

Raising *Kane*: CMS's 60-Day Rule Commands More Than Treble Damages



Frank Sheeder and **Wade Miller** are partners and **Kimyatta McClary** is a senior associate in Alston & Bird's Health Care Litigation Group, where they represent a variety of health care providers defending against civil and criminal fraud allegations brought by federal and state agencies involving the False Claims Act, whistleblower actions, and government investigations.

In August 2015, we published a client advisory¹ on the first judicial opinion interpreting the Affordable Care Act's (ACA's) "60-day overpayment rule," which requires providers to "report and return" an overpayment of Medicare or Medicaid funds to the appropriate government body within 60 days "after the date on which the overpayment was identified." *U.S. ex rel. Kane v. Healthfirst Inc., et al.*, No. 11 CIV 2325 (S.D.N.Y. Aug. 3, 2015); 42 U.S.C. § 1320a-7k(d)(1)–(3).² Since then, the Centers for Medicare & Medicaid Services (CMS) has issued a Final Rule relating to reporting and returning identified overpayments. Failure to follow this rule can subject a provider to the provisions of the federal False Claims Act (FCA).

The *Kane* decision was particularly noteworthy because it was the first to address what it means to "identify" an overpayment and to potentially define the bounds of the 60-day repayment rule under the FCA. The court ruled that "identification" of overpayments, which triggers the 60-day repayment obligation, occurs when a company is put "on notice" of potential overpayments, rejecting the provider's argument that "identified" means when the overpayment is "known with certainty."

Now a year later, Mount Sinai Health System, one of the defendants in the *Kane* litigation, has agreed to pay \$3 million to resolve allegations it violated the FCA by failing to report and return Medicaid overpayments within 60 days of when it identified them. This marks the first settlement to resolve FCA liability under the 60-day rule. The settlement was more than triple the nearly \$850,000 principal amount that Mount Sinai's hospitals repaid after learning about the inadvertent double-billing of Medicaid.

In *Kane*, the federal district court interpreted the 60-day rule in the same way that CMS previously interpreted the ACA provision in its Proposed Rule on

overpayments for Part A and B providers. The decision likely provided support for CMS to move forward with the issuance of the final overpayments rule in February of this year; it took effect in March.

The CMS Final Rule provides further clarity on what it means to “identify” and defines “identification” as when a person “has or should have, through the exercise of reasonable diligence,” determined and quantified the amount of the overpayment. This definition resolves the ambiguity in the Proposed Rule about whether the time spent investigating the amount of a potential overpayment would toll the 60-day clock or count toward the 60 days.

While the Final Rule is relatively short, it is preceded by a 200-page preamble that gives insight into CMS's positions on some key issues. First, it says that “reasonable diligence” includes “both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment.” In light of this, CMS could challenge a provider's diligence by alleging that it did not have an effective compliance program. Second, CMS has stated that the 60-day period begins when reasonable diligence is completed or the provider received credible information about the potential overpayment but failed to conduct reasonable diligence. Such diligence includes identifying and quantifying the overpayment. Third, there are limits to the diligence period. CMS has set six months as the standard for timely

investigation, which provides for a total of eight months between the receipt of notice and the reporting and return of any overpayment. Fourth, the look-back period for potential overpayments is six years, which is more favorable than the 10-year period in the previous proposed rule.

The recent first-of-its-kind settlement in the *Kane* litigation and CMS's Final Rule confirm that the failure to report and return overpayments is, and will continue to be, a focus for government enforcers. In order to maintain proactive compliance, it is vitally important that providers diligently and promptly conduct investigations into any potential overpayments. Notably, federal enforcement agencies appear to view credit balances attributable to federal health care program patients for any reason, including the Medicare Secondary Payer rule and duplicate payments, as potential overpayments that are subject to these standards. Therefore, it would be prudent for providers to review both their potential overpayments procedures and the documentation of their compliance efforts. Providers that do not have efficient and effective processes for preventing, identifying, quantifying, reporting, and returning overpayments with dispatch now face heightened risks under the FCA.

Endnotes:

1. www.alston.com/advisories/liability-under-false-claims
2. Under the False Claims Act (FCA), any provider that knowingly fails to report and return an overpayment within the 60-day time period is in violation of the FCA's reverse false claims act provision and may be liable for a penalty between \$5,500 to \$11,000 for each false claim, treble damages and other remedies.