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# The Good, the Bad, and the Ugly: The Unnecessarily Broad Impact of Qui Tam Civil False Claims Act Cases on Rural Health Care Providers

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# THE GOOD, THE BAD, AND THE UGLY: THE UNNECESSARILY BROAD IMPACT OF *QUI TAM* CIVIL FALSE CLAIMS ACT CASES ON RURAL HEALTH CARE PROVIDERS

*Andrew M. Hyer*<sup>†</sup>

## ABSTRACT

The civil False Claims Act (FCA) imposes harsh penalties against parties who misappropriate federal funds. The statute's *qui tam* whistleblower provisions create strong financial incentives for private individuals to bring and pursue FCA cases against health providers on the government's behalf—even where government attorneys decline to intervene. FCA cases where the government declined to intervene account for less than 2 percent of all recoveries in health care FCA cases. Yet the costs of defending such cases may be very high, especially for rural providers with small operating margins. Federal provider self-referral and anti-kickback laws carve out various exceptions to support the financial viability of rural providers. The FCA, however, contains no such exceptions. Although Department of Justice (DOJ) policy directs officials to take into account community access to care in pursuing FCA cases against rural providers, the ability for private whistleblowers to pursue cases where the government declines to intervene undermines the DOJ's ability to achieve that aim. This Article highlights the liability risks rural providers commonly face under the FCA and argues for amending the FCA to allow a whistleblower claim to proceed against providers serving designated underserved areas only where government authorities intervene in the case.

## CONTENTS

INTRODUCTION .....	460
I. THE FALSE CLAIMS ACT, WHISTLEBLOWER PROVISIONS, AND RURAL HEALTH CARE PROVIDERS .....	461
A. <i>Current Application of the FCA to the Health Care Industry</i> .....	462
B. <i>FCA Cases Pursued Unilaterally by Whistleblowers</i> .....	465
II. RURAL HEALTH AND RURAL PROVIDERS .....	469
A. <i>Rural Health in the United States</i> .....	469
B. <i>Designation as an Underserved Rural Area</i> .....	471

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C. Programs, Laws, and Policies Intended to Support the Financial Viability of Rural Providers.....	476
1. Rural Health Clinics.....	477
2. Federally Qualified Health Centers and Their Look-Alikes.....	478
3. Critical Access Hospitals.....	482
4. National Health Service Corps Loan Repayment Programs.....	483
5. Stark and Anti-Kickback Provisions Impacting Rural Providers .	484
a. The Stark Law.....	484
b. The Anti-Kickback Statute.....	486
III. PREVENTING UNILATERAL WHISTLEBLOWER CLAIMS AGAINST CERTAIN RURAL PROVIDERS.....	488

## INTRODUCTION

Over the years, the federal False Claims Act (FCA) has led to various highly publicized, billion-dollar settlements against large pharmaceutical companies and hospital systems.<sup>1</sup> Despite this apparent focus on larger entities by federal health care fraud enforcement authorities, small rural providers are not immune from becoming entangled in expensive and protracted civil FCA litigation. This is especially true in light of the fact that federal FCA claims can be initiated and pursued solely by private whistleblowers independent of action by a government agency.

Although lawmakers and agencies have created various legislative and regulatory exceptions aimed at easing administrative burdens and costs for rural providers working in underserved communities, lawmakers have not created similar exceptions for FCA whistleblower claims. Most problematic is the fact that a whistleblower may unilaterally pursue such a claim on the government's behalf even if governmental authorities do not see cause to pursue one—or are opposed to doing so. Such a situation arguably runs counter to various policy efforts to maintain the financial viability of critical access providers in underserved areas. This Article highlights the potential risks that rural providers face under the FCA and discusses whether, as a matter of public policy, Congress should reassess broad application of the FCA's whistleblower provisions to rural providers in underserved areas. Although this Article's primary focus is to show the need for a change in the FCA's whistleblower provisions to protect the financial viability of health practice in underserved rural areas, it will also assist rural providers seeking to understand potential liability under the FCA.

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1. See, e.g., Dinesh Kumar, Note, *Adverse Events: Ethical Issues in the Prosecution of Qui Tam Health Care Fraud Cases under the False Claims Act*, 25 GEO. J. LEGAL ETHICS 661, 666 tbl. 1 (2012) (discussing major FCA recoveries in recent years); Evan Perez, *Lawsuits Bring in \$3 Billion for U.S.*, WALL ST. J., Nov. 23, 2010, at A4; Duff Wilson, *Novartis Settles Off-Label Marketing Case Over 6 Drugs for \$422.5 Million*, N.Y. TIMES, Oct. 1, 2010, at B5.

Part I provides a brief overview of the FCA and its whistleblower provisions as applied to the health care industry. It highlights how FCA claims may be brought and pursued solely by a private whistleblower even where government authorities choose not to intervene and explains why this practice is problematic for rural providers. Part II discusses rural health care and the various federal laws and programs designed to make practicing in underserved rural areas more financially viable. Part III argues that policymakers should consider amending the FCA to allow whistleblower claims to proceed against certain rural providers only if government authorities choose to intervene in the case.

## I. THE FALSE CLAIMS ACT, WHISTLEBLOWER PROVISIONS, AND RURAL HEALTH CARE PROVIDERS

The FCA and its whistleblower provisions were enacted in the wake of the Civil War to address concerns of rampant fraud perpetrated by government contractors during Reconstruction.<sup>2</sup> The policy behind the FCA is to create strict penalties for those who misappropriate government funds.<sup>3</sup> To encourage those with “insider information” of fraudulent activities to come forward, the FCA contains whistleblower provisions allowing a private citizen to bring an FCA claim on the government’s behalf and receive a portion of the money recovered through that action.<sup>4</sup>

After significant amendments to the FCA in 1986, federal authorities and private whistleblowers began applying the statute to the health care

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2. See Act of Mar. 2, 1863, ch. 67, 12 Stat. 696, 696–98 (1863); see also *Vermont Agency of Natural Resources v. United States*, 529 U.S. 765, 781 (2000) (“[T]he FCA was enacted in 1863 with the principal goal of ‘stopping the massive frauds perpetrated by large [private] contractors during the Civil War.’”) (quoting *United States v. Borstein*, 423 U.S. 303, 309 (1976)); see also *United States v. McNinch*, 356 U.S. 595, 599 (1958); Robert Salcido, *The Government’s Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457, 460 (2003).
  3. See Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 461 (1998) (noting that the FCA’s primary purposes are: “(1) protecting the public fisc and the integrity of federal programs by deterring the submission of false or fraudulent claims, (2) securing restitution of government losses by fraud, and (3) punishing those who defraud the government”); see also Thomas F. O’Neill III, et al., *The Buck Stops Here: Preemption of Third-Party Claims by the False Claims Act*, 12 J. CONTEMP. HEALTH L. & POL’Y 41, 43 (1995).
  4. 37 U.S.C. § 3730(d) (2011). Depending on the value of the whistleblower’s contribution to the case and whether the government joins in the case, a whistleblower is entitled to 10–30 percent of the government’s recovery. § 3730(d)(1)–(2). A prevailing whistleblower is entitled to an additional award of his or her attorney’s fees. § 3730(d)(4).

industry.<sup>5</sup> One commentator notes that after these 1986 amendments, “the FCA now lies at the heart of the federal government’s war on healthcare fraud.”<sup>6</sup> Between 1987 and 2011, settlements and judgments in health care-related FCA actions totaled approximately \$21 billion.<sup>7</sup> The FCA’s scope and its whistleblower provisions were further broadened as part of the Fraud Enforcement and Recovery Act (FERA) of 2009<sup>8</sup> and the Patient Protection and Affordable Care Act of 2010.<sup>9</sup>

A. *Current Application of the FCA to the Health Care Industry*

As amended, an individual or organization violates the FCA by “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment” with federal funds.<sup>10</sup> A violator can be held liable for up to three times the actual monetary damages incurred by the government and \$5000 to \$10,000 per false claim.<sup>11</sup> Additionally, the defendant is required to pay a prevailing whistleblower’s attorney’s

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5. See David J. Ryan, *The False Claims Act: An Old Weapon with New Firepower Is Aimed at Health Care Fraud*, 4 ANNALS HEALTH L. 127, 129–30 (1995) (discussing the 1986 amendments and subsequent increase in use of the FCA in the health arena).
  6. Joan H. Krause, *Twenty-Five Years of Health Law Through the Lens of the Civil False Claims Act*, 19 ANNALS HEALTH L. 13, 13 (2010).
  7. CIVIL DIVISION, U.S. DEP’T OF JUSTICE, FRAUD STATISTICS – OVERVIEW (2012), available at [http://www.justice.gov/civil/docs\\_forms/C-FRAUDS\\_FCA\\_Statistics.pdf](http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf).
  8. 111 Pub. L. No. 21, 123, § 4(a), Stat. 1617 (2009). Among other amendments made by FERA, the definition of the term “claim” was broadened to apply to situations where a subcontractor presents false claims to a private primary contractor with no intent or even knowledge that the claim would result in the government over-paying the primary contractor. 31 U.S.C. § 3729(b)(2)(A)(ii) (2011) (defining the term “claim” to include a request for money “made to a contractor, grantee, or other recipient” where the original source of the money is the federal government). This amendment effectively overruled the U.S. Supreme Court’s interpretation of FERA’s prior definition of “claim” in *Allison Engine Co. v. United States ex rel. Sanders*, wherein the Court held that FERA requires “the defendant to intend that a claim be ‘paid . . . by the Government’ and not by another entity.” 553 U.S. 662, 670 (2008).
  9. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901 (2010).
  10. 31 U.S.C. § 3729(a)(1)(A) (2011).
  11. *Id.* § 3729(a)(1). FERA has a provision limiting liability to “not less than 2 times the amount of damages which the Government sustains” if the defendant fully cooperates in the investigation. *Id.* § 3729(a)(2)(B). As explained below, however, because FCA cases against health care providers almost never go to trial damages are very rarely assessed by a court. Accordingly, this “reduced damages” amendment may have only a negligible impact on the outcome of future FCA cases.

