60-DAY OVERPAYMENT RULE
MEDICARE PARTS A AND B

by

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I. REPORTING OVERPAYMENTS – HISTORY AND LEGAL FRAMEWORK

The federal government has worked to establish an affirmative refund obligation for Medicare providers and suppliers for many years. The following statutes and regulations comprise the legal framework for reporting and returning overpayments:

A. Section 1128B of the Social Security Act provides that whoever "(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized" shall be guilty of a felony punishable by fines of not more than $25,000 or imprisonment up to 5 years. 42 U.S.C. 1320a-7b.

B. The U.S. Department of Health and Human Services Office of Inspector General (OIG) began publishing industry compliance guidance that addressed repayment obligations in the late 1990s. For example, the 1998 Compliance Guidance for Hospitals provides that "Failure to repay overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby

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establishing an independent basis for a criminal violation with respect to the hospital, as well as any individuals who may have been involved." 63 Fed. Reg. at 8998 (Feb. 23, 1998).

C. The Fraud Enforcement and Recovery Act of 2009 (FERA) amendments to the False Claims Act (FCA) (31 U.S.C. 3729 *et seq*.) added FCA liability where "Any person who… knowingly conceals or knowingly and improperly avoids or decreases an *obligation* to pay or transmit money or property to the Government," and defined "obligation" as "An established duty, whether or not fixed, arising from… *the retention of any overpayment*" [emphasis added]. 31 U.S.C. 3729(a)(1)(G), (b)(3). The Senate Report that accompanied the FERA amendments explained "The Committee does not intend [the FERA] 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 the payments from the Government when the recipient is not entitled to such Government money or property," and indicated that any known and improper retention of an overpayment beyond or following the final submission of payment "would be actionable." S. Rep. 111-10 (2009) at 15.

D. The Affordable Care Act (ACA) established a new section 1128J(d) of the Social Security Act that requires Medicare Part A and B providers and suppliers to report and return overpayments within 60 days after the overpayment was identified in most instances. 42 U.S.C. 1320a-7k.

   1. Section 1128J(d)(1) – Requires a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and to notify the Secretary, state, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

2. Section 1128J(d)(2) – Requires 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.

3. Section 1128J(d)(3) – 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)).

Failure to return and report overpayments in accordance with this provision could expose a provider or supplier to FCA liability, civil monetary penalties, and/or program exclusion. 42 U.S.C. § 1320a-7k(d)(1)(3); 31 U.S.C. § 3729(a)(1)(G); 42 U.S.C. § 1320a-7a.

E. Published in 2016, the Centers for Medicare & Medicaid Services (CMS) final rule established a set of requirements for providers and suppliers to follow when reporting and returning overpayments under SSA § 1128J(d) (Final Rule). 81 Fed. Reg. 7654-7684 (Feb. 12, 2016); 42 C.F.R. §§ 401.301 *et seq.*

F. The Final Rule applies to Medicare Parts A and B overpayments. A separate rule, published in 2014, addressed Medicare Parts C and D overpayments. 79 Fed. Reg. 29844 (May 23, 2014). No final rule has been published for Medicaid.

II. DEFINING OVERPAYMENTS

A. Overpayment means any funds that a Medicare provider or supplier has received or retained to which the provider or supplier, after *applicable reconciliation* is not entitled. 42 C.F.R. § 401.303. Applicable reconciliation occurs when the cost report is filed (whether an initial filing or an amended filing). 42 C.F.R. § 401.305(c). As a result, all potential issues would need to be disclosed within 60 days (via cost report amendment or otherwise) rather than being addressed at the time of settlement. Exceptions to this standard include Supplemental Security Income (SSI) ratios used in the calculation of disproportionate share hospital (DSH) payment adjustment and outlier reconciliation, which is performed at the time the cost report is settled if certain thresholds are exceeded. 42 C.F.R. §§ 401.303, .305(c); 81 Fed. Reg. at 7668.

B. An overpayment is the difference between what was received and what the provider should have received; the cause of the overpayment is irrelevant. There is no de minimus overpayment exception – all identified overpayments must be returned. 81 Fed. Reg. at 7656, 7658. Overpayments cannot be offset by identified underpayments. 81 Fed. Reg. at 7658. If not an overpayment, then the Final Rule doesn't apply. 81 Fed. Reg. at 7657.

