

CMS Final Rule: Reporting and Returning Overpayments

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Today's Roadmap

- Brief history of the repayment rule and how we arrived here
- Summary of the Final Rule
- What constitutes “identified” for purposes of triggering reporting and repaying obligations
- What constitutes “reasonable diligence” for identifying overpayments
- Navigating the 6-year lookback period
- Pragmatic approaches to repayment obligations
- Interface between the report and repay Final Rule and the CMS Self-Referral Disclosure Protocol and the OIG Self-Disclosure Protocol
- Other considerations – case law and new requirements out of DOJ's Fraud Section

CMS Issues Overpayment Final Rule



The Final Rule for Reporting and Returning Overpayments

- **The Final Rule requires providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of:**
 - 60 days after the date on which the overpayment was identified, or
 - The date any corresponding cost report is due, if applicable.
- **Providers and suppliers who fail to report and return overpayments face potential False Claims Act (FCA) liability, Civil Monetary Penalties Law (CMPL) liability, and exclusion from federal health care programs.**

The Affordable Care Act

- Section 6402(a) of the Affordable Care Act established new section 1128J(d) of the Social Security Act which requires a person who has received an overpayment to report and return it to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate.
 - “Person” is defined as a provider or supplier
- In addition, Section 1128J(d) requires the person reporting and returning the overpayment to also provide written notice of the reason for the overpayment.

CMS Response

- To implement section 1128J(d), on February 16, 2012, CMS proposed to establish a new subpart D in 401 of its regulations, to revise §401.607, and to add sections to part 405 to address report and repay obligations for Medicare Parts A and B.
- On May 23, 2014, CMS published a final rule that addresses Medicare Parts C and D (79 FR 29844).
- No final rule has been published that addresses Medicaid requirements, although the requirements of section 1128J(d) are currently applicable to overpayments in the Medicaid program as well.

Issuance of the Final Rule

- CMS received over 200 comments to the proposed rule but did not issue the Final Rule until February 11, 2016.
- The Final Rule becomes **effective March 14, 2016**.
- Importantly, the Final Rule implements and clarifies section 1128J(d), even though providers and suppliers have been under an obligation to return overpayments since the passage of the ACA in March 2010.

Anticipated Cost of the Rule

- The Medicare program is estimated to be the primary payer of health care for approximately 15 million enrolled beneficiaries.
- CMS specifically recognizes that there are significant costs associated with the new rule in the time and effort necessary for providers and suppliers to identify, report, and return overpayments in a way described by the rule.
 - CMS projects an annual cost burden of between \$120.87 million and \$201.45 million, with a midrange projection of \$161.16 million.

Key Provisions – Meaning of “Identified”

- In the proposed rule, 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 Final Rule bypasses the ambiguities of the “knowing” requirement as well as the characterizations of “reckless disregard” or “deliberate ignorance.”
- **Under the Final Rule, 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.**

Two Essential Elements

- The Final Rule thus contains two essential elements for identifying an overpayment:
 - **Reasonable diligence** in identifying overpayments, and
 - **Quantification** of the amount of the overpayment.



First Element – “Reasonable Diligence”

- The Final Rule clarifies that the obligation to use reasonable diligence in identifying overpayments creates two separate and distinct requirements:
 - a. Providers and suppliers have a duty to undertake **regular “proactive” compliance activities** conducted in good faith by qualified individuals to monitor for the receipt of overpayments.
 - b. Providers and suppliers also have a duty to conduct **“reactive” investigations** in good faith and in a timely manner in response to credible information that an overpayment has been received.

Examples of Identified Overpayments

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

Examples of Identified Overpayments

- **A provider of services or supplier:**
 - performs an internal audit and discovers that overpayments exist;
 - 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;
 - Experiences a significant increase in Medicare revenue and there is no apparent reason – such as a new member in the practice – for the increase.

60-Day Time Period for Repayment

- This all means that when a person obtains credible information concerning a potential overpayment, the person needs to undertake reasonable diligence to determine whether an overpayment has been received and quantify the amount.
- The 60-day time period for repayment begins when either the reasonable diligence is completed or on the day the person received credible information of potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment.

Credible Information

- **Credible information is anything that raises a realistic potential that an overpayment has been received, thereby triggering the duty to conduct a reasonable inquiry.**
 - **CMS uses the example of a hotline complaint. Whether hotline complaint qualifies as credible information is a factual determination.**
 - **For example, receiving repeated hotline complaints about the same or similar issues may lead a reasonable person to conclude that they have received credible information that obligates conducting reasonable diligence.**
 - **However, one hotline complaint may be detailed enough to lead a reasonable person to the same conclusion.**

Timely Investigation

- The Final Rule excludes the term "all deliberate speed" from the preamble used in the proposed rule.
- Instead, according to CMS, a timely, good faith investigation of credible information is, at most, **6 months from receipt of the credible information**, except in extraordinary circumstances.
 - Extraordinary circumstances may include unusually complex or vague investigations that the provider or supplier reasonably anticipates will require more than 6 months to investigate.
 - Providers and suppliers are advised to maintain records and accurately document their reasonable diligence efforts to be able to demonstrate their compliance with the rule.

