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an interview with Janie McKinney

Compliance Coordinator & IRB Coordinator
Washington Regional Medical Center

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by Harry R. Silver

The *Kane* decision: A flawed interpretation of the 60-day rule

» *Kane v. Healthfirst, Inc.* is the first decision by any court to interpret the meaning of the word "identified" as used in the 60-day rule.

» In *Kane*, the court ruled that the 60-day clock starts ticking when a provider receives notice of a possible overpayment.

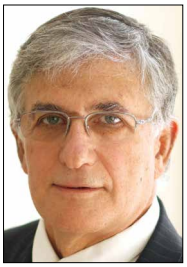
» The decision was a ruling on a procedural motion, not on the merits.

» The court's analysis of the issue is flawed and its definition of "identified" is by no means definitive and should not be treated as the final word on the issue.

» In reaching its decision, the court ignored CMS's proposed regulations, which provide the only guidance from the government on the meaning of the word "identified" in the 60-day rule.

Harry R. Silver *(hsilver@potomaclaw.com is Of Counsel at the Potomac Law Group, PLLC in Washington, DC.*

As anyone involved in healthcare compliance is undoubtedly aware, the Affordable Care Act (ACA) requires providers (and suppliers) to report and return any overcharges to Medicare or Medicaid within 60 days after such overpayments have been "identified." Because the ACA does not define "identified," it is far from clear exactly when this 60-day time period commences. Because a failure to meet the 60-day deadline constitutes a violation of the federal False Claims Act, a wrong guess about when the 60 days begins can have severe consequences. As anyone who has grappled with the identification and quantification of overcharges knows, this is not a simple matter.



Silver

First, every regulatory violation does not necessarily result in an overpayment. More to the point, however, when confronted with a credit balance, a provider must determine the source or sources of the credit balance and the amount attributable to each payer, including whether Medicare was primary, secondary, or tertiary. In many cases, this task is virtually impossible to complete within 60 days. That is why a definition of the term "identify," which marks the beginning of the 60-day period, is so badly needed.

On August 3, 2015, the United States District Court for the Southern District of New York became the first court to attempt to define "identify." In *Kane v. Healthfirst, Inc.*,[1] the court acknowledged the practical problems inherent in identifying and quantifying an overpayment. Nevertheless, the court determined that an overpayment has been identified when a provider receives information indicating that there is the possibility of an overpayment. The government and whistleblowers are likely to view the *Kane* decision as the definitive interpretation of the meaning of the word "identified." For the reasons discussed in this article, the court's analysis of the issue is flawed and its definition of "identified" is by no means definitive and should not be treated as the final word on the issue.

Because the 60-day rule is part of a series of amendments to the False Claims Act (FCA), most recently by the ACA, any discussion of the *Kane* decision should begin with a brief summary of the FCA and its various amendments.

The False Claims Act

A violation of the FCA typically consists of "knowingly" presenting a false or fraudulent claim for payment or approval.[2] Any person who is found to have violated the FCA is liable for a civil penalty of $5,500–$11,000 per claim, plus treble damages. This can result in healthcare providers facing potential liability in the hundreds of millions of dollars.

The terms "knowing" and "knowingly" are defined as "actual knowledge" that a false claim has been submitted, "deliberate ignorance" of the truth or falsity of the claim, or "reckless disregard" of the truth or falsity of the claim.

The FCA allows an action to be initiated by either the United States or by a private citizen, who is entitled to up to 30% of any recovery.[3] Actions initiated by private citizens (relators) are called *qui tam* actions.

The FCA was initially enacted in 1863, and was substantially amended in 1943, and in 1986. Although the FCA had been aimed at fraud by government contractors, it increasingly focused on healthcare fraud after the 1986 amendments.

The FERA and ACA amendments to the FCA

In May 2009, the FCA was amended as part of the Fraud Enforcement and Recovery Act of 2009 (FERA) in an effort to prevent fraud in connection with federal stimulus funds. The FCA was amended again in 2010 as part of the ACA.

One of the 2009 FERA amendments to the FCA was the expansion of the so-called "reverse false claims" provision, which made the avoidance of an "obligation" to pay money to the government an FCA violation.[4] The 2009 amendment made the avoidance of an obligation to pay the government a violation of the FCA, even if the avoidance of the obligation did not result from the submission of a false record or statement.

Following up on the FERA amendment, in 2010 the ACA made additional substantive changes to the reverse false claims provision by (1) requiring any person who has received an overpayment to return it, and report the reason for the overpayment to the payer within 60 days after the overpayment has been identified; and (2) defining the retention of an overpayment after 60 days as an obligation for purposes of the reverse false claims provision.[5]

Because the ACA failed to define several critical terms, such as "identified," it is far from clear when the 60 days start running. In what was hoped to be a clarification of the statutory language, on February 14, 2012, the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, published proposed regulations. CMS proposed to define an overpayment as being identified when a person has "actual knowledge of the existence of an overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment." The 60-day clock does not start running (i.e., an overpayment is not identified) until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of a suspected overpayment. The receipt of information, by a provider or supplier, about a possible overcharge creates a duty to conduct this reasonable inquiry promptly ("with all deliberate speed"). A failure to do so may be found to constitute reckless disregard or deliberate ignorance of the overpayment under the FCA.[6]

Although the proposed regulations remain just that, and CMS has deferred the issuance of final regulations until February 16, 2016,[7] the statutory duty to report and refund overpayments within 60 days remains in effect and exposes providers and suppliers to civil false claims liability.

