

**Health Care Compliance Association
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Compliance Scenarios and Resolutions**

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Overview

- **The False Claims Act**
- **The 60 Day Rule**
 - Creation of the Rule – the Affordable Care Act
 - 60 Day Rule Requirements
 - Options for Reporting / Returning Overpayments
- **Limitations of the 60 Day Rule**
- **60 Day Rule Enforcement**
- **How to Structure a Compliance Program to Mitigate Overpayment Risk**
- **Self-Disclosure**
- **Cooperation Credit**

The False Claims Act

The False Claims Act – 31 U.S.C. § 3729

- **Prohibitions include:**
 - Knowingly submitting or causing to be submitted false or fraudulent claims
 - Knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim
- **“Reverse” False Claims Prohibition**
 - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government

The False Claims Act – 31 U.S.C. § 3729 (Cont'd.)

- **PENALTIES**
 - Treble damages
 - Penalties currently \$11,181 - \$22,363 per false claim
- Many cases brought by *qui tam* relators who receive a percentage of the recovery plus their attorney fees
- Number of cases and recovery amounts increasing

The 60 Day Rule

Creation of the 60 Day Repayment Requirement

- The Affordable Care Act requires providers to report and return any overpayment within 60 days after identification (or the date any corresponding cost report is due), whichever is later – Section 1128 J(d) of the Social Security Act
- “Overpayment” is defined as any funds that a person receives or retains from Medicare or Medicaid to which the person, after any applicable reconciliation, is not entitled
- Overpayments include payments received for claims submitted in violation of the Stark Law or the Anti-Kickback Statute
- Any overpayment retained after the repayment deadline is considered an obligation for purposes of the False Claims Act

The 60 Day Rule (Medicare Parts A & B)

- **Final regulations for the 60 Day Rule (Medicare Parts A & B) published on February 12, 2016 (81 Fed. Reg. 7654)**
- The regulations:
 - Clarify when an overpayment is identified
 - Establish a six-year lookback period
 - Describe options for reporting and returning identified overpayments
- **There is no minimum monetary threshold; all identified overpayments must be returned**

The 60 Day Rule (Medicare Parts A & B) (Cont'd.)

- “[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.**” (emphasis added)
- “Reasonable diligence” includes both (1) proactive compliance activities and (2) reactive investigations conducted in a timely manner in response to credible information of a potential overpayment

The 60 Day Rule (Medicare Parts A & B) (Cont'd.)

- “Minimal compliance activities to monitor the appropriateness and accuracy of claims would be a failure to exercise reasonable diligence”
- Identification of a single overpaid claim requires further investigation
- “Part of identification is quantifying the amount, which requires a reasonably diligent investigation.”

The 60 Day Rule (Medicare Parts A & B) (Cont'd.)

- The 60 day time period for reporting / returning begins when either:
 - The reasonable diligence is completed; or
 - On the day the provider received credible information of a potential overpayment (if the provider fails to conduct reasonable diligence)
- For an investigation to be conducted in a “timely” manner, providers typically must complete the investigation within 6 months from receipt of credible information indicating there may be an overpayment
 - 6-month timeframe may potentially be extended under “extraordinary circumstances”
 - *8 months generally the maximum total time to return overpayments.*
- The government recommends that providers maintain records documenting “reasonable diligence”

The 60 Day Rule (Medicare Parts A & B) (Cont'd.)

- **Six-year lookback period**
 - Sometimes possible to use a shorter period depending on the facts at issue
- **Amount to be repaid**
 - May vary depending on the method used to report / return, e.g., Medicare administrative contractor (“MAC”) v. self-disclosure
- **Overpayment notification**
 - After receiving an overpayment notification from the government, you should investigate for related overpayments, e.g., other time period.

What About Medicare Parts C & D?

- Final regulations for the 60 Day Rule published on May 23, 2014 (79 Fed. Reg. 29844)
 - 42 C.F.R. § 422.326 (Part C) and 42 C.F.R. § 423.360 (Part D)
- Part C & D regulations are generally similar to those for Parts A and B
 - An overpayment is “identified” when the MA organization / Part D sponsor “has determined, or should have determined through the exercise of reasonable diligence” that it had received an overpayment
 - Overpayment must be reported and returned within 60 days after the date it was identified
- BUT ... due to structural differences, the overpayment return concepts and methodologies are implemented differently in Parts C and D
 - E.g., lookback period = 6 most recent completed payment years.

