and how) concerning the scheme, from its conception through its perpetration, should be prepared. The following questions should be considered:
   a. When was the scheme initially implemented? By whom?
   b. What were its primary objectives?
   c. What were the methods by which it was implemented?
   d. Where was it put into operation and for how long?
   e. What was the nature of the scheme, the types of merchandise or service involved?
   f. Describe the magnitude, nature, and characteristics of the scheme (for example, number of units shipped, and amount of money involved).
   g. Describe the victims as to health, economic status, or other features.
   h. Identify for each proposed defendant or target any evidence reflecting that the offense was committed knowingly and willfully (intentionally).
   i. Identify potentially cooperative witnesses.
   j. Describe any noteworthy investigational problems encountered.
5. ***History***
   State briefly the regulatory history of the firm and the individual defendants. Point out any cooperative work FDA has done with the state or other Federal agencies. Indicate any prior Federal action and any state legal action taken against the proposed defendants as well as any previous in rem actions.
6. ***Prior Notice***
   As more fully explained in Chapter 10, when it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's policy to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

   Indicate how and to whom prior notice was provided. If formal prior notice has not been given, indicate how the proposed defendants are aware of the consequences of their violative acts, or explain why prior notice is not necessary or appropriate in this situation.
7. ***Other Correspondence***
   Provide reference to and copies of any correspondence that the agency (district, center, or other headquarters' unit) and state may have regarding matters subject to the recommended action.
8. ***Witnesses For Inspectional And Analytical Findings***
   Arrange the samples (if any) by proposed count numbers listing the collecting investigator and the analysts. Identify the documentary and physical evidence associated with each witness and describe how this evidence was obtained, e.g., interview, inspection, surveillance, or other means. For a case with support samples, assign count numbers as in Exhibit 6-25.
9. ***Other Witnesses***
   List the names, addresses, telephone numbers, and titles of any other known witnesses, including cooperating subjects of the investigation, FDA representatives from the center, and nongovernment expert witnesses with a summary of their anticipated testimony.
10. ***Recommendation***
    List the persons being recommended for prosecution and the corresponding sample numbers (if any) or scheme that is the basis for prosecution. If any such persons have been previously convicted or are the subject of other legal action, include a paragraph stating the nature of the charge, the date the case was terminated, the disposition, the penalty imposed, the jurisdiction, and the case number (and an FDC, lead sample, or other FDA identifying numbers, if any). Indicate whether warnings were given and summarize the recommended defendant's response or corrective action. Indicate what harm has or can result from the criminal activity at issue, such as, type and total amount of loss, number and type of victims, and similar information. See also the RPM section on Prior Notice.
11. ***Permanent Abeyance of Samples or Non-Inclusion of Individuals***
    If the district decides to place any of the samples listed in the Section 305 notice in permanent abeyance or to not include cited individuals as proposed defendants, the reasons for these decisions should be given in this section. Excluded samples should not be destroyed until the termination of the action by plea or trial. If all samples and individuals listed in the Section 305 notice are included in the prosecution recommendation, this section may be omitted.
12. ***Sample Data***
    This section is designed to furnish a brief summary of the available information in the file regarding each sample. Ordinarily, a criminal case should include more than one count and only in very unusual circumstances, which must be explained in the memorandum, will a one-count Information be referred to DOJ. Thoroughly discuss any potential problem areas with respect to the samples, such as a modification of official analytical methods during analysis, deviations from normal procedures in the collection of the samples, errors in the collection records, seals, analytical records which had to be corrected, or any inconsistencies between affidavits and records.
    a. Date lot shipped/received: For 301(a) or (d) violations, state the date the defendants shipped the lot or delivered it for shipment.For 301(k) violations, state the date the defendants received the lot, and for 301(c) violations state the date the lot was received and the date it was delivered or profferred for delivery. Occasionally, the receiving date in a 301(k) violation is not available. In such a case, the date of the offense is the day on which the investigator can testify that she or he saw the subject lot at the proposed defendant's premises. Occasionally, a 305 notice will issue with the date of shipment being the date furnished in an affidavit signed by the dealer, but subsequent investigation uncovers records indicating that the lot was actually shipped or delivered on another date. As long as the 305 notice stated "on or about" with respect to the date, this is acceptable. The correct date will be listed in the Information or Indictment, even if it differs from that listed in the Section 305 notice. Complete information regarding the conflicting dates should be furnished under the caption "Documentation of Interstate Commerce."
    b. Date lot sampled/by whom: If the sampling of the lot takes place over a period of several days, that should be stated here. In the case of a 301(k) violation, if the lot remains in the regular storage area for saleable goods, the Information or Indictment will indicate that it was held for sale between the date of receipt and the last day of the inspection. If the lot is moved to a quarantine area and it is clear that it is not to be sold, the day the product was moved (or destroyed, denatured, or embargoed) will be used in the Information or Indictment. In addition to the name of the collecting investigator, indicate where he or she is located at the time of the writing of the recommendation. If the investigator has transferred to another district, resigned, or retired, he or she should be contacted when the Information or Indictment is submitted to DOJ, advised that prosecution is pending, and requested to keep the district informed of his or her location so that the investigator can be contacted if the case goes to trial.
    c. Description of lot and sample size: The size of the lot should be listed and, in 301(k) sanitation cases, a brief description of the lot should be given. For example, the description should contain the statement that the investigator looked at (number of) bags, found urine on (number of) bags, (number of) bags were rodent gnawed, and should indicate whether filth was only on the exterior of the lot or on containers covered by other

containers, whether or not the lot was received palletized, whether containers in the lot had been restacked by the firm, etc.

