

# APPLICATION OF THE FEDERAL FALSE CLAIMS ACT TO REGULATORY COMPLIANCE ISSUES IN THE HEALTH CARE INDUSTRY

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## I. INTRODUCTION

This Article addresses the propriety of applying the False Claims Act ("FCA") to enforce regulatory compliance for federally funded health care programs such as Medicare and Medicaid. Proponents of such use contend that providers explicitly and implicitly certify that they will comply with the applicable regulatory standards for the provision of quality of care as a condition of participation in and billing for federally funded healthcare programs. This theory suggests that providers are liable for the submission of false claims and false statements under the FCA when they are not in full compliance with the regulatory standards. The recent and heightened efforts by government and relator<sup>1</sup> counsel to use the FCA to punish regulatory noncompliance contradict the "well-established principle that the FCA is not a vehicle for regulatory compliance."<sup>2</sup>

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1. Relators are private persons or entities suing under the *qui tam* provisions of the FCA. 31 U.S.C. § 3730(b) (1994) (authorizing a private person to bring an action for a violation of the FCA on behalf of "the person and for the United States Government"). The phrase "*qui tam*" is short for "*qui tam pro domino rege quam pro seipso*," which means "he who as much for the king as for himself." JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 1-7 (1993 & Supp. 1999).

2. United States *ex rel.* Luckey v. Baxter Health Care Corp., 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998).

Numerous courts have made clear that the FCA cannot be used as a vehicle for enforcing all rules and norms.<sup>3</sup> Instead, read properly, the Act reaches only that fraud which is directly and explicitly linked to the filing of claims for reimbursement. The government has never made satisfaction of any particular standard of care a condition of payment for the federal health programs, and providers are not required to certify that the care for which they are seeking reimbursement has been provided in a manner consistent with any particular standard of care.<sup>4</sup> Accordingly, the FCA is not an appropriate tool in the fight against substandard care.

From a policy perspective, the FCA is a poor and unnecessary weapon against substandard care. It is a poor weapon because it is far too blunt and because it simply makes no sense for federal prosecutors, no matter how well intentioned or expert, to establish clinical care norms. It is unnecessary because an array of expert federal, state and private authorities are already responsible for monitoring quality of care concerns and, moreover, have recently demonstrated renewed energy toward improving quality of care.<sup>5</sup>

These issues are discussed in detail below. First, this Article addresses the origins and development of the FCA. Second, it sets forth the requirements for a claim under the FCA. Third, it lays out the complex and often non-specific regulatory environment in which federally funded health care programs operate. Fourth, it discusses how courts have responded, some favorably and some unfavorably, to attempts to use the FCA for the enforcement of regulatory compliance. Finally, it raises several policy reasons why the FCA should not be used to enforce compliance with quality of care regulations.

## II. ORIGINS AND DEVELOPMENT OF FCA AND *QUI TAM* PROVISIONS

The False Claims Act (in something akin to its current form) predates the federal government's large-scale entrance

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3. See *infra* pp. 20-52.

4. *Id.*

5. See *infra* pp. 53-54.

into the business of funding health care by over 100 years. The FCA was enacted in 1863, at the height of the Civil War.<sup>6</sup> Its adoption was prompted by alarming reports "of widespread corruption and fraud in the sale of supplies and provisions to the union government during the war."<sup>7</sup> "Testimony before the Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war."<sup>8</sup>

From its inception, the FCA contained a *qui tam* provision. While common law *qui tam* actions have been available since the founding of our country,<sup>9</sup> statutory *qui tam* actions are a relic of the Civil War. The *qui tam* provision in the FCA was designed to entice private individuals to come forward by offering a share of the money recovered.<sup>10</sup> In 1943, in the midst of World War II, Congress significantly revised the FCA to narrow both a *qui tam* relator's ability to bring suit and any potential bounty a relator was eligible to receive. The 1943 amendments provided, among other things, that if the government had prior knowledge of the allegations, the relator could not bring a lawsuit even if the relator had independent and direct knowledge of the factual matters underlying the allegations.<sup>11</sup> The amendments also reduced the award available to relators. As a result of the 1943 amendments, the number of *qui tam* actions declined.

In 1986, Congress again amended the FCA; this time, however, it expanded the scope of the FCA and the *qui tam* provisions. The 1986 amendments stemmed primarily from concern over "rising government fraud, especially in the areas of defense contracting and health care benefits."<sup>12</sup> The 1986 amendments

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6. *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1467 n.1 (9th Cir. 1996).

7. See 132 CONG. REC. 22, 335 (1986).

8. *United States v. McNinch*, 356 U.S. 595, 599 (1958).

9. *Qui tam* actions date back to 13th century England, where they provided private citizens, known as "relators," a way to gain access to royal courts. BOESE, CIVIL FALSE CLAIMS, *supra* note 1, § 1-7.

10. See 31 U.S.C. § 3730(d).

11. See *Sherr v. Anaconda Wire & Cable Co.*, 149 F.2d 680 (2d Cir. 1945).

12. *Hagood*, 81 F.3d at 1467 n.1 (citing S. REP. NO. 345, at 2-4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5267-69).

were designed to enhance a *qui tam* relator's ability to assist the government in investigating, detecting and litigating FCA suits. Congress required that any *qui tam* complaint be filed and sealed for at least 60 days, and it prohibited service of the complaint on the defendant until ordered by the court.<sup>13</sup> The 60-day seal period allows the government to review the relator's allegations, to assess their impact on any pending criminal investigation, and to prevent alerting potential criminal defendants of an investigation.<sup>14</sup> The 60-day seal period also gives the government time to decide whether to intervene and take over the action itself. If the government assumes the litigation, it may settle the case upon court approval, following a fairness hearing similar to that conducted in a class action suit, or the government may dismiss the action if the court has afforded the relator an opportunity to be heard on the issue.<sup>15</sup> Unless the government settles or dismisses the action, the relator may continue "unrestricted participation" in the litigation, provided that the government or the defendant does not demonstrate that the relator's continued participation is dilatory, harassing, repetitious, irrelevant or unduly expensive.<sup>16</sup> Further, even if the government intervenes, the relator may seek the court's permission to resume control of the litigation under certain circumstances if the government fails to act with "reasonable diligence" in prosecuting it.<sup>17</sup>

In the 1986 amendments, Congress expanded the potential bounty available to relators by increasing the bounty to a range of 15% to 25% of the recovery where the government intervened and to a range of 25% to 30% where the government declined to intervene.<sup>18</sup> Further, Congress enhanced the relator's potential recovery by raising the civil penalty to between \$5,000 and \$10,000 for any false statement and damages equal to a trebling of the amount of the government's loss.<sup>19</sup>

Finally, in 1986, Congress expanded the pool of individuals

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13. 31 U.S.C. § 3730(b)(2).

14. *Id.*

15. *Id.* § 3730(c)(2)(A)-(B).

16. *Id.* § 3730(c)(2)(C)-(D).

17. *Id.* § 3730(c)(4).

18. 31 U.S.C. § 3730(d)(1), (2).

19. *Id.* § 3729(a).

eligible to become *qui tam* relators by allowing a relator to bring a *qui tam* action even if information on the false claim was available to the government or was publicly disclosed, as long as the relator was the "original source" of the information.<sup>20</sup> Even where the relator was not the "original source" and the government had prior knowledge of the allegations, the FCA now provides that the relator may recover up to 10% of the proceeds of the litigation, depending upon the court's assessment of "the significance of the information and the role of the person bringing the action in advancing the case to litigation."<sup>21</sup>

The Supreme Court has provided little guidance on the scope of the Act. What guidance it has given has been ambiguous and, in any event, has yet to address the recent application of the FCA to health care quality of care regulations.

In 1958, the Supreme Court in *United States v. McNinch*<sup>22</sup> held that a bank's false application for credit insurance to the Federal Housing Administration—which had been caused by the defendant's false statements to the bank—was not a false claim.<sup>23</sup> The Court stated that the Act was designed to stop the type of "plundering of the public treasury" that occurred during the Civil War, but that it "was *not* designed to reach every kind of fraud practiced on the Government," including the fraud at

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20. *Id.* § 3730(e)(4). There has been much debate and wide conflict among the circuits regarding the definitions of "public disclosure" and "original source." *See, e.g., United States ex rel. Matthews v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999) (indicating that "disclosure to a public official with direct responsibility for the claim in question of allegations or transactions upon which a *qui tam* claim is based constitutes public disclosure within the meaning of [the FCA]"); *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1355 (4th Cir. 1994) (stating that "*qui tam* plaintiff need not be a source to the entity that publicly disclosed the allegations on which the *qui tam* action is based in order to be an original source"); *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992) (noting that "[p]ublic disclosure of the allegations divests district courts of jurisdiction over *qui tam* suits, regardless of where the relator obtained his information"); *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992) (stating that if allegations are publicly disclosed, then a court has no subject matter jurisdiction unless the relator "ha[s] a hand in the public disclosure of allegations"); *United States ex rel. Stinson v. Prudential Ins., Co.*, 944 F.2d 1149, 1161 (3d Cir. 1991) (noting that relators "may . . . qualify [as an original source] if their information results from their own investigations" even if similar information has been publicly disclosed).

21. 31 U.S.C. § 3730(d)(1).

22. 356 U.S. 595 (1958).

23. *McNinch*, 356 U.S. at 599.

issue in that case.<sup>24</sup>

Several years later, the Court, without overruling *McNinch*, reached a somewhat different conclusion in a very similar case.<sup>25</sup> In *Neifert-White*, the Court held that the FCA prohibited not only false claims made directly to the government (i.e., "legally enforceable" claims), but it also prohibited the submission of "false statement[s] [in the form of false loan applications to the Commodity Credit Corporation] made with the purpose and effect of inducing the Government immediately to part with money."<sup>26</sup> And, in language that is now widely quoted, the Court stated that "the [FCA] was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government,"<sup>27</sup> and that the FCA "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money."<sup>28</sup>

### III. CURRENT STATUTORY REQUIREMENTS FOR LIABILITY UNDER THE FCA

#### A. *The FCA Statute*

Liability under the FCA is predicated upon a violation of one or more of the seven subsections of the FCA.<sup>29</sup> The subsection most frequently relied upon by government and relator counsel is § 3729(a)(1), which is the false *claims* prong of the FCA.<sup>30</sup> This subsection provides that "[a]ny person who knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . . is liable to the United States Government."<sup>31</sup>

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24. *Id.* (emphasis added).

25. See *United States v. Neifert-White Co.*, 390 U.S. 228 (1968).

26. *Neifert-White*, 390 U.S. at 232.

27. *Id.*

28. *Id.* at 233.

29. 31 U.S.C. § 3729(a)(1)-(7) (1994).

30. BOESE, CIVIL FALSE CLAIMS, *supra* note 1, § 2-9.

31. 31 U.S.C. § 3729(a)(1).

This provision has been interpreted by courts as establishing five elements:

- (1) a claim;
- (2) submitted to the U.S. government;
- (3) which is false or fraudulent;
- (4) with sufficient knowledge by the defendant of the falsity of the claim; and
- (5) constituting a negative and direct effect on the federal treasury.<sup>32</sup>

Section 3729(a)(2), the false *statements* prong, is the other important substantive provision in the FCA. As discussed below, there are important differences between the false *claims* prong and the false *statements* prong. These differences, however, are often lost in court opinions that fail to draw any distinction between these two prongs. Consequently, opinions involving one prong often may apply, or have been applied, to allegations involving the other prong.

### *B. Definitional Issues under the False Claims Prong of the FCA*

Under the false claims prong of the FCA, the two most heavily litigated issues are whether the claim was “false” and whether the defendant had the requisite knowledge that the claim was false. Another important issue relates to the intent element under the FCA. An often ignored issue deals with whether “materiality” is an element under the false claim prong.

*1. Falsity.*—“Falsity” has at least two dimensions under the FCA. First, a claim may be false because it seeks reimbursement for services or goods not provided or for services or goods provided in a manner different from that described in the claim form.<sup>33</sup> Second, a claim may be false in light of relevant law or

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32. See BOESE, CIVIL FALSE CLAIMS, *supra* note 1, §§ 2-8 to -9 (stating that some courts have not required a negative financial impact on the federal government); John T. Boese, *An Overview of Recent Developments in the Enforcement of the Civil False Claims Act*, 1998 ABA, NAT'L INST. ON THE CIVIL FALSE CLAIMS ACT AND QUI TAM ENFORCEMENT B3 (1998) [hereinafter Boese, *Enforcement of the Civil False Claims Act*].

33. See *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1045 (N.D. Ill.

contract terms.<sup>34</sup> In the health care area, these two sources of falsity sometimes merge, usually with dire consequences for defendants. The first type of "falsity" is fairly characterized as factual falsity, viz, the claim either incorrectly describes the services or goods provided or seeks reimbursement for goods or services not provided.<sup>35</sup> In these cases, the claim may be considered to be intrinsically false. The initial FCA cases were ones involving allegations of factual or intrinsic falsity. In recent years, however, FCA cases increasingly involve allegations of a different sort, which are described in the next paragraph.<sup>36</sup> The second type of "falsity" may be characterized as "legal" falsity, viz, the claim is not factually false (i.e., not false on its face), but it is false for an extrinsic legal, regulatory or contractual reason.<sup>37</sup>

2. *Knowledge*.—Under the false claims prong, liability may be imposed only where the defendant "knowingly" presents or causes to be presented a false claim.<sup>38</sup> The 1986 amendments ease the burden to plead and prove FCA violations by expanding the definition of "knowingly" to include "deliberate ignorance" and "reckless disregard" and by eliminating the requirement that the actual knowledge of falsity by the defendant be demonstrated in order to establish FCA liability.<sup>39</sup> For reasons discussed below, the knowledge test should also include the question of whether the defendant knew that the government would not have paid the bill had it known the truth.

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1998) (noting that the "key inquiry is whether the 'claim in question' has the practical purpose and effect, and poses the attendant issue, of inducing wrongful payment" (quoting *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 985 (E.D. Wis. 1998))).

34. See *infra* note 114.

35. See *Luckey*, 2 F. Supp. 2d at 1045.

36. See, e.g., *Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991).

37. See *infra* note 161 and accompanying text; note 164 and accompanying text; note 181 and accompanying text.

38. 31 U.S.C. § 3729(a)(1) (1994).

39. *Id.* § 3731(c). Prior to the 1986 amendments, the circuits were split on the standard to apply. See *Federal Crop Ins. Corp. v. Hester*, 765 F.2d 723 (8th Cir. 1985); *United States v. Thomas*, 709 F.2d 968 (5th Cir. 1983); *United States v. Milton*, 602 F.2d 231 (9th Cir. 1979); *United States v. Elkelman*, 532 F.2d 545, 548 (6th Cir. 1976).