Audits, Statistical Sampling, and Extrapolation

- Reasonable diligence can include audits, statistical sampling and extrapolation when investigating an overpayment and as a way to calculate an overpayment amount.
- If a provider or supplier uses a statistical sampling methodology to calculate the overpayment, it must describe the statistically valid sampling and extrapolation methodology in the report.
§401.305(d)(1).

Second Element - Quantification

- The Final Rule addresses a critical omission in the proposed rule by clarifying that an overpayment is not identified until the amount of the overpayment has been quantified.
- The Final Rule expressly allows that the amount of an overpayment may be quantified using statistical sampling, extrapolation methodologies, and other methodologies as appropriate, so long as there is a good faith basis for the methodology used, the quantification is conducted in a timely manner, and the basis for the methodology is provided in the repayment report.

Navigating the Lookback Period

- The 60-day provision of the ACA did not set forth a specific lookback period for providers making repayments.
- The proposed rule used a 10-year look back period (which coincided with the outside statute of limitations under the False Claims Act).
- The AHA, FAH, other provider associations, and industry experts vehemently opposed the 10-year lookback and, instead, urged a 4-year lookback.

Navigating the Lookback Period

- The Final Rule settles on a **6-year lookback period**.
- Accordingly, providers may request that Medicare contractors reopen claims up to 6 years old for the purpose of reporting and returning overpayments.
- The new lookback period is not retroactive. Providers that made repayments prior to the effective date of the rule (March 14, 2016), and that made good faith efforts to comply with the statutory requirements will not be held to a 6-year lookback period.
- Providers reporting overpayments under CMS' Self-Referral Disclosure Protocol (SRDP) prior to the effective date of the Final Rule will be governed by the 4-year look back period mandated by that process.
 - Those reporting overpayments through the SRDP after the effective date will be subject to the 6-year lookback period.

Applicable Reconciliation

- In the Final Rule, CMS defines an “overpayment” as “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 has addressed concerns that this definition is overly broad by expanding the ways in which overpayments may be reported and returned, including claims adjustment or reversal, the credit balance reporting process, CMS' Self-Referral Disclosure Protocol, and the OIG's Self-Disclosure Protocol.
 - While providers sometimes seek to incorporate underpayments to reduce the amount of an overpayment, CMS explicitly excludes the treatment of underpayments from the Final Rule.

Applicable Reconciliation

- Under the Final Rule “applicable reconciliation” was finalized to mean “the reconciliation that enables a person to identify funds to which the person is not entitled.”
- As it pertains to cost reports, applicable reconciliation means the provider’s year-end reconciliation of payments and costs to create the cost report.
 - Cost reports must be filed within 5 months of the end of the provider's fiscal year, which is intended to allow the provider time to reconcile payments and costs and identify any funds to which the provider is not entitled.
 - This overpayment should be returned at the time the cost report is filed.
 - If a provider self-identifies an overpayment after submission and applicable reconciliation of the Medicare cost report, the provider is responsible for reporting and returning the overpayment within 60 days of identification.
 - In this situation, the provider must submit an amended cost report along with the overpayment refund and the amended cost report must include sufficient documentation and data to identify the issues so that the MAC can adjust the cost report.

Applicable Reconciliation

- **Providers also have a duty to revise past cost reports based on a MAC audit identifying improper treatment of certain costs.**
 - Under the Final Rule, providers are required to submit amended cost reports for all other audited cost reporting years in which the provider treated those costs in a similar fashion.
 - If a MAC notifies a provider of an improper cost report payment, the provider has received credible information of a potential overpayment and must conduct reasonable diligence on other cost reports within the 6-year lookback period to determine if it has received an overpayment.

Applicable Reconciliation

- **Overpayments resulting from periodic interim payments (PIP) must be returned at the time the initial cost report is due.**
 - If, however, a provider is aware that its PIP payment may not be accurate, it should inform its MAC of the issue.
- **An overpayment resulting from an outlier reconciliation is identified when a provider receives that information from its MAC as part of the cost report process.**
 - A provider is not responsible for attempting to identify the cost report outlier reconciliation overpayment in advance of the MAC's reconciliation calculation.

Reporting and Returning Requirements

- The Final Rule preserves the existing process for reporting and returning overpayments and keeps open the possibility of subsequent development of new processes.
- Providers can fulfill the obligation to report and return an overpayment through CMS's Self-Referral Disclosure Protocol or OIG's Self-Disclosure Protocol.
- The Final Rule allows providers to report and return an overpayment by using an applicable claims adjustment, credit balance, self-reported refund, or other process set forth by the applicable Medicare contractor to report an overpayment.

