

**CLIENT  
Alert**

**April 16, 2010**

**RECENT HEALTH CARE AND FALSE CLAIMS ACT DEVELOPMENTS**

On March 23, 2010 President Obama signed into law the Patient Protection and Affordable Care Act (the “PPACA”),<sup>1</sup> and a week later the President signed a second law which amended the PPACA, the Health Care and Education Reconciliation Act of 2010 (the “Reconciliation Act”).<sup>2</sup> These new laws affect not only health care providers, but all companies contracting with the federal government.

Together, the PPACA and the Reconciliation Act (collectively, the “Health Reform Law”) contain provisions designed to expand access to health insurance coverage; improve the quality and efficiency of health care; prevent chronic disease and improve public health; increase, support and strengthen the health care workforce; promote transparency and program integrity; improve access to innovative medical therapies; and impose new taxes and fees on health industry sectors.

This Client Alert focuses particularly on the provisions of the Health Reform Law that are designed to promote transparency and the integrity of the Medicare and Medicaid programs. The impact of most of these provisions primarily will be sustained by providers and suppliers in the health care industry, though others also will share some of the impact, particularly due to certain changes to the False Claims Act (the “FCA”).<sup>3</sup> This Client Alert first outlines how the Health Reform Law may affect providers and suppliers in the health care industry and then addresses its impact on those outside of the health care industry.

**Provisions Aimed at Health Care Providers and Suppliers***Health Care Anti-Kickback Statute*

The Health Reform Law confirms that a claim submitted for health care items or services which violates the criminal health care fraud laws<sup>4</sup> (including, without limitation, the Anti-Kickback Statute (“AKS”)<sup>5</sup>) constitutes a false or fraudulent claim for purposes of the FCA.<sup>6</sup> While numerous

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<sup>1</sup> H.R. 3590, Public Law No. 111-148.

<sup>2</sup> H.R. 4872, Public Law No. 111-152.

<sup>3</sup> See 31 U.S.C. § 3729-3733.

<sup>4</sup> See 42 U.S.C. § 1320a-7b.

<sup>5</sup> See 42 U.S.C. § 1320a-7b(b).

<sup>6</sup> PPACA, § 6032(b)(1).

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cases have previously adopted this position,<sup>7</sup> the Health Reform Law makes this principle clear by including explicit language in the statutory text.

In addition, the Health Reform Law also amends the AKS and the other criminal health care fraud laws to provide that a person need not have actual knowledge of the laws or specific intent to commit a violation.<sup>8</sup> However, rather than amending the existing intent provisions of the criminal health care fraud laws, the Health Reform Law adds a new paragraph stating that “a person need not have actual knowledge of this section or a specific intent to commit a violation of this section.”<sup>9</sup> Because courts have interpreted the existing intent provisions of the criminal health care fraud laws to require specific intent and because the Health Reform Law adds new language that appears to conflict with these court decisions, courts will now likely be called on to interpret this apparent conflict. By both declaring that specific intent language is not required, and by clarifying that a violation of the AKS may also constitute an FCA violation, these amendments likely will increase government prosecution and private litigation involving AKS violations.

#### *New Liability for Overpayment Retention*

The Health Reform Law makes three changes with respect to Medicare and Medicaid overpayments that are applicable to health care providers and suppliers.<sup>10</sup> First, the Health Reform Law requires the report and return of any Medicare or Medicaid overpayment within 60 days of when the overpayment is identified or when any corresponding cost report is due (as applicable).

Second, health care providers or suppliers who know of an overpayment and fail to return the overpayment are subject to civil monetary penalties of up to \$50,000.

Third, the Health Reform Law attempts to make the retention of an overpayment a violation of the FCA. As we noted in our June 3, 2009 Client Alert, available at [www.kutakrock.com](http://www.kutakrock.com), the Fraud Enforcement and Recovery Act (the “FERA”) redefined the term “obligation” in the FCA to include the “retention of any overpayment.” The Health Reform Law seeks to make the knowing retention of an overpayment beyond the 60-day report-return window a violation of the FCA.