fees.<sup>12</sup> Defendants in civil FCA cases may be named as defendants in parallel administrative and criminal proceedings, and any health care provider found liable under the FCA faces potential exclusion from all federal health programs (namely Medicare and Medicaid).<sup>13</sup>

The FCA casts a broad net as to the types of conduct potentially in violation of the statute. It expansively defines the term “knowingly” to include not only “actual knowledge” of the false statements but also acts made in “deliberate ignorance” or in “reckless disregard” of the information’s truth or falsity.<sup>14</sup> The statute’s definition of “knowingly” clarifies that the FCA is violated even where there is “no proof of specific intent to defraud” the government.<sup>15</sup> As one court explained, Congress defined knowledge broadly “to reach what has become known as the ostrich type situation where an individual has buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted.”<sup>16</sup>

Under this broad definition of knowledge, Medicaid and Medicare providers can be held liable under the FCA for not only willful fraudulent billing but also for sloppy billing or a failure to supervise and train billing staff if such conduct rises to the level of “reckless disregard.” Additionally, under FERA, a failure to timely return to the government any overpayments may also give rise to FCA liability.<sup>17</sup>

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12. 31 U.S.C. § 3730(d)(1) (2011). Under this statute, a whistleblower may recover attorney’s fees and costs if the defendant is found liable or makes a payment to settle the case. *See id.* (stating that a whistleblower is entitled to a portion “of the proceeds of the action or settlement of the claim” and that “[a]ny such person shall also receive an amount for reasonable expenses which the courts finds to have been necessarily incurred, plus reasonable attorneys’ fees and costs”).
  13. 42 U.S.C. § 1320a-7(b)(6) (2011) (setting forth discretionary authority to exclude providers found liable under FCA from participation in federal health programs). As one commentator explains, “exclusion is tantamount to an economic death penalty, because few providers can survive without the ability to receive revenues associated with the care of Medicare and Medicaid patients.” Robert B. Ramsey, III, *Corporate Integrity Agreements: Making the Best of a Tough Situation*, HEALTHCARE FINANCIAL MANAGEMENT, Mar. 2002, at 58.
  14. 31 U.S.C. § 3729(b)(1)(A).
  15. *Id.* §3729(b)(1)(B).
  16. Wang v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992).
  17. Industry commentaries reflect concern that this additional provision may increase the potential for FCA liability. Robert C. Blume & Andrew S. Tulumello, *President Obama Signs Legislation Significantly Expanding the Scope of the False Claims Act*, GIBSON DUNN (May 26, 2009), <http://www.gibsondunn.com/publications/Pages/PresidentObamaLegislationExpandsScope-FalseClaimsAct.aspx> (noting that this amendment “opens up new avenues of exposure against federal contractors or grantees for knowingly retaining government ‘overpayments’”). *See also* Mark Taylor, *Feds Refocus on Fraud: Hospitals Must Ramp Up Compliance Programs to*

From the perspective of a provider seeking to avoid potential FCA issues, these consequences point to the need to have and implement an effective compliance program and to have properly qualified health information management and compliance professionals overseeing the billing process.<sup>18</sup> Such preventative measures minimize the occurrence of erroneous overpayments, better assure that overpayments are promptly returned, and help prove that the provider was not acting with “reckless disregard” in the event of an FCA claim. Because of the importance of employing well-trained compliance and billing individuals to avoid FCA liability, the shortage of technically qualified professionals in many rural areas may pose a problem for providers in those areas.<sup>19</sup>

If an FCA claim is brought against a provider, the statute’s broad definition of “knowingly” makes defending and resolving the case complicated and expensive for the defendant provider. In a traditional common law fraud claim, a defendant could have the case dismissed in the pretrial phase unless the plaintiff offers evidence that the defendant had a knowing and willful intent to defraud.<sup>20</sup> Under the FCA, however, there is room for a fact-intensive inquiry into the gray area between what constitutes negligent billing mistakes and errors arising out of

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*Meet New Provisions*, TRUSTEE, Feb. 2011, at 20 (quoting health attorney Robert Homchick that this amendment “increases the stakes in how hospitals will deal with what they uncover during their compliance reviews, audits or something that surfaces in the ordinary course of business”).

18. Taylor, *supra* note 17, at 17.
19. See Charles W. Fluharty, *Refrain or Reality: A United States Rural Policy?: Implications for Rural Health Care*, 23 J. LEGAL MED. 57, 64 (2002) (“[F]ewer young adults in rural areas seek post-secondary education, have college degrees, or have no high school diplomas . . . .”); COMM. ON THE FUTURE OF RURAL HEALTH CARE, INST. OF MED. OF THE NAT’L ACADS., QUALITY THROUGH COLLABORATION: THE FUTURE OF RURAL HEALTH 79 (2005), available at [http://www.nap.edu/catalog.php?record\\_id=11140](http://www.nap.edu/catalog.php?record_id=11140) (“For decades, rural and frontier communities have struggled to attract and retain an adequate supply of the various health care professionals . . . .”). Demand for health information management professionals involved with billing and compliance in rural areas is expected to increase in coming years. See Candi Helseth, *HIT Workforce a Growing Concern for Critical Access Hospitals*, RURAL ASSISTANCE CENTER, <http://www.raconline.org/newsletter/spring12/feature.php#story2> (last updated Apr. 24, 2012) (“Primary care workforce shortages are a given in rural health care. Now rural providers—particularly in Critical Access Hospitals (CAHs)—are facing another daunting workforce shortage: technology professionals in high demand and short supply.”).
20. See 37 AM. JUR. 2D *Fraud and Deceit to Fraudulent Conveyances and Transfers* § 23 (2001) (“The five traditional elements of fraud, each of which must be established by evidence that is not equally consistent with either honesty or deceit include: a false representation; in reference to a material fact; made with knowledge of its falsity; with the intent to deceive; and on which an action is taken in justifiable reliance upon the representation.”).

“willful ignorance” or “reckless disregard.” As such, it is more difficult for a defendant in an FCA case—even one who would probably not be found liable at trial—to convince a court to dismiss the case in the pretrial phase. Moreover, considering the high penalties and damages associated with liability under the FCA, the potential for exclusion from Medicare and Medicaid, and the high litigation costs involved in pursuing a complex claim, often the only realistic option for an FCA defendant is to settle.<sup>21</sup> Thus, even if a defendant has a strong defense and plausible odds of prevailing at trial, the potential consequences of losing may be too great to risk. Some commentators suggest that the fact that such defenses are never presented at trial emboldens whistleblowers’ attorneys and government authorities to seek unreasonably high settlements in cases with relatively weak evidence and untested legal theories.<sup>22</sup> As explained below, such a situation may be particularly problematic where authorities opt not to intervene in a case, and a whistleblower unilaterally pursues an FCA settlement against a critical access provider in an underserved rural area.

*B. FCA Cases Pursued Unilaterally by Whistleblowers*

FCA cases may be initiated by the government or a private whistleblower with insider information. Actions brought by whistleblowers are commonly referred to as *qui tam* cases.<sup>23</sup> The vast majority of FCA matters in the health care arena somehow involve a *qui tam* whistleblower.<sup>24</sup> For example, during the first three quarters of 2011, the Department of Justice reported 417 new FCA matters involving federal

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21. Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 276 (2004) (“Given the balance of power, it should come as no surprise that prosecutors have the power to ‘encourage’ settlements, even where abstract legal analysis might favor the defendant.”).
  22. See Sharon Finegan, *The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law*, 111 PENN. ST. L. REV. 625, 651 (2007) (“[I]t is nearly inevitable that a health care provider accused of wrongdoing will settle a civil or criminal suit, because the risks involved in proceeding to trial are far too high and may jeopardize the provider’s very existence.”); Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 127 (2001) (“Within the industry, there is a growing concern that the Act’s enormous penalties may force health care providers to settle cases that could not be proven in court, such as allegations of falsity stemming from good faith interpretations of ambiguous regulations.”).
  23. 31 U.S.C. § 3730(d) (2011). The language of the FCA refers to the whistleblower as the *qui tam* plaintiff. Courts frequently refer to the whistleblower as the “relator.”
  24. See FRAUD STATISTICS, *supra* note 7.

health programs where a whistleblower was involved and only thirty-seven where a whistleblower was not involved.<sup>25</sup>

Because schemes to defraud the government may be difficult to detect by authorities, the FCA's whistleblower provisions have been crafted to create strong financial incentives for a private individual with insider information to come forward.<sup>26</sup> Successful whistleblowers are entitled to 10 to 30 percent of the government's total recovery and a separate award of attorney's fees.<sup>27</sup> To sustain a *qui tam* claim under the FCA, the whistleblower must be the "original source" of information that has not previously been "publicly disclosed."<sup>28</sup> The Department of Health & Human Services Office of the Inspector General (HHS OIG) explains that "[w]histleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors."<sup>29</sup>