3. *Intent*.—The 1986 amendments also eliminate the requirement that an FCA plaintiff prove specific intent to defraud.<sup>40</sup> Under existing case law, the “requisite intent is the knowing presentation of what is known to be false.”<sup>41</sup> “In short, the claim must be a lie.”<sup>42</sup> However, innocent mistakes and mere negligence remain non-actionable under the FCA.<sup>43</sup>

4. *Materiality*.—The materiality of the falsehood is an element of liability under the false *statements* prong of the FCA.<sup>44</sup> Materiality in this context means that the government or relator counsel must prove that the statement had “[the] natural tendency to influence, or was capable of influencing the decision of [the government] in making a determination required to be made.”<sup>45</sup> Put differently, the “key inquiry is whether the ‘claim’ in question ‘has the practical purpose and effect, and poses the attendant risk, of inducing wrongful payment.’”<sup>46</sup>

Materiality is an element of an action brought under the false statements prong of the FCA;<sup>47</sup> there is, however, authority for the proposition that materiality is not an element in litigation under the false *claims* prong of the FCA.<sup>48</sup> No court or treatise explains this disparate treatment of these two important prongs of the FCA, perhaps because no rationale is readily apparent.<sup>49</sup> This zero-tolerance approach to actions under the

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40. 31 U.S.C. § 3729(b).

41. *Hagood*, 929 F.2d at 1421.

42. *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995).

43. See *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996).

44. 31 U.S.C. § 3729(a)(2).

45. *United States v. Beer*, 518 F.2d 168, 171 (5th Cir. 1975) (quoting *United States v. Krause*, 507 F.2d 113, 118 (5th Cir. 1975) (citations omitted)); *Hopper*, 91 F.3d 1261. But see *United States ex rel. Berge v. Board of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1460 (4th Cir. 1997) (reversing jury verdict and finding that alleged false statement was not material to government decision to approve research grants).

46. *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 985 (E.D. Wis. 1998) (citations omitted), *aff'd* by *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013 (7th Cir. 1999).

47. See BOESE, CIVIL FALSE CLAIMS, *supra* note 1, § 2-17 (noting that reliance or materiality is required under “cause to be presented” cases under 31 U.S.C. § 3729(a)(1) and false claims/statements actions under 31 U.S.C. § 3729(a)(2)); see also Boese, *Enforcement of the Civil False Claims Act*, *supra* note 32, at 5.

48. See, e.g., *United States v. White*, 27 F.3d 1531, 1534-35 (11th Cir. 1994).

49. Compare *White*, 27 F.3d at 1534 (discussing the split among jurisdictions

false claims prong is consistent with the line of cases enunciating the principle that "men must turn square corners when they deal with the government."<sup>50</sup> The "square corners" rule applies fully in the context of the FCA.<sup>51</sup> In the context of the heavily regulated health care field, however, the application of the FCA to compliance certifications threatens to create so many corners for health care providers that the corners turn into circles.

Perhaps the unspoken rationale for dispensing with a materiality analysis under the false claims prong is that most courts have found that false claims liability may exist without a showing of damages to the government. The need to establish materiality, however, exists regardless of whether the government has suffered actual damages. As discussed below, some courts addressing false claims actions under the FCA have implied a materiality requirement without expressly adopting the requirement.<sup>52</sup> In so doing, these courts have relied upon language from cases involving the false *statements*, not the false *claims*, prong of the FCA without acknowledging the distinction.<sup>53</sup> Nevertheless, engaging in a materiality-type analysis has enabled courts to reach more principled results in false claims litigation than might otherwise have occurred.

5. *DOJ Clarification.*—In June 1998, the Department of Justice ("DOJ") issued a memorandum supporting the exercise of prosecutorial discretion when it recognized that "falsity" within the meaning of the FCA often has a statutory or regulatory gloss.<sup>54</sup> This memorandum sets out the factors to be considered

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over the materiality issue), *with* *United States v. Durcholz*, 997 F. Supp. 1159, 1167 (S.D. Ind. 1998) (finding a materiality requirement "appropriate" and consistent with the FCA).

50. *See, e.g., Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 385 (1947) (denying crop insurance benefits to farmer who failed to comply with technical requirements of federal crop insurance program, despite substantial compliance with substantive provisions of the program).

51. *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007 (5th Cir. 1972).

52. *See, e.g., Luckey*, 2 F. Supp. 2d at 1045-49 (recognizing the need for a materiality element without explicitly holding that the element is a prerequisite); *see also* *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir. 1999) (finding that a prerequisite standard in false certification cases is essentially a heightened materiality requirement).

53. *See, e.g., Hopper*, 91 F.3d at 1266.

54. *See* U.S. DEPT OF JUSTICE MEMORANDUM: GUIDANCE IN THE USE OF THE

by DOJ lawyers in determining whether to allege FCA violations in the health care area.<sup>55</sup> In particular, the department's memorandum delineates the factors to be considered with respect to falsity and knowledge.<sup>56</sup> With respect to "falsity," it admonishes prosecuting attorneys to, *inter alia*,

examine relevant statutory and regulatory provisions, as well as any applicable guidance from the program agency or its agents, to determine whether the claims are false. In certain circumstances, such as when a rule is technical or complex, [DOJ] attorneys should communicate with knowledgeable personnel within the program agency . . . concerning the meaning of the provision.<sup>57</sup>

Furthermore, with respect to determining whether a provider had the requisite knowledge<sup>58</sup> regarding the falsity of the claim, the Memorandum states that the following factors, among others, need to be considered in deciding whether to pursue a case under the FCA:

- a. Notice to the Provider. [Did] the provider have actual or constructive notice . . . of the rule or policy upon which a potential case would be based?;
- b. The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?;
- c. The Pervasiveness and Magnitude of the False Claims[;]
- d. Compliance Plans and Other Steps to Comply with Billing Rules[;]
- e. Past Remedial Efforts [; and]
- f. Guidance by the Program Agency or its Agents. . . . Did the provider reasonably rely on such guidance in submitting the false claims?<sup>59</sup>

Of course, relators have no reason to engage in such an analysis

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FALSE CLAIMS ACT IN CIVIL HEALTH CARE MATTERS (visited Aug. 31, 1999) <<http://www.usdoj.gov/04foia/readingrooms/chem.htm>> [hereinafter DOJ MEMORANDUM].

55. DOJ MEMORANDUM, *supra* note 54, at 1.

56. *Id.* at 2.

57. *Id.*

58. "False claims and false statements are submitted 'knowingly' if the provider had actual knowledge of their falsity, or acted with deliberate ignorance or reckless disregard as to their truth or falsity." *Id.*

59. *Id.* at 2-3.

or to exercise any kind of restraint. Accordingly, it falls to the courts and the government to guard against *qui tam* lawsuits that may sound plausible at first glance but that do not really constitute an appropriate use of the FCA. One example of such abuse is the enforcement of the myriad health care quality of care standards.

#### IV. THE REGULATORY SCHEME GOVERNING FEDERALLY FUNDED HEALTH CARE

The Social Security Act generally limits payment for "reasonable and necessary" health care services.<sup>60</sup> Conversely, providers are obligated to assure that all services provided meet professionally recognized standards and are supported by medical necessity.<sup>61</sup> These dual, highly ambiguous standards produce a juxtaposition that constrains healthcare providers to deliver "enough" but not "too much" healthcare. The interpretation of these terms is further complicated by the comprehensive, bewildering array of government and administrative regulations and review processes applicable to the health care sector.<sup>62</sup>

##### *A. Highly Regulated Oversight of the Healthcare Industry: A Spotlight on Skilled Nursing Facilities*

In addition to the Scylla of providing too much care and the Charybdis of providing too little care, health care providers face a host of complex and comprehensive regulations. Not only are health care providers governed by federal regulations,<sup>63</sup> but they also must comply with state regulations<sup>64</sup> and with the federal<sup>65</sup> and state<sup>66</sup> agencies that enforce the regulations.

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60. 42 U.S.C. § 1395y(a)(1) (1994).

61. *Id.* § 1320c-5(a); see also 42 C.F.R. §§ 466.71(d), 1004.10 (1998).

62. See, e.g., 42 U.S.C. § 1395i-3(d)(2), (4).

63. See, e.g., 42 C.F.R. §§ 482 (Conditions of Participation for Hospitals), 483 (Requirements for States and Long Term Care Facilities), 488 (Survey, Certification and Enforcement Procedures), and 489 (Provider Agreements and Supplier Approval) (1998).

64. See, e.g., 42 U.S.C. § 1395i-3(d)(2), (4) (requiring skilled nursing facilities to comply with state regulations).

65. See *id.* § 1395i-3(g) (1994 & Supp. III 1997) (requiring states to conduct

These regulations and their enabling legislation are extensive and extremely detailed in some respects while vague in others. For example, nursing homes are required by law to fulfill a number of roles in addition to providing health care, such as managing residents' personal funds,<sup>67</sup> providing residents with reasonable access to telephones where calls can be made in private,<sup>68</sup> providing residents with activities,<sup>69</sup> and providing residents with social services.<sup>70</sup> Consequently, skilled nursing facilities must literally be fully functioning, self-contained communities. Moreover, the federal Health Care Financing Administration ("HCFA") regulates such minutiae as how many nursing home residents may be placed in a room,<sup>71</sup> requires resident bedrooms to be equipped with windows to the outside,<sup>72</sup> requires each bed in facilities certified after 1992 to have "ceiling suspended curtains . . . to provide total visual privacy,"<sup>73</sup> and requires each resident to have "at least 80 square feet . . . in multiple resident bedrooms, and at least 100 square feet in single resident rooms."<sup>74</sup> Hospitals also have similar requirements regulating their physical environment.<sup>75</sup>

The HCFA enforces these regulations pertaining to skilled nursing facilities by using states as HCFA agents to conduct surveys to ensure compliance with federal regulations.<sup>76</sup> Sur-

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surveys of skilled nursing facilities).

66. See *id.* § 1395i-3(g)(3) (requiring the Department of Health and Human Services to conduct onsite surveys of a representative percentage of skilled nursing facilities within two months of being surveyed by the state).

67. See 42 C.F.R. § 483.10(c) (1998).

68. See *id.* § 483.10(k).

69. See 42 U.S.C. § 1395i-3(b)(4)(A)(v) (requiring that a facility provide "an ongoing program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of *each* resident") (emphasis added); see also 42 C.F.R. § 483.15(f) (listing, *inter alia*, the qualifications for a director of activities).

70. 42 C.F.R. § 483.15(g).

71. See *id.* § 483.70(d)(1)(i) ("no more than four residents").

72. *Id.* § 483.70(d)(1)(vi).

73. *Id.* § 483.70(d)(1)(v).

74. *Id.* § 483.70(d)(1)(ii).

75. 42 C.F.R. § 482.41(b)(1)(iii)(2) (providing examples of procedures for the proper routine storage and prompt disposal of trash).

76. See 42 U.S.C. § 1395i-3(g)(1)(A) ("Pursuant to an agreement under section 1395aa of this title, each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities . . . with the requirements . . . of this section.").

veys must be conducted on every facility at least once every fifteen months<sup>77</sup> ("standard surveys") and whenever there is reason to question the compliance of a skilled nursing facility.<sup>78</sup> The survey must be performed by a "multidisciplinary team of professionals," which includes a registered professional nurse.<sup>79</sup> The team is to have no affiliation with the facility,<sup>80</sup> and it is required to complete a training program developed by the HCFA<sup>81</sup> and to use a protocol developed by the HCFA.<sup>82</sup> Standard surveys are unannounced and federal law may impose monetary sanctions upon anyone who forewarns a facility of an inspection date.<sup>83</sup>

The HCFA requires consistency<sup>84</sup> and monitors the accuracy of surveys to ensure that the state survey teams acting as the HCFA's agents are accurately enforcing the HCFA regulations.<sup>85</sup> The HCFA monitors state surveys by resurveying at least five percent of the facilities surveyed by the state<sup>86</sup> within two months after the facilities are surveyed by the state.<sup>87</sup> If the HCFA survey team finds that the state survey team has failed to adequately enforce HCFA regulations, the HCFA must provide a remedy to the situation such as retraining the survey team.<sup>88</sup> In addition, if the HCFA team determines that a facility is not in compliance with HCFA regulations despite a state survey finding the facility compliant, the HCFA survey takes

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77. *Id.* § 1395i-3(g)(2)(A)(iii)(I) (noting that the average interval between surveys is not to exceed 12 months).

78. *Id.* § 1395i-3(g)(3)(D).

79. *Id.* § 1395i-3(g)(2)(E)(i).

80. *Id.* § 1395i-3(g)(2)(E)(ii) (requiring that no member of the survey team shall have served within the past two years as a staff member or as a consultant to the surveyed facility).

81. 42 U.S.C. § 1395i-3(g)(2)(E)(iii).

82. *Id.* § 1395i-3(g)(2)(C); *see id.* § 1395i-3(g)(2)(A)(ii) (requiring surveys to take a stratified sample of residents to evaluate quality of care indicators such as dietary services, activities, sanitation, infection control, resident assessments and other factors).

83. *Id.* § 1395i-3(g)(2)(A)(i).

84. *Id.* § 1395i-3(g)(2)(D) (requiring each state and the Secretary to "implement programs to measure and reduce inconsistency in the application of survey results among surveyors").

85. 42 U.S.C. § 1395i-3(g)(3)(A).

86. *Id.* § 1395i-3(g)(3)(B).

87. *Id.* § 1395i-3(g)(3)(A).

88. *Id.* § 1395i-3(g)(3)(C).

precedence with regard to determination of certification.<sup>89</sup>

In addition to these two layers of review and re-review, Congress may utilize the General Accounting Office ("GAO") to investigate whether the survey process is effective and whether residents at skilled nursing facilities receive adequate care.<sup>90</sup> Congress uses the GAO to investigate the effectiveness of state and federal oversight of the nursing home industry in order to pass legislation to remedy any failings in the system.<sup>91</sup> Thus, there are at least two layers of executive oversight and one layer of direct legislative oversight of the nursing home industry.

### *B. Provider Participation in Federally Funded Healthcare Programs*

To participate in federally funded healthcare programs, a provider must submit an application that constitutes a binding contract with the government.<sup>92</sup> The provider also might enter into an electronic data interchange ("EDI") agreement for submitting bills electronically. The contractual forms are prepared by the government with language requiring certain forward-looking promises. For example, the current EDI agreement form requires the provider to agree, *inter alia*, that the "services were performed as billed," that "it will submit claims that are accurate, complete, and truthful," and that it "will acknowledge that . . . anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to [a submitted] claim . . . may, upon conviction, be subject to a fine and/or imprisonment under applicable federal law."<sup>93</sup> Providers participating in Medicaid also may be required to enter an agreement with the states that includes requirements

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89. *Id.* § 1395i-3(g)(3)(A).