#### *Mandatory Compliance Programs*

The Health Reform Law places new obligations on nursing homes (both nursing facilities and skilled nursing facilities) that require the nursing homes to have an effective compliance and ethics program adopted and operational within 36 months of enactment of the Health Reform Law. The program must be effective in preventing and detecting criminal, civil and administrative violations and in promoting quality care. The Secretary is required to issue regulations to implement this provision of the Health Reform Law and may include a model compliance program in the regulations.<sup>11</sup>

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<sup>7</sup> See, e.g., *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 245 (3d Cir. 2004).

<sup>8</sup> PPACA, § 6032(f)(2).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at § 6402(a).

<sup>11</sup> *Id.* at § 6012.



In addition, the Secretary, in consultation with the Office of Inspector General of the United States Department of Health and Human Services (the “OIG”) will require certain categories of providers and suppliers identified by the OIG and the Secretary to adopt a compliance program as a condition of their enrollment in Medicare. The details of this mandatory compliance program will be set forth in regulations issued by the Secretary.<sup>12</sup>

#### *Payment Suspension Pending Investigation and Other Significant Penalties*

The Health Reform Law provides authority for the Secretary to suspend Medicare or Medicaid payments to a provider or supplier *pending* an investigation of a credible allegation of fraud.<sup>13</sup> The Secretary is required to consult with the OIG to determine whether there is a credible allegation of fraud and to establish regulations to carry out this provision. Depending upon the regulations which will be developed, this provision has the potential to be a powerful tool for the government to use to force early settlement of cases given the significant impact suspension of payment would have on most providers.

In addition, the Health Reform Law provides the government with new weapons in its enforcement arsenal and enhances the weapons already available. For example, the Health Reform Law (i) sets forth new bases on which civil monetary penalties may be imposed,<sup>14</sup> (ii) increases the amount of civil monetary penalties that may be imposed for certain actions,<sup>15</sup> (iii) provides the government with new testimonial subpoena authority in exclusion actions,<sup>16</sup> and (iv) provides additional funding to fight fraud, waste and abuse in the Medicare and Medicaid programs.<sup>17</sup>

#### *Transparency Provisions*

The Health Reform Law contains a number of provisions designed to increase the transparency and accountability of providers and suppliers in the Medicare and Medicaid programs. These transparency provisions include, among others:

- Provisions designed to encourage greater transparency in the relationships between physicians and/or teaching hospitals and manufacturers of covered drugs, devices, or biological or medical supplies and between physicians and group purchasing organizations.<sup>18</sup>
- Provisions imposing transparency requirements on certain imaging services performed in a physician office setting,<sup>19</sup> prescription drug samples,<sup>20</sup> and pharmacy benefit managers.<sup>21</sup>

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<sup>12</sup> *Id.* at § 6401(a).

<sup>13</sup> *Id.* at § 6402(h).

<sup>14</sup> *Id.* at §§ 6402(d), 6408(a).

<sup>15</sup> PPACA, § 6408(a).

<sup>16</sup> *Id.* at § 6402(e).

<sup>17</sup> *Id.* at § 6402(i).

<sup>18</sup> *Id.* at § 6002.

<sup>19</sup> *Id.* at § 6003.

<sup>20</sup> *Id.* at § 6004.

<sup>21</sup> PPACA, § 6005.



- Provisions that expand the amount of information required to be disclosed by nursing homes enrolling in the Medicare program, including, among other information, information relating to (i) the facility’s organizational structure, (ii) additional information on officers, directors, trustees and managing employees of the nursing home, and (iii) information on any “additional disclosable party.” The term “additional disclosable party” is defined to mean any person that exercises operational, financial or managerial control over the nursing facility, provides policies or procedures for any of the operations of the facility, or provides financial or cash management services to the facility; any person that leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5% of the total value of such real property; or any person who provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.<sup>22</sup>
- Provisions requiring the registration of agents, clearinghouses or other alternate payees that submit claims on behalf of health care providers under the Medicare program with the State Medicaid agency and with the Secretary of the United States Department for Health and Human Services (the “Secretary”) in a manner specified by the Secretary.<sup>23</sup>
- Provisions requiring physicians who prescribe durable medical equipment or home health services to be enrolled in the Medicare program pursuant to regulations to be issued by the Secretary.<sup>24</sup>
- Provisions adding a new permissive exclusion provision for false statements provided on enrollment applications and subjecting individuals who make false statements on applications or contracts to participate in a federal health care program to civil monetary penalties of up to \$50,000.<sup>25</sup>

