

## The 60-Day Rule and the *Healthfirst* Case

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## Introduction

Since its major overhaul in the 1980s and again in 2009 and 2010, the False Claims Act (FCA)<sup>1</sup> has progressively extended its reach to cover more conduct and impose liability under more circumstances, particularly in the health care industry. A relatively recent and important development in the life of the FCA began in 2010 when Congress created the “60-Day Rule” as part of the Affordable Care Act (ACA).<sup>2</sup> This rule extends FCA liability to health care providers who fail to report and return overpayments within 60 days of identification if that overpayment came from a federal health program, such as Medicare or Medicaid.

Though the rule has been in existence since the 2010 enactment of the ACA, several ambiguities related to application of the 60-Day Rule have left providers and health care attorneys with little, to no, practical guidance on complying with the rule. The most significant area of uncertainty is what it means for a provider to “identify” an overpayment so as to trigger the 60-day deadline. Although the Centers for Medicare & Medicaid Services (CMS) has issued some proposed guidance on this and other issues related to application of the 60-Day Rule, providers and health care attorneys have for the most part been left to their own interpretations. This is partly because, although CMS issued its proposed rule implementing the 60-Day Rule in 2012, CMS has yet to finalize that rule as applied to Medicare Parts A and B.<sup>3</sup> Having no sources for definitive guidance, many health care providers and attorneys anxiously awaited the first court decision involving application of the 60-Day Rule in the *Healthfirst* case.<sup>4</sup> Unfortunately, as discussed below, the *Healthfirst* decision did not resolve all existing ambiguities and, therefore, the contours of the 60-Day Rule still remain somewhat unclear.

*Healthfirst* is an FCA qui tam action originally filed in 2011 in the Southern District of New York, and is the first case in which the federal government intervened in an action based on an alleged violation of the 60-Day Rule. On August 3, 2015, U.S. District

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<sup>1</sup> 31 U.S.C. § 3729 *et seq.*

<sup>2</sup> 42 U.S.C. § 1320a-7k(d).

<sup>3</sup> 80 Fed. Reg. 8247 (Feb. 17, 2015).

<sup>4</sup> *United States ex rel. Kane et al. v. Healthfirst, Inc., et al.*, Case No. 1:11-cv-02325, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015).

Judge Edgardo Ramos issued a ruling denying the *Healthfirst* defendants' motion to dismiss and permitting the government's FCA case to move forward into discovery.<sup>5</sup> Because Ramos' decision represents the first judicial interpretation of the 60-Day Rule, the decision will likely serve as persuasive authority to other courts in similar cases and may even influence the final rule that CMS ultimately promulgates.

This Member Briefing will briefly discuss the relevant statutory scheme including the FCA, the reverse false claims provision, and the 60-Day Rule itself. The Member Briefing also will address the court's decision in *Healthfirst* in detail, as well as a recent FCA settlement involving another 60-Day Rule case, followed by a discussion of the future of the 60-Day Rule and its application post-*Healthfirst*.

## **Background**

### ***The False Claims Act in Brief***

The FCA is one of the government's chief weapons to investigate and punish allegations of health care fraud and abuse. FCA actions can be brought directly by the government or by private whistleblowers on behalf of the government through "qui tam" actions. Congress originally passed the FCA in 1863 to protect the Union's war chest from contractors who sold subpar goods to the Union Army during the Civil War.<sup>6</sup> Though Congress passed the FCA against the backdrop of protecting government funds during war, from its beginning, the FCA has broadly aimed to punish any manner of fraud against the federal government.

The FCA creates liability for, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval; knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; or conspiring to do those things.<sup>7</sup> A person acts with knowledge under

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<sup>5</sup> *Id.*

<sup>6</sup> Available at [www.justice.gov/opa/pr/justice-department-celebrates-25th-anniversary-false-claims-act-amendments-1986](http://www.justice.gov/opa/pr/justice-department-celebrates-25th-anniversary-false-claims-act-amendments-1986).