Factual background

This recitation of the facts is taken from the court's decision. Because the court was ruling on a motion to dismiss, the court relied largely on the allegations of the plaintiffs.

The *Kane* case involved three hospitals in New York City (the hospitals), which were members of a hospital network operated by Continuum Health Partners Inc. (Continuum). The hospitals belonged to the Healthfirst Medicaid managed care network. Under its contract with New York Medicaid, Healthfirst provides covered services to enrollees in its Medicaid managed care program in exchange for a monthly payment from the New York Department of Health (DOH). Healthfirst is limited to this monthly payment and may not bill for any additional amount.

Healthfirst issues computer-generated electronic remittance statements to its participating providers indicating the amount of payment due for services rendered by the provider. The remittance statements contain codes indicating whether the provider can seek additional payment from any secondary payer. Beginning in 2009, an error in the software that generates the remittance statements resulted in remittances that erroneously contained the code authorizing providers to seek payment from secondary payers. As a result, claims were submitted to DOH on behalf of the hospitals for additional payment to which the hospitals were not entitled. DOH compounded the error by paying many of these claims.

In September 2010, state auditors raised questions regarding these erroneously paid claims and the software error was soon discovered. The software vendor furnished a corrective patch within three months.

Continuum assigned one of its employees, Robert Kane, to identify the claims containing the erroneous billing code. In February 2011, Kane sent an email to Continuum management, attaching a spreadsheet that identified more than 900 claims that contained the erroneous billing code, and advising management that further analysis was required to confirm that the 900 claims were, in fact, improper. Four days after sending the email, Kane's employment was terminated by Continuum. It was subsequently determined that approximately 50% of the claims identified by Kane did not result in an overpayment. Shortly after his termination, Kane initiated a *qui tam* action under the FCA. After investigating, both the United States and New York State intervened in the action, and the United States took over its prosecution. (For the sake of simplicity, Kane, DOH, and the United States shall collectively be referred to as "the government.")

The government alleged that, while Continuum commenced repayment of the overcharges in April 2011, the overpayments were not repaid in full until March 2013, thus demonstrating that Continuum fraudulently delayed repayment for two years after knowing the extent of the overpayments. Indeed, the government alleged that Kane's email and spreadsheet identified overpayments within the meaning of the 60-day rule, thus triggering the duty to report and return them within 60 days. The government further alleged that, rather than fulfilling its obligation, Continuum never even advised the New York State auditors of the existence and the content of Kane's analysis. Thus, according to the government, the hospitals, Healthfirst, and Continuum (the defendants) violated the FCA by "intentionally or recklessly" failing to take the necessary steps to identify the claims erroneously filed and to repay the overpayments in a timely manner.

The court's ruling

The defendants filed a motion to dismiss the complaint, contending that Kane's email and spreadsheet only provided notice of *potential* overpayments, and that this alone is not sufficient to trigger the commencement of the 60-day clock. The defendants argued that "identified" means "classified with certainty," while the government contended that "identified" means being put on notice that a claim *may* have been overpaid.

Because the term "identified" had not been defined in the ACA, and because *Kane* was the first case to raise the issue of the meaning of "identified," the court examined the "plain meaning" of the ACA, the legislative history of the ACA and the FCA, the policies underlying the 60-day rule, and the manner in which CMS has interpreted "identified" for purposes of the 60-day rule. The court did not consider the agency's interpretation to be worth much, if any, weight, but it did mention that CMS's regulations interpreting the 60-day rule for purposes of Medicare Parts C and D supported the government. While noting the existence of the more relevant proposed regulations interpreting the 60-day rule for purposes of Medicare Parts A and B, the court simply concluded that they contemplated the adoption of "the same definition of 'identified' that was adopted for Medicare Parts C and D."[8] In so doing, the court failed to recognize that the definition of "identified" in the adopted regulations for Parts C and D is not the same as the proposed definition for Parts A and B. The court also failed to recognize that the reimbursement mechanisms for Part C organizations and Part D sponsors are not the same as those for Part A and B providers.[9] Thus, contrary to the proposed regulations, the court concluded:

> To define "identified" such that the 60-day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained, is compatible with the legislative history of the FCA [as amended by FERA].[10]

The court acknowledged that this interpretation can impose a demanding, or even unworkable, burden on providers. According to the court, even if a provider undertook an internal audit immediately upon receiving notice of a possible overpayment, advised the government on the 60th day that it had not yet identified and returned every overpayment, on the 61st day that provider would be in violation of the 60-day rule and the FCA because "[t]he ACA itself contains no language to temper or qualify this unforgiving rule; it nowhere requires the Government to grant more leeway or more time to a provider who fails timely to return an overpayment but acts with reasonable diligence in an attempt to do so." To ameliorate this harsh result, the court would rely on "prosecutorial discretion" to preclude the initiation of an enforcement action "[w]hich would be inconsistent with the spirit of the law and would be unlikely to succeed."[11] Of course, such prosecutorial discretion would not inhibit a *qui tam* relator, such as Kane, from initiating an action.