*New Stark Self-Disclosure Protocol and Nursing Home Self-Disclosure Protocol*

The Health Reform Law requires the Secretary, in consultation with the OIG, to develop a self-disclosure protocol (“SDP”) within six months of its enactment to allow health care providers to voluntarily report potential violations of the Stark physician self-referral law.<sup>26</sup> The Health Reform Law also explicitly provides the Secretary with authority to negotiate settlements of Stark law violations for less than the full value of the affected claims. Specifically, the Secretary may consider (i) the nature and extent of the improper or illegal practice, (ii) the timeliness of the self-disclosure, (iii) the provider’s cooperation in providing additional information related to the self-disclosure, and (iv) such other factors that the Secretary considers appropriate.

Additionally, the Health Reform Law provides the Secretary with authority to provide up to a 50% reduction in civil monetary penalties to be imposed against a nursing home for noncompliance with program requirements if the nursing home self-reports and promptly corrects the deficiency

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<sup>22</sup> *Id.* at § 6101(a).

<sup>23</sup> *Id.* at § 6503.

<sup>24</sup> *Id.* at § 6405.

<sup>25</sup> *Id.* at § 6402(d).

<sup>26</sup> *Id.* at § 6409.



within 10 calendar days.<sup>27</sup> However, note that reductions will not be made for more than one self-reported deficiency per year for self-reported deficiencies that result in a pattern of harm or widespread harm, that immediately jeopardize the health or safety of a resident or that result in the death of a resident.

#### *Other Provisions*

The Health Reform Law contains many other provisions that are designed to increase transparency and/or promote integrity within the Medicare and Medicaid programs. These include, without limitation:

- Provisions that provide for a nationwide program for national and state background checks on direct patient access employees of nursing homes and other providers;<sup>28</sup>
- Provisions that combine the information in the Healthcare Integrity and Protection Data Bank into the National Practitioner Data Bank in order to create a national health care fraud and abuse data collection program for reporting adverse actions taken against health care providers, suppliers and other practitioners;<sup>29</sup>
- Provisions that limit the maximum period of time for submission of Medicare claims to 12 months from the date of service and other provider screening and other enrollment requirements under Medicare and Medicaid;<sup>30</sup>
- Provisions that place a requirement on a physician to provide documentation on referrals to programs at high risk of waste and abuse (including referrals for durable medical equipment and certifications for home health services);<sup>31</sup>
- Provisions that require either a physician or certain other practitioners have a face-to-face encounter with a Medicare or Medicaid patient prior to issuing a certificate for home health services, providing a written order to a patient for durable medical equipment, or referring a patient for certain other services;<sup>32</sup>
- Provisions that expand the Recovery Audit Contractor (or RAC) Program to Medicaid, Medicare Part C and Medicare Part D;<sup>33</sup> and
- Provisions providing for a 90-day period of enhanced oversight for initial claims of durable medical equipment suppliers.<sup>34</sup>

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<sup>27</sup> PPACA, § 6111.

<sup>28</sup> *Id.* at § 6401(a)-(b).

<sup>29</sup> *Id.* at § 6403.

<sup>30</sup> *Id.* at § 6404.

<sup>31</sup> *Id.* at § 6406.

<sup>32</sup> *Id.* at § 6407.

<sup>33</sup> PPACA, § 6411.

<sup>34</sup> Reconciliation Act, § 1304.

