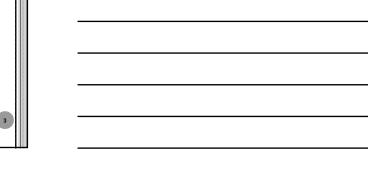
verse False Claims Act rsal of Fortune?
Presented by:
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Introductions and Disclaimer

- Robert Kaufman Office of the General Counsel CMS Division, U.S. Department of Health & Human Services
- Wendy Weiss is a Managing Director with Navigant Consulting.
 Judy Waltz, a partner at Foley & Lardner LLP in San Experience.
- Zuzana Ikels, a partner at Polsinelli LLP in San
- This presentation reflects our opinions and not necessarily those of the Office of the General Counsel, the U.S. Department of Health and Human Services, or the Centers for Medicare & Medicaid Services, Navigant, Foley and/or Polsinelli.

Agenda

- Brief Overview of Federal False Claims Act ("FCA")
- What is a reverse false claim?
- How did FERA 2009 change the statute?
- How did ACA 2010 (60-Day Refund Rule) further change the landscape?
- Do the CMS rules and pending rules resolve the ambiguities?
- Remaining Questions, Takeaways and Discussion.



The Expectations for Compliance Officers Are Higher Than Ever Before

- The statutes "align" to make it easier to establish a violation of the FCA if an overpayment exists and is not dealt with appropriately.
- The FCA includes provisions for whistleblower recoveries, incentivizing some cases.
- The ACA changes include a time frame (60 days to report and refund in claims overpayments), and failure to act quickly enough can be the basis for an allegation of improperly retained funds.

Key Liability Provisions

- False claims 31 U.S.C. § 3729 (a)(1)(A)
- False records material to false claims (a)(1)(B)
- Conspiracy 31 U.S.C. § 3729 (a)(1)(C)
- Reverse false claims 31 U.S.C. § 3729 (a)(1)(G)
- Medicare/Medicaid Refund Obligations 42
 U.S.C. § 1320a-7k(d)



Where Do FCA Cases Come From?

- Government audits and investigations
- Whistleblowers
 - Current and former employees
 - Competitors
 - "Professional whistleblowers"
 - Consultants engaged by the Company
 - Government contractors (rare)



The FCA Process

- Relator files the case under seal
- Government investigates the allegations, and decides whether to intervene
- Case remains under seal until the decision to intervene, absent court authority to share the filing
- Defendant may be contacted before the government decides to intervene, and must decide whether and how to proactively present a defense
- Case settles or not

SEALED

Damages/Penalties

- Also applies to Medicaid (FFP)
- The Government can bring a case; or
- A private litigant (a "relator" or "whistleblower) can bring a qui tam action on behalf of the government.
- 31 U.S.C. § 3729(a) damages:
 - Treble damages;
 - Penalties of \$5,500-\$11,000 per claim;
 - Discretionary ban on participation in federal programs;
 - Relators entitled to 15-30%.



What is a Reverse False Claim?

- "[G]overnment money or property that is knowingly retained by a person even though they have no right to it."
 - o Senate Rept. No. 111-10 (March 23, 2009).
 - "Failure by the government to *receive* funds owed to the United States, rather than the *disbursement* of federal money to persons who are not entitled to receive it."
 - o DOJ Brief, Bourseau v. United States (January 2009)



The	Current	"Reverse"	FCA	Provision

• "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."

31 U.S.C. § 3729 (a)(1)(G)



Key Elements

- Government money or property
- Knowingly retained as overpayment even if lawfully obtained
- No right to it
- Examples:
 - Services determined to be medically unnecessary
 - Stark overpayments due to lapsed agreements
 - Claims for whom Medicare is not primary (MSP)
 - · Improper payments discovered after receipt
 - Computer glitches
 - $\bullet\,$ Discovery of errors in calculations



Relevant Legislative Changes

- Fraud Enforcement Recovery Act of 2009 (FERA) – May 20, 2009
- Patient Protection and Affordable Care Act (ACA) – March 23, 2010)
- Dodd-Frank Financial Reform Bill (July 21, 2010)

ACA FERA

Dodd-Frank

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- Fraud Enforcement and Recovery Act of 2009 ("FERA") modified the False Claims Act to strengthen the government's pursuit of FCA liability against persons who knowingly retain overpayments of government funds.
- FERA expanded liability for reverse false claims— FCA allegations no longer limited to situations where the government could show some effort by making a false statement or record to "conceal, avoid, or decrease" an obligation.

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FERA 2009 -

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

pay or transmit money or property to the Government, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

• FERA: 3729(a)(1)(G) • Pre-FERA: 3729(a)(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.



