

Understanding the (not so) Voluntary Disclosure Rule.

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Understanding the (not so) Voluntary Disclosure Rule

PRESENTATION GOALS

- FCA provision requiring disclosure and repayment
- Understand the key components of the rule:
 - The 60 day clock and when it starts.
 - What constitutes “credible information” of an overpayment.
 - What it means to exercise “reasonable diligence” in identifying overpayments both proactively and reactively
 - The six-year lookback period.
- Risks and penalties associated with non-compliance
- Submission requirements



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THE VOLUNTARY DISCLOSURE RULE

- History of Development
 - Before the Fraud Enforcement Recovery Act of 2009, compliance was purely voluntary
 - FERA expanded liability under the FCA to the improper “retention of overpayments”.
 - Old - 31 U.S.C. §3729(a)(1)(7)
 - (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
 - New - 31 U.S.C. §3729(a)(1)(G)
 - (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 defined the term “obligation” as including “retention of an overpayment”



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- **Affordable Care Act**
 - Section 6402(a) of the Affordable Care Act established a new section 1128J(d) of the Social Security Act (the Act). Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment and to notify the contractor to whom the overpayment was returned in writing of **the reason for the overpayment**.
 - Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned 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.
 - Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an **obligation** (as defined in [31 U.S.C. 3729\(b\)\(3\)](#)) for purposes of [31 U.S.C. 3729](#).



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- **Final Rule**
 - Statute became law on March 23, 2010
 - CMS asserts that the law has been enforceable since the law's passage and court decisions support that position
 - Final Regulations effective March 14, 2016
 - Applies only to Medicare Parts A & B
 - Separate rulemaking was issued with respect to Parts C & D May 23, 2014
 - No rulemaking for Medicaid but the statutory obligation still exists for Medicaid as well as all overpayments involving federal money.



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THE VOLUNTARY DISCLOSURE RULE

- Final Rule
 - Key Definitions 42 CFR §401.303
 - **Overpayment** means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.
 - Note: This has nothing to do with fault.
 - Note: A claim can be overpaid in full (not medically necessary or covered) or overpaid in part (upcoded claim, Incident-to reporting error).
 - **Person** means a provider (as defined in § 400.202 of this chapter) or a supplier (as defined in § 400.202 of this chapter).



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THE VOLUNTARY DISCLOSURE RULE

- **Final Rule - Requirements for reporting and returning of overpayments.**
 - (a) General. (1) A **person** that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.
 - (2) A **person** has **identified** an overpayment when the person **has, or should have** through the **exercise of reasonable diligence**, determined that the **person** has received an overpayment and **quantified the amount of the overpayment**. A person **should have** determined that the person received an overpayment and quantified the amount of the overpayment if the person **fails to exercise reasonable diligence and the person in fact received an overpayment**.
 - (b) Deadline for reporting and returning overpayments.
 - (1) A person who has received an overpayment must report and return the overpayment by the later of either of the following:
 - (i) The date which is **60 days** after the date on which the overpayment **was identified**.
 - (ii) The date any corresponding cost report is due, if applicable.

Medicare Program; Reporting and Returning of Overpayments, 81 FR 7654-01



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- **Final Rule – Official Comments**

- **The meaning of “Identified” - 81 FR 7654-01.**

- In proposed § 401.305(a)(2), we stated that 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.
 - The terms “knowing” and “knowingly” have the meaning given those terms in the FCA ([31 U.S.C. 3729\(b\)\(1\)](#)).
 - We also stated that defining “identification” in this way gives providers and suppliers **an incentive** to exercise reasonable diligence to determine whether an overpayment exists.
 - We also noted in the February 2012 proposed rule ([77 FR 9182](#)) that, in some cases, a provider or supplier **may receive information** concerning a potential overpayment that **creates a duty** to make a reasonable inquiry to determine whether an overpayment exists.



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- **Final Rule – Official Comments**

- **The meaning of “Identified” - 81 FR 7654-01 – Selected Examples**

- 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 services were provided by an unlicensed or excluded individual on its behalf.
 - 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**. (When a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has a duty to accept the finding or make a reasonable inquiry).