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## Provisions That Affect Government Contractors and Health Care Providers

### *Erosion of the Public Disclosure Bar*

Before the enactment of the PPACA, the FCA prohibited a court from retaining jurisdiction over a *qui tam* FCA claim if the claim was based on a public disclosure. The public disclosure bar serves to prevent relator's from "free-riding" off investigations by the government or the news media. The PPACA significantly lowers the public disclosure bar in several key ways. First, the Justice Department now has the ability to prevent the dismissal of a relator's *qui tam* claim based on a public disclosure. It is unclear at this time how the government will exercise its discretion in this area, but given that it has the option to intervene at any time, it would rarely make sense to permit the dismissal of a case when the potential exists for a favorable verdict or settlement.

Second, the revised public disclosure bar no longer deprives the courts of subject-matter jurisdiction, but has been reduced to simply one of the many defenses which may be asserted by the defendant. As a result, defendants may no longer be able to file motions under FRCP 12(b)(1) to dismiss and limit discovery solely to the jurisdictional issue (i.e., whether there has been a public disclosure). Instead, because parties will likely dispute the circumstances surrounding the alleged public disclosure, courts likely will be unable to decide the issue until much later in the litigation.

Finally, the PPACA reverses prior judicial decisions which held that a *qui tam* suit based on information obtained from state and local government investigations and reports was prohibited by the public disclosure bar. The PPACA reverses those decisions and limits the public disclosure bar to investigations and reports by the *federal* government and the news media.

### *Expanded Original Source Exception*

In addition to revising the public disclosure bar, the PPACA has also revised the "original source" exemption. The new "original source" definition will permit a whistleblower to bring an FCA claim even if there has been an earlier public disclosure, so long as the whistleblower has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). The amendment removes the requirement that an "original source" have "direct" knowledge of the information on which the FCA claims are based. The revised language appears to significantly broaden the original source exemption and may result in a larger number of whistleblower suits.



## Prior False Claims Act and Federal Acquisition Rule Developments for Government Contractors (2009)<sup>35</sup>

The most significant recent developments in the law affecting government contractors arise under the False Claims Act (the “FCA”)<sup>36</sup> and Federal Acquisition Regulations (the “FAR”).<sup>37</sup> On May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act (the “FERA”), a significant overhaul of the FCA.<sup>38</sup> In light of the amendments to the FCA, government contractors should also be aware of case law providing guidance regarding viable defenses to actions brought under the FCA. Finally, government contractors should analyze major changes to legally required regulatory compliance programs and new *mandatory* reporting requirements.

### I. False Claims Act Expansion Under the FERA

The False Claims Act has long been a primary tool used by government prosecutors to pursue government contractors, health care providers, and others suspected of submitting false claims for payment to the United States. Indeed, the Department of Justice (“DOJ”) announced it had recovered \$2.4 billion in civil FCA cases in 2009 alone.<sup>39</sup> Nearly \$2.0 billion of that amount derived from claims first brought under the *qui tam*, or whistleblower provisions of the FCA. As described below, the FERA enhances this already formidable prosecutorial weapon.

The FERA not only increases the types of conduct which prosecutors and whistleblowers may attack, but will likely add to the costs of litigating or resolving health care and other fraud cases, including “mere” overpayment matters.<sup>40</sup> Government contractors should carefully analyze the FERA’s effect on existing compliance programs and repayment strategies and should redouble their efforts to avoid the long reach of this powerful enforcement tool.

The FERA markedly expands the reach of the FCA and greatly strengthens the government’s already formidable weapons to combat health care and other program fraud. Under the new law, government contractors, health care providers and others now may face severe penalties for the knowing retention of government overpayments even though the provider or contractor made no false or improper claim for such payments. The FERA also overturned last year’s Supreme Court decision, *Allison Engine Co. v. United States ex rel. Sanders*,<sup>41</sup> now making the FCA apply even if a false claim

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<sup>35</sup> The below developments described below were reported in Kutak Rock’s June 3 Client Alert and are repeated here for convenience.

<sup>36</sup> False Claims Act of 1863, ch. 67, 12 Stat. 696 (1863), 31 U.S.C. § 3729-3733 (amended by Pub. L. 111-21, 123 Stat. 1621).