A whistleblower alleging a violation of the FCA brings a claim by filing a complaint under seal.<sup>30</sup> The complaint remains under seal for sixty days or longer while the government investigates the case and determines whether it will intervene.<sup>31</sup> If the government intervenes, the whistleblower's attorneys and the government's attorneys will pursue the case together.<sup>32</sup> If the government chooses not to intervene, the whistleblower's attorneys may pursue the case on their own.<sup>33</sup> Although the DOJ does not publish data on the proportion of *qui tam* cases in which

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25. *Id.* Between 1987 and 2011, there were a total of 4365 *qui tam* cases, compared to only 727 non-*qui tam*. *Id.*
26. 31 U.S.C. § 3730(d) (2006); see also Brian G. Santo, *The False Claims Act: Analysis of the Recently Expanded Legislation on Qui Tam Actions and Related Impact on Whistleblowers*, ABA HEALTH ESOURCE, [http://www.americanbar.org/newsletter/publications/aba\\_health\\_esource\\_home/Volume6\\_SE2\\_Santo.html](http://www.americanbar.org/newsletter/publications/aba_health_esource_home/Volume6_SE2_Santo.html) (last updated July 22, 2010) (explaining that the FCA "was established to elicit help from private citizens to fight fraud, permitting people to sue in the name of the United States and collect a portion of the recovery the government obtains").
27. 31 U.S.C. § 3730(d).
28. *Id.* § 3730(e). The PPACA amended the statute's definition of "original source" to broaden and clarify the type of information a whistleblower may contribute in order to bring a suit under the FCA's *qui tam* whistleblower provisions. See Santo, *supra* note 26.
29. OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, A ROADMAP FOR NEW PHYSICIANS: AVOIDING MEDICARE AND MEDICAID FRAUD AND ABUSE 3, [http://oig.hhs.gov/compliance/physician-education/roadmap\\_web\\_version.pdf](http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf) (last visited June 3, 2013) [hereinafter OIG ROADMAP].
30. 31 U.S.C. § 3730(b)(2).
31. *Id.* § 3730(b)(2)–(3).
32. Kumar, *supra* note 1, at 663–64.
33. 31 U.S.C. § 3730(c).

it intervenes,<sup>34</sup> it does report the annual amounts recovered through *qui tam* cases based on whether the government intervened. Between 1987 and 2011, the total recovery in cases where the government chose not to intervene was a small fraction—only 2.3 percent—of the government’s total recoveries in health care *qui tam* cases.<sup>35</sup> If one includes the amount the government has recovered in health care FCA cases not involving a whistleblower, cases in which the government has not intervened account for only 1.7 percent of the FCA recoveries in the health arena since 1987.<sup>36</sup> Accordingly, it is apparent that *qui tam* cases in which the government has not intervened play, in relative terms, a very small role in recovering fraudulently obtained governmental funds.

Although, in terms of amounts recovered, *qui tam* cases where the government has not intervened are fairly insignificant, such cases may still be quite expensive for a health care provider to defend. Moreover, professional malpractice liability insurance policies likely will not cover FCA liability under most circumstances,<sup>37</sup> so providers must pay defense costs out-of-pocket or have another type of insurance coverage. And although some types of Directors and Officers Liability insurance policies may cover civil FCA liability and legal defense costs,<sup>38</sup> other policies contain standard exclusions that may “have profound and often unanticipated consequences in the context of FCA claims.”<sup>39</sup> To the extent insurance coverage may be available for FCA-related issues in a Directors and Officers policy, obtaining such coverage may require strict adherence to insurer notice requirements and involve a legal dispute with the insurance carrier.<sup>40</sup> Finally, although some insurance carriers offer

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34. See FRAUD STATISTICS, *supra* note 7.

35. *Id.* From 1987 to 2011, the government recovered a total of approximately \$15.8 billion in *qui tam* health care cases; of this amount, approximately \$15.5 billion was recovered in cases where the government intervened. *Id.*

36. *Id.* The DOJ reports recovering approximately \$5.15 billion in civil health fraud cases not involving a *qui tam* relator between 1987 and 2011. *Id.*

37. See, e.g., *Zurich American Ins. Co. v. O’Hara Regional Centers for Rehabilitation*, 529 F.3d 916, 918–20 (10th Cir. 2008) (holding that the “acts or omissions” provision in a professional liability insurance policy does not cover FCA liability, even where FCA liability is premised upon the argument that the provider wrongfully billed for substandard care). For helpful discussions on the potential for FCA liability based on providing (and then billing the government for) substandard care, see *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1152–53 (W.D. Mo. 2000).

38. Stephen T. Raptis, *Surviving False Claims Act Allegations: What Every Government Contractor Needs to Know to Maximize Insurance Coverage*, CONTRACT MANAGEMENT, Apr. 2012, at 59.

39. *Id.*

40. See *id.* at 63 (noting that insurance “policy language is subject to legal interpretation”).

policies directly related to FCA and other false claim-related issues,<sup>41</sup> purchasing such coverage may be unduly costly for rural providers.

In short, while the potential financial exposure associated with defending FCA cases is significant for any health care provider participating in federal programs,<sup>42</sup> such exposure may be particularly problematic for less sophisticated rural providers with tight operating budgets. DOJ internal policy accordingly directs its attorneys to consider the potential effects of a lawsuit on the community's access to care:

When dealing with rural and community hospitals and other health care providers, Department attorneys shall consider the impact an action may have on the community being served. In determining an appropriate resolution, or deciding whether to bring an action, care must be taken to consider the community's interest in access to adequate health care along with any other relevant concerns.<sup>43</sup>

In dealing with a provider who is vital to the community, and where the alleged conduct is not egregious,<sup>44</sup> DOJ attorneys may properly decide to forgo a claim. A whistleblower pursuing a case unilaterally, however, is not required to take such factors into account. To the contrary, the whistleblower has strong financial incentives to obtain a substantial recovery regardless of the impact it may have on a rural provider's financial viability and the community's access to care.

If a health care provider was to prevail in an FCA case brought unilaterally by a whistleblower, the FCA provides a narrow remedy for the provider to recover attorney's fees upon a showing that the lawsuit was "clearly frivolous, clearly vexatious, or brought primarily for

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41. *See, e.g., Physician Regulatory Insurance/RAC Audit Insurance*, GALLAGHER HEALTHCARE, <http://www.gallaghermalpractice.com/products/fraud-abuse/> (last visited May 3, 2013) (advertising insurance products specifically addressed to FCA liability).
  42. *See* Pamela H. Bucy, *The Path from Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 ST. LOUIS U. L.J. 3, 40–42 (2000) (discussing the financial burden health care fraud investigations potentially create for teaching hospitals).
  43. Memorandum from Eric H. Holder, Jr., Deputy Att'y Gen., U.S. Dep't of Justice, to All U.S. Attorneys et al. (June 3, 1998), *available at* <http://www.justice.gov/dag/readingroom/chcm.htm>.
  44. For example, a health care provider may face potential FCA liability for the wrongful conduct of another entity or individual with whom it contracts—even if the provider itself has done nothing wrong. *See* *The Heart Doctors v. Layne*, No. 6:05-636, 2006 WL 2692694, at \*3 (E.D. Ky. Sept. 13, 2006); Keely E. Duke & Andrew M. Hyer, *Between a Rock and a Hard Place: Limitations on a Health Care Provider's Right to Indemnification when It Is Targeted Under the False Claims Act as a Result of the Fraudulent Activities of a Third Party with Which It Contracts or Associates*, FEDERAL LAWYER, Feb. 2009, at 28.

purposes of harassment.”<sup>45</sup> Under this stringent standard, an award of attorney’s fees is only awarded to a *prevailing* defendant. As mentioned above, the high defense costs and potentials for high damages and exclusion from participation in Medicare and Medicaid leave most defendants with no option but to settle if the defendant cannot obtain a dismissal in the pretrial stage. And even if a defendant were to prevail, it must also show that the lawsuit was frivolous, vexatious, or brought for harassment.<sup>46</sup> This sets a high bar,<sup>47</sup> and courts will refuse to award attorney’s fees to prevailing defendants in the absence of “clear” evidence of this type of conduct.<sup>48</sup>

## II. RURAL HEALTH AND RURAL PROVIDERS

Although all health care providers that accept any form of governmental funding should be aware of the potential risk of FCA liability, the cost and expense of defending a whistleblower FCA claim may be particularly onerous for some rural providers. As illustrated below, a general goal of many government programs and policies is to promote the financial viability of providers in underserved rural areas. Accordingly, this Section first provides an overview of the status of health care in rural America and the characteristics of rural providers. It then explains provider shortage designations used by federal agencies and the major policies and laws intended to increase the attractiveness and viability of practicing in underserved rural areas.

### A. *Rural Health in the United States*

For reasons related to both patient demographic characteristics and lack of access to care, rural populations in the United States often suffer

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45. 31 U.S.C. § 3730(d)(4) (2006).

46. *Id.*

47. *See United States ex rel. Rafizadeh v. Cont’l Common, Inc.*, 553 F.3d 869, 875 (5th Cir. 2008) (“An action is not frivolous if existing law or a reasonable suggestion for its extension, modification, or reversal supports the action.”).

