Safeguarding federal health programs and their beneficiaries

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The answers to our ongoing questions and concerns regarding the “60-day rule” are finally in. On February 12, 2016, the Centers for Medicare and Medicaid Services (CMS) issued the long-anticipated “final rule” regarding the reporting and returning of Medicare overpayments. The infamous 60-day rule requires any Medicare provider, supplier, or managed care contractor who has received an overpayment to provide written notice to CMS within 60 days of the date the overpayment was identified—or within 60 days of the due date of any corresponding cost report.2

The recently published final rule applies only to overpayments stemming from Medicare Parts A and B funds. There is no final rule currently in place regarding Medicaid overpayments, though several states have enacted individual requirements.

Failure to comply triggers FCA liability

Several provisions in the final rule are of significant importance to compliance, because they explicitly trigger the False Claims Act (FCA) under the enforcement provision of the Social Security Act, a provision stating that failure to report and return any overpayment after the specified deadline is an obligation for purpose of the FCA.5

Final rule violations are particularly daunting, because overpayment liability is present even when overpayments arise from mistakes or errors on behalf of others—even CMS errors. The 60-day rule says that once a provider or supplier becomes aware of a potential overpayment, they are obligated to investigate, report it to the CMS, and repay the amount overpaid within 60 days. Missing this 60-day mark can result in severe civil monetary penalties.
Understanding final rule regulations is vital to healthcare professionals who wish to protect themselves from FCA liability. Final rule regulations became effective on March 14, 2016, so all Medicare Part A and B provider and suppliers should take a moment to familiarize themselves with the requirements. Here, we highlight the major aspects of the final rule and define best practices that providers and suppliers should implement to ensure compliance success.

**Final rule modifies 2012 proposed rule**
The 60-day rule-originated in 2010 as part of Obama’s Affordable Care Act (ACA). Since its inception, a number of questions, comments, and concerns have been circulating on the definition of “identification,” where exactly the 60-day countdown begins, the “lookback” length, and other unclear issues.

A modification of the February 2012 proposed rule, the final rule was released to address these concerns and clarify 60-day rule requirements. Several of the modifications thankfully offer some respite regarding the original provisions, but the final rule still enforces substantial burden and responsibility on healthcare providers and suppliers. A proactive mindset is essential here.

**Several final rule provisions influence FCA liability**
Several provisions of the final rule significantly impact FCA liability regarding unlawful retention of Medicare funds. First, we should define “overpayment” as any Medicare funds that a person receives to which they are not entitled (amount in excess of what they were entitled for actual services rendered).

**60-day clock starts at identification**
As for the start of the 60-day clock, the final rule requires Medicare overpayment report and return within 60 days after the day the overpayment is “identified” or within 60 days of the due date of any applicable cost report (whichever is the later date).

Prior to the final rule, it was unclear whether “identified” meant when there was an allegation, when an overpayment was verified, or when the amount of the overpayment was calculated. CMS now explains that an overpayment is “identified” when a provider or supplier has or “should have,” through exercise of “reasonable diligence,” discovered the receipt of an overpayment and quantified the overpayment amount.

Regarding “should have,” the final rule states that if a person fails to exercise reasonable diligence and in fact received an overpayment, that person should have discovered and quantified the overpayment.

Thankfully, the 60-day timer no longer starts at the mere possibility of an overpayment. This gives healthcare providers and suppliers time to examine and calculate overpayments before the 60-day clock starts.

**Reasonable diligence is required**
Under the final rule, identification activates the requirement to initiate “reasonable diligence.” This differs from the 2012 proposed rule which said “identification” happens when a person gains actual knowledge of an overpayment or acts in reckless disregard or deliberate ignorance of the overpayment’s existence. CMS has now decided that providers and suppliers must exercise “reasonable diligence” through “timely, good faith
investigation of credible information” regarding an overpayment.

The FCA's “reverse false claims” provision provides a powerful means of enforcing the 60-day rule. Without reasonable diligence, the provider or supplier can be liable for knowingly retaining a Medicare overpayment due to reckless disregard or ignorance – resulting in FCA reverse false claims liability. Under the FCA, providers and suppliers are held liable for “knowingly concealing, or knowingly or improperly avoiding or decreasing” an obligation to the government (“obligation” being reporting and returning a Medicare overpayment within 60 days of identification). Whether or not reasonable diligence was exercised is going to be a big component in determining the level of liability in an FCA claim.

Timely investigation should take six months or less
According to CMS, in exercising reasonable diligence, a “timely” investigation should take no longer than six months, absent extraordinary circumstances. Extraordinary circumstances could include Stark Law cases disclosed under the Voluntary Self-Referral Disclosure Protocol (SRDP). Therefore, providers and suppliers have six months from receipt of the credible information to start the 60-day timer. The term “reasonable diligence” replaced “all deliberate speed” in the 2012 proposed rule.

It is important to note that, under the final rule, investigations include both proactive and reactive Medicare billing reviews; mere audits triggered by allegations are not considered “investigations.”