<sup>7</sup> 31 U.S.C. § 3729(a)(1).

the FCA if that person has actual knowledge, or acts in deliberate ignorance or reckless disregard for the truth or falsity of the information.<sup>8</sup>

### ***The Reverse False Claims Provision of the FCA***

The “reverse false claims” provision of the FCA is a relatively recent development in the life of the FCA. That provision establishes liability for any person who “knowingly conceals or knowingly and improperly avoids or decreases *an obligation* to pay or transmit money or property to the government.”<sup>9</sup> The FCA expressly defines “obligation” to include “the retention of any overpayment.”<sup>10</sup> As with the other types of conduct prohibited by the FCA, a violation of the reverse false claims provision, including the retention of an overpayment, carries with it the threat of treble damages and per-claim penalties.<sup>11</sup>

The original reverse false claims provision was added to the FCA in 1986, although that version was significantly narrower than the provision that exists today. In 2009, Congress broadened the reverse false claims provision as part of the Fraud Enforcement and Recovery Act (FERA).<sup>12</sup> FERA amended the FCA to expressly provide that the retention of an overpayment created an obligation that could expose individuals and entities to FCA liability.<sup>13</sup>

### ***The 60-Day Rule***

In 2010, Congress raised the stakes even higher by creating the 60-Day Rule as part of the ACA.<sup>14</sup> As discussed above, the 60-Day Rule requires a person to report and return any overpayment within 60 days from the date the overpayment is identified, or the date

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<sup>8</sup> *Id.* § 3729(b)(1).

<sup>9</sup> *Id.* § 3729(a)(1)(G) (emphasis added).

<sup>10</sup> *Id.* § 3729(b)(3).

<sup>11</sup> *Id.* § 3729(a)(1).

<sup>12</sup> Pub. L. No. 111-21, 123 Stat. 1617.

<sup>13</sup> 31 U.S.C. § 3729(a)(1)(G).

<sup>14</sup> 42 U.S.C. § 1320a-7k(d).

when a corresponding report is due.<sup>15</sup> The 60-Day Rule makes clear that “[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation” for purposes of the FCA.<sup>16</sup> The rule broadly defines “overpayment” as “any funds that a person receives or retains under [the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled . . . .”<sup>17</sup> Thus, even providers that receive overpayments completely innocently (as was the case in *Healthfirst*) will be liable under the FCA if they do not report and refund the overpayments within 60 days.

CMS issued its proposed rule implementing the 60-Day Rule for purposes of Medicare Part A and B overpayments on February 16, 2012.<sup>18</sup> The comment period for that proposed rule closed in April 2012, and the proposal was due to be finalized no later than February 16, 2015—three years after the initial proposal.<sup>19</sup> However, on February 17, 2015, CMS extended the timeline for publication of its final rule by one year—until February 16, 2016—noting that “[b]ased on both public comments received and internal stakeholder feedback . . . there are significant policy and operational issues that need to be resolved in order to address all of the issues raised by comments to the proposed rule and to ensure appropriate coordination with other government agencies.”<sup>20</sup>

Importantly, however, the lack of a finalized rule from CMS does not diminish the statutory efficacy of the 60-Day Rule. As CMS expressly stated in its 2015 notice, “even without a final regulation [stakeholders] are subject to the statutory requirements found in [the ACA] and could face potential FCA liability, Civil Monetary Penalties, and exclusion from Federal health care programs for failure to report and return an overpayment.”<sup>21</sup> The threat of significant FCA liability for violating a rule, the contours of which have not been defined by CMS, has understandably left many health care providers and their attorneys with significant concerns.

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<sup>15</sup> *Id.* § 1320a-7k(d)(1)–(2).

<sup>16</sup> *Id.* § 1320a-7k(d)(3).

<sup>17</sup> *Id.* § 1320a-7k(d)(4)(B).

<sup>18</sup> 77 Fed. Reg. 9184 (Feb. 16, 2012).

<sup>19</sup> 80 Fed. Reg. 8247 (Feb. 17, 2015).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 8248.

## Recent Application of the 60-Day Rule

### *The Healthfirst Case*

#### *Factual and Procedural Background*

The hospital defendants in *Healthfirst* contracted with a Managed Care Organization to issue electronic remittances that contained codes indicating whether the hospitals could seek additional payment from secondary payers such as Medicaid.<sup>22</sup> According to the government's complaint, beginning in 2009 as the result of a software glitch, the remittances contained coding that erroneously indicated that the hospitals could seek additional payment from a secondary payer where such additional payments were, in reality, not allowed.<sup>23</sup> The result was that the hospitals' electronic billing programs automatically generated bills to secondary payers, including Medicaid, where no secondary billing was appropriate.<sup>24</sup> Nothing in the government's complaint alleges, or even implies, that the hospitals were in any way at fault for the initial erroneous billing.