48. *See, e.g., United States ex rel. Ubl v. IIF Data Solutions*, 650 F.3d 445, 458 (4th Cir. 2011) (reversing trial court’s award of attorney’s fees to prevailing FCA defendant under abuse of discretion standard, reasoning that the relator’s FCA claims “objectively” had some “reasonable chance of success”); *Rafizadeh*, 553 F.3d at 875 (upholding district court’s denial of defendant’s motion for attorney’s fees on the basis that the relator’s suit was not “clearly vexatious”). *But see Vuyyuru v. Jadhav*, 555 F.3d 337 (4th Cir. 2009) (upholding award of attorney’s fees to prevailing FCA defendant where relator’s action was jurisdictionally barred because the information had been publically disclosed and he was not the original source of the information).

worse health outcomes than populations in other parts of the country.<sup>49</sup> Compared to populations in more urban areas, those in rural areas are generally older, have lower education levels, lower income, and must travel greater distances to obtain health care.<sup>50</sup> Rural residents are also more likely to be in fair or poor health and have chronic conditions.<sup>51</sup> In light of these factors, in creating the Agency for Healthcare Research and Quality (AHRQ) in 1999, Congress identified “the delivery of health care in . . . rural areas (including frontier areas)” as an area of concern.<sup>52</sup> Each year, AHRQ produces an annual report tracking health disparities among individuals from various underserved or vulnerable “priority populations,” which includes individuals residing in rural areas.<sup>53</sup> Rural areas face significant challenges because of financial difficulties and a shortage of qualified professionals. Only 11.4 percent of physicians in the United States practice in rural areas despite 19.2 percent of the population living in those areas.<sup>54</sup> Nationwide health data from 2004–2008 reveals that residents of nonmetropolitan areas had higher inpatient heart attack mortality rates than residents of large fringe metropolitan areas.<sup>55</sup> In 2005, nonmetropolitan areas of the country had an age-adjusted mortality rate of approximately eighty deaths higher per 100,000 people than in metropolitan areas.<sup>56</sup> Similarly, in 2000, approximately 20.5 percent of the population aged 16–64 in nonmetropolitan areas reported having a disability in contrast to the metropolitan percentage of 18.2 percent.<sup>57</sup>

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49. See LEIYU SHI & DOUGLAS A. SINGH, DELIVERING HEALTH CARE IN AMERICA: A SYSTEMS APPROACH 440 (5th ed. 2012) (“Access to health care [in rural areas] is affected by poverty, long distances, rural topography, weather conditions, and limited availability of personal transportation.”); CAROL ADAIRE JONES ET AL., HEALTH STATUS AND HEALTH CARE ACCESS OF FARM AND RURAL POPULATIONS, U.S. DEP’T AGRIC. ECON. RES. SERV. 7–9 (2009), [http://www.ers.usda.gov/media/155453/eib57\\_1\\_.pdf](http://www.ers.usda.gov/media/155453/eib57_1_.pdf).
  50. JONES ET AL., *supra* note 49, at 5.
  51. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, DEP’T OF HEALTH & HUMAN SERVS., NATIONAL HEALTH DISPARITIES REPORT 239 (2011), *available at* <http://www.ahrq.gov/qual/nhdr11/nhdr11.pdf>.
  52. Healthcare Research and Quality Act, 42 U.S.C. § 299 (2006).
  53. AHRQ, *supra* note 51, at 234. Other priority populations include racial and ethnic minorities, low-income groups, women, children, older adults, and “[i]ndividuals with special health needs, including individuals with disabilities and individuals who need chronic care or end-of-life care.” *Id.*
  54. ROGER A. ROSENBLATT ET AL., WWAMI RURAL HEALTH RES. CTR., THE FUTURE OF FAMILY MEDICINE AND IMPLICATIONS FOR RURAL PRIMARY CARE PHYSICIAN SUPPLY 6 (2010), *available at* [http://depts.washington.edu/uwrhrc/uploads/RHRC\\_FR125\\_Rosenblatt.pdf](http://depts.washington.edu/uwrhrc/uploads/RHRC_FR125_Rosenblatt.pdf).
  55. AHRQ, *supra* note 51, at 61.
  56. *Id.*
  57. *Id.* at 9.

*B. Designation as an Underserved Rural Area*

In recent years, there has been some debate as to how to define the term “rural.”<sup>58</sup> The Economic Research Service in the U.S. Department of Agriculture has identified nine definitions of rural used for different purposes.<sup>59</sup> The criteria used by the U.S. Census Bureau and the Office of Management and Budget laid the foundation for definitions of rural commonly used for health programs.<sup>60</sup> Specifically, the U.S. Census Bureau identifies Urbanized Areas (of 50,000 or more people) and Urban Clusters (of 2,500 to 50,000) and then defines “rural” as “encompass[ing] all population, housing, and territory not included with [Urbanized Areas or Urban Clusters].”<sup>61</sup> The Office of Management and Budget, on the other hand, groups more populous areas as either “metropolitan statistical areas” (areas with at least one urbanized area of at least 50,000)<sup>62</sup> or “micropolitan statistical areas (areas with at least one urban cluster of 10,000 to 50,000),<sup>63</sup> with all less populous areas referred to as “outside core based statistical areas.”<sup>64</sup>

For rural health care providers, the more significant issue is the debate over various methodologies used to designate which providers qualify for special federal assistance for providing care to underserved areas or populations. As explained below, such programs generally require designation as either a Health Professional Shortage Area (HPSA) or Medically Underserved Area or Population (MUA/P). What follows is a brief overview of the criteria used for each of these designations and a look at current proposals to change the criteria and methodologies for these designations.

One of the most commonly used designations is for HPSAs. Formerly termed “Health Manpower Shortage Areas,” the designation was created

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58. See John Cromartie & Shawn Bucholtz, *Defining the “Rural” in Rural America*, AMBER WAVES, June 2008, at 28–29, <http://webarchives.cdlib.org/sw1vh5dg3r/http://ers.usda.gov/AmberWaves/June08/PDF/RuralAmerica.pdf>.

59. See *Rural Definitions: Data Documentation and Methods*, USDA ECONOMIC RESEARCH SERVICE, <http://www.ers.usda.gov/data-products/rural-definitions/data-documentation-and-methods.aspx> (last updated July 5, 2012).

60. See *Defining the Rural Population*, HRSA, [http://www.hrsa.gov/ruralhealth/policy/definition\\_of\\_rural.html](http://www.hrsa.gov/ruralhealth/policy/definition_of_rural.html) (last visited May 14, 2013) (identifying these two agencies’ definitions as the “two major definitions of ‘rural’ that the Federal government uses”).

61. Urban Area Criteria for 2010 Census, 76 Fed. Reg. 53,030, 53,039 (Aug. 24, 2011).

62. 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas, 75 Fed. Reg. 37,246, 37,252 (June 28, 2010).

63. *Id.*

64. *Id.*

under the Health Professionals Educational Assistance Act of 1976.<sup>65</sup> This designation has its roots in the National Health Services Corps program and was originally created to assess eligibility for programs intended to recruit health professionals to underserved areas.<sup>66</sup> Although the use of the word “area” in the term “HPSA” tends to imply a geographically based definition, the HPSA designation may be given to geographic areas, specific population groups, or specific public or nonprofit provider facilities.<sup>67</sup> There are also separate HPSA designations for various types of professionals: primary care, dental care, mental health care, vision care, podiatric care, and pharmacy.<sup>68</sup> As such, there are different HPSA designation criteria depending on what is receiving the designation (a geographic area, population, or facility) or the types of professional for which there is a shortage.

For example, a geographic area meets the definition of a primary medical care HPSA if: (1) there is a “rational area[] for the delivery of primary medical care services,”<sup>69</sup> (2) the population in the area has a full-time equivalent primary care physician ratio of least 3500:1,<sup>70</sup> and (3) primary care professionals in contiguous areas are “excessively distant, overutilized or inaccessible.”<sup>71</sup> A primary care HPSA designation for a population group, however, generally requires that the members of the population group (1) live in an area that is “rational for delivery of

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65. Pub. L. No. 94-484, § 332(a)(1), 90 Stat. 2243, 2270 (1976).
66. Negotiated Rulemaking Committee on the Designation of Medically Underserved Populations and Health Professional Shortage Areas, *Final Report to the Secretary*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 21 (Oct. 31, 2011), <http://www.hrsa.gov/advisorycommittees/shortage/nrmcfinalreport.pdf> [hereinafter NRMC] (“[T]he HPSA designation process . . . is statutorily tied to the National Health Service Corps program, the Federal program that offers recruitment incentives, in the form of scholarship and loan repayment support, to health professionals committed to providing care in areas with health professional shortages.”).
67. See 42 U.S.C. § 254e(a)(1) (2011) (defining “health professional shortage area” under the Public Health Services Act to include “an urban or rural area . . . , a population group which the Secretary determines has such a shortage, or a public or nonprofit private medical facility”); see also 42 C.F.R. § 5.1 (2012) (“These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional(s) shortage areas.”).
68. See generally 42 C.F.R. §§ 5 apps. A–E, G (2012).
69. 42 C.F.R. § 5 app. A, pt. I.B.1 (2012).
70. See *id.* at pt. I.D.1. The area also meets this physician ratio criterion if the area has a full-time equivalent primary care physician to population ratio of greater than 3000:1 and an “unusually high need [for primary care services] or insufficient capacity [of existing primary care providers].” *Id.* at pt. I.D.2.
71. *Id.* at pt. I.A.6.

primary care medical care,” (2) have barriers to care access, possibly including “economic, linguistic, cultural or architectural” factors, and (3) have a primary-care-physician-to-population ratio of less than 3,000:1.<sup>72</sup> Finally, such primary care HPSA designation for facilities applies to certain correctional institutions<sup>73</sup> and public or nonprofit medical facilities that serve a HPSA geographic area or population and have “insufficient capacity to meet the primary care needs of that area or population group.”<sup>74</sup>

The HPSA designation criteria for other types of health professionals follow a similar model, although the specific requirements differ.<sup>75</sup> As such, certain areas or populations may be a designated HPSA for one or multiple types of health professionals. In August 2012, HRSA reported that there were 54.4 million people living in 5,721 different primary care HPSAs. In contrast, there were 43.3 million people living in 4,405 dental HPSAs and 87.1 million people living in 3,689 mental health HPSAs. A total of nearly 30,000 additional primary care, dental, and mental health professionals would need to begin practicing in these areas to fully address this workforce shortage.<sup>76</sup>

Other federal programs base eligibility on what are commonly referred to as medically underserved area or populations (MUA/Ps).<sup>77</sup> This designation is generally used for clinics and health centers that qualify

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72. *Id.* at pt. II.A.1.

