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Admitted to the practice of law in California (Cal Bar ID 260146), the United States Supreme Court and the US District Courts in the Southern District of California and the Western District of Pennsylvania.
Learning Objectives

We will review…
• legal authorities relating to repayments and disclosures under Medicare and Medicaid;
• why the FCA has become the DOJ’s Fraud Enforcement Vehicle of Choice;
• how the FERA and PPACA have enhanced DOJ’s Enforcement Authority; and
• new obligations for disclosure of overpayments under FERA and the PPACA

FCA Facts

• FCA is the government’s Fraud Enforcement vehicle of choice.
• $4.3B Recovered in 2013
• $4.2B Recovered in 2012
• More than $26B recovered since launch of the The Federal Health Care Fraud and Abuse Control Program in 1997.
• Recovery of $8.10 for every dollar spent over the prior 3 years.
• Potential penalties available to government provide strong incentive to settle.
• Whistleblower provisions create strong incentives for the filing of cases by private persons (disgruntled staff usually).
• Lowest required intent standard is reckless disregard.
What is Fraud?


- The Fraud Standard
  - Legally false claim
  - Presented to the United States
  - Knowledge of falsity
  - Damage to the government (most cases do not require a showing of damage)

Ambiguity in Coding Rules

- What Rules?
  - Statutory provisions, regulations, interpretive guidance from CMS, LCDs, additional CMS publications.
  - Assuming a Controlling Rule, is the Standard Capable of More than One Interpretation?
  - A rule, regulation or billing code must be capable of *multiple reasonable* interpretations.
  - The billing rule must *not unambiguously speak for itself*.
  - Any interpretation of an ambiguous billing rule must be *reasonable* even if it is incorrect ultimately.
  - When a billing rule is legitimately ambiguous, and the provider considers the billing practice at issue to be the “generally accepted practice”, that position is legally defensible as long as the defendant does not suspect something is wrong and does not deliberately avoid learning more.
Ambiguity in Coding Rules

  - If the **payor fails to issue formal guidance to clarify an ambiguous billing rule**, the rule remains ambiguous and non-compliance is at worst a mistake and does not establish FCA liability.
  - On the other hand, a payor’s issuance of **formal guidance can cure an ambiguity** and create FCA liability for non-compliance if evidence of sufficient publication (but not necessarily receipt) exists.
    - MedLearn capable of clarifying an ambiguity?
    - Local Contractor Websites?
  - The payor’s failure to “negative” any reasonable interpretation that would make the defendant’s statement factually correct continues to result in ambiguity.
    - Request for formal guidance from Medical Director or CMS.
    - Taking reasonable steps to attempt to ensure compliance with an ambiguous rule, such as seeking clarification, internal audits, documentation of how you resolved the ambiguity, help to establish the ambiguity defense.

Degree of Wrongness

- Knowingly and the Degree of Knowledge:
  - Mistake
  - Negligence
  - Recklessness
- Express/Implied False Certification Theories
  - Implied False Certification – submitting a claim implies compliance with all governing rules that are a precondition to payment. *Mikes v. Straus*
    - Conditions of participation vs. Conditions of Payment
  - Mistakes/negligence are not fraud. Recklessness is required. *Wang v. FMC Corp*
  - Duty to be familiar with payment rules. *U.S. v. Mackby*
Mistakes Not Fraud

• Complexity of Rule Causing Mistaken Interpretation of Requirements
  • Complexity of reimbursement standard often justifies judicial empathy in FCA cases.
  • Court will not “hold a defendant to the government’s strict interpretation [of a statutory requirement], so long as defendant's interpretation was reasonable”. Luckey v. Baxter Healthcare Corp.
  • Judicial empathy where provider could be liable for substantial penalty. U.S. v. Krizek

• Pattern of Mistakes?

• Conclusions
  • Fraud doesn’t exist in very many cases let alone every case where there is an error leading to an overpayment.
  • Mistakes nonetheless mean you have to pay the money back.

Intent Standard

• U.S. ex rel Heffner v. Hackensack University Medical Center, 495 F.3d 103 (3rd Cir. 2007)
  • The False Claims Act “does not punish honest mistakes or incorrect claims submitted through negligence.” This is the first time the Third Circuit has expressly held that mistakes and even negligence are not subject to FCA liability.
  • The duplicate claims, although technically false, were not fraudulent because the system was complicated and there was evidence of at worst negligence, but most likely a mistake, neither of which are actionable under the FCA.
Intent Standard

- **U.S. ex rel Heffner v. Hackensack University Medical Center, 495 F.3d 103 (3rd Cir. 2007)**
  - No *reckless disregard* of the billing rules existed even though the billing department had a compliance plan in effect. Stated another way, *a compliance plan does not have to absolutely ensure that no mistakes are made.* Just because a mistake occurred in the context of a compliance plan, that does not mean the provider recklessly disregarded the billing rules and is subject to FCA liability.
  - Mere failure of a billing system or a compliance plan to catch an error does not establish reckless disregard.

- **NOTE:** Where the overpayment was caused by a failure to following the requirements of the compliance plan, a Court’s conclusion might differ greatly.

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Intent Standard

- **U.S. ex rel Heffner v. Hackensack University Medical Center, 495 F.3d 103 (3rd Cir. 2007)**
  - *Lack of reckless disregard* is demonstrated, at least indirectly, when the provider hires a consultant to help improve its compliance.