FERA Was A Response to Allison Engine

- Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008).
- U.S. Supreme Court held that to succeed on a § 3729(a)(2) claim, plaintiff had to establish that: (1) the defendant *intended*, or had the purpose of, getting the false claim approved or paid by the federal government; and (2) the defendant's *false* statement or record was *material to the government's decision to approve or pay* the claim.

Effect of Change to Materiality

- FERA codified the broader definition of material. 31 U.S.C. § 3729(b)(4)
- New standard arguably lowers burden of proof: need only demonstrate that an alleged false claim "could have influenced" the government in its decision to pay the claim, rather than showing it did in fact influence the government's decision to pay.



Definition of "Obligation"

- FERA defined Obligation:
- "[A]n established duty, whether or not fixed, 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."
- 31 U.S.C. §3729 (b)(3)



FERA 2009

- "Obligation" includes:
 - Fixed and contingent duties owed to the Government
 - oFixed liquidated obligations such as judgments
 - o Fixed unliquidated obligations such as tariffs on imported goods
 - o "the instance where there is a relationship between the Government and a person that 'results in a duty to pay the Government money, whether or not the amount owed is yet fixed."
- Senate Report



Reporting/Returning Overpayments

- CMS published a proposed rule for A/B overpayments in the February 16, 2012 edition of the *Federal Register* (77 FR 9179)
- Implements portions of section 6402 of the Affordable Care Act
 - (42 USC 1320a-7k(d))

Statutory Provision

1128J(d) Reporting and Returning of Overpayments.—

- (1) In general.—If a person has received an overpayment, the person shall— $\,$
 - (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

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Statutory Provision

- (2) Deadline for reporting and returning overpayments.—An overpayment must be reported and returned under paragraph (1) by 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.

(3) Enforcement.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such

Statutory Provision

- (4) Definitions.—In this subsection:
- (A) Knowing and knowingly.—The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of title 31, United States Code.
- (B) Overpayment.—The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.
- (C) Person.-
- (i) In general.—The term "person" means a provider of services, supplier, Medicaid managed care organization, Medicare Advantage organization, or PDP sponsor.
- (ii) Exclusion.—Such term does not include a beneficiary.

Definition of Knowledge

- The definition of "knowingly" is:
 - · Actual knowledge;
 - Deliberate ignorance; or
 - · Reckless disregard of the truth or falsity of the
 - requires no proof of specific intent to defraud.

31 U.S.C. 3729(b)(1).

Key Questions

- When does the clock start running?
- What does it mean to identify?
- What is the lookback period?
- How should overpayments be reported and returned?

The Proposed Rule – Scope

- Applies to Medicare Part A and Part B providers and suppliers
- Cautions "all stakeholders that even without a final regulation they are subject to the *statutory* requirements" in the ACA.

Examples of Overpayments

- Medicare payments for noncovered services
- Medicare payments in excess of the allowable amount for an identified covered service
- Errors and nonreimbursable expenditures in cost reports

Examples of Overpayments

- Duplicate payments
- Receipt of Medicare payment when another payor had the primary responsibility for payment

Identified

- A person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.
- Statute defines "knowing" and "knowingly" but does not use these terms in the relevant provision.
- Deliberate ignorance and reckless disregard standard encourages self-directed compliance.

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Reporting and Returning Deadlines

- Difference between claims-related overpayments and those that are reconciled on the cost report.
- Caution to providers and suppliers against relying too heavily on the potential delay related to cost report submission.
- $\ \ \, \mathbf Duty$ to make a reasonable inquiry

- A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.
- A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment.
- A provider of services or supplier learns that services were provided by an unlicensed or excluded individual on its behalf.

Examples of Identification

- A provider of services or supplier performs an internal audit and discovers that overpayments exist.
- A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry.



Examples of Identification

• A provider or supplier experiences a significant increase in Medicare revenue and there is no apparent reason--such as a new partner added to a group practice or a new focus on a particular area of medicine--for the increase. Nevertheless, the provider or supplier fails to make a reasonable inquiry into whether an overpayment exists.