Options For Reporting / Returning Overpayments

- **MAC reporting process**
- **Self-disclosure protocols**
 - A submission to the OIG or CMS protocols suspends the 60 day requirement for returning overpayments until a settlement agreement is executed
 - OIG's Self-Disclosure Protocol (SDP)
 - CMS Voluntary Self-Referral Disclosure Protocol (SRDP)
- Part C & D regulations are generally similar to those for Parts A and B
 - Self-disclosures to other agencies do not suspend the repayment deadline
 - e.g., Department of Justice, local U.S. Attorney's Office, Medicaid Fraud Control Unit

Limitations Of The 60 Day Rule

What the 60 Day Rule Leaves Unanswered

- Medicaid
- Provider report and return obligations to Part C and D plans or sponsors
- Types of non-compliance that result in overpayments
 - Some “overpayments” are easily identifiable (e.g., routine billing errors, claims submitted in violation of the Stark Law)
 - What about non-compliance with certain regulatory requirements, e.g., licensure, privacy, security?

MEDICAID

- ACA requirement encompasses Medicaid
- Regulations do not apply to Medicaid
- But ... the statute expressly states that providers are required to report and return overpayments to Medicaid within 60 days of identification, despite lack of regulatory guidance from CMS

MEDICARE Parts C And D

- Part C and D final rule applies to plans or sponsors
- At least one court has found that failing to report / return in the Medicare Advantage context could create FCA liability
- Part C contracts with providers (contractual obligation to report / return)
- Process ?

Types of Non-compliance Resulting in Overpayments?

- FCA “implied certification” theory
 - *Universal Health Services, Inc. v. United States ex rel. Escobar (2016)*
 - Supreme Court upheld implied certification, but established framework for types of non-compliance that can lead to FCA liability under the theory
 - FCA liability can be predicated on non-compliance with requirements that aren’t express conditions of payment
 - But not all non-compliance can lead to FCA liability

***ESCOBAR* Framework**

- Conditions for implied certification:
 - Claim makes a specific representation about goods / services provided;
 - Defendant knowingly fails to disclose noncompliance with material statutory, regulatory, or contractual requirements, making representation “misleading half-truths”; and
 - Misrepresentation is material to the Government’s decision to pay the claim.

***ESCOBAR* Framework (Cont'd.)**

- Materiality standard
 - Can be established with evidence that the defendant knows the government has consistently refused to pay the claim
 - Often hinges on whether the government has actual knowledge of the noncompliance yet continues to pay the claim
- Application to facts in *Escobar*
 - Defendant allegedly failed to meet Medicaid requirements for qualifications of professional staff
 - Submitting billing codes corresponding to specific counseling services, along with NPI numbers corresponding to specific job titles was a representation by defendant to Medicaid that it provided the services through professionals with certain qualifications.
 - Government would not have paid the claims but for the misrepresentation (i.e., wouldn't pay for unlicensed individuals or improperly supervised individuals to provide the services)

Types of Non-compliance Resulting in Overpayments?

- Where does that leave the analysis for purposes of the 60 day rule?
 - *Escobar* doesn't provide examples of behavior that would qualify for the implied certification theory under the FCA, beyond the facts at issue in the case
 - The *Escobar* framework should be used to analyze non-compliance with regulatory requirements for potential overpayment liability
 - Other case law interpreting *Escobar*

60 Day Rule Enforcement

Early Enforcement of Overpayment Requirement (Pre-60 day rule)

- *Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D. NY. 2015)
 - District Court interpreted “identified”
 - Providers “identify” overpayments when they are “*put on notice of a potential overpayment*, rather than the moment when an overpayment is conclusively ascertained. . .”
 - Holding likely limited by facts at issue and, to some extent, by new regulations
 - Parties settled in August 2016 for \$2.95M (treble damages, but no per claim penalties)
- Pediatric Services of America (“PSA”) – DOJ Settlement (Aug. 2015)
 - PSA and related entities agreed to pay \$6.88 million to resolve allegations that it failed to report and return overpayments it received from Medicare and Medicaid.