<sup>37</sup> Federal Acquisition Regulation, FAR Case 2007-006, Contractor Business Ethics Compliance Program and Disclosure Requirements, 73 Fed. Reg. 67064 (Nov. 12, 2008) (codified at 48 C.F.R. pts. 2, 3, 9, 42 & 52).

<sup>38</sup> Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617.

<sup>39</sup> See Press Release, DOJ, Nov. 19, 2009 ([www.justice.gov](http://www.justice.gov)).

<sup>40</sup> See, e.g., *White House Press Release*, dated May 20, 2009 (“to ensure that the knowing retention of an overpayment is a violation”).

<sup>41</sup> *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008).



had *not* been submitted directly to the government. In addition, the FERA enhances whistleblowers' ability to investigate alleged FCA violations and provides them enhanced protections.

### A. Liability for Overpayments

Under the FERA, contractors may be liable for “knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the government.”<sup>42</sup> Defining “obligation” to include “an established duty . . . arising . . . from the *retention of any overpayment*”<sup>43</sup> from the government, prosecutors will likely interpret the FERA to apply to the “knowing” retention of excessive Medicaid, Medicare or other government payments.<sup>44</sup> Indeed, the government may contend that a contractor violates the FERA even without any affirmative fraudulent act, any false statement of record or any fraudulent intent to solicit an overpayment. However, under one provision, the FERA requires that the avoidance of an obligation may be actionable only if it is knowing and improper,<sup>45</sup> which arguably limits contractor liability in the overpayment arena. At this early stage, it is impossible to predict with certainty how courts will apply these important terms in the new law.<sup>46</sup>

### B. Overturning Supreme Court Limitations

In 2008, the Supreme Court decided *Allison Engine Co. v. United States ex rel. Sanders*, which limited FCA liability to situations where a claimant intentionally submitted false claims for payment *directly* to the government. However, the FERA reverses the rule adopted in *Allison Engine Co.* by removing the language in the FCA on which the Supreme Court relied to limit corporate liability.<sup>47</sup> And though the Supreme Court determined that FCA liability would be “boundless,” without a clear

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<sup>42</sup> 31 U.S.C. § 3729(a)(1)(G). Furthermore, Section 3729(a)(1)(D) could also result in liability for the retention of overpayments: “[Any person who] has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property [is liable].” Fines for Section 3729(a) violations include \$5,500 to \$11,000 per violation plus three times the amount of damages which the Government sustains resulting from the false claim.

<sup>43</sup> 31 U.S.C. § 3729(b)(3).

<sup>44</sup> Under the FERA, a “claim” includes “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property [that is presented to the government (or its contractors if the money is to be spent on the government’s behalf)].”

<sup>45</sup> See 31 U.S.C. § 3729(a)(1)(G) (“knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government . . . or knowingly and *improperly* avoids or decreases an obligation to pay or transmit money or property to the Government”) (emphasis added).

<sup>46</sup> For example, if courts determine that § 3729(a)(1)(D) applies to the retention of overpayments, rather than § 3729(a)(1)(G), the former section has no “improperly” modifier; the mere “possession, custody, or control” of overpayments would subject an entity to FCA liability.

<sup>47</sup> Specifically, the FERA redacts the phrase “to get” from 31 U.S.C. § 3729(a), which the Supreme Court relied upon in *Allison Engine Co.*: “‘To get’ denotes purpose, and thus a person must have the purpose of getting a false or fraudulent claim ‘paid or approved by the Government’ in order to be liable under § 3729(a)(2).” *Allison Engine Co.*, 128 S. Ct. at 2130. Furthermore, Congress made § 3729(a)(1)(B) effective as of June 7, 2008, the date of the *Allison Engine Co.* decision. Congress may have intended to apply the new definition of “claim” retroactively to conduct occurring since June 7, 2008—a proposition that raises constitutional questions. As discussed *infra*, several courts, however, have refused to apply the FERA Amendments to claims arising prior to May 20, 2009.



link between a false claim and payment by the government, Congress eliminated the requirement for such a link.<sup>48</sup>

### C. FCA Investigations

The FERA now allows the Attorney General or his designee to disclose any information gathered through the Civil Investigative Demand (“CID”) process with any whistleblower (qui tam relator) at the discretion of the Attorney General or designee.<sup>49</sup> Whistleblower investigations against health care entities may now proceed more quickly and with better access to government-obtained evidence. Because the FERA amended the FCA to allow for the collection of litigation expenses (in addition to the imposition of fines and treble damages required under the FCA), unsuccessful defendants may incur greater expense for their FERA violations.