90. *See, e.g.*, U.S. GENERAL ACCOUNTING OFFICE, CALIFORNIA NURSING HOMES: CARE PROBLEMS PERSIST DESPITE FEDERAL AND STATE OVERSIGHT (1998) [hereinafter CALIFORNIA NURSING HOMES].

91. *See id.* at 1-2 (discussing Congress' request that the GAO investigate allegations of substandard care in nursing homes and assess federal and state efforts to ensure compliance with federal nursing home standards).

92. 42 U.S.C. § 1395cc(a)(1).

93. HCFA Electronic Data Interchange (EDI) Enrollment Form (visited May 10, 1999) <<http://www.hcfa.gov/medicare/edi/ed15.htm>>.

for participation. For example, the California Department of Health Services requires such an agreement for electronic billing, and that agreement form requires that the provider "agrees and shall certify under penalty of perjury that all claims for services submitted [by magnetic tape or disk] have been personally provided to the patients by the Provider or under his direction by another person."<sup>94</sup>

The provider agreements do not themselves result in government payment until the submission of bills for services provided. Bills are generally submitted to the government on a form created by the National Uniform Billing Committee, commonly called a "UB-92."<sup>95</sup> The UB-92 Form does not require that the health care facility comply with all quality of care regulations as a precondition of submitting it. Rather, the Form merely requires a facility to certify that the information contained in the Form "is true, accurate, and complete," and that the submitting provider "understand[s] that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State Laws."<sup>96</sup>

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94. State of California Health and Welfare Agency, *Medi-Cal Telecommunications Provider and Biller Application/Agreement* (1996). Some have argued that these agreements constitute implicit promises of compliance with all regulatory requirements for participation. See, e.g., *United States ex rel. Joslin v. Community Home Health*, 984 F. Supp. 324, 385 (D. Md. 1997). Even if this were true, however, failure to comply would constitute a breach of contract rather than fraud under the FCA, unless the provider had no intention of complying when it entered the agreement. As pointed out by the court in *United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996), agreements with the government do not form the basis for an action under the FCA unless the provider made an "intentional, palpable lie" at the time when it agreed to comply with all applicable regulations. *Hopper*, 91 F.3d at 1267 (citation omitted) (discussing promissory fraud). See also *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1036 (S.D. Tex. 1998) (finding that "[n]o cause of action exists under the FCA for a breached promise that was not false when it was made"). Moreover, past noncompliance does not necessarily constitute sufficient evidence that a provider intentionally lied about future compliance. *Hopper*, 91 F.3d at 1268.

95. *Thompson*, 20 F. Supp. 2d at 1024 (citing *MEDICARE INTERMEDIARY MANUAL* § 3602.5, ex. 2 to app. (1995)).

96. HCFA Form 1450 ¶ 8 (UB-92) (last modified May 10, 1999) <<http://www.hofa.gov/medicare/edi/ed15.htm>>.

In order to establish reimbursement rates and true-up accounts payable and receivable with the government, providers also submit cost reports.<sup>97</sup> The cost report forms require the provider to certify that "I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations."<sup>98</sup> However, while the cost report form specifically refers to at least one such law, viz, the one prohibiting kickbacks,<sup>99</sup> it does not refer to any of the specific quality of care regulations. This fact, coupled with the aspirational tone, vague nature, and the sheer number of regulations pertaining to quality of care<sup>100</sup> indicates that this certification in the Cost Report was not intended to require any particular measures to satisfy the quality of care requirements. Moreover, these elements certainly cannot form the basis for an FCA violation because the provider would not "knowingly" certify that any particular measures were taken. Stated another way, providers risk FCA liability for guessing what circumstances a government surveyor might believe to constitute "unavoidable." Furthermore, there are no laws or regulations of general applicability that delineate what specific measures constitute "adequate" or "appropriate" care. Therefore, even if the government found that a provider's opinion of what constituted "adequate" or "appropriate" care was incorrect, that would not constitute any "knowing" failure to satisfy these standards when the cost report

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97. 42 CFR § 413.20 (1998) (noting that cost reports are required on an annual basis); *id.* § 413.24 (requiring adequate cost data); Agency Reformation Collection Activities: Submission for OMB Review & Comment Request, 64 Fed. Reg. 8388 (1999). The cost reports are submitted on the HCFA Form 2552 for hospitals and the HCFA Form 2540 for skilled nursing facilities. HCFA Form 2552, HCFA Form 2540 (last modified May 10, 1999) <<http://www.hcfa.gov/pubforms/forms/forms.htm>>.

98. *Thompson*, 20 F. Supp. 2d at 1035 n.21 (quoting HCFA Form 2552).

99. See HCFA Form 2552.

100. See, e.g., 42 C.F.R. § 483.25(c)(2) (1998) (requiring that a facility must "prevent new sores from developing" on residents who already have pressure sores); *id.* § 483.25(d)(2) (noting that a facility must "prevent urinary tract infections and . . . restore as much normal bladder function as possible"); *id.* § 483.25(a) (requiring that a "facility must ensure that . . . [a] resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable"); *id.* § 483.25(e) (explaining that a "facility must ensure that . . . [a] resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable").

was submitted.<sup>101</sup>

Finally, the certifications on bills and cost reports at most guarantee only that the services outlined in the cost report were provided. These documents do not preclude a provider from billing for services actually provided simply because the government later determines that additional services should have been provided in addition to those which were billed. In other words, these documents reflect only those services actually provided. The documents do not reflect any additional services that were not provided and consequently not billed.<sup>102</sup>

### C. *Conditions of Participation versus Conditions of Payment*

The government has not stipulated that satisfaction of quality of care standards is a condition of payment under the federal health programs, nor has the government required providers to explicitly certify that their claims have been provided in a manner consistent with the standard of care. Further, neither the Medicare nor the Medicaid program conditions payment on the satisfaction of any specific clinical norms. While these programs, including the Office of Civilian Health and Medical Programs of the Uniformed Services ("CHAMPUS"), certainly have "conditions of participation" that affect clinical care, those should not be confused with conditions of payment.<sup>103</sup>

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101. *Tyger Constr. Co., Inc. v. United States*, 28 Fed. Cl. 35, 56 (1993) (finding that it is "fundamental that fraud cannot be predicated upon the mere expression of an opinion," quoting *Soukaras v. United States*, 135 Ct. Cl. 88, 92 (1956), and that "[a]ttaching FCA liability to expressions of legal opinion would have an impermissibly stifling effect on the legitimate presentation of claims").

102. For example, the UB-92 for a resident at a skilled nursing home typically states that the service provided was "Room and Board" or "Semi-Private Room." Similarly, the cost report will support such bills by identifying the actual costs for the various items that go into "Room and Board" for all residents during the billing period, such as the total cost for nursing, linens, soap, etc. However, neither constitutes a representation that the services provided were anything more than what was actually provided. *Accord* HCFA Form 1450 (UB-92), *supra* note 96 (certifying that services including on the form are "medically indicated" and "necessary").

103. *United States ex rel. Joslin v. Community House Health of Md., Inc.*, 984 F. Supp. 374, 385 (D. Md. 1997) (holding that "[t]he relevant statute and regulation simply state that such compliance is a condition of *participation* in the Medicare program, but no evidence has been presented suggesting that certification of such

In contrast, conditions of participation address such issues as medical staff, nursing services, laboratory services, discharge planning and infection control.<sup>104</sup> These conditions are extremely detailed. By way of example, the Medicare condition of participation for "physical environment" requires that each hospital have "emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells" and requires that flashlights be available in other hospital locales.<sup>105</sup> Similarly, the condition of participation governing the content of medical records states that "[a]ll entries must be legible."<sup>106</sup>

But these conditions are *not* conditions of payment. To the contrary, the relevant Medicare regulations make clear that if a condition of participation is not satisfied, the provider is not excluded from the program, and payment is not stopped unless the HCFA determines that an immediate threat to the health or safety of patients exists.<sup>107</sup> Instead, providers who fail, on inspection, to satisfy a condition of participation are "granted a reasonable time to achieve compliance."<sup>108</sup> The provider is expected to take the action necessary to achieve compliance within sixty days of being notified of the deficiencies.<sup>109</sup> As part of this process, the provider proposes and carries out a plan of correction, which must be approved by the state or the HCFA.<sup>110</sup>

Although the HCFA may ultimately terminate a provider agreement for failure to comply with conditions of participa-

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compliance is a condition to *payment*, the *sine qua non* of FCA liability") (emphasis added).

104. *E.g.*, 42 C.F.R. §§ 482.21 to 482.66 (1998) (setting out Medicare conditions of participation for hospitals).

105. *Id.* § 482.41.

106. *Id.* § 482.24(c)(1).

107. *Id.* § 488.28.

108. *Id.*

109. 42 C.F.R. § 488.28.

110. *Id.* Essentially the same rules govern skilled nursing facilities, provided that the violations do not cause immediate jeopardy to residents. The HCFA may allow a skilled nursing facility to continue to participate for up to six months from the date of a survey which uncovers deficiencies. If the facility is not substantially compliant within three months, only then will the HCFA and the state deny payment for new admissions. Furthermore, termination occurs only when the facility had not corrected the cited deficiencies within six months. *See id.* § 488.12.

tion,<sup>111</sup> loss of payment is not automatic or immediate. First, the provider has the right to appeal the termination.<sup>112</sup> Moreover, payment is available for up to 30 days after the effective date of termination for inpatient and certain other hospital-related services.<sup>113</sup>

#### V. CASES INVOLVING USE OF THE FCA TO ENFORCE REGULATORY REQUIREMENTS IN THE HEALTH CARE AREA

The prosecution of health care fraud through FCA and *qui tam* lawsuits is becoming increasingly common. Indeed, while FCA cases have traditionally focused mainly on the military sector in recent years, the health care area has made up the largest portion of activity under the FCA and its *qui tam* provisions.<sup>114</sup> This important development reflects several interrelated factors: (1) starting with the Social Security Act of 1965, the federal government has paid for much of the health care provided to the elderly and the poor; (2) health care has become the fastest growing *and* largest sector of the American economy; (3) recent federal legislation has dramatically increased prosecutorial and investigative resources allocated to enforcement activities in the health care sector; (4) the proportion of Americans needing healthcare has grown rapidly and will continue to do so for decades as a result of the aging of the "baby boomer" generation; and (5) there is a chasm between the inconsistent demands for increased quality of care and reduced government expenditures for such care.

After the 1986 amendments to the FCA, most of the cases brought under the FCA involved defense contractors:<sup>115</sup>

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111. *Id.* § 489.53.

112. *Id.* § 489.54.

113. 42 C.F.R. § 489.55. In much the same manner, CHAMPUS provides to institutions with "minor violations" of one or more standards a "grace period of 30 days," which may be extended to 90 days, to correct discrepancies. *Id.* § 199.9. More severe sanctions are levied for violations threatening the life, health or safety of patients. *Id.* Moreover, CHAMPUS provides extensive appeal procedures for providers who are adversely affected by decisions regarding their status as a participating provider. *Id.* § 199.10.

114. See generally Stanley G. Andul, *Laws Regulating Physicians that Drive Doctors (and their Attorneys) Crazy*, ALI-ABA 531, 563 (1999).

115. U.S. GENERAL ACCOUNTING OFFICE, MEDICARE: APPLICATION OF THE FALSE

However, as spending on federal health programs and interest in combating health care fraud have grown, the FCA has been applied more frequently to health care providers than in the past. The number of civil health care fraud matters pending at the Justice Department at the end of [1997] rose from 270 in fiscal year 1992 to more than 4,000 in fiscal year 1997, as compared with all civil fraud matters pending at the end of fiscal year 1997, which totaled about 6,500.<sup>116</sup>

The DOJ recently released a report which showed the dramatic increase in FCA/*qui tam* litigation and recoveries in the health care area.<sup>117</sup> From 1987 to 1997, the number of *qui tam* cases filed increased from 33 to 534, or 1527%.<sup>118</sup> From 1988 through 1997, recoveries in *qui tam* cases pursued by the DOJ increased from \$355,000 to \$625,000,000, or an astonishing 17828%.<sup>119</sup> More importantly for the health care sector, the DOJ reports that the percentage of *qui tam* cases involving the Department of Health and Human Services ("DHHS") as the client agency increased from 12% in 1987 to 54% in 1997.<sup>120</sup>

It is entirely appropriate to use the FCA to recover damages and to impose penalties on health care providers who submit claims which certify that specific services were provided when those services were not provided. Recent attempts to expand the FCA as a weapon to sue health care providers for alleged failures to comply with the detailed yet vague regulations that require the provision of "adequate" quality of care have lacked justification. The theory underlying these attempts is that providers purportedly certify, either explicitly or implicitly, that they are in substantial or full compliance with all of the applicable regulations at the time they submit each bill for payment for services provided.<sup>121</sup> Under this theory, the provider is argu-

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CLAIMS ACT TO HOSPITAL BILLING PRACTICES 6 (1998).

116. *Id.*

117. See BOESE, CIVIL FALSE CLAIMS, *supra* note 1; Boese, *Enforcement of the False Claims Act*, *supra* note 32, at Attachment B (citing FCA Statistics supplied by the Department of Justice).

118. Boese, *Enforcement of the False Claims Act*, *supra* note 32, at Attachment B.

119. *Id.*

120. *Id.*

121. 42 U.S.C. § 1320c-5(a) (1994); 42 C.F.R. §§ 466.71(d), 1004.10 (1998). See generally *supra* notes 60-61 (Section IV).

ably liable for violations of the FCA if the provider was not in compliance with the regulatory standards at the time of billing, even if the specifically billed-for services were, in fact, provided.

As discussed below, the certification argument has had mixed success when applied to allegations that health care providers have not complied with the applicable regulations.<sup>122</sup> Furthermore, in most cases, the alleged false certification was of a clear-cut statute or regulation, such as the anti-kickback rules, and none of the cases specifically dealt with such general and vague regulations as those requiring "adequate" care. Accordingly, the issue of whether the FCA constitutes an enforcement mechanism for quality of care regulations remains unresolved.