Lookback period reduced to six years
Another point of the 2012 proposed rule that underwent revision was the lookback period for retained overpayments. A lookback period is the amount of time a provider or supplier must go back to examine payment records for overpayments. The final rule establishes a 6-year lookback period beginning on the date of receipt (reduced from the 10-year period in the proposed rule).

Though the timeframe has been reduced, it is still a significant chunk of time to go back and evaluate payment records. Requests for reduction to a 4-year Medicare lookback period have been rejected, implying the seriousness the CMS places on detecting and returning overpayments. This 6-year lookback period is not retroactive and went into effect on March 14, 2016.

Numerous available reporting outlets
The final rule also expands on several avenues that Medicare providers and suppliers can use to report overpayments. These include credit balances, claims adjustments, self-reported refunds, and other appropriate reporting processes provided by the Medicare contractor. Extrapolation can be used in calculating an overpayment if exact figures aren’t available. In this case, repayments must include the statistical sampling methodology used in the calculation.

Disclosing an overpayment under the CMS Voluntary SRDP or the OIG Self-Disclosure Protocol will also meet reporting obligations set forth in the final rule. As of right now, these reporting methods are still subject to a 4-year lookback period, though CMS will likely apply the 6-year lookback in the near future.

No obligation to return third-party kickback overpayments
Claims arising out of violation of the Anti-Kickback Statute (AKS) are false claims and considered overpayments. Healthcare providers and suppliers often submit claims for Medicare payment that involve a third party,
and many times this third party could be involved in a kickback arrangement of which the initial party has no knowledge of or participation in.

As in the 2012 proposed rule, CMS will continue to suspend repayment obligations for providers or suppliers who have inherited overpayments originating from a third party’s violation of the AKS until after the kickback violation is resolved by the government. Only the parties involved in the kickback scheme will be responsible for repayment – except in “the most extraordinary circumstances.” CMS offers this alternative since individuals who are not participating in a kickback arrangement are unlikely to “identify” the overpayment.

In cases where the provider or supplier has sufficient knowledge of the kickback arrangement, the 60-day rule applies.

**Practical steps in mitigating risk of final rule violation**

Failure to report and return a Medicare overpayment is serious business. It can trigger potential FCA liability, potential exclusion from federal healthcare program participation, and potential Civil Monetary Penalties Law liability. *Qui tam* actions can be filed by whistleblowers that include individuals inside or outside of the operation who have knowledge of a suspected overpayment. Under the FCA, a provider or supplier can be liable for actual plus treble damages and up to $11,000 per false claim.

To mitigate compliance risk and FCA liability, providers and suppliers should consider implementing the following best practices in meeting with the new regulations of the final rule.

**Establish a proactive compliance program**

CMS explains that “undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier’s Medicare claims would expose a provider or supplier to liability... based on the failure to exercise reasonable diligence...” A robust compliance program should identify and continually evaluate activities that could reveal potential overpayments, including claim denials, submission protocols, internal and external audits, document retention, and compliance reports. This program must include significant documentation to provide evidence of reasonable diligence.

**Evaluate contracts with third-party billing services and contractors**

Providers and suppliers need to report and return Medicare overpayments, even when they do not feel they were the direct cause of the overpayment. Compliance activities must also be able to detect errors made by third parties, because overpayments outside of the provider/supplier’s control are still included in the 60-day requirement.

**Investigate all potential overpayments promptly**

Though the final rule suggests an investigation does not necessarily start the 60-day countdown, failure to use reasonable diligence can trigger the 60-day start point on the day credible information of a potential overpayment is received. Providers and suppliers should therefore take investigative action as soon as possible upon receipt of credible information regarding a potential overpayment.

Develop an investigation plan that can be completed within six months, including time required to calculate the overpayment amount. Conduct the investigation from start to finish. Interruptions may be interpreted as an absence of reasonable diligence. Document investigation processes and any statistical sampling and extrapolation methods used in determining overpayment amount. Lack of
sufficient documentation can be the foundation of overpayment liability.

In the event that an overpayment has not occurred, document the evidence leading to this conclusion and the reasoning behind choosing not to report.

**Report and return all overpayments**

Confirm and implement the appropriate procedures for reporting and returning any Medicare overpayments. Ensure that your final rule compliance program educates staff members on the proper paths and procedures to follow when reporting overpayments.

The final rule went into effect on March 14, 2016. All providers and suppliers reporting and returning overpayments on or after March 14, 2016 are subject to the new requirements. This includes overpayments received prior to March 14, 2016.

**Conclusion**

CMS’s recent publication of its final rule clarifying the 60-day rule will undeniably spark an interest among whistleblowers aware of potential overpayments to file *qui tam* FCA claims. The provisions of the final rule should serve as a guide in enacting compliance policies, investigating potential overpayments, and reporting and returning overpayments in a timely manner to avoid FCA liability. Medicare providers and suppliers should familiarize themselves and educate staff on the final rule regulations and recognize their responsibilities in discovering, investigating, and reporting overpayments to ensure compliance success. 🌟

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2. 42 CFR 401.301 – 305; 401.607
4. Social Security Act § 1128J(d)
5. 31 U.S.C. § 3729, et. seq
7. Ibid, Ref #1
8. 42 C.F.R. § 401.303.