### D. Expansion of Whistleblower Protections

The FERA extends broad protection to whistleblowers, defining “retaliation” as conduct directed not only against employees, but also against contractors and agents. The FERA thus eliminates the requirement that an employment relationship exist to safeguard a whistleblower.<sup>50</sup> Health care entities and government contractors should proceed with even greater caution after an FCA claim has been made or threatened by an employee, contractor or agent.

## II. Other Developments in FCA Case Law

Although the FCA underwent significant expansion under the FERA, government contractors should be aware of case law providing guidance regarding several defenses against FCA claims, which in particular may assist government contractors in defending against frivolous suits brought by qui tam relators. We set forth below a sampling of legal defenses which may apply to FCA actions filed against contractors and health care providers.

### A. Pleading with Specificity Under Rule 9(b)

Complaints alleging violations of the FCA must comply with the special pleading requirements of Federal Rule of Civil Procedure Rule 9(b).<sup>51</sup> Accordingly, a complaint under the FCA must plead such facts as the time, place and content of the defendant’s false representations, as well as the details of the defendant’s fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.<sup>52</sup>

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<sup>48</sup> In addition, the FERA expands the definition of “claims” to include not only requests for money to the government, but also to requests to any “contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest” if the United States will be providing or reimbursing any of the requested money. See 31 U.S.C. § 3729(a)(1)(G) and (b)(2)(A)(ii).

<sup>49</sup> 31 U.S.C. § 3733(a)(1).

<sup>50</sup> 31 U.S.C. § 3730(h).

<sup>51</sup> See, e.g., *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003).

<sup>52</sup> See, e.g., *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009).



In the Eighth Circuit, claims under the False Claims Act must meet the specific pleading requirements of Rule 9(b), or face immediate dismissal. For example, in *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*,<sup>53</sup> the relator alleged that a hospital submitted false claims for Medicare and Medicaid reimbursement for a physician's anesthesia services and that the physician had conspired with the hospital in a scheme to defraud the government. The Eighth Circuit Court of Appeals dismissed the allegations pursuant to Rule 9(b) because the relator failed to allege the details of any false claim with particularity:

Absent from the complaint is any mention of . . . *who was involved* in the fraudulent billing aspect of the conspiracy, . . . *what services* were provided and to which patients the services were provided, . . . *what the content* was of the fraudulent claims, . . . *what dates* the defendants allegedly submitted the false claims to the government, . . . *what monies* were fraudulently obtained as a result of any transaction, or how [relator] Joshi, an anesthesiologist, learned of the alleged fraudulent claims and their submission for payment.<sup>54</sup>

The Eighth Circuit has also recently reaffirmed that allegations of a scheme to defraud the government alone will not be sufficient to plead an FCA claim. Instead, Rule 9(b) requires specific allegations regarding specific claims that were actually submitted to the government.<sup>55</sup>

## **B. Original Source/Subject-Matter Jurisdiction**

Under the FCA, the “public disclosure bar”<sup>56</sup> prohibits a court from exercising jurisdiction over an action based on public disclosure of the allegations or transactions in the suit, unless the plaintiff (called a “relator” in FCA cases) is an “original source” of the information and thus has “direct and independent knowledge of the information on which the allegations are based[.]”<sup>57</sup> Thus, if the complaint is based on public disclosure of the allegations and is not an original source, the court lacks subject-matter jurisdiction and the qui tam relator's FCA claim will be dismissed with prejudice. A relator's review of documents obtained by the government while case was pending under seal constitutes a “public disclosure.”<sup>58</sup>

This defense often may not be apparent from the face of the complaint and may require expedited discovery to ascertain whether the complaint is vulnerable to dismissal. Where allegations are made on “information and belief,” however, the relator may be basing the allegations on public information. The original source defense may be asserted at any time, including after an initial motion

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<sup>53</sup> 441 F.3d 552, 556 (8th Cir. 2006).