### A. Cases Involving Certification of Compliance

1. *United States ex rel. Luckey v. Baxter Healthcare Corp.*—One of the only cases addressing alleged failure to provide adequate services for which the provider billed is also one of the most recent cases, *United States ex rel. Luckey v. Baxter Healthcare Corp.*<sup>123</sup> In *Luckey*, a former laboratory employee brought a *qui tam* suit, claiming in two separate factual bases that Baxter had made false claims to the federal government in connection with its sales of plasma derivatives to federally funded hospitals.<sup>124</sup> The provider was accused of using inadequate procedures for plasma collection and of concealing this fact.<sup>125</sup> Relying on numerous theories, the court granted summary judgment for the defendant, finding that Baxter had not knowingly

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122. The certification argument is related to the concept of "but-for" causation, which refers to damages that occurred because the defendant violated some law, but the violation is not, strictly speaking, the proximate cause of the harm. PROSSER & KEETON ON THE LAW OF TORTS 266 (5th ed. 1984) ("[I]f the event would not have occurred 'but for' the defendant's negligence, it still does not follow that there is liability."). For example, assume a driver whose license has expired runs over a pedestrian. Technically, the driver is in violation of the law because the driver should not have been on the road at all. Thus, "but-for" the driver violating this law the accident would not have occurred. However, assuming the driving itself was not reckless, it would be incorrect to say that the legal violation is the proximate cause of the injury. *Id.*

123. 2 F. Supp. 2d 1034 (N.D. Ill. 1998).

124. *Luckey*, 2 F. Supp. 2d at 1037-38.

125. *Id.* at 1037-38, 1041-42.

filed false claims.<sup>126</sup>

The relator's initial argument was that Baxter had a policy of suppressing incident reports in order to hide poor quality and that this constituted a violation of Baxter's certification of compliance with applicable laws and regulations.<sup>127</sup> In rejecting this argument, the court found that regulatory compliance was not a condition to Baxter's receiving payment or other benefits from the government.<sup>128</sup> In so holding, the court explicitly rejected the relator's argument that Baxter had made "implied certifications" of regulatory compliance.<sup>129</sup> The relator's "implied certification" argument hinged largely on the assertion that Baxter "once certified that it complied with all federal regulations to procure its original establishment license."<sup>130</sup> The court rejected this argument on the ground that the relator had not shown that "Baxter's compliance with any statutes or regulations was a material condition to [it] receiving payment from the government."<sup>131</sup> In particular, the court found that the relator had not demonstrated that the alleged regulatory deficiency (suppressing incident reports to hide poor quality) "violated the heart of [Baxter's] agreement with the government," and/or the government would have withheld payment if it had been aware of this alleged practice.<sup>132</sup> The *Luckey* court also reiterated the "well-established principle that the FCA is not a vehicle for regulatory compliance" and that "a finding of a false implied certification under the FCA for every request for payment accompanied by a failure to comply with all applicable regulations, without more, improperly broadens the intended reach of the FCA."<sup>133</sup>

An equally important part of the court's reasoning was that the contract between Baxter and the government "clearly define[d] the remedy for Baxter's failure to comply with any applicable statutes or regulations;" viz, the contract would remain in

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126. *Id.* at 1041-42.

127. *Id.* at 1038-41.

128. *Id.* at 1044.

129. *Luckey*, 2 F. Supp. 2d at 1044.

130. *Id.*

131. *Id.* at 1045.

132. *Id.*

133. *Id.* (citing *United States ex rel. Joslin v. Community House Health of Md.*, 984 F. Supp. 374, 384-85 (D. Md. 1997)).

effect unless the affected government agency determined to take other action, and then it could compel correction.<sup>134</sup> The court determined that this contract "provision contradicts any attempt by [the relator] to demonstrate that regulatory compliance was a prerequisite to receiving payment from the government."<sup>135</sup>

The relator's second argument was that Baxter had expressly certified that it would comply with all applicable laws and regulations.<sup>136</sup> Baxter conceded that one of its contracts did, in fact, contain such a certification, and the court found that "if Baxter certified its compliance with regulations to the government, in connection with getting payment, Baxter can surely be tested as to whether it did or did not comply with regulations."<sup>137</sup> The court found, however, that the relator failed to identify any specific regulation requiring the precise level of testing that the relator insisted was required to be "adequate."<sup>138</sup> Furthermore, the *Luckey* court recognized that "[c]ourts have consistently declined to find that a contractor's exercise of scientific or professional judgment as to an applicable standard of care falls within the scope of the FCA."<sup>139</sup> This holding is important to the broader issue of whether the FCA should apply to quality of care regulations because generally they are so vague that reasonable experts may differ on what specific steps constitute generally accepted standards for the provision of care that are "adequate."

2. *Aranda v. Community Psychiatric Centers, Inc.*—Besides *Luckey*, the only reported opinion addressing violations of less than clear-cut standards is *United States ex rel Aranda v. Community Psychiatric Centers, Inc.*<sup>140</sup> In *Aranda*, a case in which the government intervened, a psychiatric hospital was alleged to have violated the FCA by filing claims for reimbursement but "not providing to its patients appropriate quality of care and a

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134. *Luckey*, 2 F. Supp. 2d at 1046.

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.* at 1047 (noting that "a review of the regulations fails to indicate that a certain type of plasma screening is required").

139. *Luckey*, 2 F. Supp. 2d at 1047 (citing *United States ex rel. Milam v. Regents of the Univ. of Cal.*, 912 F. Supp. 868, 886 (D. Md. 1995)).

140. 945 F. Supp. 1485 (W.D. Okla. 1996).

safe and secure environment.”<sup>141</sup> The government further alleged that this constituted a violation of the FCA because, by submitting bills, the defendant “implicitly certif[ied] that it was abiding by applicable statutes, rules and regulations’ requiring provision to patients of ‘appropriate quality of care and a safe and secure environment,’ but ‘knew that it was not providing to its patients appropriate quality of care and a safe and secure environment.’”<sup>142</sup> The specific failures centered on allegations that “appropriate precautions were not taken and that physical injury to and sexual abuse of patients occurred because of inadequate conditions, such as understaffed shifts, lack of monitoring equipment, and inappropriate housing assignments.”<sup>143</sup> Thus, while the allegations referred to requirements for both “quality of care” and “safe and secure environment,” the underlying issues were more akin to the latter than the former because the government did not focus on the actual care provided.<sup>144</sup>

The provider hospital moved to dismiss, contending that the government had not identified a statute or rule imposing an objective standard of safety or quality of care applicable to a billing requirement, and absent such a rule, the hospital could not have “knowingly” submitted false claims.<sup>145</sup> The provider also argued that, in any event, “the existence of a comprehensive regulatory scheme designed to assure compliance with conditions of participation” precluded FCA liability.<sup>146</sup> In denying the motion to dismiss, the court noted that “[s]tatutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider’s failure to meet such standards is a ground for exclusion from the program.”<sup>147</sup> The court rejected the argument that the term “professionally recognized standards for health care” was so vague that it could not be violated “knowingly,” and it held that “a problem of measurement should not pose a bar to pursuing an

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141. *Aranda*, 945 F. Supp. at 1487 (quoting Second Amended Complaint at 20-21, ¶¶ 101-102, *United States ex rel Aranda v. Community Psychiatric Centers, Inc.*, 945 F. Supp. 1485 (W.D. Okla. 1996) (No. CIV-94-608-A)).

142. *Id.*

143. *Id.* at 1488 (citing Second Amended Complaint, *Aranda* (No. CIV-94-608-A)).

144. *Id.* at 1487.

145. *Id.* at 1488.

146. *Aranda*, 945 F. Supp. at 1488.

147. *Id.* (citing 42 U.S.C. § 1320a-7(b)(6)(B) (1994)).

FCA claim."<sup>148</sup> The court also rejected the argument that the existence of a comprehensive regulatory scheme for "monitoring quality of care issues under the Medicaid program precludes this FCA suit."<sup>149</sup>

*Aranda* does not present a well-reasoned analysis of the FCA, has not been relied on for this proposition in any subsequent published opinions, and should not be followed for a number of reasons. First, the principal basis of FCA liability in *Aranda* seems to be the court's finding of an "implicit certification]" in the defendant's claims for reimbursement that it was complying with applicable "statutes, rules and regulations" which required the defendant to provide patients an "appropriate quality of care and a safe and secure environment."<sup>150</sup> However, the court cited no case law in support of the proposition that FCA liability may be incurred on the basis of any implied certification, much less the vague implied certification actually at issue in the case.<sup>151</sup>

Second, the court relied heavily upon the terms "reasonably safe environment" and "appropriate quality of care and a safe and secure environment" as establishing the applicable standard for determining FCA liability,<sup>152</sup> but these terms are ambiguous and are undefined by the regulations. Furthermore, these terms, and similar ones like "adequate care," are inherently subjective and also subject to changing industry standards. Accordingly, they do not form an adequate predicate upon which to

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148. *Id.*

149. *Id.* at 1489.

150. *Id.* at 1487.

151. In *Aranda*, plaintiffs apparently did not argue that the claims for reimbursement contained an *express* certification of compliance with the conditions of participation. *Aranda*, 945 F. Supp. at 1487. In a subsequent case, *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, No. 96-40868, 1996 U.S. Dist. LEXIS 14350 (S.D. Tex. Oct. 23, 1996), *remanded*, 125 F.3d 899 (5th Cir. 1997), which is discussed below, the court found that the certification contained in a cost report submitted by an acute care hospital established the predicate for FCA liability. *Thompson*, 1998 U.S. Dist. LEXIS 14350, at \*58. The defendant in *Thompson* certified "that the services identified in this cost report were provided in compliance with . . . laws and regulations [regarding the provision of health care services]." *Id.* at 57 n.21. This certification is contained on the Cost Report form mandated by HCFA, known as Form HCFA 2552. This same certification appears on the Cost Reports submitted by the defendants in *Aranda*. *Aranda*, 945 F. Supp. at 1487.

152. *Aranda*, 945 F. Supp. at 1487.

base FCA liability.

Third, the aforementioned terms are contained in the "conditions of participation," which are requirements that a provider must meet in order to qualify for participation in the Medicaid program. These conditions of participation are contained in a complex set of regulations that are enforced through an elaborate regulatory scheme, which includes regular inspections by federal and state inspectors. These inspections often take the form of surveys, and the survey process yields survey reports. The specific purpose of the survey process is to determine compliance with, *inter alia*, the conditions of participation. In *Aranda*, state surveyors had issued annual reports which had resulted in affirmative certifications that the defendants were in compliance with the applicable conditions of participation.<sup>153</sup> The defendants had argued that these affirmative survey reports precluded a finding that the defendants had "knowingly" violated the conditions of participation and thus could not be found liable under the FCA.<sup>154</sup> Despite the logical force of this argument, the court cavalierly disposed of that argument on the ground that it "will not be considered here."<sup>155</sup> It would seem that positive annual survey reports would provide a virtually insurmountable barrier to proving a "knowing" violation of the conditions of participation.

Fourth, *Aranda* raises concerns about potential inter-agency conflict by permitting one government department, the DOJ, to accuse a facility of not qualifying for certification when an existing government department, the HCFA, already has primary responsibility for making such decisions. Moreover, these disputes would arise after the HCFA has already certified the provider. In addition, these disputes would be seeking to have yet another government branch, the courts, rule on whether the provider merited certification. At the very least, this suggests that the courts considering FCA claims based on alleged failure to

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153. *Id.*

154. *Id.* at 1488 n.2.

155. *Id.* Perhaps the *Aranda* court refused to consider the government's certifications and surveys because the issue was being raised on a motion to dismiss rather than one for summary judgment. However, this rationale does not hold because the court could have considered such material on a motion to dismiss through judicial notice.

satisfy the requirements for certification should defer the issue to the HCFA based on the doctrine of primary jurisdiction.<sup>156</sup> The Supreme Court has explained that "[t]he doctrine of primary jurisdiction . . . is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties," and the doctrine is applicable in federal courts when an action "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body."<sup>157</sup> The extensive regulatory mechanisms placed at issue in *Aranda* would appear to be prime candidates for application of the primary jurisdiction doctrine to the extent that one accepts the predicate certification argument upon which *Aranda* based its application of the FCA.<sup>158</sup>

Fifth, *Aranda* expressly declined to consider the argument that the annual surveys required by the Medicaid program, which resulted in affirmative certifications that the defendant was in compliance with applicable conditions of participation, by definition, prevented the defendant from knowingly violating the

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156. See, e.g., *Johnson v. Nyack Hosp.*, 964 F.2d 116, 122 (2d Cir. 1992) (ruling that to "question whether defendants had a proper medical reason to terminate Johnson's privileges requires a skilled evaluation of whether Johnson provided inadequate treatment to Nyack's patients. . . . The medical expertise of [the Medicare-mandated state quality agency] will prove extremely helpful in sorting through these complex records, and resolving the factual questions at stake"); *Gordon v. Forsyth County Hosp. Auth.*, 409 F. Supp. 708, 722 (M.D.N.C. 1975) ("determination of the amount, type, and priority of dispensing of medical care to admittedly qualified . . . patients" involving "propriety of standards and rules which the hospital has adopted and the state agency has approved . . . presents the classical situation in which primary jurisdiction rests with the appropriate state and federal agencies charged with the responsibility of administration of the program"), *aff'd and vacated in part* by *Gordon v. Forsyth County Hosp. Auth.*, 544 F.2d 748 (4th Cir. 1976). *But see* *United States ex rel. Haskins v. Omega Inst., Inc.*, 11 F. Supp. 2d 555 (D.N.J. 1998) (refusing to apply the doctrine of primary jurisdiction to FCA action because the responsible agency did not have authority to adjudicate FCA claims); *Luckey v. Baxter Healthcare Corp.*, No. 95-C-509, 1996 WL 242977 (N.D. Ill. 1996 May 9, 1996) (finding that the doctrine of primary jurisdiction was inapplicable where agency could not adjudicate FCA claims).

157. *United States v. Western Pac. R.R.*, 352 U.S. 59, 63, 64 (1956).

158. The HCFA typically uses state health departments to act as its agent for certification surveys. Accordingly, the primary jurisdiction ultimately may be referred by the HCFA for preliminary consideration to the respective state's health department. See 42 U.S.C. 1395i-3(g) (1994 & Supp. III 1997)).

FCA.<sup>159</sup> The court did not explain its failure to consider this argument, despite the overarching significance of the knowledge element to the FCA.

