

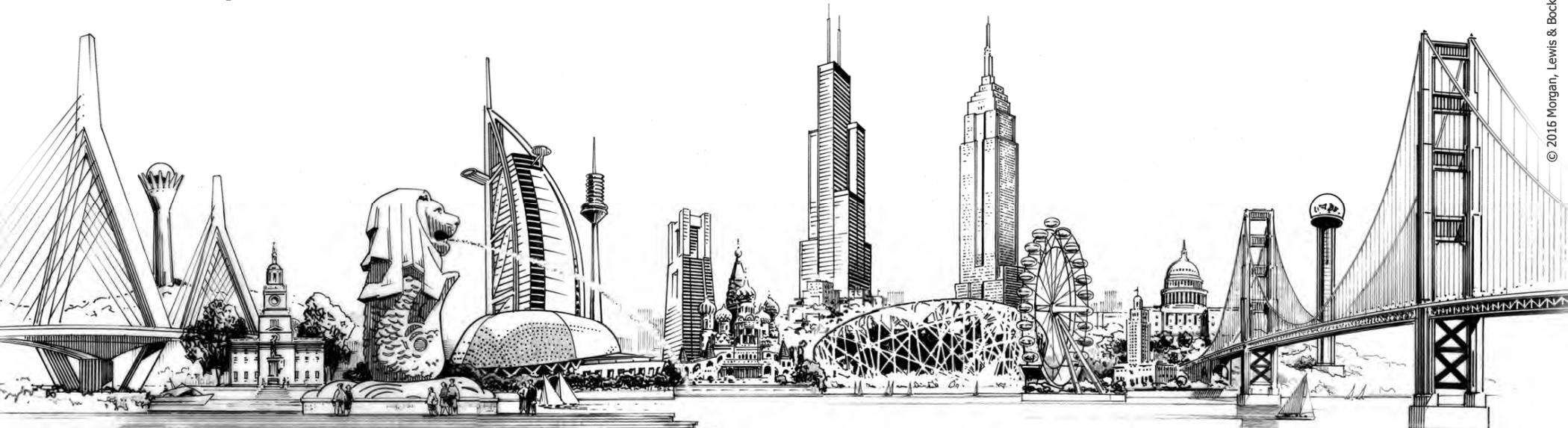
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60 DAY OVERPAYMENT RULE: PRACTICAL TIPS FOR COMPLIANCE

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AGENDA

- **HISTORY/BACKGROUND**
- **OVERPAYMENTS**
 - **WHAT ARE THEY?**
 - **WHEN DO YOU "IDENTIFY" AN OVERPAYMENT?**
- **"CREDIBLE INFORMATION" AND TIMING ISSUES**
- **COST REPORT ISSUES AND "APPLICABLE RECONCILIATION"**
- **MECHANISMS FOR REPORTING AND RETURNING OVERPAYMENTS**
- **INTERSECTION OF THE 60 DAY RULE AND THE FCA**
- **RELEVANT CASE LAW AND SETTLEMENTS**
- **PRACTICAL CONSIDERATIONS**
- **QUESTIONS**

History of Overpayment Refund Obligations

- Government has been working to establish affirmative refund obligation for many years:
 - SSA Section 1128B
 - Late 90's / Early 2000's OIG Industry Compliance Guidance
 - CMS has made several attempts to establish a repayment rule
 - FERA – 2009
 - ACA – March 2010 (required final rule within 3 years)
 - Proposed Rule – Feb. 2012
 - Final Rule – Feb. 2015 (after 3-year max period and a 1-year extension)

Proposed Rule

- Issued in February 2012 by CMS
- Proposed an “all deliberate speed” standard and did not clearly define “identified”
- Also proposed a 10-year overpayment lookback period to reflect outer limit of FCA statute of limitations
- Met with significant criticism from industry

What's an Overpayment?

- Medicare payments received or retained by a Provider which the Provider, after “applicable reconciliation,” is not entitled to retain
- Examples
 - Medicare payments for noncovered services; duplicate payments; receipt of Medicare payments when another party had primary responsibility for payment; inappropriate coding or upcoding; payments received in violation of the AKS; payments received in violation of the Stark law
- No *de minimus* overpayment exemption

What's an Overpayment?

- Overpayment is the difference between what was received and what the provider should have received
- The cause of the overpayment is irrelevant
- Cannot offset overpayments by identified underpayments

When do you Identify an Overpayment?

- A Provider identifies an overpayment when:
 - It has, or should have through the exercise of “reasonable diligence,” determined that it has received an overpayment;
and
 - Quantified the amount of overpayment
- 60 Day Clock begins running when...
 1. “when reasonable diligence is completed and the overpayment is identified”
 2. “on the day the [provider] received credible information of a potential overpayment if the [provider] fails to conduct reasonable diligence and the [provider] in fact received an overpayment”

Reasonable Diligence

- “Reasonable diligence” standard
 - Reactive investigative activities in response to receipt of “credible information” of overpayments
 - Proactive compliance activities to monitor claims
 - Self-audits
 - Establishing/maintaining adequate monitoring processes (think “7 elements of an effective compliance program”)
 - Recognition that compliance activities may differ based on size or type of provider
 - But all providers and suppliers have duty to report and return overpayments they may receive.