Lookback Period

- Report and return overpayments identified within 10 years of the date the overpayment was received
 - Balances need for certainty with protecting the Trust Funds
- Amended reopening rules to allow claims to be reopened for 10 years
 - Consistent with lookback period

Nuances – Inability to Repay the Overpayment

- Use Extended Repayment Schedule (formerly "Extended Repayment Plan")
 - CMS Publication 100-06 (Financial Management Manual), Chapter 4
- Financial Data Must Be Disclosed

Enforcement

- An overpayment retained after deadline under the regulation creates an obligation for purposes of 31 USC 3729
- Liability under the Civil Monetary Penalty Law
 - Possible exclusion

C/D Final Overpayments Rule

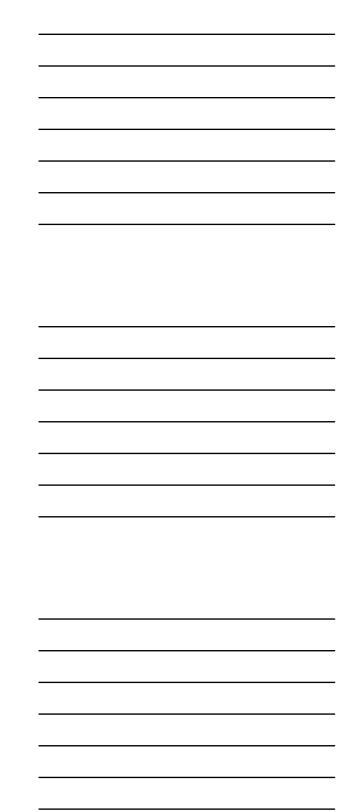
- 79 Fed. Reg. 29844 (May 23, 2014)
- Applicable Reconciliation
 - Annual deadline for submitting risk adjustment data
 - Annual deadline for submitting PDE data for Part D payment reconciliations
- Six-year lookback

C/D Final Overpayments Rule

- Report and return in the manner specified by CMS 60 days after identification
- The Part D sponsor or MA organization has "identified an overpayment" when it has determined, or should have determined through the exercise of reasonable diligence, that it received an overpayment.

Questions Re: Reporting

- Voluntary Refund Policy appears to require provider to prepare and submit extensive report for every overpayment, found in Chapter 4 of the Medicare Financial Management Manual ("MFM")?
- Unclear if CMS will include/exclude other normal procedures, e.g., credit balance reports, or other existing procedures for returning overpayments?
- What triggers notice? Suspicion?
 Anonymous complaint? Uncertainty of amount? Good faith exemption?



Disclosure Obligations

- 42 U.S.C. 1395g(a)
 - Part A
 - Payments to providers are to be made with "necessary adjustments on account of previously made overpayments or underpayments."



Disclosure Obligations

 ACA Section 6401: Medicare Providers and Suppliers with the same Tax Identification Number may now be subject to necessary adjustments to payments for past due obligations of an obligated provider or supplier, as determined by the Secretary.



60-Day Refund Rule: Disclosure Obligations

- Failure to Disclose Receipt of Excess Benefits (42 U.S.C. 1320a-7b(a)(3))
 - Felony punishable by 5 years in prison; \$250,000 fine for individuals and \$500,000 for corporations.
 - Does not require repayment, just disclosure (but compare OIG's views).



2012 CMS Proposed Rules: Time to Investigate

- CMS proposes a standard for the timeframe within which a hospital must conduct and complete its investigation.
- The Proposed Rule: investigation should conduct a "reasonable inquiry" with "all deliberate speed."



2014 CMS's Proposed Rules (Managed Care)

- 2014 CMS Proposed Rules:
- Establish a formal process to report and appeal overpayments that result from the "submission of erroneous payment data by a Medicare Advantage Organization (MAO) or Part D sponsor when the organization or sponsor fails to correct those data after notice by CMS."



2014 CMS – Overpayments (Parts C & D) (422.326, 423.360).

- Defines "Overpayments" After "Applicable reconciliation", provider concludes that "Funds" cannot be retained.
- Defines "erroneous payment data" Data submitted by MAOs or Part D sponsors that are inaccurate or inconsistent with Medicare Part C and Part D requirements.





2014 CMS – Identification: Parts C&D (422.326, 423.360)

 Must report and return an overpayment within 60 days of identification. Identification is: (a) actual knowledge of; or (b) acting in reckless disregard or deliberate ignorance of the overpayment.

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2014 CMS Proposal: Risk Adjustment Data Requirements (422.310).

- Medicare Advantage Plans (MA) must conduct, as part of the annual risk adjustment data validation of sample medical record review, accuracy of diagnoses to determine both underpayments and overpayments.
- Not finalized.



CMS 05/23/14 Final Rule (Parts C & D)

Response to comments: "It is important to understand the distinctions among identifying, reporting, and returning an overpayment in this rulemaking for the purposes of the MA and Part D programs. Once an organization has identified that it has received an overpayment, the 60-day period for reporting and returning the overpayment begins. Because of the nature of the Part C and Part D programs, we did not propose that "identified" includes completion of the act of quantification of an overpayment amount...identification of an overpayment means knowing that [the entity] submitted erroneous data to CMS...."