73. *See id.* at pt. III.A.

74. *Id.* at pt. III.B.1.

75. For example, the geographic HPSA designation for dental care professionals requires a higher full-time-equivalent dentist ratio of 5000:1. *See* 42 C.F.R. § 5 app. B, pt. I.D.1 (2012). In contrast, for mental health professionals, the geographic HPSA designation applies different ratios depending on the specific type of mental health professional. *See* 42 C.F.R. § 5 app. C, pt. I.A.2 (2012).

76. HRSA has identified the need for an additional 5848 primary care providers, 4585 dental providers, and 3802 mental health providers to meet the needs of each of these respective HPSAs. *Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations*, HRSA, <http://www.hrsa.gov/shortage> (last visited Apr. 4, 2013).

77. The term MUA/P encompasses two separate designations contained in the same regulation. *See* 42 C.F.R. § 51c.102(e) (2011). MUAs are designated by the Secretary after consideration of factors including the available resources, health indices, and economic factors. *Id.* § 51c.102(e)(1)–(3). MUP, on the other hand, is used to refer to “the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.” *Id.* § 51c.102(e). *See also* NRMC, *supra* note 66, at 16 (using MUA in reference to “the entire population of a geographic area” and using MUP “only based on the members of the underserved population”).

for federal assistance.<sup>78</sup> Whereas HPSAs focus on where there is a shortage of providers, the “MUA and MUP designations target Federal resources to those areas and populations where individuals have poor health status, low ability-to-pay, limited availability of primary care providers, and barriers to accessing primary care.”<sup>79</sup> HHS considers the following four factors in designating MUA/Ps:

- (1) Available health resources in relation to size of the area and its population, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology to population;
- (2) Health indices for the population of the area, such as infant mortality rate;
- (3) Economic factors affecting the population’s access to health services, such as percentage of the population with incomes below the poverty level; and
- (4) Demographic factors affecting the population’s need and demand for health services, such as percentage of the population age 65 and over.<sup>80</sup>

For MUAs, the agency considers these factors in relation to the population as a whole in a given area.<sup>81</sup> For MUPs, the agency considers these factors only in relation to the underserved population of interest.<sup>82</sup> In practice, HHS applies these regulatory provisions using the Index of Medical Underservice (IMU), with any area or population scoring 62.0 or less (where zero represents “completely underserved” and 100 represents “best served”) qualifying as an MUA/P.<sup>83</sup>

Although the HPSA designation was developed with a focus on *provider* recruitment and the MUA/P was developed with a focus on underserved *populations*, there is significant overlap between these designations.<sup>84</sup> Over the last several decades, there have been several failed efforts by policymakers to create a comprehensive methodology.<sup>85</sup>

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78. NRMC, *supra* note 66, at 21.

79. *Id.*

80. 42 C.F.R. § 51c.102(e)(1)–(4).

81. NRMC, *supra* note 66, at 16.

82. *Id.*

83. *Medically Underserved Areas & Populations (MUA/Ps)*, HRSA, <http://bhpr.hrsa.gov/shortage/muaps/index.html> (last visited July 4, 2013).

84. NRMC, *supra* note 66, at 21.

85. In 1998 and 2008, HRSA issued proposed final rules combining the HPSA and MUA/P designations. “In both cases, many public comments were received, and the concerns expressed resulted in a HRSA decision to reconsider and develop a new proposal to be published at a later date; no final revised rule as yet been adopted.” Designation of Medically Underserved Populations and Health Professions Shortage Areas; Intent to

Under a provision in the Patient Protection and Affordable Care Act, however, HRSA is directed to undertake negotiated rulemaking<sup>86</sup> to establish “a comprehensive methodology and criteria” for the HPSA and MUA/P designations.<sup>87</sup> In November 2011, HRSA’s Negotiated Rulemaking Committee on the topic issued its final report recommending a number of changes. While the Committee did not recommend that the methodologies used for assigning the HPSA and MUA/P designations be combined,<sup>88</sup> it proposed a number of other changes in designation methodologies. Most significantly, for both the MUA/P and Primary Care HPSA designations, the Committee proposed including nurse practitioners, physician assistants, and certified nurse midwives in the determination of primary care provider-to-population ratios.<sup>89</sup> The Committee also proposed lowering the provider-to-population thresholds required to qualify as an underserved area<sup>90</sup> and increasing emphasis on patients’ ability to pay in designating MUAs.<sup>91</sup>

The recommendations in the Committee’s report were approved by a vote of twenty-one to two (with five members absent).<sup>92</sup> As of this writing, however, HHS has not yet issued an interim or proposed final rule based on the Committee’s report, and it is unclear whether the

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Form Negotiated Rulemaking Committee, 75 Fed. Reg. 26,167, 26,167 (May 11, 2010).

86. Negotiated rulemaking is governed by the procedures of the Federal Negotiated Rulemaking Act, 5 U.S.C. §§ 561–570. Under these procedures, the agency creates a “negotiated rulemaking committee” to draft a proposed rule, 5 U.S.C. §§ 562(6)–(7), rather than following the more common notice-and-comment rulemaking procedures under the federal Administrative Procedures Act. *See also* William Funk, *Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest*, 46 DUKE L.J. 1351, 1356–58 (1997) (providing a general overview of the development of negotiated rulemaking).
87. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 5602(a)(1), 124 Stat. 678 (2010).
88. NRMC, *supra* note 66, at 21 (“The Committee recommends maintaining the current distinction between these two major types of shortage/underservice designations: health professional shortage and health service shortage. Although the legislative requirements for the two designation types are similar in many respects, they are rooted in distinct legislative histories and each has unique practical applications.”).
89. *Id.* at 26.
90. *Id.* at 32.
91. *Id.* at 34–35.
92. At the outset of the negotiated rulemaking, the Committee defined the term “consensus” to mean unanimous support. *Id.* at 7. Accordingly, the Committee technically failed to reach a consensus in this regard. *Id.*

agency will proceed with finalizing the recommended changes.<sup>93</sup> The Committee estimates that approximately 12 million people live in areas that stand to lose the geographic HPSA designation under the proposed criteria, with another 20 million living in areas that would gain the designation. Additionally, 16 million people live in areas that would lose the MUA designation under the Committee's proposed criteria, and 48 million live in areas that would be designated as MUAs. Accordingly, if the HPSA and MUA/P designation methodology is changed according to the Committee's recommendations, there could be a substantial shift in the types of providers that benefit from programs under the new designations. Specifically, the increased emphasis on ability-to-pay in designating MUAs may lead to the loss of this designation in areas where the current designation is based more on a shortage of providers rather than on a high poverty rate. Similarly, the inclusion of nurse practitioners, physician assistants, and certified nurse midwives in the provider-to-population ratio may impact the staffing decisions made by providers located in geographic HPSAs. As explained below, the MUA/P and HPSA designations have substantial impacts on a provider's eligibility for a variety of federal assistance programs. A rural health care provider should take measures to ensure the accuracy of any data it provides that may be used in determining MUA/P or HPSA designations; providing inaccurate data could arguably constitute a false claim under the FCA.<sup>94</sup>

*C. Programs, Laws, and Policies Intended to Support the Financial Viability of Rural Providers*

In light of the significant workforce and financial challenges many rural providers face, Congress and HHS have created a variety of programs and legal or regulatory exceptions to support rural providers. An overview of these programs and exceptions serves to highlight the

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93. Under the PPACA, HHS is directed to publish an interim final rule and then, following a public notice-and-comment period, a final rule. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 5602(g), 124 Stat. 119, 679 (2010). Because the Negotiated Rulemaking Committee failed to reach a technical "consensus," it is unclear how HHS will proceed at this point. The PPACA provides that if the Negotiated Rulemaking Committee is "unlikely to reach . . . consensus . . . the Secretary [of HHS] may terminate such process and provide for the publication of a rule through such other methods as the Secretary may provide." § 5602(e). As of yet, HHS has apparently not attempted a subsequent rulemaking. *See Negotiated Rulemaking Committee on Designation of MUPs and HPSAs*, HRSA, <http://www.hrsa.gov/advisorycommittees/shortage/> (last visited Apr. 5, 2013) (reporting actions since November 2011).

94. In such a situation, however, a provider could potentially assert that designation as an MUA/P or HPSA is not a "condition of payment" where there is potential FCA liability for making false certifications. *See United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1219 (10th Cir. 2008).

support offered to rural providers and draw attention to how such programs may give rise to additional FCA concerns.

