In a significant development for healthcare providers, the Centers for Medicare & Medicaid Services (CMS) has released its long-awaited final rule detailing Medicare and Medicaid providers’ and suppliers’ responsibilities to report and return identified overpayments. The Final Rule was promulgated under the 2010 Patient Protection and Affordable Care Act’s statutory provisions creating the so-called 60-day rule, which governs when an “identified” overpayment must be repaid to the government before it becomes subject to federal False Claims Act (FCA) liability. The Final Rule is scheduled for official publication in the Federal Register today and a pre-publication PDF is also available on the Federal Register’s website.

The 60-day rule requires anyone who has received an overpayment from Medicare or Medicaid to report and return the overpayment within the latter of (1) 60 days after the date on which the overpayment was identified and (2) the due date of a corresponding cost report (if any). Those who fail to timely report and return an identified overpayment may be subject to substantial liability under the FCA.

Since 2010, healthcare providers and suppliers have been awaiting clarification about a number of aspects of the 60-day rule, including what it means to have “identified” an overpayment for purposes of starting the 60-day...
clock, what affirmative obligations an organization has once it becomes aware of a potential overpayment, and how far a provider or supplier must “lookback” when investigating and quantifying a potential overpayment.

CMS’s new guidance clarifies that an overpayment has not been “identified” under the 60-day rule until a provider has or should have, through “reasonable diligence,” quantified the overpayment. CMS’s new interpretation comes just months after a federal judge in New York sided with government attorneys and found that the government had sufficiently asserted a provider’s failure to exercise reasonable diligence in *Kane v. Continuum Health Partners, Inc.* Read more about the *Kane* decision here. CMS’s interpretation of “identified” endorses a common-sense understanding promoted by many in the industry: as long as a provider diligently pursues quantifying an overpayment once a potential issue is identified, then it should not be deemed to have an “identified” overpayment pending the results of those efforts.

Along the same lines as the *Kane* decision (where the court found that more than a year had passed before the provider made concerted efforts to address credible information of a potential overpayment – and ultimately only did so in the face of a regulatory investigation), CMS was also clear that diligent pursuit does not mean indefinite pursuit. In its commentary, CMS establishes that the completion of such reasonable diligence should take no more than 6 months from receipt of the credible information, absent extraordinary circumstances – which CMS states may include “unusually complex investigations” such as those involving self-referral violations that are referred to the CMS Self-Referral Disclosure Protocol.

In another favorable move for providers and suppliers, CMS also clarified that the 60-day rule applies only to overpayments identified within 6 years after they were received. In its proposed rule, published in 2012, CMS suggested a 10-year “lookback” period for potential overpayments. CMS reduced the lookback period to 6 years in order to avoid imposing unreasonable burdens or costs on providers and suppliers. Notably, CMS clarified that overpayments reported and/or repaid before the effective date of the Final Rule (30 days from today) are not subject to the Final Rule, which means they will only be subject to the 4 year lookback CMS previously gave through informal published guidance.

In terms of a provider or supplier’s duty to conduct reasonable diligence to determine if there has been an overpayment, CMS has adopted a “credible information” standard. If a provider or supplier receives “credible information” of a potential overpayment, it may not rely on the “ostrich defense” or it may be deemed to have acted in deliberate ignorance of the overpayment and could be held liable under the FCA. What constitutes “credible information” is a fact-specific inquiry.

The Final Rule also states that providers and suppliers may use an applicable claims adjustment, credit balance, self-reported refund, or other appropriate existing process to satisfy the reporting and repayment obligations.

CMS’s guidance is a reminder that providers should use reasonable diligence to identify, report, and repay overpayments to avoid government scrutiny and significant FCA liability. Once providers learn they may have received an overpayment from the government, they should act promptly and diligently to best position themselves to avoid FCA liability.

**Key takeaways for providers and suppliers**

- It is important to **promptly evaluate any information** regarding a potential overpayment to determine whether the information is credible.
- If a determination is made that the information is not credible, **document the work done** to reach that conclusion and why it was deemed not to be credible.
- If the information is credible or potentially credible, **promptly begin an inquiry** and outline what reasonable diligence is needed to determine: (i) whether an overpayment may exist; and (ii) if there is an overpayment, how to accurately and efficiently quantify it.
- Carefully **document the diligence performed**, the scope of the inquiry, and the methodology used to quantify the overpayment, understanding that a 6-year lookback period will apply to any overpayments reported or repaid on or after March 13, 2016. It may be necessary to seek objective counsel for guidance through the process and validation that the inquiry was sufficient and conducted in good faith.

Find out more about the implications of the 60-day rule by contacting the authors.