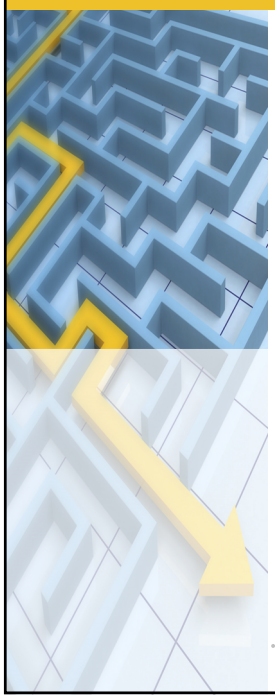

Not Your Average Fraud Seminar:
A Strategic Approach to Managing Risk in an Environment of Heightened Scrutiny

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Joshua Berman
joshua.berman@kattenlaw.com
202.625.3533

Michael Callahan
michael.callahan@kattenlaw.com
312.902.5634

Laura Keidan Martin
laura.martin@kattenlaw.com
312.902.5487

Gil Soffer
gil.soffer@kattenlaw.com
312.902.5474

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Important Background for Today's Presentation

- 2009 False Claims Act Amendments
- Patient Protection and Affordable Care Act (PPACA)
  - Significant "Integrity" Provisions
  - Significant "Transparency" Provisions
- Recommendations
  - Compliance
  - Transactions

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FERA (2009): Procedural Changes to FCA

- Expands Use of CIDs
- Authorizes the Sharing of CID Information with *Qui Tam* Relators
- Provides for "Relation Back" of Government Complaint

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FERA: Substantive Changes to FCA

- Extends Conspiracy to Reverse False Claims
- Expands Reach of Reverse False Claims Liability
  - No longer need to show that defendant took an affirmative act to conceal an obligation to repay.
  - Need only show that defendant retained an overpayment despite an "obligation" to repay.

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FERA: Obligation to Repay

- "Obligation" Defined
  - An "established duty" arising from "the retention of any overpayment."
  - What constitutes an "established duty"?
- FCA Requires "Knowing Violation"
  - Includes not only "actual knowledge" but "deliberate indifference" or "reckless disregard" of the truth or falsity of a claim.
  - How does this definition apply to overpayments?

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PPACA: Significant "Integrity" Provisions

- Increased funding for enforcement
- Expansion of RAC program
- Easier to prove "intent" standard under Anti-Kickback Statute
- False Claims Act changes
- Stark law amendments
- Stark self-disclosure protocol
- Mandatory return of overpayments within 60 days
- Civil Monetary Penalty (CMP) changes
- Exclusions under Medicaid
- Mandatory compliance programs

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PPACA: Significant "Transparency" Provisions

- Life Science/Pharma "Sunshine" Provisions
  - Covered manufacturers required to report payments in excess of $10 (in cash or in kind) made to and investments held by physicians ***and*** teaching hospitals.
  - Tracking begins January 2012 and reporting begins March 2013.
  - Drug sample requests and distributions also must be reported.
- Exempt hospital community needs assessments.
- Patient notifications of physician investments in hospitals and certain in-office ancillary services.
- PBM disclosures (e.g., % retail v. mail order, general dispensing rates, rebates, discounts and price concessions and "mark up" data).
- Nursing facility transparency (e.g., ownership, organizational structure disclosures, expenditures, comparative data).
- Physician ownership in GPOs (and information regarding ROI).

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Increased Funding for Enforcement

- Omnibus Appropriations Act of 2009 provided a one-time additional $198 million.
- 2010 Budget invests $311 million in two-year funding (50% increase over FY09).
- 2011 Budget seeks $250 million to expand the Health Care Fraud Prevention & Enforcement Action Team (HEAT).
- PPACA increases Health Care Fraud and Abuse Control (HCFAC) Account for FY11-20 by $10 million a year.
- Reconciliation Act added an additional $250 million to the account between 2011 and 2016.

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Expansion of RAC Program

- Expands the Recovery Audit Contractor program to cover Medicare Parts C and D
  - Existing program covers Parts A and B.
- Expands coverage to Medicaid program.
- Expansion takes place not later than December 31, 2010.

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Easier to Prove AKS Intent Standard

- In *Hanlester Network v. Shalala*, the Ninth Circuit interpreted the Anti-Kickback Statute's "willfully" intent requirement to mean that the government had to prove that a defendant knew that the AKS prohibited the conduct at issue. 51 F.3d 1390 (9th Cir. 1995).
- PPACA makes clear that the AKS requires only that a defendant knew his conduct was unlawful (not that it violates the AKS), resolving circuit split.
- Removing this burden in the Ninth Circuit allows prosecutors to charge and present cases based on a substantially reduced evidentiary foundation and may encourage increased utilization of the AKS.

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Public Disclosure Standard

- PPACA narrows the FCA's "public disclosure bar."
- PPACA provides that a whistleblower suit cannot be barred unless "substantially the same allegations or transactions were publicly disclosed" in: (1) "a Federal criminal civil or administrative hearing in which the government or its agent was a party"; (2) "a congressional, [GAO], or other Federal report, hearing, audit, or investigation"; or (3) "from the news media."
- No more bar based on prior state and local disclosure.
- PPACA expands "original source" to include any individual who has knowledge that is "independent of and materially adds to the publicly disclosed allegations or transactions, and who voluntarily provided the information to the government" before filing the suit.