### 1. Rural Health Clinics

In 1977, Congress created a program allowing certain rural providers to be federally designated as Rural Health Clinics (RHCs).<sup>95</sup> In creating this program, Congress sought to address threats to financial stability that many rural providers experience, including: difficulty replacing retiring providers, a disproportionately elderly population, relatively high operation costs, and a lack of revenue from private, third-party payers.<sup>96</sup> A provider who qualifies for designation as a RHC is able to take advantage of Medicare's potentially more lucrative cost-based reimbursement methodology.

RHCs obtain their status based on a series of location, personnel, and service criteria. To qualify as a RHC, a health facility must be located in a non-urbanized area in which there is an inadequate supply of health care providers.<sup>97</sup> RHCs are required to provide ordinary primary care service<sup>98</sup> and have first response capabilities.<sup>99</sup> If a RHC is not able to provide radiology services or hospital care, the clinic must arrange for patients to receive these services at another facility.<sup>100</sup> Finally, RHCs are required to employ at least one mid-level provider (such as a physician assistant, nurse practitioner, or nurse midwife) who must staff the RHC at least 50 percent of the time the clinic is open.<sup>101</sup>

If a provider obtains certification from the Centers for Medicare and Medicaid Services (CMS) that it is a RHC, it can bill Medicare through cost-based reimbursement.<sup>102</sup> Cost-based reimbursement is calculated by

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95. NAT'L RURAL HEALTH ASS'N, ISSUE PAPER: RURAL HEALTH CLINICS 1 (2007), available at <http://www.ruralhealthweb.org/index.cfm?objectid=3F504056-1185-6B66-8862A255663EE0E5>; see Pub. L. No. 95-210, § 1(c), 91 Stat. 1485, 1485 (amending Section 1861, part B of title XVIII of the Social Security Act to provide payment for rural health clinic services).

96. NAT'L RURAL HEALTH ASS'N, *supra* note 95.

97. 42 U.S.C. § 1395x(aa)(2)(K)-(K)(i) (2006).

98. *Id.* § 1395x(aa)(1).

99. *Id.* § 1395x(aa)(2)(B).

100. *Id.* § 1395x(aa)(2)(D).

101. *Id.* § 1395x(aa)(2)(J). A RHC may obtain a one-year waiver to this requirement if it can demonstrate that it "has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period." *Id.* § 1395x(aa)(7)(A).

102. See 42 C.F.R. § 405.2462 (2011); OFFICE OF RURAL HEALTH POLICY, HRSA, STARTING A RURAL HEALTH CLINIC—A HOW-TO MANUAL 6-1 to 6-2 (2004), <http://www.narhc.org/uploads/pdf/RHCmanual1.pdf> (explaining RHC cost reporting and reimbursement).

dividing allowable costs (expenses that have an associated maximum value) by the number of visits made to a RHC.<sup>103</sup> HHS has observed that all-inclusive averages usually amount to more than fee-for-service payments and that most RHCs see a 25–75 percent increase in revenue once they become eligible for cost-based reimbursement.<sup>104</sup> As such, the RHC designation is potentially valuable for a clinic in a rural area that relies heavily on Medicare patients.

One area of concern identified by HHS OIG relates to methodologies used by CMS to identify rural or underserved areas and populations.<sup>105</sup> In a 2005 review of the RHC program, OIG concluded that the methodologies and review processes currently in place allowed for potentially several hundred RHCs to operate in areas that were not truly underserved rural areas.<sup>106</sup> OIG consequently recommended “requiring current and prospective RHCs to provide additional evidence of community need.”<sup>107</sup> OIG further recommended that CMS be able to “terminate those clinics that do not meet the basic location requirements unless they demonstrate that the clinics are essential community providers for their service areas.”<sup>108</sup> OIG’s recommendations focus on the need for CMS to update its designation criteria and do not suggest concern that RHCs are currently misrepresenting their status. However, to the extent that CMS adopts practices requiring many RHCs to show that they “are essential community providers,” misleading or inaccurate representations by the provider to assure continued designation as a RHC could potentially be considered a “false claim” under the FCA. Rural providers must therefore assure that any such representations are not potentially false or misleading.

## 2. Federally Qualified Health Centers and Their Look-Alikes

The Federally Qualified Health Center (FQHC) program was enacted and expanded under the 1989 and 1990 Omnibus Budget Reconciliation

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103. CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE CLAIMS PROCESSING MANUAL § 20.4 (2010), *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c09.pdf>.

104. OFFICE OF RURAL HEALTH POLICY, *supra* note 102.

105. *See generally* OFFICE OF INSPECTOR GENERAL, U.S. DEP’T HEALTH & HUMAN SERVS., STATUS OF THE RURAL HEALTH CLINIC PROGRAM (2005), *available at* <http://oig.hhs.gov/oei/reports/oei-05-03-00170.pdf>.

106. *Id.* at 8–9. The report found that 279 RHCs were in areas that were neither designated as a health shortage area or a non-urban area. Another 946 RHCs in health shortage areas had not been reviewed within the past three years to determine whether the area should still carry this health shortage designation. *Id.* at 8.

107. *Id.* at 16.

108. *Id.* at 17.

Acts, respectively.<sup>109</sup> Although a FQHC may be in an urban or rural region, the facility must serve a MUA/P.<sup>110</sup> The FQHC designation is only available to public agencies and non-profit corporations that run under a board of directors.<sup>111</sup> A FQHC is required to supply primary care and make available the following services either onsite or through arrangements with another facility: emergency care, pharmacy, lab testing, radiology services, preventative health and dental, transportation, hospital care, and case management.<sup>112</sup> Although the qualification standards are much more complex, the federal assistance available to rural providers designated as FQHCs is much greater than what is available to RHCs.

By statutory definition, a FQHC is generally an entity that receives a grant from (or operates under a facility that receives a grant from) the federal government under Section 330 of the Public Health Services Act (PHSA).<sup>113</sup> A facility that meets the requirements for receiving such a grant but does not acquire one is known as an FQHC Look-Alike.<sup>114</sup> Apart from the potential for federal grant funding, other benefits for FQHCs and Look-Alikes include access to discounted prescription drugs under the Drug Discount pricing program authorized by Section 340 of the PHSA, eligibility to bring in new personnel associated with the National Health Service Corps loan repayment program,<sup>115</sup> and the

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109. HEALTH RESOURCES & SERVS. ADMIN., DEPT. OF HEALTH AND HUMAN SERVS., COMPARISON OF THE RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER PROGRAMS 7 (2006), *available at* <http://www.ask.hrsa.gov/downloads/fqhc-rhccomparison.pdf>.

110. *Id.* at 11.

111. *Id.* at 12.

112. *Id.* at 13.

113. 42 U.S.C. § 1395x(aa)(4)(A)(i) (2006) (defining FQHC as “an entity which is receiving a grant under section 330 of the Public Health Service Act”). There are several other types of entities that also meet the definition of FQHC. *Id.* § 1395x(aa)(4)(A)(ii)–(D).

114. *See* 42 U.S.C. § 1395x(aa)(4)(B) (2006). The term “look-alike” is not in the statutory definition of FQHCs. However, this term is commonly used in Medicare guidance to describe the types of entities defined in § 1395(aa)(4)(B). *See, e.g.*, CMS MEDICARE LEARNING NETWORK, FEDERALLY QUALIFIED HEALTH CENTER, RURAL HEALTH FACT SHEET SERIES 1 (2012), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fqhcfactsheet.pdf>.

115. NAT’L ASS’N OF CMTY. HEALTH CTRS., SO YOU WANT TO START A HEALTH CENTER . . . ? : A PRACTICAL GUIDE FOR STARTING A FEDERALLY QUALIFIED HEALTH CENTER 2 (2011), <https://www.nachc.com/client/documents/So%20you%20want%20to%20Start-Final%20July%202011.pdf>.

ability to hire a Medicaid eligibility worker with the authority to grant Medicaid coverage to those who qualify.<sup>116</sup>

Additionally, any medical malpractice claims against providers working for FQHCs that receive grant funding cannot be brought in state court.<sup>117</sup> Rather, such claims must be filed in federal court under the Federal Tort Claims Act<sup>118</sup> and federal government attorneys will defend the FQHC at no cost to the FQHC.<sup>119</sup> Thus, many health professionals who work at FQHCs may avoid the expense of carrying malpractice insurance.<sup>120</sup>

FQHCs that receive grant funding under the PHSA should be particularly aware of the potential for FCA claims on the basis of “false certification.”<sup>121</sup> In cases involving a false certification theory, liability “is predicated upon a false representation of compliance with a federal statute or regulation or prescribed contractual term.”<sup>122</sup> Considering the potential breadth of these types of claims,<sup>123</sup> courts have indicated that a

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116. TEXAS ASSOCIATION OF COMMUNITY HEALTH CENTERS, OUTSTATIONED ELIGIBILITY WORKERS AT FQHCs: A LOOK AT COST EFFECTIVENESS 2 (2006), [http://www.tachc.org/content/Outstationed\\_Eligibility\\_Workers\\_at\\_FQHCs.pdf](http://www.tachc.org/content/Outstationed_Eligibility_Workers_at_FQHCs.pdf).

117. 42 U.S.C. § 233(a), (c) (2011). In order to receive this benefit, the FQHC must obtain a designation as a “Public Health Service employee” and meet certain criteria, including implementing appropriate risk-reduction procedures and verifying the professional credentials of its practitioners. *Id.* § 233(h).