3. *Pogue v. American Health Corp., Inc.*—In *United States ex rel. Pogue v. American Health Corp., Inc.*,<sup>160</sup> the court held

that violations of the anti-kickback statute and the self-referral statute could render a claim false even though “the claims were not false in the sense that [d]efendants sought compensation for services that were not rendered or were unnecessary[;] they were nonetheless fraudulent because by submitting the claims, [d]efendants *implicitly* stated that they had complied with all statutes, rules, and regulations governing the Medicare Act, including federal anti-kickback and self-referral statutes.”<sup>161</sup>

The court concluded that if the defendants had not concealed their violations of the anti-kickback and self-referral statutes, then the government would not have paid the claims.<sup>162</sup> For that reason, the court ruled that the claims were intended to defraud the government and were therefore fraudulent.<sup>163</sup>

The “implied” certification theory discussed in *Pogue* has been described as the “Achilles heel” in that decision, and there is reason to doubt that even *Pogue* really intended to rely solely on this theory.<sup>164</sup> Furthermore, *Pogue* did not need an “im-

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159. *Aranda*, 945 F. Supp. at 1488 n.2.

160. 914 F. Supp. 1507 (M.D. Tenn. 1996).

161. *Pogue*, 914 F. Supp. at 1509 (emphasis added). In *United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504 (S.D. Ohio 1994), a situation similar to *Pogue* resulted in the same outcome, but without any specific analysis of whether the defendants had explicitly or implicitly certified their compliance with the latter statute when submitting claims. Rather, *Roy* held that there was a “tenuous connection” between the two statutes, but a connection that “is sufficient to overcome the burden of a 12(b)(6) motion.” *Roy*, 914 F. Supp. at 1506. *Roy* explained that “[u]nder the facts alleged, the Plaintiff could produce evidence that would show that the kickbacks allegedly paid to the defendant physicians somehow tainted the claims for Medicare.” *Id.* Additionally, *Roy* held that “the Plaintiff may establish that the claims for Medicare payments were constructively false or fraudulent.” *Id.* at 1506-07.

162. *Roy*, 914 F. Supp. at 1513.

163. *Id.*

164. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1048 n.33 (S.D. Tex. 1998) (discussed *infra* section V.A.4). See also *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 n.8 (4th Cir. 1999) (accepting express certification theory but questioning implied certification theory for FCA cases). Although the *Pogue* court seemed enamored with the “implied certifi-

plied" certification argument to apply the FCA to the anti-kickback rules because cost reports, which are submitted on HCFA Form 2552, contain an "express" certification that "if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative fines and/or imprisonment may result."<sup>165</sup>

The distinction between an "express" and "implied" certification is particularly significant for quality of care issues because cost reports do *not* contain an express certification of compliance with all quality of care. The certification in a cost report merely states that "[m]isrepresentation or falsification of any information contained in this cost report may be punishable."<sup>166</sup> This general certification means that the specific services reflected on the cost reports must have been actually provided. It does not mean that the cost report constitutes an assertion that additional services were provided that were not billed. Furthermore, the "implied" certification suffers from the obvious defect of constituting a vague standard on which to hold a provider liable for submitting a *knowingly* false certification. Accordingly, if the government intended to create FCA liability for providers who submitted bills while not in compliance with the quality of care regulations, then it would and could have added an express certification to that effect in the cost report forms, as was done for the anti-kickback rules. Conversely, the absence of such an express certification requirement for each bill suggests that the government did not intend to cover quality of care issues within the rubric of the FCA.

4. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*—*Thompson* involved issues analogous to

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cation" theory, it later characterized the relator as arguing that "although there is no allegation that [d]efendants overcharged Medicare or charged it for services not rendered, [d]efendants' failure to comply with Medicare laws prohibiting kickbacks and self-referrals rendered the Medicare claims submitted by [d]efendants false or fraudulent." *Roy*, 914 F. Supp. at 1510. It is thus unclear whether the *Pogue* court's finding of potential FCA liability rested on an "implied certification theory" or on the type of analysis applied in *Roy*.

165. See *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 938 F. Supp. 399, 406 (S.D. Tex. 1996) (quoting HCFA Form 2552).

166. *Thompson*, 938 F. Supp. at 406.

*Pogue*. In *Thompson*, a physician alleged that a provider violated the FCA by submitting claims for services rendered in violation of the anti-kickback statute and the self-referral statute.<sup>167</sup> The physician-relator also alleged that the defendants had violated the FCA by falsely certifying in annual cost reports that the Medicare services identified therein were provided in compliance with laws and regulations regarding the provision of health care services.<sup>168</sup> It was further alleged that the defendants had violated the FCA by submitting Medicare claims for medically unnecessary services.<sup>169</sup> The district court initially dismissed the complaint on several grounds. First, after analyzing many prior FCA cases, including *Pogue*, the district court held that claims for services rendered in violation of a statute or regulation do not necessarily convert a claim into a false claim within the meaning of the FCA.<sup>170</sup> Second, the district court rejected the use of a false certification argument as a basis for violation of anti-kickback rules on the grounds that the court already concluded liability under the FCA "requires that the claims themselves be false or fraudulent."<sup>171</sup> Third, the district court dismissed the allegations regarding lack of medical necessity, holding that the complaint lacked the specificity required by Federal Rule of Civil Procedure 9(b).<sup>172</sup>

The appeals court affirmed the first and third of these grounds for dismissal.<sup>173</sup> It also held that government and private studies demonstrating that 40% of claims submitted by providers for services rendered in violation of the anti-kickback statute or the Stark II law were for services that were not medically necessary did not, without more, satisfy Rule 9(b).<sup>174</sup>

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167. *Id.* at 401.

168. *Id.*

169. *Id.* at 401-02.

170. *Id.* at 402-05.

171. *Thompson*, 938 F. Supp. at 406-07.

172. *Id.*

173. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997).

174. *Thompson*, 125 F.3d at 902-03. In accepting the argument that "claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA," the Fifth Circuit relied on two important non-health care cases: *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (holding that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA") and *United States ex rel. Weinberger v. Equifax*,

However, the appeals court rejected the district court's dismissal of the false certification argument and remanded the case for further factual development on "whether, or to what extent, payment for services identified in defendants' annual cost report was conditioned on defendants' certification of compliance" with the anti-kickback statute and Stark laws.<sup>176</sup> The appeals court also directed the district court to determine whether claims for services rendered in violation of the self-referral statute in and of themselves violate the FCA in light of the express provision in Stark II prohibiting payment for services rendered to patients referred to that provider in violation of Stark II.<sup>176</sup>

On remand, the district court ruled that FCA liability could be imposed upon defendants if they had provided services in violation of the anti-kickback statute and/or Stark II because this would render false their "express" cost report certifications.<sup>177</sup> Specifically, the district court relied upon express language in the cost reports warning that "if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result."<sup>178</sup> Significantly, while citing with approval the similar outcome in *Pogue*, the district court in *Thompson* challenged the *Pogue* court's reliance on an "implied" certification theory as *Pogue*'s "Achilles heel."<sup>179</sup> This is significant because cost reports do not contain a similar "express" certification

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Inc., 557 F.2d 456, 460-61 (5th Cir. 1977) (holding that claims submitted by a government contractor who allegedly violated the Anti-Pinkerton Act, 5 U.S.C. § 3108 (1994), did not necessarily constitute false or fraudulent claims under the FCA since the FCA is not an enforcement device for the Anti-Pinkerton Act).

175. *Thompson*, 125 F.3d at 902-03.

176. *Id.* at 903.

177. The court did not address whether, in light of the regulatory requirement (42 C.F.R. § 411.353 (1994)), reimbursement obtained in violation of Stark II must be refunded or whether the cost reports created FCA liability as "reverse false claims." See 31 U.S.C. § 3729(a)(7) (1994).

178. *Thompson*, 20 F. Supp. 2d at 1035 n.21. The district court also considered persuasive for overcoming the motion to dismiss a declaration from the HCFA submitted by the government contending that the HCFA considers cost reports to constitute certifications of compliance with the anti-kickback and Stark rules. *Id.* at 1046. However, the court arguably had no need to consider this declaration once it had found that the express language of the cost reports covered anti-kickback and Stark rules.

179. *Id.* at 1048 n.33.

of compliance with all quality of care regulations. Accordingly, *Thompson* is easily distinguishable when the underlying alleged violation involves the less clear-cut regulatory standards for care rather than the more clear-cut anti-kickback and Stark laws.

The *Thompson* district court also seemed to go beyond its remand mandate by holding that concealing anti-kickback and Stark II violations from the government (in the context of submitting reimbursement claims) may intrinsically violate that portion of the anti-kickback statute which criminalizes a failure to disclose certain information.<sup>180</sup> However, this again distinguishes *Thompson* from cases involving the quality of care regulations because they do not similarly criminalize failures to comply with them or even concealment of such failures.<sup>181</sup>

5. *United States ex rel. Joslin v. Community House Health of Maryland*—Like *Pogue* and *Thompson*, *United States ex rel. Joslin v. Community House Health of Maryland*<sup>182</sup> addressed the certification issue in the context of allegations that a health care provider failed to comply with the regulations necessary to participate in Medicare. Specifically, the relator in *Joslin* alleged that the provider billed Medicare without first obtaining a required “certificate of need” (“CON”) from the State and that the

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180. *Id.* at 1047-48 (discussing 42 U.S.C. § 1320a-7b(b)).

181. It is noteworthy that in its opinion on remand, the district court did not address the question of whether the alleged false certifications could create FCA liability even though the complaint did not satisfy the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. See *Thompson*, 20 F. Supp. 2d at 1037-39. Rule 9(b) imposes a heightened pleading requirement with respect to allegations of fraud. The Rule provides that averments of fraud shall be stated with “particularity.” FED. R. CIV. P. 9(b). As noted by the *Thompson* district court in its initial decision, Rule 9(b) applies to FCA cases, and it “requires allegations of the particulars of time, place and contents of the false representations.” *Thompson*, 938 F. Supp. at 406. Even assuming that allegations of false certifications may be sufficient to state a cause of action within the meaning of Rule 12 of the Federal Rules of Civil Procedure, the allegedly false certification also needs to pass muster under Rule 9(b) in order to overcome a motion to dismiss. Thus, government or relator counsel not only needs to identify the specific certification which is claimed to be false, but he also must identify the specific claims that were rendered false as a result of the false certification. In a case such as *Thompson*, for instance, the plaintiff would be required to allege that the certification was false because the defendant had violated the anti-kickback statute, and he would further be required to identify the specific relationships that violated the anti-kickback statute. Moreover, he must do this in a manner which satisfies Rule 9(b).

182. 984 F. Supp. 374 (D. Md. 1997).

defendant violated the FCA when it "certified" in bills and cost reports that it had complied with all applicable state laws and regulations required to participate in Medicare.<sup>183</sup> Thus, *Joslin* appears to represent an attempt to extend the certification argument beyond "express" certifications of compliance with specific requirements, such as the anti-kickback rules at issue in *Thompson and Pogue*.

The *Joslin* court granted summary judgment for the defendant and, in doing so, rejected two false certification arguments.<sup>184</sup> First, the court rejected an argument of "implied certification" with respect to the bills submitted by a home health care provider.<sup>185</sup> The court found that even assuming the provider had certified compliance with "[s]tate laws and regulations . . . [t]he relevant statute and regulation simply state that such compliance is a condition of participation in the Medicare program [and] . . . no evidence has been presented suggesting that certification of such compliance is a condition to *payment*, the *sine qua non* of FCA liability."<sup>186</sup> Second, the court rejected an argument of "express" certification with respect to defendant's annual cost reports.<sup>187</sup> In doing so, the court recognized that the cost reports' HCFA Form 1728 states: "I HEREBY CERTIFY that . . . I am familiar with the laws and regulations regarding provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations."<sup>188</sup> The court stated that "the factual record does not demonstrate that this certification in the annual cost reports was a prerequisite to obtaining Government payment."<sup>189</sup> The latter finding is particularly significant be-

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183. *Joslin*, 984 F. Supp. at 377.

184. *Id.* at 374.

185. *Id.* at 384.

186. *Id.* at 385.

187. *Id.*

188. *Joslin*, 984 F. Supp. at 385.

189. *Id.* *Joslin* found support for its certification holdings based, in part, on United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) (citations omitted). In *Hopper*, the Ninth Circuit focused on the need for *actual* certification. See *Hopper*, 91 F.3d at 1266-67. It held that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA. *It is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit.*" *Id.* at 1266 (emphasis added). It further held that "[m]ere regulatory violations do not give rise to a viable FCA action. This is partic-

cause it suggests that the relator was *unable* to present any evidence, despite having an opportunity for discovery, that the HCFA considered compliance with this type of regulatory requirement—as opposed to the anti-kickback rules at issue in *Thompson*—relevant to payment under the Medicare program.

### *B. Cases By Government Ending in Consent Decrees*

The theory that substandard care may violate the FCA has been advanced by certain government prosecutors in at least three cases that resulted in consent decrees before the issues were fully litigated. The fact that these providers elected to enter into consent decrees without any finding of liability reflects the enormous power that the government can wield merely through the perceived threat of such actions.

1. *GMS Management-Tucker, Inc.*—In February 1996, the government filed an FCA complaint against *GMS Management-Tucker, Inc. et al.*, the owner and manager of a nursing

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ularly true here where regulatory compliance was not a *sine qua non* of receipt of state funding. There are administrative and other remedies for regulatory violations." *Id.* at 1267. Furthermore, under a section heading entitled "Promissory Fraud," *Hopper* rejected the notion that regular, generalized promises to comply with all applicable regulations constitute the requisite certification. *Id.* at 1267. Although *Hopper* involved regulatory standards for publicly funded education, not health care, it provides sufficiently analogous guidance on the certification issue. Furthermore, the two fields are themselves analogous because both involve the provision of services whose standards are often difficult to define and are subject to change depending on demographic and political trends. *Joslin* also relied on the Fifth Circuit's opinion in *United States ex rel Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997), which remanded on the issue of whether certification of compliance with anti-kickback and Stark rules was a prerequisite to payment. *Joslin*, 984 F. Supp. at 384. As discussed above, the post-remand opinion in *Thompson* accepted the argument that such certification was a prerequisite to obtaining government payment. *See Thompson*, 125 F.3d at 902. However, the different outcomes in the two cases likely arose because they involved alleged certification with different requirements. Specifically, *Thompson* involved false certification of compliance with the self-referral statute, which precludes the submission of bills for prohibited transactions and which is expressly referenced by the cost reports. *Id.* In contrast, *Joslin* involved false certification of the state's certificate of need rules, which do not on their face condition the submission of bills on compliance and which are not expressly referenced in the cost reports. *Joslin*, 984 F. Supp. at 380. Furthermore, *Thompson* generally utilized motion to dismiss standards while *Joslin* involved a motion for summary judgment. *Compare Thompson*, 125 F.3d at 903, with *Joslin*, 984 F. Supp. at 376.

home.<sup>190</sup> The complaint alleged that the owner and operator submitted or caused to be submitted false claims because they had failed to provide adequate nutrition and wound-care to three former residents.<sup>191</sup> The government contended that the claims were false because the services for which reimbursement was sought were not provided in conformity with the Nursing Home Reform Act ("NHRA").<sup>192</sup> The NHRA requires a nursing facility to "care for its patients in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident."<sup>193</sup> The NHRA also requires nursing facilities to "provide services and activities to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident."<sup>194</sup> Finally, the conditions of participation applicable to nursing homes require that each facility ensure that a resident "[r]eceive[s] a therapeutic diet when there is a nutritional problem."<sup>195</sup> The government alleged violations of these NHRA requirements on the grounds that three former residents had developed numerous severe decubitus ulcers at the facility and had become malnourished to the point where it became impossible for their bodies to heal from the ulcers.<sup>196</sup> In short, the government alleged that the residents' nutritional requirements had not been met.<sup>197</sup> The case resulted in the entry of a wide-ranging consent decree.<sup>198</sup>

As explained by David Hoffman, the Assistant U.S. Attorney

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190. See David Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, FALSE CLAIMS ACT AND QUI TAM QUARTERLY REV., July 1996, at 17 (discussing *United States v. GMS Management-Tucker, Inc.*, Civ. A. No. 96-1271 (E.D. Pa. filed 1996)). See also M. Mustokoff et al., *The Government's Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Ingenuity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANN. HEALTH L. 137 (1997) (discussing *GMS Management* and the applicability of the FCA); cf. David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANN. HEALTH L. 147 (1997).

191. Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, *supra* note 190, at 17.

192. See *id.* at 20 (referring to 42 U.S.C. § 1396r).

193. 42 U.S.C. § 1396r(b)(1)(A).

194. *Id.* § 1396r(b)(2).

195. 42 C.F.R. § 483.25(i)(2) (1998).

196. Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, *supra* note 190, at 20.

197. *Id.*

198. *Id.* at 21.

who prosecuted the case, the government's theory of prosecution in *GMS Management-Tucker* was that the nursing home had entered into a provider agreement which contained the following provision: "the submission by, or on behalf of, the Facility of any claim, either by hard copy or electronic means, shall be certification that the services or items from which payment is claimed actually were provided."<sup>199</sup> According to Mr. Hoffman, "these provisions make clear that the submission of a claim to the government for payment certifies that the services billed were actually provided. The Government interpreted these requirements to include the provision of the services in a manner that comports with federal and state law and regulations."<sup>200</sup> Contrary to Mr. Hoffman's argument, however, there is a difference between arguing that services were not actually provided and arguing that services were not actually provided *because they were rendered in a manner which does not comport with federal and state law and regulations*. The issue of whether services were *actually* provided is conceptually and factually distinct from the question of whether the services were provided in compliance with law. This is true especially where the law and regulations, in the form of the conditions of participation, merely set forth general requirements but are not specific as to the content of those requirements.

Mr. Hoffman also seemed to recognize another problem with using the FCA as a vehicle for enforcing conditions of participation. Although there is no private right to enforce the NHRA, permitting the FCA to be used as an enforcement vehicle for the NHRA indirectly permits private enforcement through the *qui tam* provisions of the FCA.<sup>201</sup> A case such as *GMS Management-Tucker* underscores the need to preclude relators from going forward with an FCA action where the government has declined to intervene, especially where, as in *GMS Management-Tucker*, the underlying statute does not contain a private right of action.

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199. *Id.* at 19.

200. *Id.* at 20.

201. Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, *supra* note 190, at 22.

2. *Chester Care*.—Similarly, in January 1998, the government brought an FCA action against Chester Care et al., nursing home owners and operators, on theories virtually identical to those contained in the *GMS Management-Tucker* complaint.<sup>202</sup> The one significant addition was an FCA claim based upon the death of a resident who had been scalded to death in a tub containing 138-degree water. The resident had been put in the tub by a certified nurse's aide, and the government alleged that the facility had knowledge of a malfunctioning boiler, had been cited by the State Department of Health in prior surveys for improper water temperatures, and had submitted a plan of correction to cure the problem.<sup>203</sup> *Chester Care* was settled on terms similar to those in *GMS Management-Tucker Inc.*<sup>204</sup>

While *Chester Care* involved factual allegations no less serious than those in *GMS Management-Tucker Inc.*, it is equally flawed from an FCA standpoint. FCA liability should not arise on the basis of "implied certification" theories, especially where the underlying laws and regulations are vague and aspirational. In addition, pursuing the scalding-death incident under an FCA theory is a highly doubtful approach, both from a legal and a factual standpoint. This is so, notwithstanding the fact that it could be appropriate to pursue criminal certification and licensing actions against the nurse's aide, the facility and perhaps even supervisory and managerial personnel.

3. *Northern Health Facilities*.—On September 14, 1998, the government announced that it had filed a civil FCA action against Northern Health Facilities, Inc., which operates a nursing home called Greenbelt Nursing and Rehabilitation, based on alleged substandard care.<sup>205</sup> This case resulted in an agreed-upon preliminary injunction, which applied to the practices that the DOJ had alleged to be inadequate and fraudulent.<sup>206</sup> The alleged substandard care involved a failure to provide adequate medical care using psychotropic and anti-depressant medication

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202. *United States v. Chester Care*, No. CIV.A.98-CV-139 (E.D. Pa. filed 1998).

203. *Chester Care*, No. CIV.A.98-CV-139.

204. *Id.*

205. *United States v. Northern Health Facilities, Inc.*, 25 F. Supp. 2d 690 (D. Md. 1998).

206. *Northern Health Facilities*, 25 F. Supp. 2d at 691.

and a failure to provide minimum standards of care guaranteed by law.<sup>207</sup> Specifically, the government alleged:

inappropriate administration of medication dosage; delay in notifying a physician for eight (8) hours of change in resident's condition; failure to administer hypertension medication for a week; failure to identify that a resident was receiving two different and inconsistent antibiotics; delay of over three (3) weeks in scheduling an ophthalmology consultation for a resident with soreness and redness in both eyes; and delay in notifying a physician of change of condition of a resident with stasis ulcers, who was admitted to the hospital for treatment.<sup>208</sup>

*Northern Health Facilities* is different than the other substandard care cases brought by the government in at least two important respects. First, the alleged care deficiencies appear to be considerably less serious than in *Chester Care, GMS Management-Tucker, Inc.*, and *Aranda*.<sup>209</sup> Second, the Greenbelt facility had been notified by state health care agencies that it was not in compliance with the conditions of participation because it was providing substandard care and that it would be terminated from the Medicare and Medicaid programs.<sup>210</sup> Greenbelt sought to avoid suspension by certifying that it was, in fact, in compliance with program participation requirements, but subsequent federal and state investigations determined that Greenbelt continued to provide substandard care and that its certificate of compliance was false.<sup>211</sup> The government contended that the certification of compliance which Greenbelt had given in order to avoid suspension "constitutes a claim for payment to the United States in reckless disregard or deliberate ignorance of the truth or falsity of the claims and statements made to obtain payment from the United States and constitutes a violation of the FCA."<sup>212</sup> Although the underlying ambiguities in the conditions of participation make *Northern Health Facilities* a problematic case from an FCA standpoint, the fact that the defendant re-

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207. *Id.* at 690-91.

208. Appellant's Complaint at 27, *United States v. Northern Health Facilities, Inc.*, 25 F. Supp. 2d 690 (D. Md. 1998) (No. AW 98-343).

209. Appellant's Complaint ¶ 27, *Northern Health Facilities* (No. AW 98-343).

210. *Id.* ¶ 19.

211. *Id.* ¶ 25.

212. *Id.* ¶ 28.

ceived a non-compliance notice prior to the lawsuit diminishes the fairness concerns which exist in *Aranda*, *GMS Management-Tucker* and *Chester Care*.

The Preliminary Injunction generally was irrelevant because it merely required Greenbelt to comply with the non-specific standards set forth in the quality of care regulations with which it already was required to comply, such as to "[p]rocur[e] sufficient nursing staff to ensure adequate continuity of resident care," to "ensure that they maintain medical records for each resident that comport [sic] with accepted professional standards," and to "make timely and appropriate notes in the residents [sic] records."<sup>213</sup> Moreover, the Preliminary Injunction expressly stated that "a cited deficiency by state or federal surveyors [does not, in and of itself] establish noncompliance with this Preliminary Injunction."<sup>214</sup> Accordingly, the Preliminary Injunction neither provided sufficient specifics to establish regulatory non-compliance nor accepted the underlying theory that regulatory non-compliance alone—which is what deficiency citations demonstrate—constitutes a violation of the FCA.<sup>215</sup>

4. *Pending Qui tam Lawsuits.*—A series of identical *qui tam* cases in the Eastern District of California, still unsealed as of late 1998 and none of which involve government intervention, demonstrate the unfortunate elasticity with which enterprising counsel are attempting to stretch the FCA.<sup>216</sup> In these suits,

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213. *Northern Health Facilities*, 25 F. Supp. 2d at 697.

214. *Id.* at 691.

215. Notwithstanding Greenbelt's agreement to a settlement with the DOJ which included a consent decree to provide certain standards of care, the DHHS decided to exclude the facility from participating in the Medicare and Medicaid programs. The DHHS's authority to do so was upheld on appeal to the U.S. District Court for the District of Maryland. *Northern Health Facilities, Inc. v. United States*, 39 F. Supp. 2d 563 (D. Md. 1998). This result demonstrated that the FCA is not necessary to enforce compliance with the regulatory standards for federal participation because the DHHS has the necessary power and ability to handle such enforcement. Indeed, the DOJ's attempted use of the FCA here produced results contrary to those that the DHHS, the agency with responsibility for enforcement, deemed appropriate for this facility. *Northern Health Facilities*, 39 F. Supp. 2d at 557.

216. See, e.g., *United States ex rel. Foundation Aiding the Elderly*, No. CIV.A.S-97-0546 (E.D. Cal. filed Apr. 4, 1997); *United States ex rel. Escott v. Sun-Mar Health Care*, No. CIV.A.S-96-106 (E.D. Cal. filed Jan. 22, 1997); *United States ex rel. McKenzie v. Crestwood Hosp., Inc.*, No. CIV.A.S-97-0107 (E.D. Cal. filed Jan. 22, 1997); *United States ex rel. Gotzmer v. Crestwood Hosp., Inc.*, No. CIV.A.S-96-2173

the relators are attempting to impose FCA liability on the basis of transparently aspirational regulatory language. In *McKenzie*, for example, the relator alleged, *inter alia*, that skilled nursing facilities falsified patient records to conceal the provision of what they contend was "substandard" care and thereby filed false claims.<sup>217</sup>

One of the specific care deficiencies alleged related to the fact that certain skilled nursing facility residents had died, and certain of the death certificates stated that pressure sores (i.e., decubitus ulcers) were one of the causes of death.<sup>218</sup> In support of their allegations, the relators attached a declaration from a physician who had not seen any of the patients.<sup>219</sup> The physician declared that she had formed the following opinions: (1) that pressure sores are preventable;<sup>220</sup> (2) that people should not die with pressure sores;<sup>221</sup> (3) if people develop pressure sores and/or die with pressure sores as indicated on death certificates, "it is probable they were not repositioned every two hours (which is standard procedure in the prevention and treatment of pressure sores), regardless of whether their medical records and/or charts, say that they were,"<sup>222</sup> and (4) where pressure sores developed as set forth in the death certificates, it is "probable that the defendants' monthly Claims Certifications for services for Medicare/Medicaid patients under the Medicare/Medicaid programs were false."<sup>223</sup> The alleged falsity related to the following matters: (1) that the patient medical charts falsely reflected repositioning every two hours and (2) that the defendants had falsely certified compliance with the condition of participation, which requires providers to ensure that residents do not

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(E.D. Cal. filed Dec. 16, 1996). The authors represent two of the defendants in the *McKenzie* action and all defendants in the *Gotzmer* action.

217. Plaintiff's Complaint ¶ 22, *United States ex rel. McKenzie v. Crestwood Hospitals, Inc.*, No. CIV-S-97-0107 (E.D. Cal. filed Jan. 22, 1997) (No. CIV-S-97-0107).

218. Declaration of Kathryn L. Locatell, M.D., in support of Plaintiffs' Consolidated Opposition to Motions to Dismiss ¶ 4, *McKenzie* (No. CIV-S-97-0107).

219. *Id.*

220. *Id.* ¶ 5.

221. *Id.*

222. *Id.* ¶ 6.

223. Declaration of Kathryn L. Locatell, M.D., in Support of Plaintiffs' Consolidated Oppositions to Motions to Dismiss ¶ 7, *McKenzie* (No. CIV-S-97-0107).

develop pressure sores.<sup>224</sup> If a resident has pressure sores, the provider must see that the resident receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.<sup>225</sup>

This condition of participation imposes a duty on providers to do certain things, but contrary to the language of the condition, the scope of the duty set out in the condition cannot be absolute. It would be nonsensical to impose FCA liability on a provider for violating its duty to "ensure that residents do not develop pressure sores" simply because one or more patients developed pressure sores and/or died as a result of pressure sores. If the provider's duty is not absolute, by what criteria should the duty be measured? Common sense tells us that we must imply a standard of reasonableness, notwithstanding the apparently unconditional, open-ended language contained in the condition of participation. But how is a provider to know when it has unreasonably failed to discharge its duty, and can such a subjective test form the basis for FCA liability? It is grossly unfair to hold a provider or supplier liable under the FCA where it did not know, and could not have been reasonably expected to know, that the government would have withheld payment had it known that a condition of participation was violated, especially where the violation cannot be penalized by non-payment. There is no principled basis for imposing FCA liability on a provider who had no reason to know that it was not entitled to receive payment even though it was in violation of the conditions of participation.

If a provider is required only to act reasonably by way of discharging its duty, what criteria should we use to define reasonableness? It would appear that the definition of reasonableness should be, among other things, resource-based, i.e., it would have to take into account the resources made available to the provider by the government and the resources actually allocated by the provider to discharge its duty. Surely a provider is not obligated to expend limitless resources by way of discharging this duty. If the government does not provide unlimited resources to enable the provider to discharge its duties, which surely it

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224. 42 C.F.R. § 483.25(c)(1) (1998).