According to the government's complaint, in September 2010 auditors from the New York Comptroller's office questioned the hospitals regarding a small number of claims that it concluded had been improperly submitted to the New York State Department of Health (DOH) for Medicaid reimbursement.<sup>25</sup> Subsequent discussions between the Comptroller, the hospitals, and the software vendor revealed the cause of the problem, and the software vendor sent out a corrective software patch in early December 2010.<sup>26</sup>

After the problem was discovered, hospital management asked Robert Kane (a hospital employee) to ascertain which claims had been improperly submitted to Medicaid as a result of the software error.<sup>27</sup> On February 4, 2011, Kane emailed a spreadsheet to hospital management which contained more than 900 claims (totaling more than \$1

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<sup>22</sup> Complaint-In-Intervention, *United States v. Continuum Health Partners, Inc., et al.*, Civil Action No. 11-2325, at ¶¶ 29-30 (S.D.N.Y. June 27, 2014).

<sup>23</sup> *Id.* at ¶ 31.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at ¶ 33.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at ¶ 34.

million) that Kane identified as containing the erroneous billing code.<sup>28</sup> According to the government's complaint, "[w]hile Kane's email indicated that further analysis was needed to corroborate his findings, Kane had successfully identified the vast majority of claims that had been erroneously billed."<sup>29</sup> Four days later, the hospitals terminated Kane's employment and, according to the government, "did nothing further with Kane's analysis or the claims identified therein."<sup>30</sup> That month, the hospitals reimbursed DOH for only five of the improperly submitted claims.<sup>31</sup>

Importantly, the government's complaint acknowledged that the hospitals began to reimburse DOH for some of the improperly billed claims.<sup>32</sup> However, the government alleged that the hospitals were "fraudulently delaying [their] repayments for up to two years" after they knew of the extent of the overpayments, and further noted that the hospitals reimbursed many of the affected claims only after receiving a Civil Investigative Demand from the U.S. Department of Justice (DOJ) seeking information.<sup>33</sup> The government alleged that the hospitals "intentionally or recklessly failed to take the necessary steps to timely identify the claims affected by the software issue or to timely reimburse DOH for those affected claims that resulted in overbilling to Medicaid."<sup>34</sup> The sole count in the government's complaint in intervention was for violation of the FCA's reverse false claims provision and the 60-Day Rule.<sup>35</sup>

The defendants filed a motion to dismiss in September 2014 in which they argued that Kane's February 4 email did not create an "obligation" under the FCA because it did not "identify" any overpayments as required to trigger the 60-Day Rule.<sup>36</sup> According to the defendants, the spreadsheet attached to the February 4 email simply identified a universe of claims that were "potentially affected" by the computer glitch "without

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<sup>28</sup> *Id.* at ¶ 35.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at ¶ 36.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at ¶ 38.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at ¶ 39.

<sup>35</sup> *Id.* at ¶¶ 40-42.

<sup>36</sup> Memorandum of Law in Support of Defendants' Motion to Dismiss, Civil Action No. 11-2325 (S.D.N.Y. Sept. 22, 2014), Doc. No. 55, at p. 9.

indicating whether those claims were billed or paid to the government.”<sup>37</sup> In fact, as the defendants noted, a later analysis revealed that approximately one half of the claims on Kane’s email list were not billed or paid, thereby not creating an overpayment.<sup>38</sup>

According to the defendants, the statutory scheme and legislative history of the 60-Day Rule demonstrate “that a preliminary report like Kane’s that only identifies potential overpayments (as opposed to actual confirmed overpayments) does not start the 60-day clock to establish an ‘obligation’ under the statute.”<sup>39</sup>

The defendants also pointed out the “enormous burden” that the 60-Day Rule would impose on health care providers if the government’s interpretation was adopted.<sup>40</sup> Specifically, the defendants discussed the numerous steps that most health care providers would have to take after receiving notice of a potential overpayment, including reviewing the appropriate medical records, conducting an internal investigation, consulting with coding staff and possibly with legal counsel, and making arrangements to return the overpayments.<sup>41</sup>

### *The Court’s Analysis*

The court’s ruling on the defendants’ motion to dismiss depended on whether the government properly pleaded that the defendants had an “obligation” under the FCA’s reverse false claims provision—a determination that was in turn dependent on how the court defined the word “identified” as used in the 60-Day Rule and whether Kane’s February 2011 email created an obligation to report and refund.<sup>42</sup> The defendants argued that “identified” should be understood as “classified with certainty.”<sup>43</sup> The government argued, on the other hand, that the meaning of “identified” should include

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<sup>37</sup> *Id.* at p. 1.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* (emphasis in original).

<sup>40</sup> *Id.* at p. 9.

<sup>41</sup> *Id.* at pp. 10-11.