CMS 05/23/14 - Identify (Parts C & D)

- "We are finalizing the provisions at §§ 422.326 and 423.360, with the following modifications. § 422.326(d) shall say: "an MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment, unless otherwise directed by CMS for the purpose of § 422.311."
- "Also, to increase clarity we revise §§ 422.326(c) and 423.360(c) regarding identified overpayments."

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CMS Future Proposals

- CMS indicated that it will be providing "operational guidance:" re: (a) how to report overpayment and the contents of report, (b) new rules on risk adjustment data requirements, and (c) how and when to repay – make use of existing procedures to communicate payment data.
- https://www.federalregister.gov/articles/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-andtechnical-changes-to-the-medicare-advantage-and-the#h-14



DOJ v. Continuum Health Partners & Mt. Sinai Health System

■ June 27, 2014, one of first "reverse False Claims Act" cases where the DOJ filed a complaint-in-intervention claiming a health care provider violated 31 U.S.C. § 3729(a)(1)(G) of the False Claims Act based on the premise that the provider failed to return overpayments within the 60-day timeframe set forth in the Affordable Care Act (ACA).



Allegations in Continuum Health Partners

- From 2009 through 2010, Continuum Health Partners and the Mount Sinai Health System submitted improper claims to a New York Medicaid.
- Continuum, which handled billing for the hospitals, was notified by the State Comptroller in 09/2010.
- Continuum commenced an internal investigation, and uncovered \$1 million in overpayments.
- Repaid in small batches over two year period.
- DOJ alleged: providers "intentionally or recklessly failed to take the necessary steps to timely identify the claims affected by the software issue or to timely reimburse [the government] for those affected c that resulted in overbilling to Medicaid."

Noteworthy Aspects of DOJ Intervention

- Providers' submissions were not alleged to be knowing, intentional, or willful. The complaint acknowledges that it was a computer glitch that caused the overpayment by mistake.
- The providers made periodic repayments to the Medicaid program, BUT it was (a) over a twoyear period and (b) in response to Comptroller.
- Did not repay one-third of the affected claims until after the DOJ issued a Civil Investigative Demand.
- The providers had returned all overpaymen <u>before</u> the suit.

Continuum Opinion - Identified Means "On Notice"

- August 3, 2015 Order Denying Motion to Dismiss – First Judicial Interpretation of "Identify".
- Identify means when provider "on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained."
- Defendant hospitals had argued that the 60 days begin only when a specific overpayment is "conclusively proven to be an overpayment."



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Continuum Opinion - Identified Means "On Notice"

- Judge rejected, reasoning it would create "a perverse incentive to delay learning the amount due."
- But, mindful of the draconian deadline to repay, court held "obligation" is not the same as identify, and that that deadline to repay was not triggered until amount conclusively ascertained. Court encouraged prosecutorial discretion.
- Court noted its opinion was consistent with CMS's proposed rules.



First Settlement

- A home health-care provider agreed to pay \$6.88 million to resolve allegations it failed to refund overpayments from government programs, in what the Department of Justice described as a "first of its kind" settlement in an Aug. 3, 2015 announcement (*United States ex rel. Odumosu v. Pediatric Servs. of Am. Healthcare*, N.D. Ga.).
- The U.S. claimed PSA failed to refund overpayments from TRICARE and the Medicaid programs of 20 states between 2007 and 2013.



Questions Raised in the Industry

- What does "identify" mean with respect to an overpayment; i.e., when does the 60-day period begin to run?
- How will waiver options be factored in?
- Ability to pay?
- Will refund count as a public disclosure to bar a relator's recovery?
- How to deal with limited Medicaid options for refunds?
- Given the "reckless disregard" standard an enhanced responsibility for auditing and monitoring?



Takeaways

- 60 Days Begins when discovery of: (1) invalid data support, (2) mistakes, (3) government inquiry, (4) audit, or (5) employee-raised concerns.
 - Recommendation: Employee complaints, especially through anonymous hotlines or emails, should be immediately addressed.
- "Reasonable inquiry" with "deliberate speed".
 - Recommendations: (1) Involve the compliance officer to interview and investigate and conduct an audit, document efforts; and (2) obtain legal opinion/counsel.



Takeaways

- Self-Disclosures.
 - Recommendation: Provide a cover letter with background explaining notice, description of inquiry, analysis and conclusions. Counsel input.
- Provide payment with disclosure? States differ; Federal government is still considering.
 - Recommendation: Seek guidance and written stipulation/tolling agreement re: deadline to pay.
- Upfront communication cuts off potential whistleblowers, leads to early settlement, reduces cost of litigation.