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Stark Law Amendments: In-Office Ancillary Services Exception

- Section 6003 amends the statutory exception for in-office ancillary services.
  - Requires a physician to inform a patient in writing that the patient may obtain the DHS from another entity outside the physician's group practice.
  - Applies to MRI, CT and PET, and "any other DHS specified under (h)(6)(D) that the Secretary determines appropriate."
    - Section (h)(6)(D) reference is to radiology and other services.
  - Requires a physician to provide a written list of suppliers in the area in which the patient resides.
- Effective for services furnished on or after January 1, 2010.
- CMS will promulgate regulations to implement this section.

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Stark Law Amendments: Physician Investment in Hospitals

- Section 6001 limits rural provider and "whole hospital" exceptions.
  - Prohibits physician ownership in any hospital that does not have a Medicare provider agreement as of December 31, 2010.
  - May grandfather existing hospitals with provider agreements as of December 31, 2010 (statute ambiguous), but
    - Restricts ability to expand capacity (except in limited cases)
    - Restricts ability to increase aggregate percentage of physician ownership
  - Requires written annual report to HHS regarding identity of owners and extent of ownership interests.
    - Information will be published on an HHS website
  - Tests regarding "bona fide" investment included in statute.
  - Regulations must be promulgated by January 1, 2012.

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Stark Self-Disclosure Protocol

- Section 6409 requires HHS and OIG to establish a self-referral disclosure protocol ("SRDP") within six months of enactment of PPACA.
  - Must be established by September 23, 2010.
  - CMS taking informal self-disclosures prior to enactment.
- CMS must publish on its website instructions for how to access and use the SRDP.
- Clear statement that the SRDP is not to be used as part of the advisory opinion process to determine whether there is a Stark violation.

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Mandatory Return of Overpayments within 60 Days

- Section 6402 (new 1128J of the SS Act) provides that, if an entity has received an overpayment, it is required to report and return the overpayment to the Secretary or the State Medicaid Agency or the appropriate contractor and notify it of the reason for the overpayment.
- The overpayment must be reported and returned within 60 days of the date on which the overpayment was identified, or the date any corresponding cost report is due (if applicable), whichever is later.
- Any overpayment retained past the deadline is an "obligation" (as defined in, and for purposes of, the reverse false claims provision of the False Claims Act).
  - As noted above, FERA made changes to the reverse false claims provision.
  - Whether and under what circumstances FERA imposed a duty to disclose self-discovered overpayments has been the subject of much discussion.
- "Overpayment'' is defined in section 6402 of the PPACA as any funds a person receives or retains under Medicare or Medicaid to which the person, "after applicable reconciliation," is not entitled.

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CMP Changes

- Adds penalties for
  - Knowingly making false statements in an application, bid or contract to participate or enroll as a supplier or provider.
  - Failing to report or return a known overpayment.
  - Ordering or prescribing items or services during a period when the prescriber was excluded from a federal health program and the person knows or should know that a claim will be made for the item or service.
  - Failing to grant OIG timely access for audits, investigations, evaluations, etc.
  - False statements material to a false or fraudulent claim for payment for an item or service furnished under a Federal health care program.

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Exclusions under Medicaid

- PPACA requires states to terminate individuals or entities from their state Medicaid programs if they have been terminated from Medicare or another state's Medicaid program.
- Medicaid programs must also exclude an individual or entity that owns, controls or manages another entity that has failed to repay overpayments, been suspended, terminated or excluded from Medicaid participation, or is affiliated with any such entity.

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Mandatory Compliance Programs

- As a condition of enrollment in Medicare, Medicaid and/or CHIP, providers and suppliers must develop and implement a compliance program containing "core elements" established by HHS.
- HHS will establish standards and timing through regulations.
  - We expect "core elements" to be patterned after federal sentencing guidelines and various compliance guidelines issued by the OIG.
  - Likely to have different standards for various provider/supplier categories.

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Compliance Recommendations for Providers

- Develop a "Rapid Response Protocol" to ensure prompt and appropriate responses to compliance issues.
  - Such protocol should include a mechanism for ensuring that overpayments are reported and refunded within 60 days of identification.
- Implement a routine concurrent audit policy to identify systemic risk areas and address them (hopefully before a RAC auditor or *qui tam* plaintiff raises them).
- Consider a compliance gap analysis and revise compliance program to fill any gaps with OIG compliance guidances.
  - At a minimum, be ready to commit resources once compliance program regulations are issued.
- Follow other "Counseling Tips" provided in seminar materials.
- Educate your management teams and boards on the integrity and transparency provisions, as they are ultimately accountable.

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Recommendations for Provider Transactions

- Increase regulatory due diligence, including the effectiveness of compliance function.
  - This may involve an assessment of customer compliance risk profiles.
- Beef up reps/warranties in transaction documents.
- Consider asset purchase instead of stock transactions to curtail liability when feasible from a business perspective.
- Strengthen and extend length of indemnity provisions.

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