C. Explaining that it would be impossible to enumerate "all potential factual permutations" that could result in an overpayment situation, CMS nevertheless provided the following examples in the Final Rule:

- Medicare payments for non-covered services
- Medicare payments in excess of the allowable amount for an identified covered service
- Errors and non-reimbursable expenditures in cost reports
- Duplicate payments
- Receipt of Medicare payment when another payor had the primary responsibility for payment
- Insufficient documentation
- Lack of medical necessity
- Inappropriate coding, upcoding
- Payments received in violation of the Antikickback statute
- Payments received in violation of Stark law

81 Fed. Reg. at 7656-58.

III. IDENTIFYING OVERPAYMENTS

"Reasonable Diligence"

A. A provider or supplier has identified an overpayment when the provider or supplier has, or should have *through the exercise of reasonable diligence*, determined the provider or supplier received an overpayment and *quantified* the amount of the overpayment. 42 C.F.R. § 401.305(a)(2).

B. "Reasonable diligence" includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments (e.g., self-audits, establishing/maintaining adequate monitoring processes) *and* reactive investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment. 81 Fed. Reg. at 7661.

C. Among the most far reaching aspects of the Final Rule is that providers and suppliers could be liable for failing to exercise reasonable diligence, which includes proactive 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.

D. CMS suggests a timely reasonable diligence investigation may take "at most 6 months from the receipt of the credible information, absent extraordinary circumstances." Extraordinary circumstances include "unusually complex investigations that the provider or supplier reasonably anticipates will require more than 6 months to investigate" (e.g., an overpayment that may result in a violation of the Stark law; natural disasters; state of emergency). 81 Fed. Reg. at 7662.

“Credible Information”

E. Credible information includes “information that supports a reasonable belief that an overpayment may have been received.” 81 Fed. Reg. at 7662. According to CMS, when a provider or supplier receives credible information of a potential overpayment, the provider or supplier “needs to undertake reasonable diligence to determine whether an overpayment has been received and to quantify the amount.” 81 Fed. Reg. at 7661. Whether something amounts to “credible information” is a factual determination. 81 Fed. Reg. at 7657. Not every complaint will constitute “credible information.”

F. The Final Rule provides the following examples of events that may constitute credible information: hotline calls about a potential overpayment, a significant increase in Medicare revenues, and information from a government agency of a potential overpayment. 81 Fed. Reg. at 7659.

G. An organization is responsible for the activities of its employees and agents. 81 Fed. Reg. at 7665. So the knowledge of an overpayment that may exist with one employee or agent will likely be attributed to the organization for purposes of the timing issues addressed by this outline. This can include errors originating from the Medicare Administrative Contractor (MAC), such as edit problems causing overpayment for non-covered services, or improperly implemented national/local coverage decisions.

“Quantified”

H. Quantification of an overpayment may be determined using statistical sampling, extrapolation and other methodologies. 81 Fed. Reg. at 7661, 63, 64, 67. While the CMS preamble discussion to the Final Rule does not mandate the use of statistical sampling, CMS observed sampling and extrapolation “are an appropriate component of a provider’s reasonable diligence in investigating an overpayment and can serve as an appropriate way to calculate an overpayment amount.” 81 Fed. Reg. at 7677.

I. As to whether the sample review must be extrapolated to a larger universe, the Final Rule is not definitive on this point, but strongly suggests that not extrapolating beyond a subset of claims approach would not be acceptable. “In the probe sample, it is not appropriate for a provider or supplier to only return a subset of claims identified as overpayments and not extrapolate the full amount of the overpayment.” 81 Fed. Reg. at 7664.

J. CMS expects that if even a “single overpaid claim” is found during a probe sample, further work would be required, including extrapolation. 81 Fed. Reg. at 7663. Extrapolated refunds must explain how the identified overpayment was calculated. 81 Fed. Reg. at 7676.

IV. REPORTING AND RETURNING OVERPAYMENTS

Deadlines

A. The 60-day period begins after the reasonable diligence is concluded (i.e., after identification). “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 …” 81 Fed. Reg. at 7662. However, if a provider or supplier does not exercise reasonable diligence upon receiving credible information that an overpayment exists, then the 60-day period begins when the credible information was received. 42 C.F.R § 401.305(a)(2).

B. Disclosure through the OIG Self-Disclosure Protocol (SDP) or the CMS Voluntary Self-Referral Disclosure Protocol (VSDP) will suspend the 60-day deadline until a settlement agreement is executed or the provider or supplier withdraws or is removed from the protocol. CMS, however, declined to extend this treatment to other government entities such as the U.S. Department of Justice (DOJ), local U.S. Attorney’s office and the Medicaid Fraud Control Units. 42 C.F.R. § 401.305(a)(2).

Lookback

C. The Final Rule provides for a 6-year lookback period for overpaid claims that is measured from the date the provider or supplier identifies the overpayment. 42 C.F.R. § 401.305(f). The application of the lookback period is not retrospective. 81 Fed. Reg. at 7673.