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- **Final Rule – Official Comments**
 - **The meaning of “Credible Information” - 81 FR 7654-01**
 - We believe credible information includes information that supports a reasonable belief that an overpayment may have been received.
 - **Examples**
 - Discovery of services performed by unlicensed, excluded individual and improperly billed and paid as **Incident To** services
 - **Complaints from patients/billing staff** alerting provider/entity to a problem
 - Contractor **probe audits**
 - **Internal audits**
 - Unexplained increase in Medicare revenue



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- **Final Rule – Official Comments**
 - **“Reasonable Diligence” in the identification of Overpayments- 81 FR 7654-01**
 - We adopt the standard of reasonable diligence and establish that this is demonstrated through the **timely, good faith investigation of credible information**, which is **at most** 6 months from receipt of the credible information, **except in extraordinary circumstances**.
 - We choose 6 months as the benchmark for timely investigation because we believe that providers and suppliers **should prioritize these investigations** and also to recognize that completing these investigations may require the devotion of resources and time.



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- **Final Rule – Official Comments**

- **Extraordinary Circumstances - 81 FR 7654-01**

- A total of 8 months (6 months for timely investigation and 2 months for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances affecting the provider, supplier, or their community. What constitutes extraordinary circumstances is a **fact-specific question**. Extraordinary circumstances may include **unusually complex investigations** that the provider or supplier reasonably anticipates will require more than six months to investigate, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). Specific examples of other types of extraordinary circumstances include natural disasters or a state of emergency.



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- **Final Rule – Official Comments**

- **Scope of Obligation to Exercise “Reasonable Diligence”**

- Several commenters questioned whether, after finding a **single overpaid claim**, it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim. We expect providers and suppliers to exercise reasonable diligence and to **quantify, report, and return the entire overpayment** in good faith. **Part of conducting reasonable diligence is conducting an appropriate audit to determine if an overpayment exists and to quantify it.** Providers and suppliers are **obligated to conduct audits** that accurately quantify the overpayment. After finding a single overpaid claim, **we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue** before reporting and returning the single overpaid claim.



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- **Exercise of “Reasonable Diligence”**
 - Reasonable diligence will require **proactive efforts** at identification of overpayments (internal compliance audits) and re-active efforts in response to the receipt of “credible information” (analysis in response to contractor audits, compliance reports from staff).
 - While formal compliance plans are still not required for most provider types, effective compliance efforts are necessary to avoid accusation of failing to exercise reasonable diligence in the identification of overpayment.



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- **Lookback Period**
 - Must return overpayments “identified” within **six (6) years** from the date the claim was paid.
 - Proposed rule set the lookback at ten (10) years.
- **Note:** Revised reopening rules now allow contractors a five (5) year lookback (previously only 4) and only if they can demonstrate good cause. This rule extends the window for provider initiated re-openings to six (6) years.



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- **Consequences for Non-Compliance**

- Failure to report an “identified” overpayment, or failure to exercise reasonable diligence to “identify” overpayments and return them, creates an “obligation” in the amount of the improperly retained overpayment amount.
- Failure to satisfy the “obligation” is a violation of the False Claims Act
- FCA is enforceable by the government or whistleblowers.
- Damages and punitive sanctions authorized under the FCA expose provider to substantially more liability over and above the overpayment amount.
- Failure to satisfy the “obligation” is also a violation of the CMPL (enforced by the OIG) and could expose provide to those monetary sanctions as well as exclusion.



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- **Reporting**

- Each contractor has a voluntary disclosure and refund form.
- Cover letter
 - Not clearly required but can be beneficial and should address:
 - How the overpayment(s) was/were identified.
 - How the practice identified/quantified the entirety of the overpayment
 - Corrective action measures implemented.



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SUMMING UP

- The Voluntary Disclosure Rule is No Longer Voluntary
- Reasonable diligence is required to identify then disclose and refund overpayments.
- The rule has significant implications relative to the need for effective Compliance efforts.
- Issues suggesting potential overpayments must be addressed quickly.
- Another area for Qui Tam liability
- Forces you to defend small contractor probe audits where you disagree with the result.



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Questions?

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