Reporting and Returning Requirements

- **If a provider complies with the Medicare contractor's process, it will have satisfied its obligation to report and return, with one exception:**
 - **Regardless of whether the Medicare contract requires it, to the extent that the provider calculates an overpayment amount using a statistical sampling methodology, the provider must describe the statistically valid sampling and extrapolation methodology in its report.**
- **The Final Rule instructs providers to select the most appropriate recipient of the overpayment report and refund, including the applicable Medicare contractor, the OIG via its SDP process, or CMS via its SRDP process.**
 - **The Final Rule, thus, maintains the status quo of how providers are currently processing overpayment reports and refunds, rather than implement the more regimented processes that were outlined in the proposed rule.**

Extended Payment Plans

- The Final Rule allows for an extended repayment plan for providers faced with burdensome repayment obligations.
- Providers and suppliers wishing to avail themselves of this option must specifically request an extended repayment schedule and must meet CMS' specific rules on qualification.
 - The deadline for returning an overpayment is tolled if (1) the provider request an extended repayment schedule, or (2) the provider makes the submission via the SDP or SRDP.
 - If the provider requests an extended repayment schedule, the deadline is tolled until the Medicare contractor rejects the request or the provider fails to comply with the terms of extended repayment schedule.
 - For the SDP or SRDP processes, the deadline is tolled for the entire period in which the provider is negotiating a settlement, beginning when OIG or CMS acknowledges receipt of a submission.
 - If the provider fails to reach a settlement with OIG or CMS, the provider will have the “balance of the 60-day time period remaining from the identification to the suspension of that 60-day period to make a full report and repayment of the overpayment.”

Other Considerations

The Final Rule does not affect current case.



***Kane v. Healthfirst, Inc.* (S.D.N.Y.)**

- **In August 2015, the United States District Court for the Southern District of New York issued the first decision regarding the requirements of the ACA to return identified overpayments from Medicare and Medicaid within 60 days.**
- **The Court's thoroughly-reasoned opinion provides a cautionary tale and provides excellent lessons when dealing with the report and repay rule.**

Kane v. Healthfirst, Inc. (S.D.N.Y.)

- **Basic facts of the case:**
 - Computer glitch on the part of Healthfirst, a private, nonprofit insurance program, caused three New York City hospitals (Continuum) to submit improper claims to Medicaid for services rendered to beneficiaries of a managed care program administered by Healthfirst.
 - Beginning in January 2009, Continuum submitted claims that resulted in improper overpayments.
 - In September 2010, auditors from the New York State Comptroller's office approached Continuum with questions regarding incorrect billing. These discussions revealed the software glitch.
 - After the problem was discovered, Continuum tasked its employee, Robert Kane, with ascertaining which claims had been improperly billed to Medicaid.
 - In February 2011, approximate 5 months after the Comptroller first informed Continuum about the glitch, Kane sent an email to several members of Continuum's management, attaching a spreadsheet the contained more than 900 claims (totaling over \$1 million) that Kane had identified as containing an erroneous billing codes.

Kane v. Healthfirst, Inc. (S.D.N.Y.)

- While it is undisputed that Kane's spreadsheet was overly inclusive, approximate half of the claims listed did, in fact, identify improper overpayments.
- Four days after receiving Kane's email and spreadsheet, Continuum terminated to Kane's employment.
- Continuum did nothing further with Kane's analysis, and in February 2011, Continuum reported and returned overpayments for only 5 improperly submitted claims.
- Meanwhile, the Comptroller conducted further analysis and identified several additional tranches of wrongful claims, which it brought to Continuum's attention.
- In 2011, Kane filed suit against Continuum in a *qui tam* action under the False Claim Act on the basis that Continuum had failed to report and return overpayments.
- In its Motion to Dismiss, Continuum argued that (a) Kane's email only provided notice of potential overpayments and did not identify actual overpayments so as to trigger the ACA's 60-day report and return clock, and (b) only "active and conscious action" constitutes knowing avoidance of repayment obligations under the FCA.