D. Lookback inquiries may be resource and time intensive, but CMS has not allowed for any exception based upon burden of such a lookback inquiry. As a practical matter, when conducting a potential overpayment inquiry for the full lookback period, relevant data or documentation may be unavailable.

E. An audit adjustment in one year could create review requirements for other years. The following are important questions to ask as other years are considered:

- Was the issue transparent on the face of the cost report?
- Do contractor workpapers indicate 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?

F. Disclosures submitted before the Final Rule's effective date (Mar. 14, 2016) use the 4-year lookback period (42 C.F.R. § 405.980(b)). 81 Fed. Reg. at 7673.

G. CMS amended the reopening rules to provide for a reopening period that accommodates the 6-year lookback period for reporting and returning an overpayment under 42 C.F.R. § 405.980(c)(4). 81 Fed. Reg. at 7684.

Process

H. Providers may report/return identified overpayments through a claims adjustment, credit balance, self-reported refund, or other reporting process. 42 C.F.R. § 401.305(d)(1). CMS clarified that if a contractor identifies a payment error and notifies a provider that it will adjust the claims to correct the error, the provider does not have an obligation to report and return the overpayment separately. 81 Fed. Reg. at 7667.

I. Even when an adjustment claim process is possible, providers may still find full disclosure beneficial under certain circumstances. For example, in instances where statistical sampling is performed only the specific claims identified in the sample will be adjusted and thus can be appealed. Additionally, full disclosure may be appropriate where the provider disagrees with the findings of an OIG audit and wants to reframe the repayment issue.

J. CMS clarified in the preamble discussion to the Final Rule that "While we will not recover an overpayment twice, *we do not intend to exempt from subsequent audit* by CMS, a CMS contractor or the OIG any claims that form the basis for a returned overpayment" [emphasis added]. 81 Fed. Reg. at 7667.

V. INTERNAL AUDIT TIPS FOR PROVIDERS

A. Among the most far-reaching aspects of the Final Rule is that providers could be liable for failing to exercise "reasonable diligence," which includes proactive compliance activities. Providers must examine their current processes for overpayment detection (if they exist) and assess whether the government would consider them "reasonable." The Final Rule, despite claims of a bright-line test, is anything but; much of the analysis relies on fact-specific determinations. To that end, choosing self-audit priorities based on risk stratification and other advanced auditing techniques will better position providers to detect and address overpayments to meet this “reasonable diligence” standard. For example, would the government consider current processes for overpayment detection reasonable? Is quarterly auditing of 30 claims for a 500-bed hospital sufficient? What about 100 claims or 500 claims?

B. Most providers regularly interact with various Medicare contractors, whether through cost reconciliation, comprehensive error rate testing (CERT) audits, recovery audit contractor (RAC) claims reviews, or questions addressed to the MAC. CMS is clear that these interactions can (and often do) result in “credible information,” which may require providers to delve further into a particular issue. This includes determining not just if the contractor is correct but also whether the issue affects other claims and time periods. Thus, developing an organizational summary of the various disputes that an organization has had with Medicare contractors will help ensure that the potential areas the organization is on notice of are properly addressed.

C. The Final Rule attributes knowledge of overpayments to any person in an organization, regardless of job responsibilities or seniority level. Consequently, CMS perceives the organization to receive “credible information” of an overpayment on the day that any employee or agent receives such information. Training staff, particularly those responsible for billing and revenue management, on reporting mechanisms and monitoring processes will be critical. Providers should also assess whether their current grounds for disciplinary action include failure to promptly report known or potential overpayments to management and whether providers in fact discipline employees on these grounds.

D. Social Security Act § 1128J(d) requires reporting and repayment of overpayments within the later of 60 days or the date that the corresponding cost report is due. Thus, it is important from a timing perspective for providers to make a well-reasoned and consistent judgment about which claims are subject to "applicable reconciliation" on the cost report and which are not.

E. Nearly every feature of healthcare operations now requires diligent and clear supporting documentation. The Final Rule's requirements are no different. At the broadest level, providers should have in place standard operating procedures to guide overpayment monitoring activities and the process for investigation once a potential overpayment has been uncovered. From there, providers should develop and follow audit and investigation protocols. Finally, documenting the steps that a provider has taken, is currently taking, and plans to take to identify and quantify an overpayment will be important to demonstrate "reasonable diligence."