Enforcement Post-60 Day Rule

- No court decisions on the merits with respect to the 60 Day Rule (Parts A/B) itself
 - Court decisions to date are around procedural issues (e.g., failure to sufficiently plead a claim, original source, ruling on summary judgment)
 - *Taul v. Nagel Enterprises, Inc.* - district court holding that retention of overpayment allegations are properly brought under the reverse false claims provision of FCA because ACA designates overpayment retained beyond 60 days as “obligations” and the term “obligations” appears only in reverse false claim provision
 - *U.S. ex rel. Gacek v. Premier Medical Mgmt., Inc.* - district court denied a motion to dismiss a reverse FCA suit based on defendant failing to repay funds allegedly obtained in violation of the AKS after former physician (relator) notified defendant of the potential violation

Enforcement Post-60 Day Rule (Cont'd.)

- *U.S. v. Dental Dreams, LLC*
 - District court denied defendant's motion for summary judgment with respect to reverse FCA claims finding that a reasonable jury could conclude the defendant knew it received an overpayment
 - Defendant allegedly failed to exercise reasonable diligence where defendant was informed about false billing practices and took no steps to investigate, quantify, or report or return the overpayments
- *U.S. ex rel. Graves v. Plaza Medical Centers*
 - District court denied defendant Humana's motion for summary judgment, where Humana argued that the existence of its compliance program meant it could not have acted in reckless disregard with respect to submission of inaccurate diagnosis codes for use in risk adjustment process
 - Genuine issue of fact as to whether compliance program was operated in a "diligent" manner with respect to the submitted data
 - Humana ultimately paid \$1.375 million to settle.

Enforcement Post-60 Day Rule (Cont'd.)

- University of Rochester settlement
 - \$113,722 paid to resolve allegations related to improper use of an ophthalmologic modifier resulting in increased reimbursement
 - UR self-disclosed to learning about a related, previously filed *qui tam* complaint
- First Coast Cardiovascular Institute (FCCI) settlement
 - \$448,821 paid to resolve allegations FCCI delayed repayment of approximately \$175,000 beyond 60 days
 - FCCI overpayments were the result of retaining accrued credit balances over several years
 - Relator allegedly made several attempts to get FCCI leadership to repay the credit balances

Enforcement Post-60 Day Rule (Cont'd.)

- Genesis Medical Center settlement
 - \$1.88 million paid to resolve allegations Genesis improperly retained Medicare overpayments in the form of hospital admission claims that should have been billed as either outpatient or observation services
 - *i.e.*, services that resulted in lower reimbursement
- Enforcement likely to continue increasing in light of regulations
 - Anecdotally hearing from regulators that there has been an increase in the number of voluntary disclosures related to “overpayments”

How to Structure a Compliance Program To Mitigate Overpayment Risk

Facilitating Compliance With The 60 Day Rule

- Compliance programs should include:
 - Appropriate policies and procedures
 - Periodic billing and coding audits to proactively identify overpayments
 - Focus on high-risk areas
 - Utilization of publicly available government resources to guide audit efforts
 - Investigate any suspected incidents of non-compliance with federal health care program requirements

Facilitating Compliance with the 60 Day Rule(Cont'd.)

- Recommend clients engage outside counsel and other experts when necessary to complete a thorough investigation (including quantification)
- Ensure clients understand the various risks, benefits and methods for reporting and returning overpayments, including which method is appropriate for which type of overpayment
- Ensure clients document the diligence performed as part of any potential overpayment inquiry

Self-Disclosure

Is Self-Disclosure Appropriate?