<sup>42</sup> *Healthfirst* at \*8

<sup>43</sup> *Id.*



situations where providers are put on notice that they potentially received an overpayment, as was the case in *Healthfirst*.<sup>44</sup>

#### *-Dictionary Definitions-*

Because Congress did not define the term “identified,” the court in *Healthfirst* looked to outside sources for guidance. The court first looked at various dictionary definitions and noted that the term’s common definition could be “susceptible to more than one meaning.”<sup>45</sup> Among the range of options, the court found it compelling that one dictionary listed “recognize” as a synonym of “identify” because, according to the court, “[Kane] did ‘recognize’ nearly five hundred claims that did in fact turn out to have been overpaid” in his emailed spreadsheet.<sup>46</sup>

#### *-Legislative History of “Identified”-*

Having found no single plain meaning of “identified,” the court then looked to the canons of statutory construction, starting with the legislative history of the 60-Day Rule.<sup>47</sup> The defendants noted that the original House version of the ACA containing the 60-Day Rule used the term “known” instead of “identified,” and that “known” was later changed to “identified” in the Senate version of the bill.<sup>48</sup> The defendants argued that this change signified Congress’ desire to impose a higher standard to trigger the 60-day clock.<sup>49</sup> The defendants cited *INS v. Cardoza-Fonseca*<sup>50</sup> in support of the proposition that “a word should not be interpreted to carry the same meaning as a word that, during the legislative process, was rejected in favor of the ambiguous term.”<sup>51</sup>

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<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at \*9.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at \*9-10.

<sup>48</sup> *Id.* at \*10.

<sup>49</sup> *Id.*

<sup>50</sup> 480 U.S. 421 (1987).

<sup>51</sup> *Healthfirst* at \*11.

Although the court agreed that the legislative change was significant, it ultimately found that the legislative record did not provide a definitive explanation for that change. The court explained that it was more plausible that “Congress intended for ‘identified’ to carry a slightly different meaning from ‘known’ that comports with the second dictionary definition of ‘identify’ . . . i.e. ‘pointed out’ or ‘recognized (as).”<sup>52</sup> The court noted that defining “identified” such that the 60-day clock begins to run when a provider is “put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained,” was compatible with the legislative history of the FCA.<sup>53</sup> The court further noted that this definition was compatible with the legislative history of FERA, which defined “obligation” as “an established duty, *whether or not fixed*, arising . . . from the retention of an overpayment.”<sup>54</sup> The court cited a Senate Judiciary Committee report on the FERA bill stating that an obligation under the FCA “arises across the spectrum of possibilities from the fixed amount debt obligation where all particulars are defined to the instance where there is a relationship between the Government and a person that ‘results in a duty to pay the Government money, whether or not the amount owed is yet fixed.’”<sup>55</sup>

#### *-Avoiding Absurdity-*

The court then looked to see if such a statutory construction would produce absurd results.<sup>56</sup> Although the court agreed that its interpretation did amount to a “demanding standard,” it did not find the result to be absurd.<sup>57</sup> The court noted that, under the government’s proposed definition:

an overpayment would technically qualify as an “obligation” even where a provider receives an email like Kane’s, struggles to conduct an internal

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<sup>52</sup> *Id.* In accepting this reading of “identified,” however, the court failed to address that the terms “point out” and “recognize” are themselves subjective descriptions that do little to clarify what it means to “identify” an overpayment under the 60-Day Rule.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* (quoting 31 U.S.C. § 3729(b)(3) (emphasis in original)).

<sup>55</sup> *Id.* (quoting S. Rep. No. 111-10, at 14 (2009), *reprinted at* 2009 U.S.C.C.A.N. 430, 441).

<sup>56</sup> *Id.* at \*12.

<sup>57</sup> *Id.* at \*13.

audit, and reports its efforts to the Government within the sixty-day window, but has yet to isolate and return all overpayments sixty-one days after being put on notice of potential overpayments.<sup>58</sup>

While the court acknowledged the high burden that this standard would put on providers, the court noted that the ACA “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.”<sup>59</sup>