<sup>54</sup> *Id.* (emphasis added).

<sup>55</sup> *Hypoguard*, 559 F.3d at 822 (quoting *Joshi*, 441 F.3d at 556) (“FCA complaint ‘must provide some representative examples of [the] alleged fraudulent conduct’”).

<sup>56</sup> 31 § U.S.C. 3730(e)(4)(A).

<sup>57</sup> See *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007).

<sup>58</sup> *United States ex rel. Montgomery v. St. Edward Mercy Medical Center*, No. 05-CV-00899, 2007 WL 2904111, at \*9-11 (E.D. Ark. Sept. 28, 2007).

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to dismiss. Accordingly, such a defense may be reserved for potential use after completion of initial discovery in the event that a qui tam relator successfully overcomes the hurdles of Rule 9(b).

### C. Falsity

Under the FCA, relators must plead and prove that false claims were submitted to the government for payment. Case law supports findings of no liability where the alleged falsity depends on disputed interpretations of law, regulation, contracts or other instances in which there existed a lack of objective falsity.<sup>59</sup> Where disputed legal issues arise from vague provisions or regulations, a contractor's decision to take advantage of a position cannot result in his filing a "knowingly" false claim.<sup>60</sup> This principle helps protect government contractors making good-faith claims for payment from being surprised by FCA liability arising from a plaintiff's novel or overly restrictive interpretations of applicable rules.

### D. Presentment

The FCA requires that a claim be "presented" to the government. In 2008, the Supreme Court held in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008), that liability under 31 U.S.C. 3729(a)(2) may arise only when "the defendant intended that the false record or statement be material to the Government's decision to pay." *Id.* at 2126.

This defense may still be viable for alleged FCA violations that took place prior to enactment of the FERA on March 20, 2009. In Section 4(f)(1) of the FERA, Congress sought to apply the FERA amendments retroactively to all claims under the FCA pending as of June 7, 2008, two days prior to the *Allison Engine* decision. Nonetheless, several district courts have recently refused to apply the newly amended provisions of Section 3730(a)(1)(B) retroactively contending that the FERA's retroactivity provision violates the Ex Post Facto Clause of the Constitution.<sup>61</sup>

### E. False Certification Theory

The "false certification theory" is a wide-reaching theory that supports FCA liability for government contractors who falsely certify compliance with a federal regulation.<sup>62</sup> When an FCA

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<sup>59</sup> See, e.g., *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999) ("[I]mprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false under the FCA. . . . [T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute; violations of [agency] regulations are not fraud unless the violator knowingly lies to the government about them.").

<sup>60</sup> See *United States ex rel. Siewick v. Jamieson Sci & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000).

<sup>61</sup> See *United States ex rel. Sanders v. Allison Engine Co.*, 2009 WL 3626773 (S.D. Ohio Oct. 27, 2009); *United States v. Science Applications Int'l Corp.*, 2009 WL 2929250 (D.D.C. Sept. 14, 2009).

<sup>62</sup> See *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 605 (7th Cir. 2005). The Eighth Circuit has not yet addressed this theory, but it is widely accepted in most other circuits. See *United States ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008).



claim is based on a false certification theory of liability, a key defense is whether the certification concerned a “condition of participation” or a “condition of payment.”<sup>63</sup>

As the Tenth Circuit recently explained in *U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, “Conditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.”<sup>64</sup> Accordingly, a government contractor may incur FCA liability where it falsely certifies compliance with rules which are conditions of payment. On the other hand, if the false certification merely concerns a condition of participation in a government program (e.g., Medicare), the government contractor will not be subject to FCA liability. “Conditions of participation, as well as a provider’s certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program.”<sup>65</sup>

### III. Federal Contractor Regulations

New regulations applicable to federal contractors<sup>66</sup> contain two major requirements with which government contractors must be familiar: an ethics awareness and compliance program requirement and a *mandatory* reporting requirement.<sup>67</sup> The new federal acquisition regulations (“FAR”) apply to certain contracts valued at more than \$5 million and with a performance period greater than 120 days.