- Is the matter a potential violation of the law?
- Is there an alternative to disclosure?
 - Matters exclusively involving overpayments that do not involve violations of law should be brought to the attention of the MAC
- Is the provider already operating under a Corporate Integrity Agreement

Potential Benefits

- The amount to be re-paid to the government likely will be lower than if the government identifies the issue
- The government is unlikely to impose a costly Corporate Integrity Agreement (CIA)
- Depending on the disclosure, the provider likely will receive one or more releases, protecting against certain types of liability
- If a self-disclosure is well-structured, the government is less likely to conduct its own, more intrusive investigation that could expand to other issues
- May provide better protection for individuals

Potential Risks

- The government may not limit its review to the facts and issues disclosed, which could lead to expanded exposure
 - If the government identifies overpayments or issues not identified in the self-disclosure, questions could be raised about the provider's intent
- Protocols provide no guarantees of leniency, immunity, or specific benefits
- Providers may not be accepted into the OIG or CMS protocols
- Self-disclosure to one agency may not resolve potential liability to another

Potential Risks (Cont'd.)

- Impact of self-disclosures on *qui tam* complaints filed under the federal FCA is unclear
- Certain types of self-disclosure may take a significant amount of time to resolve
- Complexity of the fraud and abuse laws may lead to unnecessary disclosure and liability

Potential Avenues of Disclosure

- Choosing the appropriate disclosure process depends on factors including:
 - The underlying facts (Overcoding issue? Stark-only issue? Stark and AKS issue? Number of claims at issue? Improper intent? Etc.)
 - The type of release wanted
- Regardless of the type of disclosure, providers should:
 - Identify the laws that were potentially violated, the timeframes during which the potential violation occurred, and acknowledge the potential violation
 - Take corrective action to end the non-compliant practice, arrangement, etc., and prevent its recurrence
 - Cooperate fully during the agency's investigation

Choice of Agency

- **OIG – Self-Disclosure Protocol**
 - Conduct involving false billing
 - Conduct involving excluded persons
 - Conduct involving the Anti-Kickback Statute (including conduct that violates both the AKS and Stark Law)
- **CMS – Self-Referral Disclosure Protocol**
 - Conduct involving only violations of the Stark Law
- **DOJ**
 - May be appropriate when provider believes a FCA release is necessary
- **Other – e.g., the MAC**
 - Usually best for relatively simple overpayment returns

Benefits and Limitations of the SDP (OIG)

Benefits

- The OIG can provide a release from exposure under the CMP law and permissive exclusion
- Lower multiplier on single damages (often 1.5) and other potential damages likely reduced
- Tolls 60 day report/return obligation
- Expedited resolution

Limitations

- No release for potential FCA liability without DOJ involvement
- DOJ participation often results in higher settlement amounts
- Costs more than returning money to the MAC

Benefits and Limitations of the SRDP (CMS)

Benefits

- CMS has discretion in determining settlement amounts (often based on excess remuneration paid; not reimbursement received)
- CMS may release disclosing party from certain limited administrative liabilities and claims
- 60-day report/return obligation tolled

Limitations

- Disclosure can involve only actual or potential violations of the Stark Law
- Limited scope release – CMS only releases overpayment liability under Section 1877(g)(1) of the Social Security Act
- CMS may coordinate with the OIG and/or DOJ for additional releases, although the settlement amount likely would increase
- SRDP process can be extremely slow

Other Avenues of Disclosure

- **DOJ**

- Typically through local U.S. Attorney's Office (USAO)
- No formal guidance or protocol
- Beneficial to providers that require an FCA release
- No guaranteed settlement formula, and anecdotal reports that some USAOs will not settle for less than double damages
- Does not toll 60 day report/return requirement

- **Medicare Administrative Contractors (MACs)**

- Best for simple overpayment matters (e.g., improper coding)
- No release given but usually least costly approach

Cooperation Credit

Compliance and Cooperation Credit

- Importance of Cooperation Credit to Organization
 - Criminal
 - Civil
- Sources:
 - Federal Sentencing Guidelines for Organizations
 - DOJ Guidelines

DOJ Guidelines on Cooperation

- Criminal Division guidance on evaluating Corporate Compliance programs (updated April 2019)
 - Is the Corporation's Compliance program well designed?
 - Is the program being implemented effectively?
 - Does the Compliance program work in practice?
- Justice Manual § 4-4.112 : Guidelines for taking disclosure, cooperation and remediation into account in FCA matters (May 2019)
 - Thorough analysis of cause of the underlying conduct
 - Improving compliance program to ensure misconduct does not recur
 - Appropriately disciplining responsible individuals



QUESTIONS?

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