d. Analysts: As with the collecting investigator, the current location of the analysts should be recorded and contact should be made with the analysts when the Information or Indictment is submitted to DOJ.

e. Analytical methods: The method of analysis should be given. If there was any deviation from an official method, complete information concerning the modification and reasons therefore should be given. (In the analysis of official preparations, the method in the compendium should be followed.)

f. Number of subs analyzed: If every sub has been analyzed, merely state "all." (It is incumbent upon the district's Compliance Branch to ensure that sufficient analytical work has been performed.)

g. Analytical findings: The results of each analysis of the product should be listed. If the problems which were encountered necessitated additional work, or deviation in or from an official method such as new methodology or analysis to resolve discrepancies in analytical results, such matters should be disclosed and discussed. In cases involving filth in foods, the analytical findings should be broken into two groups; those demonstrating actual contamination in the product [402(a)(3)] and those demonstrating 402(a)(4) conditions. The results regarding the findings of actual product contamination should be summarized basically as follows:

Section 402(a)(3) Verification

Subs _____, _____, and _____ - gnawed - incisor marks - confirmed.

Subs _____, _____, and _____ - contained rat or mouse excreta or hair - confirmed.

Sub _____ - insects (identities, if possible)

Section 402(a)(4) Verification

If there is substantial 402(a)(3) evidence, the subsamples collected from the surface and proximity of the lot need only be briefly summarized, covering each type of 402(a)(4) filth present. This includes rat or mouse excreta, rodent urine, and rodent nesting material as being confirmed or identified.

If the proposed charges differ from the data listed under "Analytical Findings" or the charge sheet that accompanied the 305 notice, the reasons for the differences should be discussed.

h. Section 702(B) Portion: In any case involving analytical work, a portion of the sample usually should be available for the defendant, should he or she request it. Verify whether the section 702(b) sample portion is available, and note the amount available. If a 702(b) portion does not exist, this fact should be conspicuously noted and an explanation provided.

Some exceptions to the requirement for 702(b) portions are codified at 21 CFR 2.10. If all subs have been analyzed, there is a presumptive 702(b) concern which should be addressed.

NOTE: Filth exhibits do not require a 702(b) portion.

i. Seizure: If the lot forming the basis for a proposed count was seized, list the case number and the FDC number and state the disposition of the seizure.

j. Documentation of interstate commerce: State the name and title of individuals signing dealer statements and affidavits, the name and address of the firm for which they work, and list the documents furnished, including information such as purchase order, invoice, freight bill, and bill of lading numbers, and the dates they were issued. Interstate commerce witnesses are sometimes called on to testify and supply the original documents in the event the case goes to trial.

k. Remarks: This section should contain detailed information concerning any potential problem areas or weaknesses in the case not covered in the description of the individual counts. Include the ages of the proposed defendants and, if known, any physical problems they may have. Also, indicate that OCI was contacted regarding the case. Finally, state why prosecution is the action of choice.

6-5-14 - Submission of Summary and Recommendation Documents

The summary and recommendation (S&R) documents are submitted to the center, DCMO and OCC, depending upon the instructions described in the applicable case procedure, "Criminal Prosecution after Section 305 Notice", “Criminal Prosecution Without Section 305 Notice", or "Referrals for Criminal Investigation."

1. ***Prosecutions Requiring Center Approval***

   a. Submit the S&R (prepared as described in “Preparation of Summary and Recommendation”) and the supporting documents listed below by uploading them into CMS.

      i. Section 305 Notice and Charge Sheet
      ii. Record of Section 305 meeting and any documents presented at the meeting
      iii. Written answer to the Section 305 notice (if meeting was not held)
      iv. Any correspondence or memoranda of telephone conversations with proposed defendants since the Citation Recommendation was submitted.
      v. Guaranty (if applicable)
      vi. Articles of Incorporation (Photocopy can be submitted in CMS and district will maintain the original. DO NOT HOLE PUNCH the original document).

      Centers should upload their approval memo into CMS.

      NOTE: If the recommendation meets the circumstances outlined in "Processing a Summary and Recommendation" and does not require further review by the center, submit the S&R and supporting documents to DCMO as described in “Direct Reference Prosecutions” below.

2. ***Direct Reference Prosecutions***

   The S&R prepared as described in “Preparation of Summary and Recommendation” should be uploaded into CMS. The district should transfer the case to DCMO by changing the current owner to DCMO pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DCMO designated to receive notification when ownership of a case has changed to that office. The S&R should contain the supporting documents listed above.

Links on this page:

1. /AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212504.htm
2. /AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212503.htm