The FAR now requires government contractors to establish ethics awareness and compliance programs that include elements such as a written code of conduct, distribution of the code to all employees working on the contract, efforts to raise awareness of and promote compliance with the code, and an internal controls system designed to detect and respond to any improper conduct in connection with federal government contracts. The internal controls required do not appear to be a significant departure from the elements of an effective ethics and compliance program set forth in the U.S. Federal Sentencing Guidelines. However, this new rule now adds the risk of suspension and debarment to the list of collateral consequences associated with failing to have an effective ethics and compliance program.

The FAR now also permits suspension and debarment of government contractors who knowingly fail to timely disclose in writing:

- A violation of federal criminal law involving fraud, conflict of interest, bribery or gratuity violations;
- A violation of civil False Claims Act (31 U.S.C. §§ 3729-3733); or
- Significant overpayments on the contract.

<sup>63</sup> See *U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1219 (10th Cir. 2008).

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

<sup>65</sup> *Id.*

<sup>66</sup> Federal Acquisition Regulation, FAR Case 2007-006, Contractor Business Ethics Compliance Program and Disclosure Requirements, 73 Fed. Reg. 67064 (Nov. 12, 2008) (codified at 48 C.F.R. pts. 2, 3, 9, 42 & 52).

<sup>67</sup> See *Corporate Compliance Survey*, Business Lawyer, Nov. 2009.



If a principal<sup>68</sup> has “credible evidence”<sup>69</sup> of any of these offenses, the government contractor (or subcontractor) has an obligation to make a “timely”<sup>70</sup> report to the government or face possible suspension or debarment. The use of the term “credible evidence” is a change from the originally proposed “reasonable grounds to believe,” and the commentary discloses that this change “indicates a higher standard, implying that the contractor will have the opportunity to take some time for preliminary examination of the evidence to determine its credibility before deciding to disclose to the government.”<sup>71</sup> Adding that “[u]ntil the contractor has determined the evidence to be credible, there can be no ‘knowing failure to disclose’” and that “[t]his does not impose upon the contractor an obligation to carry out a complex investigation, but only to take reasonable steps that the contractor considers sufficient to determine that the evidence is credible.”<sup>72</sup> In light of the new reporting requirement, government contractors should take steps to raise awareness in the organization of this new requirement and develop a process for receiving, evaluating and, if appropriate, reporting covered offenses.

The above reporting obligation applies to active contracts and to any other contract the final payment on which was received *in the three years prior to the new rules*.<sup>73</sup> Thus government contractors will need to evaluate whether they have any reportable matters. Issues brought to the contractor’s attention prior to December 2005 for contracts not fully paid until after December 2005 will be subject to reporting requirements. For example, if a contractor is presently aware of an unreported False Claims Act violation from 2001 reported and resolved (without reporting) that same year as part of an Ethics Helpline report, but final payment on the contract was not received until 2007, the clock is now ticking on that contractor’s mandatory reporting obligation. Therefore, government contractors should consider conducting a review of internal compliance records to determine if there are any matters that may need to be reported now.

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<sup>68</sup> The rule defines “principals” as “an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager, plant manager, head of a subsidiary, division or business segment, and similar positions).” 48 C.F.R. § 2.101(b)(2). The commentary accompanying the new rule indicates that this definition should be construed broadly and may include compliance officers or directors of internal audit. 73 F.R. at 67079. This broad definition means that a supervisory-level employee’s knowledge will be imputed to the organization, whether or not it was reported through the proper internal channels.

<sup>69</sup> 48 C.F.R. § 3.1003(a)(2).

<sup>70</sup> *Id.*

<sup>71</sup> 73 F.R. at 67073.

<sup>72</sup> 73 F.R. at 67074.

<sup>73</sup> 48 C.F.R. §§ 9.406-2(b)(1)(vi), 9.407-2(a)(8), 52.203-13(c)(2)(ii)(F)(3); *see also* 73 F.R. at 67074.

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