Mandatory Compliance Activities?

“We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of ... Medicare claims would expose the provider or supplier to liability under the identified standard articulated in this rule based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment.” 81 Fed. Reg. at 7661.

Credible Information – What is it?

- Information that supports a reasonable belief that an overpayment may have been received
- Whether something amounts to “credible information” is a factual determination
- Examples of events that may constitute credible information:
 - Hotline calls about a potential overpayment
 - Significant increase in Medicare revenues
 - Information from a government agency of a potential overpayment
- Not every complaint will constitute “credible information”
- Document, Document, Document



Office of Inspector General

U.S. Department of Health & Human Services

Reports

Hospital Reported Overstated Wage Data Resulting in Medicare Overpayments

Hospital (the Hospital), located in Anywhere, USA, did not always comply with Medicare requirements for reporting wage data in its fiscal year (FY) 2011 Medicare cost report. Specifically, the Hospital reported overstated wage data totaling \$4.9 million and 10,000 hours, which affected the numerator and denominator of its wage rate calculation. These errors occurred because the Hospital did not sufficiently review and reconcile the data to ensure that it was accurate, supportable, and in compliance with Medicare regulations. Because of the errors, we estimated that in FY 2014 Medicare overpaid the Hospital approximately \$249,000 and overpaid five other hospitals in the same core-based statistical area a total of approximately \$741,000.

Integrity ★ Credibility ★ Impact

Other Timing Issues

- CMS believes it should take “at most” 6 months from receipt of credible information to exercise reasonable diligence and determine whether an overpayment has been received
- Provides for a total of 8 months to report and return identified overpayments
- Exception for “extraordinary circumstances” which are based on fact-specific circumstances (e.g., an overpayment that may result in a violation of the Stark law; natural disasters; state of emergency)
- Document, Document, Document

Lookback Period

- 6 year lookback period, not the 10-year period initially proposed by CMS
- If a provider identifies an overpayment within 6 years of the date the overpayment was received, must report and return
- No phase-in period
- But application of 6 year lookback period is not retroactive
- Important for providers contemplating Stark law disclosures
 - Disclosures submitted before effective date (March 14, 2016), use current 4 year lookback (42 CFR §405.980(b))
 - Disclosures submitted after effective date, use the 6 year lookback period
- Places premium on proactive compliance activities

Practical Takeaways

- Document, document, document
- **All** staff must be trained (and possibly incentivized) to identify and report possible overpayments up the chain, particularly billing/revenue management staff
- The Final Rule effectively mandates some degree of compliance program for all providers/suppliers – necessity of ensuring “reasonable diligence”
- Don’t rely on 8 month timeframe to repay overpayments

“Credible Information” and the Cost Report

- An audit adjustment in one year could create review requirements for other years.
- Important questions to ask as other years are considered:
 - Was the issue transparent on the face of the cost report?
 - Do Contractor workpapers indicate that the issue had been expressly reviewed in prior years?
 - Did the law change, including the issuance of any “clarifications”, from one year to the next?
 - Are there any distinctions in the underlying facts?
 - Is the hospital planning to appeal the Contractor’s determination?
 - Can legal counsel reasonably support the propriety of the claim as filed?
 - What is the probability that the Contractor will reopen on its own initiative anyway?

“Applicable Reconciliation”

- Section 1128J – “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.”
- CMS states that reconciliation occurs at the time the cost report is filed, whether that be the initial filing or an amended filing.
- Exceptions
 - DSH SSI
 - Outliers that trigger outlier reconciliation

“Applicable Reconciliation” (*cont.*)

- CMS disagreed with commenters that suggested that reconciliation should equate with cost report settlement, rather than submission
 - Implication is that, after cost report submission, all potential issues need to be disclosed within 60 days (via cost report amendment or otherwise), rather than being addressed at time of settlement
 - Disrupts ordinary processes relating to entrance and exit conferences

“Applicable Reconciliation” (*cont.*)

- What is subject to “applicable reconciliation?”
 - Cost-based reimbursement items clearly qualify, such as:
 - GME
 - DSH
 - Bad debt
 - Organ transplant
 - But what about SCH/MDH determinations? Provider-based determinations?

Reporting and Returning Overpayments

- Can be performed through a claims adjustment, credit balance, self-reported refund or other reporting process
 - Return to “business as usual” forms of repayment
- Disclosures through OIG’s SDP or CMS’ Voluntary Self-Referral Disclosure Protocol also acceptable

Reporting and Returning Overpayments (*cont.*)

- Previously had proposed to include the following elements in a self-disclosure:
 - Name
 - TIN
 - How error discovered
 - Reason for overpayment
 - Claim numbers
 - DOS
 - HICN
 - NPI
 - Corrective action plan
 - Whether a CIA is in effect
 - Timeframe
 - Whether statistical sampling was used
 - Refund

Reporting and Returning Overpayments (*cont.*)