118. 28 U.S.C. § 1346(b)(1) (2006).

119. *See* 42 U.S.C. § 233(b).

120. *FTCA FAQs*, HRSA, <http://bphc.hrsa.gov/ftca/about/aboutfaqs.html> (last visited Apr. 4, 2013) (noting that “the Health Center FTCA Program saves health center grantees millions of dollars yearly”).

121. As one commentator has explained, “FCA liability in false certification cases turns on a finding that the defendant expressly or impliedly certified compliance with all Medicare and Medicaid rules, regulations and requirements, but that certification turned out to be false.” Dayna Bowen Matthew, *An Economic Model to Analyze the Impact of False Claims Act Cases on Access to Healthcare for the Elderly, Disabled, Rural and Inner-City Poor*, 27 AM. J. LEG. MED. 439, 443 (2001); *see* United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) (“It is the false certification of compliance which creates liability.”).

122. *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001). The *Mikes* court clarified that this type of claim is also referred to as “‘legally false’ certification.” *Id.* at 697 (citing Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 111–12 (1999), and distinguishing it from claims “which involve[] an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.”).

123. *See* Monica P. Navarro, *Materiality: A Needed Return to Basics in False Claims Act Liability* 8 (2012) (unpublished manuscript) (“[T]he need to

provider's false certification to the government that it is in compliance with the law only constitutes an FCA violation if such legal compliance is an express "condition to governmental payment."<sup>124</sup> For example, in *United States ex rel. Conner v. Salina Regional Health Center, Inc.*,<sup>125</sup> a whistleblower alleged that a health center violated the FCA by falsely certifying in its annual cost report that it was in compliance with Medicaid statutes and regulations.<sup>126</sup> In *Conner*, the U.S. Court of Appeals for the Tenth Circuit agreed with the district court and held that such alleged "false certification" could not form the basis for an FCA claim because the certification "does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation. Nor does any underlying Medicare statute or regulation provide that payment is so conditioned."<sup>127</sup>

It is unclear, however, to what extent the requirement that the false certification concern a condition of payment would present a viable defense to a rural provider, such as an FQHC, that allegedly made false statements in obtaining funding under the PHSAs.<sup>128</sup> In *United States ex rel. Parato v. UnaHealth*, the U.S. District Court for the Middle District of Georgia denied the defendant's motion to dismiss, finding that the plaintiff had sufficiently alleged that funding for a FQHC under Section 330 of the PHSAs was conditioned upon truthful certifications in the

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continue to define and circumscribe the purview of the express certification theory became apparent to the courts, which then began to impose additional requirements for liability under the theory.").

124. *See, e.g., Mikes v. Straus*, 274 F.3d at 697 ("We join the Fourth, Fifth, Ninth, and District of Columbia Circuits in ruling that a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."); *see also United States ex rel. Siewick v. Jamieson Science & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) ("[F]alse certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the FCA unless payment is conditioned on that certification."); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) ("We agree with the district court that claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.").
125. 543 F.3d 1211, 1211 (10th Cir. 2008).
126. *Id.*
127. *Id.* at 1219; *see also Navarro, supra* note 123, at 6 (noting that *Conner* "is a clear example of the excessive reliance that litigants placed on the express certification theory.").
128. Indeed, as one commentator has noted, the analysis applied in *Conner* is problematic because the rule regarding what constitutes "a 'condition to payment' for FCA liability, as required by the theory, was left undefined." Navarro, *supra* note 123, at 8.

grant application.<sup>129</sup> The *Parato* court distinguished *Conner* by noting that, unlike the defendant in *Conner*, “UnaHealth was a grant applicant for government funds, not a contractor participating in a program to perform services and then bill the Government for payment . . . .”<sup>130</sup> The *Parato* court granted the defendant’s motion for summary judgment because it found that the particular certification on the FQHC application at issue only applied prospectively and the plaintiff’s evidence related to alleged past noncompliance.<sup>131</sup> The significance of *Parato* is that false or misleading representations or certifications made on a *grant application* may give rise to FCA liability, even where the provider may have viable defenses in relation to similar representations made on an *application to participate* as a Medicare provider. Because FQHCs rely on this type of grant funding, such providers should be particularly aware of this area of potential liability.

### 3. Critical Access Hospitals

In addition to RHCs and FQHCs, the federal government has also shown initiative in supporting rural hospitals. The Balanced Budget Act of 1997 allowed for the establishment of Critical Access Hospitals (CAHs) in participating states.<sup>132</sup> All states except Connecticut, Delaware, Maryland, New Jersey, and Rhode Island have accepted federal funding to create programs that allow for CAHs to be developed as long as certain eligibility requirements are met.<sup>133</sup>

Although states are in charge of creating their own CAH programs,<sup>134</sup> a hospital must meet certain requirements to qualify. Specifically, a CAH facility must be not-for-profit and located in a rural area—defined as thirty-five miles from any other hospital (or fifteen miles if the area has more limited accessibility).<sup>135</sup> Each facility is also responsible for having twenty-four-hour emergency services available to serve the area and can have a maximum of fifteen beds reserved for in-patient use that exceeds no more than ninety-six hours, or twenty-five beds designated for either short- or long-term care.<sup>136</sup>

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129. *United States v. Unadilla Health Care Ctr, Inc.*, 2010 U.S. Dist. LEXIS 1796, at \*40–41 (M.D. Ga., Jan. 11, 2010).

130. *Id.* at \*19.

131. *See United States ex rel. Parato v. Unadilla Health Care Ctr.*, 787 F. Supp. 2d 1329, 1340 (M.D. Ga. 2011).

132. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4201, 111 Stat. 251, 373–74 (1997).

133. DEP’T OF HEALTH AND HUMAN SERVS., CENTERS FOR MEDICARE & MEDICAID SERVS., CRITICAL ACCESS HOSPITALS FACT SHEET 2 (2012), <http://www.cms.gov/MLNProducts/downloads/CritAccessHospfctshd.pdf>.

134. 42 U.S.C. § 1395i-4(a)–(b) (2006).

135. *Id.* § 1395i-4(c)(2)(B)(i).

136. *Id.* § 1395i-4(c)(2)(B)(ii).

CAHs receive 101 percent of the costs of approved Medicare services,<sup>137</sup> including inpatient care, outpatient visits, laboratory tests, and post-acute care in a skilled nursing facility.<sup>138</sup> In addition to receiving specialized Medicare reimbursement, rural providers who work in CAHs also receive financial incentives. A physician who works at a CAH in a HPSA may qualify for bonus pay as an additional percentage of the cost of treating a Medicare patient. Eligibility continues to increase for CAHs and more rural hospitals are able to receive the federal support that this particular program offers. The requirement that the facility be located a certain distance from a nearby hospital is easily waived, and as of October 2011, only 65 percent of CAHs actually met the obligation without a waiver.<sup>139</sup>

#### 4. National Health Service Corps Loan Repayment Programs

In addition to programs that support rural facilities, the federal government has also created incentives intended to expand the number of rural health care providers in practice through loan repayment programs. The National Health Service Corps Loan Repayment Program offers up to \$60,000 in student loan repayment per health care provider willing to spend a set amount of time working in a rural region.<sup>140</sup> Providers that work full time for up to two years or part-time for up to four years in the highest-ranked shortage areas qualify for the most repayment.<sup>141</sup> Eligibility extends to physicians, nurses, physician assistants, dentists, dental hygienists, and mental health providers in a variety of specialties.<sup>142</sup> Repayment programs for providers in HPSAs are set to increase under the PPACA.<sup>143</sup> Beginning in 2010, the federal government allocated \$195 million for the Public Health Workforce Loan Repayment program and by 2015, the National Health Services Corps will receive a funding increase of over \$1.1 billion to help repay provider loans.<sup>144</sup>

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137. *Payment Basics: Critical Access Hospitals Payment System*, MEDPAC 1, [http://www.medpac.gov/documents/MedPAC\\_Payment\\_Basics\\_11\\_CAH.pdf](http://www.medpac.gov/documents/MedPAC_Payment_Basics_11_CAH.pdf) (last updated Oct. 2011).

138. *Id.*

139. *Id.*

140. BUREAU OF CLINICIAN RECRUITMENT & SERV., U.S DEP'T OF HEALTH & HUMAN SERVS., NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM 1 (2013), <http://nhsc.hrsa.gov/downloads/lrpataglanace.pdf>.

141. *Id.* at 2.

142. *Id.* at 2.

143. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 5604 and 5207 124 Stat. 678 (2010).

144. KEITH J. MUELLER, RURAL POLICY RESEARCH INSTITUTE, THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: A SUMMARY OF PROVISIONS IMPORTANT TO RURAL HEALTH CARE DELIVERY 5 (2010), *available at*

5. Stark and Anti-Kickback Provisions Impacting Rural Providers

In addition to the various programs discussed above, other health care fraud and abuse laws and regulations contain exceptions that apply only to rural providers. By carving out these exceptions, Congress and regulatory agencies have sought to account for the circumstances under which rural providers operate.

a. *The Stark Law*

The so-called “Stark Law”<sup>145</sup> prohibits physicians from referring Medicare and Medicaid patients for “designated health services” to entities with which the physician or an immediate family member of the physician has an ownership, investment, or compensation interest.<sup>146</sup> The purpose of the law is to prevent overutilization caused by a physician’s financial interest in referring patients for unnecessary services.<sup>147</sup> The Stark Law was enacted in 1989 after a study of Medicare claims from 1987 showed that Medicare patients of physicians with a financial interest in an independent clinical laboratory “received, on the average, 45 percent more clinical laboratory services than all Medicare patients in general, regardless of place.”<sup>148</sup> The law originally applied only to referrals by physicians to clinical laboratory services but has expanded to prohibit interested referrals to providers of other designated health

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[http://www.public-health.uiowa.edu/rupri/publications/policypapers/PPACA%20Rural%20Provision%20Summary.06\\_08\\_10.pdf](http://www.public-health.uiowa.edu/rupri/publications/policypapers/PPACA%20Rural%20Provision%20Summary.06_08_10.pdf).