VI. LIMITING FALSE CLAIMS ACT EXPOSURE

FCA Liability

A. The FERA amendments impose FCA liability on "Any person who… knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…" and defines "obligation" as "An established duty, whether or not fixed, arising from… the retention of any overpayment." 31 U.S.C. 3729(a)(1)(G), (b)(3). The knowing retention of an identified overpayment can result in FCA liability as a "reverse" false claim.

B. CMS declined to clarify in the Final Rule whether the failure to report and return an identified overpayment would lead to reverse false claims liability:

> We are interpreting section 1128J of the [ACA] in this rulemaking, not the FCA. … our discussion of the FCA is limited to its explicit inclusion in the enforcement provision under section 1128J of the [ACA], which states that any overpayment retained by a person after the deadline for reporting and returning the overpayment under this rule is an obligation for purposes of the FCA.

81 Fed. Reg. at 7665.

Notable Case Law and Settlements

C. A former billing department employee brought a qui tam action against Lakeshore Medical Clinic (Lakeshore) for allegedly “ignor[ing] audits disclosing a high rate of upcoding and ultimately eliminated audits altogether.” In denying Lakeshore’s motion to dismiss, the court found a “plausible claim for relief” under the reverse false claim provision of the FCA. “[If] defendant intentionally refused to investigate the possibility it was overpaid, it may have unlawfully avoided an obligation to pay money to the government.” *U.S. ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, No. 11-cv-00892 (E.D. Wis. Mar. 28, 2013).

D. Following a software glitch that resulted in the improper retention of more than $843,000 in government funds, the U.S. District Court for the Southern District of New York held the 60-day period ran from the date on which defendants were “put on notice that a certain claim may have been overpaid.” *Kane* is notable for a number of firsts: It was the first case alleging wrongful retention of an overpayment in violation of the FCA, it was the first intervention by a U.S. Attorney in a 60-day rule case, and it was the first judicial guidance on when the 60-day clock begins. Notably, the *Kane* court cautioned that prosecutorial discretion would counsel against enforcement aimed at well-intentioned healthcare providers working with reasonable haste to address overpayments. A $2.95 million settlement was entered by the court on August 24, 2016. *U.S. ex rel. Kane v. Healthfirst, Inc.*, No. 11-cv-02325 (S.D.N.Y. Aug. 3, 2015).

E. In the first reported government settlement for failing to return overpayments, Pediatric Services of America (PSA) entered into a $6.88 million settlement with the DOJ. Allegations included PSA maintained or wrote off credit balances without investigating whether the balances were the result of an overpayment and thus failed to refund overpayments from 20 state Medicaid programs and TRICARE over 6 years. *U.S. ex. rel.*

Odumosu v. Pediatric Services of America; U.S. ex rel. McCray v. PSA, No. 1:11-cv-1007 (N.D. Ga.); No. 4:13-cv-127 (S.D. Ga.) (settlements announced Aug. 4, 2015).

F. Allegations involving a recent $440,000 settlement by First Coast Cardiovascular Institute, P.A. (FCCI) included failure to timely refund more than $175,000 in overpayments owed to government healthcare programs from accrued credit balances. According to the DOJ, FCCI "had failed to pay back the money it owed … until being notified that the Department of Justice had opened an investigation into their failure to repay the government." The FCCI settlement, which also concluded a qui tam action by a former employer, is the second reported 60-day overpayment case settled by the DOJ. *State of Florida ex rel. Malie v. First Coast Cardiovascular Institute, P.A. et al.*, No. 3:16-cv-10548 (M.D. Fla.) (settlement announced Oct. 13, 2017).

Practical Pointers to Avoid / Minimize FCA Liability

G. Engage in proactive compliance efforts. For example, monitor government enforcement activity, changes to the law and regulations, and sub regulatory guidance; compare best practices; capture and monitor risk assessment data through internal audits and control testing; and update/review methods and metrics for information gathering and risk assessments. Continuously review compliance policies and procedures and monitor operational practices that could result in enhanced risk. Ensure that funding, resources and experienced personnel are commensurate with the size and risk profile of the organization.

H. Test and train staff to identify and report overpayments. Make sure employees seeking compliance guidance feel free to raise/report compliance related concerns without fear of retaliation. Ensure the appropriate flow and elevation of reporting of potential issues and problems to management. Ensure appropriate autonomy for compliance officers and the program.

I. 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.

J. Ensure prompt repayment of the overpayment – don’t wait 8 months if it can be done faster. If it is taking longer than the 8 months to refund the overpayment, make sure the government or contractor is kept informed of the progress and reasons why it is taking longer.

K. Document all diligence done to investigate and quantify the overpayment in a manner that will help convince the government to decline intervention and any relator not to proceed with an FCA case.