225. *Id.* § 483.25(c)(2).

does not, the provider cannot be held to a standard that would require it to dedicate resources that exceed those made available to it by the government. Similarly, a provider should not be held liable under the FCA for providing care in a manner consistent with generally accepted standards employed in the profession and previously accepted by the government regulators until those standards are formally changed and that acceptance formally repudiated. Otherwise, the provider will be subjected to liability based on retroactive condemnation of that which was considered acceptable at the time the services were provided.<sup>226</sup>

The physician's declaration reveals another problem with the approach based on certification of compliance with the law. The physician has imported into the relevant condition of participation a requirement that patients be repositioned every two hours, characterizing this as "a standard procedure,"<sup>227</sup> yet no such procedure is expressly mentioned in the condition of participation. It is one thing to argue that such a "standard procedure" should form the basis for a "duty of care" in a negligence suit, but no basis exists for arguing that such a standard exists upon which to predicate FCA liability. To do otherwise would convert every negligence action into a potential FCA case. Furthermore, arguments based on disagreements about the appropriate standards of care are precisely what *Luckey* held were not appropriately subject to an action under the FCA.<sup>228</sup>

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226. For example, in these cases, the relators have argued that record-keeping was knowingly false because nurses did not fill out the paperwork reflecting the provision of activities of daily living ("ADLs") on the same day those ADLs were provided. Plaintiff's Complaint ¶ 19(a), *McKenzie* (No. CIV-S-97-0107). However, the recognized standard in the industry for completing such paperwork is a seven day standard, not a same day standard.

227. Declaration of Kathryn L. Locatell, M.D., in support of Plaintiffs' Consolidated Opposition to Motions to Dismiss ¶ 6, *McKenzie* (No. CIV-S-97-0107).

228. *Luckey*, 2 F. Supp. 2d at 1047 (noting that "the legal process is not suited to resolving scientific disputes"). For example, the relators' purported expert witness in these cases is advancing an absolutist opinion about the causes of pressure sores and the ability to treat pressure sores that does not comport with the opinions from other medical professionals who have written in this field. See, e.g., J. MAKLEBURST & M. SIEGGREEN, *PRESSURE ULCERS: GUIDELINES FOR PREVENTION AND NURSING MANAGEMENT* 14-15 (2d ed. 1995) (noting the misconception that pressure ulcers are the result of poor care or that all pressure sores are curable); Sharon L. Darkovich, *Managing Pressure Ulcers: When Is No Treatment The Treatment?*, *NURSING* 96, July 1996, at 47 (indicating that certain groups of people are predisposed to pressure ulcers, and the ulcers can develop even when patients receive exemplary care).

A more global problem relevant to these types of *qui tam* cases is that relators have no incentive to exercise the type of prosecutorial discretion that the government might use to refrain from pursuing lawsuits which might not constitute good policy to file even if an argument could be made to support filing it. As a unanimous Supreme Court recently observed: "[a]s a class of plaintiffs, *qui tam* relators are different in kind than the Government. They are motivated primarily by prospects of monetary reward rather than the public good."<sup>229</sup> Relators are "private persons acting, if you please, under the strong stimulus of personal ill will or the hope of gain."<sup>230</sup>

### C. Critique of False Certification Theories as Applied to Quality of Care Issues

The false certification cases finding liability rest on the proposition that the provider either implicitly or explicitly certified in its claims for reimbursement that it had provided the care at issue in a manner consistent with the prevailing standards of care. The "implied certification" theory has its roots in *Ab-Tech Construction v. United States*.<sup>231</sup> In *Ab-Tech*, the court held that the defendant's submission of payment vouchers constituted an implied certification of compliance with continuing eligibility requirements in the Small Business Administration's ("SBA") minority-owned business program and that the vouchers were "false claim[s]."<sup>232</sup> The court had to resort to a theory of an "implied" certification of compliance because the vouchers did not contain an *express* certification of compliance.<sup>233</sup> In reaching this result, the court noted that the defendant's false certification of continuing adherence to eligibility requirements "not only dishonored the terms of [the defendant's] agreement with [the SBA] but, more importantly, caused the Government to pay

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229. *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997).

230. *Schumer*, 520 U.S. at 949 (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.5 (1943) (quoting *United States v. Griswold*, 24 F. 361, 366 (Or. 1885))).

231. 31 Fed. Cl. 429 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

232. *Ab-Tech*, 31 Fed. Cl. at 434.

233. *Id.*

out funds in the mistaken belief that it was furthering the aims of the [minority ownership] program."<sup>234</sup> The court then stated that the "Government was duped by [the defendant's] active concealment of a fact vital to the integrity of that program. The withholding of such information—information critical to the decision to pay—is the essence of a false claim."<sup>235</sup>

The *Ab-Tech* court cited no case to support its finding of an implied certification of compliance with law, and our research has not disclosed such a case. Despite the absence of precedential support for this theory, the result in *Ab-Tech* seems correct because absent the particular fact concealed, namely that the defendant had entered into a prohibited contract which gave a non-minority firm co-equal authority over its operations, the government would not have paid *Ab-Tech's* vouchers.<sup>236</sup> The government would not have paid the claims because the concealed facts were central to the government program at issue.

Thus, the implied certification theory as developed in *Ab-Tech* differs in at least two important respects from the application of that theory in the health care context. First, the non-compliance in *Ab-Tech* related to a specific factual event, not to a failure to comply with an amorphous, aspirational regulation. Second, without specifically so stating, the *Ab-Tech* court implied an element of materiality into its FCA analysis, viz, the concealed fact "duped" the government into "pay[ing] out funds in the mistaken belief that it was furthering the aims of the [SBA] program."<sup>237</sup> The *Luckey* court correctly characterized the *Ab-Tech* case as one in which the defendant's "practice had violated the heart of its agreement with the government."<sup>238</sup>

The implied and express certification cases are based upon the assumption that the government would not have paid the claim had it known about the underlying legal violation. But the FCA is an unnecessary and unclear prism for determining whether the government would have paid the bill absent the implied or express certification. The simplest way to determine whether the government would have paid the bill had it been

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234. *Id.*

235. *Id.* (footnote omitted).

236. *Id.* at 433.

237. *Ab-Tech*, 31 Fed. Cl. at 434.

238. *Luckey*, 2 F. Supp. 2d at 1045.

aware of the defendant's non-compliance is to consult the underlying statutory and regulatory scheme. If the statute and regulations state that non-payment is a mandatory penalty for a violation, such as with the Stark II self-referral law, this would provide an adequate basis for imposing FCA liability under an express or implied certification theory. Where, however, the underlying statutory and regulatory scheme do not mandate non-payment in the event of a violation, which is the case under the federal health care anti-kickback statute and the conditions of participation, there is no principled basis for imposing FCA liability. Where the underlying statutory and regulatory scheme provide a negative answer to the fundamental question posed by the FCA, viz, whether the government would have paid the claim had it known about the underlying violation, a certification theory should not work a different result under the FCA than that contemplated by the more specific underlying statute and regulatory scheme. The FCA was not intended to broaden the scope of other statutes, yet that is precisely the result reached in many certification theory cases.

The certification cases are especially troubling in the context of substandard care. First, the certifications at issue are deemed to relate to, among other things, "conditions of participation." The conditions of participation, however, do not mandate non-payment in the event of a violation. Rather, federal and state administrative agencies are given broad discretion in fashioning appropriate remedies in the face of regulatory violations. Unless termination from the program or non-payment are mandatory sanctions, a violation of a condition of participation should not form the basis for FCA liability. In this regard, it is necessary to distinguish between conditions of *participation*, on the one hand, and conditions of *payment*, on the other.

Second, the conditions of participation set out general standards and goals. They are more aspirational than prescriptive. In the absence of clearly defined objective requirements, it is unfair to impose FCA liability for regulatory violations which are first determined to exist in the context of an FCA proceeding.<sup>239</sup>

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239. *United States v. Napco Int'l, Inc.*, 835 F. Supp. 493, 497-98 (D. Minn. 1993) (holding that in the face of ambiguous statutory requirements, where no regulations

Third, the conditions of participation are enforced through a complex enforcement process which includes frequent on-site inspections of the provider. If the provider is advised by the regulators that it is in compliance with the conditions of participation, such advice would seem to preclude the requisite finding of knowledge on the part of the provider to support a finding of FCA liability.

Fourth, merely because a provider is required to promise compliance with the conditions of participation (or other legal requirements) in order to become eligible for the Medicare program and to submit claims for reimbursement, it is not the case that subsequent non-compliance immediately vitiates program eligibility or automatically disqualifies a provider from filing reimbursement claims. Under the applicable rules, a provider who has qualified and who is certified to participate in the Medicare program is legally entitled to submit reimbursement claims notwithstanding government-observed non-compliance with regulatory requirements. The provider maintains its eligibility to submit reimbursement claims until its eligibility expires or the government takes affirmative steps to remove eligibility and bar the provider from submitting reimbursement claims.

Fifth, the argument based on a false certification of compliance with the law is predicated upon unrealistic assumptions about provider and supplier conduct, and it is directly at odds with the language contained in many of the laws and regulations upon which FCA liability is sought to be based. Indeed, the health care industry is so heavily regulated that providers and suppliers neither know nor understand, and cannot reasonably be expected to know and understand, all of the laws and regulations that govern their operations. Further, even if providers and suppliers knew and understood all of the laws and regulations which govern their operations, they cannot reasonably be

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further define those requirements, a court need not hold a defendant to the government's strict interpretation; instead, the court may exercise its own judgment). *See also Luckey*, 2 F. Supp. 2d at 1049 (concluding that a defendant cannot knowingly submit a false claim when it is submitted in good faith). *Compare United States v. Garfinkel*, 29 F.3d 1253, 1257 (8th Cir. 1994) (finding that an agency manual provided appropriate guidance and met the government's burden of refuting other interpretations regarding a form's signature), *with United States v. Adler*, 623 F.2d 1287, 1289 (8th Cir. 1980) (finding no ambiguity when the government clearly demonstrated that the defendant did not provide the services that he was claiming).

expected to know whether they are in full compliance with all of those laws and regulations. This is so because of several factors, including the ambiguity of the potentially applicable laws and regulations, the lack of uniformity in the interpretation and application of relevant laws and regulations by government agencies, carriers and fiscal intermediaries, and the sheer breadth of the operations of many providers and suppliers. In addition, many laws and regulations are phrased in high-minded rhetoric which defies compliance by providers and suppliers, especially in light of the scarce, and increasingly scarcer, resources allocated to providers and suppliers by Congress and the regulators.

Furthermore, the compliance-with-law-certification theory is overbroad for FCA purposes. There are many laws and regulations which apply only marginally to health care, and the failure to comply with those and many other of the applicable laws would not necessarily result in non-payment if the government was aware of the non-compliance. For example, non-compliance with food and drug, environmental, labor, transportation and antitrust laws and regulations, while perhaps raising serious issues, would not ordinarily result in program termination or non-payment. This raises the question of whether the compliance-with-law-certification should be interpreted to apply only to health care or perhaps only to health care fraud and abuse laws and regulations.

Even assuming that the compliance-with-law-certification is deemed to apply only to health care fraud and abuse laws, these laws have knowledge and intent requirements which are at variance with the elements necessary to establish FCA liability. For example, a Stark II violation does not require a showing of knowledge or intent; it is a strict liability statute. Presumably, however, in order to establish FCA liability, it would be necessary to show that the provider knew that its activities violated Stark II at the time of the certification. In contrast, a violation of the anti-kickback statute requires a showing that the defendant acted "knowingly and willfully." Thus, it would appear that conduct that violates the anti-kickback statute would necessarily render a certificate of legal compliance false within the meaning of the FCA. Further, many laws and regulations contemplate that non-compliance will not result in non-payment of a reim-

bursement request, yet providers and suppliers are deemed to "know" that non-compliance will result in non-payment.

Another serious shortcoming of the argument based on certificate-of-compliance-with-law is that it seeks to impose liability upon the purported expression of a legal opinion or conclusion, not an objectively verifiable statement of fact.<sup>240</sup> Finally, the recent spate of FCA cases in the health care area based upon certification and substandard care allegations underscores the need for materiality to be a required element of a false claims action.<sup>241</sup> In the absence of a materiality requirement, it appears that liability may be imposed under the false claims prong even though the non-compliance that is allegedly falsely concealed could not, as a matter of underlying law, have resulted in non-payment of the claim in the first instance. Moreover, even assuming that the failure to provide the allegedly false certification may have resulted in a denial of the claim, FCA liability should not be imposed unless denial of the claim was reasonably likely if the government had known the truth and unless the defendant knew or had reason to know that the claim was likely to be denied if the government knew the truth. Thus, a false certification that a provider complied with all applicable laws should not result in FCA liability if the provider was aware only that it had violated laws that are not central to the provision of healthcare (e.g., zoning laws, wage and hour laws, tax laws, etc.), even if payment is explicitly conditioned on the certification. It would be wrong to impose FCA liability for having falsely certified compliance with a legal or regulatory requirement which the provider could not have reasonably expected to have resulted in non-payment had the government been aware of non-compliance.

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240. *West v. Western Casualty & Surety Co.*, 846 F.2d 387, 393 (7th Cir. 1988) (indicating that "[a] statement that merely expresses an opinion . . . rather than past or present facts, does not constitute an actionable misrepresentation" (citing *Peterson Indus. v. Lake View Trust and Savings Bank*, 584 F.2d 166, 169 (7th Cir. 1978))); *Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795, 810 (D. Utah 1988) (noting that a claim under the FCA must be "a statement of fact that can be said to be true or false"). *But see West*, 846 F.2d at 393 (stating that whether a statement expresses fact or opinion depends upon the context: "[c]ourts focus on the circumstances surrounding the representation to determine whether the plaintiff may have justifiably relied on the opinion as though it were a statement of fact").

241. *See infra* pp. 35-40.

Recognition of the need for a materiality element in this context may be taking hold in recent FCA cases in the health care area, although the courts do not explicitly hold that materiality is a requirement in a false claims action under the FCA. The best example is *Luckey*, in which the court granted summary judgment for the defendant on the ground that the relator had failed to demonstrate that the defendant's "compliance with any statutes or regulations was a material condition to receiving payment from the government."<sup>242</sup> Likewise, the *Luckey* court found that the relator had "fail[ed] to demonstrate that [the relevant government agency] would have withheld payment if "it had known the truth and the alleged falsities did not "violate[] the heart of [the defendant's] agreement with the government."<sup>243</sup>

The *Luckey* court distinguished *Ab-Tech Construction v. United States*,<sup>244</sup> where the court held that the defendant's implied certification of compliance with requirements for continued eligibility in the SBA program for minority-owned businesses constituted "false claims."<sup>245</sup> The *Luckey* court found that the falsities in *Ab-Tech* (whether the claimant was, in fact, minority controlled) went to the "heart of its agreement with the government," whereas the defendant's alleged falsities in *Luckey* (absolute compliance with numerous regulatory schemes) did not.<sup>246</sup> It held that a finding of a false implied certification under the FCA for every request for payment accompanied by a failure to comply with all applicable regulations, *without more*, improperly broadens the intended reach of the FCA<sup>247</sup> and that "[t]he specific direction requiring compliance *and materiality* present in

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242. *Luckey*, 2 F. Supp. 2d at 1045.