On the other hand, the court stated that if Kane's email did not "identify" overpayments, the government would have no recourse if a provider did nothing to investigate information about possible overpayments, such as the information provided by Kane. The court stated:

> It would be an absurd result to construe this robust anti-fraud scheme as permitting willful ignorance to delay the formulation of an obligation to repay the government money that it is due.… Therefore, while the Government's interpretation would impose a stringent—and, in certain cases, potentially unworkable—burden on providers, Defendants' interpretation would produce absurd results.[12]

Implications of the *Kane* Decision

In *Kane,* the court defined the identification of an overpayment, for purposes of commencing the 60-day clock, as the time a provider is put on notice of a *potential* overpayment. This should not be taken as the final, definitive word on the subject for several reasons.

First, the court was deciding a motion to dismiss, which is a procedural pretrial ruling—not

a decision on the merits of the case. As such, it is not the court's final ruling on the issue, and is certainly not binding precedent in any court.

Second, to the extent the court's ruling is governing law anywhere, it is limited to the Southern District of New York, the federal judicial district in which it was decided, which covers Manhattan, the Bronx, and six upstate counties in New York State (i.e., Westchester, Rockland, Orange, Putnam, Sullivan, and Dutchess).

Finally, and perhaps most importantly, CMS's proposed regulations applicable to Medicare Parts A and B, state that a provider's receipt of information concerning a potential overpayment creates a duty to undertake a reasonable inquiry, "with all deliberate speed," to determine whether an overpayment has, in fact, been received. An overpayment has not been identified unless and until the reasonable inquiry has determined that an overpayment has been received. It is only then that the 60-day clock starts to run. The final regulations applicable to Parts C and D are not inconsistent with this.[13] In ruling that the language of the ACA does not permit the extension of the deadline for reporting and returning overpayments beyond 60 days after the receipt of information about a possible overpayment, the court unnecessarily rejected CMS's interpretation.

Conclusion

To violate the FCA, a defendant must be found to have acted with actual knowledge, reckless disregard, or deliberate ignorance of a false claim. A provider that, in good faith, conducts a prompt and thorough examination of a possible overpayment, but does complete it within 60 days, simply cannot be acting with the requisite knowledge, reckless disregard, or deliberate ignorance for FCA liability. The proposed regulations provide the only guidance from the government on the meaning of "identified" for purposes of determining when the 60-day clock starts to run.

The definition of "identified" in the *Kane* decision is an unworkable one because, in many cases, it is virtually impossible report and return overpayments within 60 days of receiving information that there *may* be overpayments. Because it is just this sort of situation that the proposed regulations were intended to address, the court did not have to interpret the meaning of "identified" in a manner that can leave many well-meaning providers subject to FCA liability. It certainly did not have to issue such a harsh ruling in order to decide the case because, if the allegations made by the government in the *Kane* case are proven, the defendants would be liable under the standard set forth in the proposed regulations.

The inevitable question remains: How can a provider protect itself given the absence of a clear definition of "identified." Although this should not, under any circumstance, be considered legal advice, I have advised clients who have been notified of possible overcharges to immediately undertake an investigation as contemplated by the proposed regulations. This investigation can involve legal counsel and/or accountants. A memo to file should then be prepared specifying the date on which the information was initially received, the nature of the information, the steps undertaken to initiate an investigation, and the date on which the steps were taken. The memo should also include a notation that these actions have been taken in reliance on the guidance provided in the proposed regulations. The progress made, and the status of the investigation, should be documented in a monthly updated memo to file.

1. 2015 WL 4619686
2. 31 U.S.C. §729 (a).
3. 31 U.S.C. §3730 (b), (d).
4. 31 U.S.C. §3729 (g).
5. 42 U.S.C. §1320a-7k (d)(3).
6. 77 Fed. Reg. 9179,9182 (Feb. 16, 2012).
7. 80 Fed. Reg. 8247 (Feb. 17, 2015).
8. 2015 WL 4619686 at *15-16.
9. 79 Fed. Reg. 29844, 29920-29924 (May 23, 2014).
10. 2015 WL 4619686. at *11.
11. *Id.* at *13 (emphasis added).
12. *Id.* at 13-14.
13. See 42 C.F.R. §422.326