- May still choose to use full disclosure, even if an adjustment claim process is possible
 - Necessary when statistical sampling performed
 - Beneficial when there are questions about scien^{ter} and/or trying to cut off an “original source”
 - May be appropriate if responding to an OIG audit or otherwise, where organization might not agree entirely with findings and wants to frame the repayment issue

Reporting and Returning Overpayments (*cont.*)

- What about disclosing an item that *might* be an overpayment?
 - CMS says cannot file an item under protest, or submit a report without repayment, because the organization itself has “identified” the overpayment
 - Appears to mean that organization can use its reasonable legal judgment, but then again, CMS says that a revised claim is an “initial determination” with appeal rights
 - For cost reports, this could create jurisdiction issues for appeals
 - Underscores the need for sound legal reasoning when deciding not to report and repay after receiving “credible information”

Reporting and Returning Overpayments (*cont.*)

- Is statistical sampling always required?
 - CMS declined to remove references to statistical sampling, notwithstanding the implication that some organizations might receive the impression that statistical sampling is always necessary
 - CMS references that, however calculated, the repayment amount must be “reliable and accurate”
 - Unclear if statistical sampling is always required
 - CMS expects that if even a “single overpaid claim” is found during a probe sample, further work would be required, including extrapolation
 - Organizations need to determine what form that further work will assume
 - Consider a checklist of factors that result in a determination of whether the item is likely an isolated instance of an error or a signal of a more systemic issue

Intersection of the 60 Day Rule and FCA Liability: How Did We Get Here

- 2009 FERA Expansion
 - 31 U.S.C. 3729(a)(1)(G) – Reverse False Claims
 - “Any person who... knowingly conceals or knowingly and improperly avoids or decreases an **obligation** to pay or transmit money or property to the Government...”
 - Knowingly includes actual knowledge, deliberate ignorance or reckless disregard
 - No proof of specific intent to defraud required
 - 31 U.S.C. 3729 (b)(3): Definition of “obligation”
 - “An established duty, whether or not fixed, arising from... **the retention of any overpayment**”
 - Legislative history: the Committee does not intend this language to create liability for a simple retention of any overpayment that is permitted by a statutory or regulatory process for reconciliation provided that the receipt of the overpayment is not based on any willful act of a recipient to increase payments... Accordingly any known and improper retention of an overpayment beyond or following the final submission of payments would be actionable.
 - Definition of “improperly”?

Intersection of the 60 Day Rule and FCA Liability: How Did We Get Here (cont.)

- 2010 PPACA Expansion
 - 6402(a) – Requirement to report and return any overpayment
 - Must do so by the later of the date which is 60 days from the date on which the overpayment was **identified**, or the date any corresponding cost report is due
 - Failure to report and refund an overpayment after this deadline is an “**obligation**” actionable under the FCA

Example Enforcement of Retention of Overpayments to Date

- *U.S. ex rel. Keltner – EDWI, 2013*
 - Court denied defendant’s motion to dismiss, concluding relator stated a claim where the defendant conducted an audit, found high rates of up coding, failed to follow up on other claims by the up coding physicians and eliminated auditing altogether
 - If the government overpaid and the defendant intentionally refused to investigate the overpayment, it may have illegally avoided an obligation to pay money to the government
- *U.S. ex rel. Kane – SDNY, 2015*
 - First DOJ intervention in a 60 day rule case
 - First court decision to interpret the 60 day rule
 - Court denied defendants’ motions to dismiss – DOJ adequately pled Defendants had an established duty to report and return the overpayments once they were put on notice of a set of likely overpayment claims and that they avoided returning them in a timely manner
 - Court noted prosecutorial discretion would counsel against enforcement aimed at well intentioned healthcare providers working with reasonable haste to address overpayments
- Pediatric Services of America – 2015 Settlement
 - First of its kind settlement for failing to return overpayments
 - Maintaining or writing off credit balances without investigating whether those balances were the result of an overpayment
 - \$6.88 million settlement and a CIA

Practical Pointers to Avoid Or Minimize FCA Liability

- Engage in proactive compliance efforts
- Train staff to identify and report overpayments
- Promptly investigate every report of a potential overpayment to determine if it is credible
- If the information is credible, promptly begin an inquiry and take steps to determine whether an overpayment exists and accurately and efficiently quantify it
- Ensure prompt repayment of the overpayment – don't wait 8 months if you can do it faster
- If it is taking longer than the 8 months to refund the overpayment, make sure you keep the government or contractor informed of the progress and why it is taking longer
- Document all diligence done to investigate and quantify the overpayment in a manner you can use it to convince the government to decline intervention and any relator not to proceed with an FCA case

What Could Be The FCA Battlegrounds

- Public disclosure bar implications
- What is credible information of a potential overpayment
 - Fact specific inquiry
- What constitutes reasonable diligence
 - Timely, good faith investigation of credible information
 - Proactive compliance efforts
- When does the clock start ticking
 - Completion of reasonable diligence and the overpayment is quantified
 - Failure to conduct reasonable diligence and an overpayment exists
- What constitutes extraordinary circumstances
- What happens if repayment takes more than 8 months
- Do you always have to look back 6 years
- How far do you have to look - additional tranches of claims of the same type, by the same physicians?
- Fact specific determinations hard to succeed on a motion to dismiss

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