243. *Id.*

244. 31 Fed. Cl. 429 (1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

245. *Luckey*, 2 F. Supp. 2d at 1045.

246. *Id.* Some of the earliest and best reasoning which supports the need to imply a materiality requirement in the false claims portion of the FCA may be found in Judge Brown's excellent dissenting opinion in *United States v. De Witt*, 265 F.2d 393, 404 (5th Cir. 1959) (Brown, J., dissenting) (stating the "precise problem" is whether the defendant submitted an inaccurate claim "deliberately knowing it to be incorrect and conscious that to do the latter was to claim a payment which the Government did not owe were the true facts known").

247. *Luckey*, 2 F. Supp. 2d at 1045 (emphasis added) (citing *Joslin v. Community House Health of Md.*, 984 F. Supp. 374, 384-85 (D. Md. 1997)).

*Ab-Tech* are noticeably absent here.<sup>248</sup> This analysis implies, correctly, a materiality requirement for a false claims action under the FCA.<sup>249</sup>

The interaction between the underlying statute and the FCA creates a ready-made standard of materiality. If the violation of the underlying statute or regulation would not have resulted in denial of the claim, Congress and/or the agency has already determined that such violation is not material. *Luckey* recognized this principle in pointing to the relator's failure to demonstrate that the alleged regulatory noncompliance would have resulted in non-payment.<sup>250</sup>

The development of the materiality element is further clouded because reliance and materiality are sometimes treated together in analyzing the elements of a false claim or false claims/statements action.<sup>251</sup> While reliance by the government would be one way of establishing materiality, the issue of materiality goes far beyond the question of reliance.<sup>252</sup> Reliance appears to be an element under the false statements prong.<sup>253</sup> In the false statements area, reliance is generally thought to be a necessary element in order to establish that the defendant's misconduct caused financial harm to the government.<sup>254</sup> Treating reliance and materiality together does not give proper recognition to the conceptual underpinnings of materiality and does not capture the dynamic of the payment and reimbursement process in the health care area.

Many providers are reimbursed through the submission of cost reports. The cost reports contain a certification that all goods and services covered in the cost report were furnished in a

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248. *Id.* (emphasis added).

249. See also *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 793 (4th Cir. 1999) (indicating that the "prerequisite standard in the false certification cases is essentially a heightened materiality requirement: the government must have conditioned payment of the claim upon certification of compliance with the provision of the statute, regulation, or contract at issue" (citing *Thompson*, 125 F.3d at 902; *Joslin*, 984 F. Supp. at 383-84)).

250. *Luckey*, 2 F. Supp. 2d at 1045.

251. See, e.g., *BOESE*, *supra* note 1, § 2-17.

252. In establishing liability under the false claims prong of the FCA, it should be necessary but not sufficient for plaintiffs counsel to prove that the government actually relied upon the alleged falsity in deciding whether to pay the claim.

253. *Hopper*, 91 F.3d at 1267.

254. See, e.g., *United States v. Entin*, 750 F. Supp. 512, 519 (S.D. Fla. 1990).

manner that fully complied with applicable laws and regulations. It is undoubtedly true that the government would not pay the provider unless the provider signed the certification contained in the cost report, and in that important respect, the government "relies" on that certification in making payment to the provider. Because the government "relies" on the certification in making payment, it would appear at first blush that the certification is "material." Such an analysis does not, however, capture the critical fact that the substantive matters as to which certification is made, i.e., compliance with the applicable laws and regulations, are not necessarily "material" because non-compliance with most of the applicable laws and regulations would not result in non-payment if the government had been aware of the non-compliance. In the language of *Luckey* and *Ab-Tech*, a false certification that a health care provider has complied with land use laws, antitrust laws, waste disposal laws, etc., does not "go to the heart" of the provider's agreement with the government. For that reason, a cost report certification of legal compliance which is false should not necessarily result in false claims liability.

#### VI. POLICY REASONS AGAINST USE OF THE FCA TO ENFORCE QUALITY OF CARE

Even if the FCA were sufficiently malleable to be used as a tool to address quality of care concerns, it should not be used for that purpose for several reasons. First, it simply is too blunt an instrument to be used as a policy tool. Policy should be set through rational dialogue among interested parties and, where necessary, with the assistance of experts. Rational dialogue, however, is very difficult in the shadow of an FCA suit. At the end of the day, few providers can stand up to the threat of such a suit, and thus they often have little bargaining power when fashioning what they believe to be appropriate remedies.

Second, by virtue of their training or experience, prosecutors generally are not in the best position to evaluate quality of care, even with the help of experts. That is not to say that they cannot do so correctly. But it is to say that the federal, state and private experts, such as the HCFA, State Departments of Health, and the Joint Commission on Accreditation of

Healthcare Organizations ("JCAHO"), who have been monitoring quality issues for years, generally are better positioned to evaluate clinical care and to identify and help cure deficiencies. Indeed, in an ironic twist in the *Northern Health Facilities* case discussed earlier, the federal prosecutors elected to resolve the dispute through a Preliminary Injunction that would have permitted the facility to operate when the DHHS and the Maryland State Department of Health, based on a contemporaneous review, determined that the facility did not deserve any further opportunities at improvement and thus decertified it.<sup>255</sup> This example shows that the DHHS is capable of imposing strict penalties on non-compliant facilities when appropriate and illustrates the danger that attempts to address standard regulatory issues through FCA cases may conflict with the existing framework for enforcing those regulations.

Third, it is not necessary to use the FCA to address quality of care issues. Federal, state and JCAHO inspectors generally are more than capable of performing their assigned function of verifying compliance with clinical standards.<sup>256</sup> To be sure, such inspectors do not always function perfectly. But the solution to that problem lies in improving their performance, not in turning to the FCA. In that regard, Congress, the DHHS and the states, in recent years, have engaged in extensive and diligent measures to evaluate the current enforcement mechanisms and propose affirmative steps toward improving them.<sup>257</sup> And,

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255. *Compare* United States v. Northern Health Facilities, 25 F. Supp. 2d 690 (D. Md. 1998) (permitting facility to continue operating in light of Preliminary Injunction), *with* Northern Health Facilities, Inc. v. United States, 39 F. Supp. 2d 563 (D. Md. 1998) (upholding authority of the DHHS and the Maryland Department of Health to terminate same facility's participation and funding in Medicare and Medicaid programs).

256. The defendants in *Aranda* raised precisely this point. In that case, state surveyors had issued annual reports which had resulted in affirmative certifications that the defendants were in compliance with the applicable conditions of participation. *Aranda*, 945 F. Supp. at 1487. The defendants argued that these affirmative survey reports precluded a finding that they had "knowingly" violated the conditions of participation, and thus they could not be found liable under the FCA. *Id.* at 1488. Despite the logical force of this argument, the court determined that it "will not be considered here." *Id.* at n.2.

257. U.S. GENERAL ACCOUNTING OFFICE, NURSING HOMES: STRONGER COMPLAINT AND ENFORCEMENT PRACTICES NEEDED TO BETTER ENSURE ADEQUATE CARE (1999) [hereinafter NURSING HOMES: STRONGER COMPLAINT AND ENFORCEMENT PRACTICES NEEDED]; U.S. GENERAL ACCOUNTING OFFICE, NURSING HOMES: ADDITIONAL STEPS

if all else fails, state tort law stands as a strong—some would argue overly strong—deterrent to substandard care. In light of this, there simply is no need to convert the FCA into a federal malpractice statute.

Fourth, if the quality of care does not meet all regulatory standards, it is likely the result of the disparity between the lofty care-goals that Congress and regulators have established and the refusal of Congress and the regulators to assure that providers receive the resources necessary to meet those standards. It is inappropriate and counter-productive to attempt to coerce providers to provide a standard of care for which the government refuses to pay. The appropriate response is to allocate additional resources or to lower expectations to reflect reduced reimbursement to providers, not to beat them into submission by raising the specter of the quasi-criminal penalties of the FCA. In contrast, subjecting the already limited resources of health care providers to the additional strain of responding to new theories for holding them liable under the FCA has the counterproductive effect of further reducing available resources for improved care. In this regard, the health care industry differs from the traditionally well-funded military industry to which the FCA was designed to apply. The current state of the health care in-

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NEEDED TO STRENGTHEN ENFORCEMENT OF FEDERAL QUALITY STANDARDS (1999) [hereinafter NURSING HOMES: ADDITIONAL STEPS NEEDED]; CALIFORNIA NURSING HOMES, *supra* note 90. Significantly, these reports explain that prior to policy decisions by the HCFA, state overseers and fiscal intermediaries undercut effective enforcement by not decertifying facilities despite knowledge of ongoing problems. For example, the GAO criticized the "HCFA's foregoing stance on enforcement . . . [for] allowing California [nursing] homes terminated from the program for serious [care violations] to be easily reinstated—even though they often have serious care violations in subsequent surveys" and recommended "[e]liminat[ing] the grace period for homes cited for repeated serious violations and imposing sanctions promptly." CALIFORNIA NURSING HOMES, *supra* note 90, at 22, 30. Furthermore, the enforcement system designed by the HCFA "sends signals to noncompliant nursing homes that a pattern of repeated noncompliance carries few consequences." NURSING HOMES: ADDITIONAL STEPS NEEDED, *supra*, at 23. See also NURSING HOMES: STRONGER COMPLAINT AND ENFORCEMENT PRACTICES NEEDED, *supra*, at 11 ("[The] HCFA policy prevents states from considering a reinstated home's prior record. This policy effectively gives the home a 'clean slate' and produces the disturbing outcome that termination could actually be advantageous to a home with a prior compliance history."). These findings of inattention by the HCFA and surveyors are inconsistent with the notion that providers knowingly took actions that misled the government to make payments it otherwise would not have made.

dustry reflects substantial financial constraints. For example, many of the publicly-traded health care companies have seen their stocks drop precipitously following government cutbacks in health care funding.<sup>258</sup>

Fifth, expanded use of the FCA to enforce quality of care will discourage quality providers from doing business with government payors, a phenomenon which is now overtaking the government managed-care sector. Most recently, for example, Foundation Health Systems Inc., one of California's largest managed-care companies, announced in the *Wall Street Journal* that it was withdrawing from the Medicare market in eighteen counties in California, Colorado, New Mexico, and Washington.<sup>259</sup> The *Wall Street Journal* quotes the Foundation's President and Chief Executive as stating that the Foundation "is committed to its Medicare line of business; however, we cannot continue to operate in areas where reimbursement rates don't reflect trends in actual costs."<sup>260</sup> The article goes on to report that "[i]n total, [the] Foundation said it won't renew Medicare HMO contracts in 32 counties, affecting 22,700 [Medicare] beneficiaries."<sup>261</sup> This trend may accelerate now that self-styled "patient advocates," having failed to convince Congress to allocate additional resources for patient care, have taken to the streets armed with the *qui tam* provisions of the FCA.

In short, the health care industry is the target of an unprecedented amount of prosecutorial and investigative activity. Too often this activity comes in the form of allegations that providers are providing insufficient quality of care drawn from statutory and regulatory language that was arguably intended to assure the highest quality care for program beneficiaries. Unfortunately, and notwithstanding Congressional and administrative

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258. For example, nursing home companies have experienced dramatic decreases in value from 1998 to 1999 as new Medicare reimbursement procedures, such as the shift to the care system, have gone into effect. See *5 Healthcare Firms Ratings Cut by S&P Over Medicare Changes*, CAPITAL MARKETS REP., Mar. 3, 1999, at 1, available in WL, CMREPPLUS database. As a result of new reimbursement procedures, these companies have experienced such problems as extensive layoffs or failures to meet outstanding debt responsibilities. See, e.g., Milt Freudenheim, *Sun Healthcare Is Hit Hard by Medicare Payment Cuts*, N.Y. TIMES, Apr. 10, 1999, at C2.

259. *Foundation Health Systems, Inc.*, WALL ST. J., Oct. 6, 1998, at A14.

260. *Id.*

261. *Id.*

rhetoric to the contrary, providers simply are not given enough money to meet the high standards imposed by Congress and the regulators. This important problem is best solved by allocating more resources so that providers can improve the quality of care given to program beneficiaries and by improving the existing regulatory tools of enforcement. Bringing quasi-criminal litigation will ultimately have the effect of discouraging quality providers from participating in government managed-care programs.

## VII. CONCLUSION

The use of the FCA as an enforcement mechanism for quality of care issues advances neither the purposes underlying the FCA nor quality of care goals. With regard to the former, there is no support for the position that the FCA was intended to serve any purpose other than protecting the public from claims for payment for goods or services that were not in fact provided. Courts have clearly indicated that the FCA is not intended to serve as a strict liability statute designed to punish technically inaccurate claims. Indeed, the Justice Department's recent statements regarding the use of the FCA in the health care industry recognize the enormous complexity (and potential inconsistencies) of the rules and regulations in the area, and they reflect the all-important role that prosecutorial discretion should play in determining whether a claim that is arguably "false" due to noncompliance with reimbursement regulations indicates conduct that is appropriate for action under the FCA.<sup>262</sup>

With regard to the latter issue, there exists an elaborate array of federal and state enforcement agencies whose primary purpose is to advance the quality of health care services. In addition to more fundamental conditions of care, regulatory agencies monitor such issues as patient room size, patient access to telephones, etc. Through years of experience, these agencies have developed enforcement mechanisms that are tailored to address violations in accordance with their severity. Moreover, they have experience in interpreting and applying some of the

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262. See DOJ MEMORANDUM, *supra* note 54.

very subjective statutory and regulatory standards (e.g., skilled nursing facilities' obligation to provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident).<sup>263</sup> The removal of quality of care issues from the domain of the HCFA and state health agencies into the domain of the federal courts is simply nonsensical. If the adequacy of the HCFA's and state agencies' ability to monitor quality of care issues and to enforce against violations was at issue, the remedy would be to improve the quality of those agencies rather than to deluge the federal courts with technical issues of quality of health care that they are ill-equipped to address.

Finally, the absence of an express private right of action under federal "quality of care" statutes and regulations reflects a considered determination that the government (with appropriate prosecutorial discretion) is the appropriate party to take enforcement action when quality standards are not met. Accordingly, "back-door" access to the courts by *qui tam* relators on these issues is inappropriate. It allows quality of care standards to become a mechanism to line the pockets of relators rather than a tool to serve the public good.

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263. See 42 U.S.C. § 1395i-3(g) (1994).