Importantly, however, the court emphasized that while such claims might qualify as “obligations,” “the mere existence of an ‘obligation’ does not establish a violation of the FCA.”<sup>60</sup> Instead, the court noted that a provider only faces liability under the reverse false claims provision when an obligation is “knowingly concealed or knowingly and improperly avoided or decreased.”<sup>61</sup> “Therefore, prosecutorial discretion would counsel against the institution of enforcement actions aimed at well-intentioned healthcare providers working with reasonable haste to address erroneous overpayments. Such actions would be inconsistent with the spirit of the law and would be unlikely to succeed.”<sup>62</sup> The court noted that while the government’s position would lead to burdensome results, the defendants’ interpretation “would make it all but impossible to enforce the reverse false claims provision of the FCA in the arena of healthcare fraud.”<sup>63</sup> The court went on to find that “[i]t would be an absurd result to construe this robust anti-fraud scheme as permitting willful ignorance to delay the formation of an obligation to repay the government money that it is due.”<sup>64</sup>

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* (emphasis omitted).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

*-Legislative Purpose-*

The court then looked to legislative purpose to support its interpretation, noting that “[t]he absurdity of Defendants’ proposed reading is all the more striking against the backdrop of Congress’s purpose in passing the FCA, amending it through the FERA, and incorporation, in the ACA, a mandate to report and return Medicaid overpayments.”<sup>65</sup> The court noted that the 1986 amendments to the FCA “sought to loosen restrictive judicial interpretation of the Act’s liability standard . . .”<sup>66</sup> Similarly, in passing FERA, Congress noted that the FCA’s effectiveness had “recently been undermined by court decisions limiting the scope of the law . . .”<sup>67</sup> “Each time Congress has weighed in on the purpose and power of the FCA,” the court noted, “it has endorsed a reading of that statute as a robust, remedial measure aimed at combatting fraud against the federal government as firmly as possible.”<sup>68</sup>

Finally, the court noted that, in creating the 60-Day Rule, “Congress intentionally placed the onus on providers, rather than the Government, to quickly address overpayments and return any wrongly collected money.”<sup>69</sup> Based on the court’s understanding of the legislative purpose of the FCA, FERA, and the ACA, the court noted that the defendants’ proposed reading of the 60-Day Rule “would frustrate Congress’s intention to subject willful ignorance of Medicaid overpayments to the FCA’s stringent penalty scheme.”<sup>70</sup>

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<sup>65</sup> *Id.* at \*14.

<sup>66</sup> *Id.* (citations omitted).

<sup>67</sup> *Id.* (citations omitted).

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at \*15.

*-Agency Interpretations-*

The court also looked to CMS' final rule implementing the 60-Day Rule with respect to Medicare Parts C and D as persuasive authority.<sup>71</sup> In that final rule, CMS explained that an "identified overpayment" exists "when the entity has determined, or should have determined through the exercise of reasonable diligence, that it has received an overpayment."<sup>72</sup> CMS explained that "reasonable diligence might require an investigation conducted in good faith and in a timely manner by qualified individuals in response to credible information of a potential overpayment."<sup>73</sup> The court noted that, in response to those commenters who urged that "identify" be defined to require "actual knowledge," CMS observed that such a rule would permit organizations to "easily avoid returning improperly received payments,' thus defeating the purpose of that section of the ACA."<sup>74</sup> The court noted that this was consistent with CMS' 2012 proposed rule for Medicare Part A and B, although it noted that, as a proposal, it was not entitled to any formal deference.<sup>75</sup>

*-Healthfirst Recap-*

Pursuant to *Healthfirst*, an overpayment has been "identified" for purposes of the 60-Day Rule when a provider is put on notice of a potential overpayment, even if the exact contours of that overpayment are yet to be determined.<sup>76</sup> The rule is "unforgiving" in that it does not require the government to grant more leeway or more time to a provider who fails to return an overpayment within 60 days, but acts with reasonable diligence in an attempt to do so.<sup>77</sup> Instead, where a provider has identified (or through the exercise of

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<sup>71</sup> *Id.* The court noted that although this rule did not technically apply in the Medicaid context, "its logic plainly does." *Id.* at \*16.

<sup>72</sup> *Id.* at \*15 (alterations omitted) (citing 42 C.F.R. §§ 422.326(c), 423.360(c)).

<sup>73</sup> *Id.* (citing 79 Fed. Reg. 29923-24 (May 23, 2014)).

<sup>74</sup> *Id.* (citing 79 Fed. Reg. at 29,924).

<sup>75</sup> *Id.* at \*16. The court in *Healthfirst* went on to hold that the government properly alleged that the defendants knowingly "concealed" or knowingly and improperly "avoided" or "decreased" an obligation (*id.* at \*17), and that the defendants had an obligation with regard to the federal (as opposed to state) government. *Id.* at \*19.

<sup>76</sup> *Id.* at \*11.