  **Note:** Again, provided that the clinic made reasonable attempts to follow the consultant’s advice.
  - *There is no reckless disregard or FCA liability when a provider voluntarily refunds mistakenly obtained reimbursement* to the government, particularly when the government has no idea about the billing mistake in the first place.
Mitigating Intent

- Voluntary Disclosure as a Means of Negating FCA Liability
  - Disclosure must truly be voluntary (i.e. not in response to an investigation).
  - If any person in the entity knows of an overpayment, the entity has knowledge for purposes of the reverse false claims provision of the FCA (§3729(G)).
  - Must identify:
    - What caused the overpayment
    - How it was discovered
    - The means used to identify the entirety of the overpayment.
  - Once an actual overpayment is identified, ACA requires disclosure and repayment within 60 days.
  - Look back period under proposed rule is 10 years.

Overview of FERA Changes

- Fraud Enforcement and Recovery Act
  - “Clarifies” the applicability of the FCA to claims that are either directly or indirectly paid with government money.
  - Codifies the materiality requirement
  - Expands the definition of “claim”
  - Expands conspiracy liability
  - Procedural amendments strengthen DOJ authority
  - Expands FCA liability for retention of overpayments.
  - Modifies retaliation provision applicable to qui tam relators.
FERA – Substantive Changes

• Expands liability to any claim even indirectly paid with government money.
  – Medicare Part C
  – Medicaid
  – Claims by subcontractors; e.g. claims by entity providing purchased component of diagnostic test.
• Materiality
  – Codifies materiality requirement using the objective standard recognized by majority of Circuit Courts
  – Defines “material” as whether the misrepresentation is “capable of influencing” or “has the natural tendency to influence” the government's payment decision.
  • Liability exists even where the government was not actually influenced and didn’t even pay the claim.

FERA – Substantive Changes

• Expanded Conspiracy Liability
  – Before FERA, conspiracy liability was limited to an agreement or common purpose associated with getting the claim paid.
  – After FERA, conspiracy liability can exist with respect to any liability prong of the FCA.
  – Any agreement or common purpose to violate any of the FCA liability provisions is sufficient to create conspiracy liability.
• Retaliation
  – FERA extends liability for retaliation against employees only to retaliation against “contractors and agents” in addition to employees.
FERA – Substantive Changes

• Reverse False Claim Provision Modified.
  Any person that...
    • (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government
    • (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 knowing and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

FERA – Substantive Changes

• Significance
  – Previously, an affirmative act; i.e. making a “false record or statement”, was required to violate the FCA.
  – Now purely passive conduct; i.e. “knowing” and “improper” concealment or avoidance of an obligation, is also sufficient.
FERA – Substantive Changes

• Definitions
  – Knowingly – Defined in FCA as follows:
    (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;

FERA – Substantive Changes

• Definitions
  – Improperly – not defined in FCA but legislative record
    reveals the following:
    • “Knowingly and improperly” requires “improper motives or
      inherently improper means.” Sen. John Kyle
  – Obligation, previously undefined, but is now defined under
    FERA as follows:
    • “[A]n 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.”
    • Pennies from heaven…?
FERA – Substantive Changes

• Under FERA, for Reverse False Claim Liability
  – Is a claim required?
  – Is falsity required?
  – Is any affirmative act required?

• Compliance Guidance
  – Open item posting of payments
  – Mechanism for identification and prompt return of overpayments
  – State false claims acts…

Overview of PPACA

• Patient Protection and Affordable Care Act
  – Patient protections – focused on protecting patients from losing or being unable to obtain insurance due to pre-existing conditions.
  – Will/has significantly increase premium cost(s).
  – Payment model is the same – does not address the affordability of care.
  – Incentives for interoperability and efficiency, which are believed will reduce care costs.
  – Significantly increased resources to address “fraud, waste and abuse” = More post payment liability for providers
    • Adds to FERA by creating a 60 day refund clock for overpayments.
PPACA– Substantive Changes

• PPACA provides a 60-day period for reporting and returning overpayments.
• The deadline is the later of:
  – (A) the date which is 60 days after the date on which the overpayment was identified or
  – (B) the date any corresponding cost report is due, if applicable.
• Makes the retention of an overpayment after the 60-day period an “obligation” as defined by the FERA amendments to the Reverse False Claims Provision of the FCA.
• But...one must still “knowingly and improperly” retain the overpayment to create FCA liability.

PPACA– Substantive Changes

• “Overpayment” defined to mean Medicare and Medicaid (and other Federal Health Program Funds) that a person “after applicable reconciliation” is not entitled to retain.
• “Person” is defined to mean providers, suppliers – anyone receiving federal health program dollars either directly or indirectly.
  – What type of “indirect” federal payments do you receive?
PPACA—Substantive Changes

- Revised language pertaining to public disclosure bar making it easier to survive defense motions to dismiss.
- Redefined “original source” as including someone without direct knowledge of the allegedly fraudulent conduct. This will create more *qui tam* relators.
- FCA liability for billings under the newly created health exchanges
- Violation of AKB statute is made an explicit basis for FCA liability
  - Claim for items or services resulting from an AKB Statute violation constitutes a false claim under the FCA
- Unrefunded overpayments are per se False Claims
  - The inconsequential “Probe” Audit
  - What does or should the error rate alleged tell you?

PPACA—Substantive Changes

- Implications to State False Claims Acts
  - DRA of 2005 created incentive under Section 1909 of the SSA for states to pass their own FCA statutes that are at least as effective as the federal FCA.
  - To qualify for the financial incentive, a State’s false claims act must:
    - establish liability to the State for false or fraudulent claims, as described in the Federal False Claims Act (FCA), with respect to Medicaid spending,
    - contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the FCA,
    - contain a requirement for filing an action under seal for 60 days with review by the State Attorney General, and
    - contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.

- States with State FCA’s:
  - CA, CO, CT, DE, FL, GA, HI, IL, IN, LA, MA, MI, MN, MT, NC, NH, NJ, NM, NV, NY, OK, RI, TN, TX, VA, WA, WI.
Questions?
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