***Kane v. Healthfirst, Inc.* (S.D.N.Y.)**

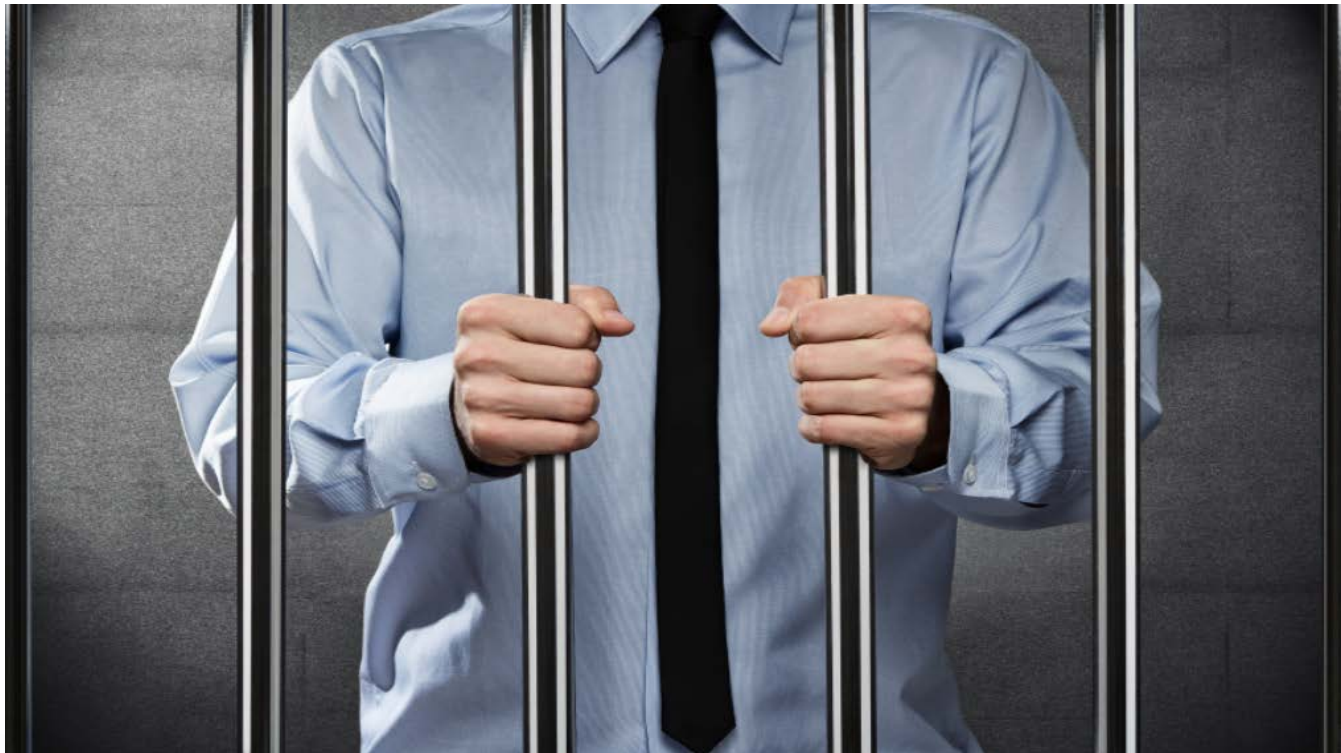
- **The Court soundly rejected Continuum’s arguments that “identified” means “classified with certainty.”**
- **Rather, the Court held that identification occurs when health care providers are “put on notice” of potential overpayments.**
- **In addition, the Court found that knowing avoidance of repayment obligations includes situations in which a hospital “is put on notice of a potential issue, is legally obligated to address it, and does nothing.”**

Lessons from *Kane v. Healthfirst*

- *Kane v. Healthfirst* is a template for how not to respond to notice of potential overpayments.
- Providers must respond seriously when reliable information exists suggesting a provider has received an overpayment.
- Providers need a policy for the investigation of potential overpayments, including thorough documentation of such efforts.
- In addition, the Final Rule underscores the importance of proactive compliance programs to identify potential overpayments.
- Be very, very careful when terminating the employment of a potential whistleblower and never do so without independent, verified and well-documented reasons for doing so.
- While the Final Rule changes some of the terminology used by the Court, it comports with the findings in *Kane* and likely will not alter the course of such opinions going forward.

New DOJ Action

- Recently (February 2016) the U.S. Justice Department's fraud section indicated that it will now require certification from companies that they fully disclosed all information about individuals involved in wrongdoing before finalizing a settlement agreement.



The Yates Memo

- The so-called "Yates memo" (drafted by Deputy Attorney General Sally Quillian Yates) puts a renewed focus on prosecuting individuals in white-collar crime.
- The memo specifies that to obtain any cooperation credit in a settlement, a company must provide all relevant information about individuals involved in the wrongdoing.
- While the certification process is still in development, it will almost surely apply to health care providers and will require that individuals involved in fraudulent activities be specifically identified.
- We will update the details of new certification process and other requirements as they become available.

Additional Holland & Hart Resources

- Future webinars
 - 3/3/16 **Provider Networks**
 - 3/17/16 **CMS' New Bundled Payment Initiatives**
 - 3/24/16 **Checking Databanks: Excluded Entities, Govt Contractors and the NPDB**
- *Healthcare Update and Health Law Blog*
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