<sup>77</sup> *Id.* at \*13.

reasonable diligence should have identified) a potential overpayment but that overpayment is not reported and refunded within 60 days, the provider has likely improperly avoided an obligation and violated the FCA.

### ***Pediatric Services of America Settlement***

Although *Healthfirst* is the first (and to date only) judicial decision analyzing the 60-Day Rule, there has been at least one settlement involving the rule. On August 4, 2015 (the day after the *Healthfirst* decision), DOJ announced that it had reached a nearly \$7 million settlement with Pediatric Services of America Healthcare Inc., Pediatric Healthcare Inc., and Pediatric Home Nursing Services (collectively, PSA).<sup>78</sup> According to the government's press release, the settlement resolved allegations that PSA, among other things, knowingly failed to disclose and return overpayments:

PSA had been maintaining numerous credit balances on its books that related to claims it had submitted to various federal health care programs, some of which had been on PSA's books for several years. Additionally PSA wrote off and absorbed credit balances that had resulted from overpayments into their revenue because they had not investigated the reason for the credit balances before doing so.<sup>79</sup>

According to DOJ, this was the first settlement under the FCA involving a health care provider's "failure to investigate credit balances on its books to determine whether they resulted from overpayments made by a federal health care program."<sup>80</sup>

### **Takeaways and Future Outlook of the 60-Day Rule**

Both the *Healthfirst* decision and the PSA settlement highlight the need for health care providers to immediately investigate and, if necessary, quickly report and return, any

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<sup>78</sup> Available at [www.justice.gov/usao-sdga/pr/pediatric-services-america-and-related-entities-pay-\\$6.88-million-resolve-false-claims](http://www.justice.gov/usao-sdga/pr/pediatric-services-america-and-related-entities-pay-$6.88-million-resolve-false-claims).

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

potential overpayments received from federal health care programs, even if the provider was blameless in receiving the overpayment in the first place. However, even where the provider promptly initiates an internal investigation into potential overpayments, but takes longer than 60 days to report and refund, the provider may be found to have violated the 60-Day Rule and, therefore, the FCA, despite its good-faith attempt at compliance. Although Judge Ramos opined that this problem might be avoided by the exercise of “prosecutorial discretion,”<sup>81</sup> there is nothing in the rule or any interpretative guidance that would prevent such an application.

Although the *Healthfirst* decision is not binding outside of the Southern District of New York, because it is the first decision on the topic, it will likely be viewed as persuasive by future courts. The decision is also likely to influence the contours of CMS’ final rule when that rule is ultimately issued, likely in 2016. If CMS’ final rule does follow the court’s reasoning in *Healthfirst*, future courts would likely give deference to that agency interpretation, thereby even further solidifying Ramos’ (and the government’s) strict interpretation.

Even after *Healthfirst*, however, there are important and concerning uncertainties related to the application of the 60-Day Rule. For example, *Healthfirst* indicates that the 60-Day Rule is triggered where a provider identifies an overpayment, or should have done so “through the exercise of reasonable diligence.”<sup>82</sup> What remains unclear is what it means for a provider to exercise “reasonable diligence.” On that topic, CMS’ 2012 proposed rule provides:

In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the

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<sup>81</sup> 2015 WL 4619686, at \*13.

<sup>82</sup> *Id.* at \*15.

provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment.<sup>83</sup>

Even this language, however, leaves significant ambiguity as to what it means to make a “reasonable inquiry” or act “with all deliberate speed.” These ambiguities will remain in existence until another court, or CMS in its final rule, provides more definitive guidance. Further, there is no guarantee that other courts will agree with the *Healthfirst* decision. The possibility of a split in authority would leave health care providers and their attorneys in continued limbo regarding application of the 60-Day Rule until the issue worked its way through the federal court system, which could be a very slow process.

Until the exact contours of the 60-Day Rule are established—whether through further federal court litigation, congressional clarification, or through CMS’ eventual final rule—it is imperative for health care providers and their attorneys to work extremely quickly to identify the full extent of, and fully report and refund, any overpayments to Medicare or Medicaid at the first sign of a potential overpayment. Even where an internal investigation or audit is still ongoing and the exact parameters of the overpayment are yet to be determined, providers and their attorneys would likely benefit from alerting the government to the issue and ensuring the government that a report and refund will be forthcoming as soon as possible. Although, as discussed by Judge Ramos, this would technically not absolve a violation of the 60-Day Rule, it would make it significantly less likely that DOJ would pursue an FCA case in such circumstances.

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<sup>83</sup> 77 Fed. Reg. at 9182.



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