145. The law, as originally enacted, is called the “Ethics in Patient Referrals Act,” Pub. L. No. 101-239, § 6204, 103 Stat. 2137, 2236, but it is commonly called the “Stark Law” after its sponsor, Democratic representative Pete Stark from California. The section of the United States Code containing the law is labeled “Limitation on certain physician referrals,” 42 U.S.C. § 1395nn, and it is also commonly referred to as the “physician self-referral law.” See *Physician Self-Referral*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html> (last updated Mar. 27, 2012).

146. *Id.* § 1395nn(a)(1)(A).

147. See Susan O. Scheutzwilg & Steven A. Eisenberg, *The Employee Exceptions to the Anti-Kickback and Stark Laws After Tuomey: What’s a Physician’s Employer to Do?*, 4 J. HEALTH & LIFE SCI. L. 146, 160 n.21 (2011) (“The Stark Law’s main purposes are to prevent overutilization by prohibiting a physician from making a referral for certain services to an entity with whom the physician has a compensation arrangement or ownership interest except in certain situations, and to ensure that physicians’ medical judgments are not compromised by improper financial incentives and are based solely on the best interests of the patient.”).

148. OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH & HUMAN SERVICES, OAI-12-88-01410, FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES: REPORT TO CONGRESS 18 (1989), available at <http://oig.hhs.gov/oei/reports/oi-12-88-01410.pdf>.

services (DHSs).<sup>149</sup> The impact of this law is that a physician cannot invest in an entity offering DHSs and then refer Medicare and Medicaid patients for such services unless the arrangement falls within one of the exceptions to the Stark law.<sup>150</sup> Although the statute has been amended to expand the scope of the law,<sup>151</sup> the statute and accompanying regulations also provide a number of exceptions for common financial arrangements in the health arena.<sup>152</sup>

Although there is no provision exempting rural physicians and DHS providers from the entire Stark Law, there are various exceptions that substantially limit the scope of the law in rural areas. Under one of the most sweeping exceptions, physicians are permitted to make referrals to DHS entities in which they have ownership interests if the DHS provider is located in a rural area<sup>153</sup> and “substantially all (not less than 75 percent)” of such services are provided to individuals living in the rural area.<sup>154</sup> In other words, the Stark self-referral prohibition does not apply to a physician making an ownership investment interest in a DHS provider such as a clinical laboratory and then referring Medicaid and Medicare patients to it. This rural area exception, however, does not

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149. 42 U.S.C. § 1395nn(h)(6).

150. Although Stark does not prohibit a physician from having an ownership interest in a DHS provider, “the law makes it impractical to do so in many situations, by prohibiting certain referrals as well as reimbursement . . . .” DEAN M. HARRIS, *CONTEMPORARY ISSUES IN HEALTHCARE LAW AND ETHICS* 149–50 (3d ed. 2008).

151. David E. Matyas, *Fundamentals of Health Law Fraud and Abuse*, in *FUNDAMENTALS OF HEALTH LAW* 149, 174 (Barry Alexander et al. eds., 5th ed. 2012) (noting that the law “originally only applied to the provision of clinical laboratory services”).

152. See 42 U.S.C. § 1395nn(b)–(d) (2006) (providing statutory exceptions to Stark’s self-referral prohibition). The statute’s definition of the term “referral” puts certain other activities outside the scope the Stark Law. *Id.* § 1395nn(h)(5)(C). Additionally, the statute’s definition of the term “referral” puts certain other activities outside the scope the Stark Law. See *id.* § 1395nn(h)(5)(C). Finally, provisions in HHS regulations interpreting the Stark Law also carve out various other limited exceptions. See, e.g., 42 C.F.R. § 411.357(t) (2011) (describing a regulatory exception permitting, under certain circumstances, a hospital to make “[r]etention payments” to a physician practicing in an underserved area). A full discussion of the complex array of exceptions to the Stark law is beyond the scope of this Article. For a helpful introduction to the topic, see Matyas, *supra* note 151, at 180–94.

153. 42 U.S.C. § 1395nn(d)(2). For the purposes of Stark, a rural area is considered any non-urban area. *Id.* § 412.62(f)(iii) (2011). In other words, Stark essentially applies the definition of “rural” used by the Office of Management and Budget. See *What is Rural? Frequently Asked Questions*, RURAL ASSISTANCE CENTER, <http://www.raconline.org/topics/ruraldef/ruraldeffa.php> (last visited Aug. 31, 2013).

154. 42 C.F.R. § 411.356(c)(1) (2011).

apply to “compensation” arrangements between a physician and DHS provider. CMS also carved out a regulatory exception for payments made directly to physicians by a hospital that provides DHSs to encourage the physicians to keep their practice in a HPSA.<sup>155</sup>

*b. The Anti-Kickback Statute*

The Anti-Kickback Statute (AKS) prohibits “knowingly and willfully” soliciting, receiving, offering, or paying “any remuneration” in return for referring or directing patients whose care will be paid for “in whole or in part under a Federal health care program.”<sup>156</sup> Unlike the Stark Law, which imposes strict liability, the AKS is a criminal statute that requires knowing and willful conduct. However, HHS regulations have created various voluntary safe harbors that “protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution.”<sup>157</sup> A number of these safe harbors apply specifically to providers in rural and other underserved areas, thus facilitating a broader range of financial arrangements for rural providers.

More recently, HHS created a safe harbor that applies to FQHCs, many of which are located in and serve rural areas.<sup>158</sup> Specifically, this safe harbor excludes from the AKS’s definition of “remuneration” many “goods, items, services, donations or loans” provided to an FQHC to support the FQHC’s operations so long as certain criteria are met.<sup>159</sup> Significantly, the safe harbor requires that there be a signed, written agreement, that the amount of the contribution be fixed or set by a fixed methodology not conditioned on referrals or business generation, that contribution to the FQHC be “medical or clinical in nature,” and that the FQHC “reasonably expects the arrangement to contribute meaningfully” to the health center’s mission.<sup>160</sup>

There are also safe harbors to the AKS related to investments in health care companies by individuals who may be in a position to refer or prescribe products or services offered by those companies.<sup>161</sup> For some investments in rural areas, the criteria for the investment to come within the safe harbor are relaxed. There is a fairly straightforward safe harbor for investments in large, publicly traded corporations.<sup>162</sup> This safe

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155. 42 C.F.R. § 411.357(t) (2011); *see also* Matyas, *supra* note 151, at 188.

156. 42 U.S.C. § 1320a-7b(b)(2) (2011).

157. OIG ROADMAP, *supra* note 29, at 4.

158. 42 C.F.R. § 1001.952(w) (2011).

159. *Id.* § 1001.952(w)(1)–(9).

160. *Id.* § 1001.952(w)(1)–(3).

161. *See id.* § 1001.952(a)

162. *Id.* § 1001.952(a)(1). In order to fall within this safe harbor, if the entity invested in has a net worth of greater than \$50 million, the investment is a security registered with the Securities and Exchange Commission, and the

harbor, which applies equally to urban and rural providers, allows for the common situation of a physician owning a pharmaceutical company's stock as part of an investment portfolio without the physician risking running afoul the AKS. For investment interests in smaller health care companies, however, HHS created a separate and much more complex safe harbor. This "small investment interest" safe harbor requires strict adherence to eight criteria.<sup>163</sup> Among these criteria are the requirements that no more than 40 percent of the investment interest can be held by investors in a position to generate referrals or business and that no more than 40 percent of gross revenue can come from referrals or business generated by investors.<sup>164</sup> For providers serving MUAs (including medically underserved rural areas), up to 50 percent of the investment interest can be held by such investors and there is no limit to the percentage of revenue that comes from investor-generated business and referrals.<sup>165</sup> As such, this provision makes it easier for physicians in rural areas to pool their resources to invest the capital necessary to bring ancillary services to rural areas.

HHS has also provided a safe harbor for payments by hospitals and other activities to recruit physicians to practice in HPSAs.<sup>166</sup> To come within this safe harbor, there are nine requirements, including the execution of a written agreement and that there be no requirements for the recruited physician to refer patients to the recruiting hospital.<sup>167</sup> Another safe harbor exists for obstetrical malpractice insurance subsidies for practitioners working in HPSAs.<sup>168</sup>

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investment interest is obtained on the same terms and for the same price as the general public. *Id.* § 1001.952(a)(1)–(a)(1)(ii).

163. *Id.* § 1001.952(a)(2). These eight criteria are: (1) no more than 40 percent of the investment can be held by individuals in a position to generate referrals or business; (2) the terms of the investment must be the same regardless of whether or not the investor is in a position to generate referrals and business; (3) the terms of the investment cannot be tied to the generation of referrals or business; (4) cannot require investors to generate referrals; (5) no requirement that an investor market the company's items or products; (6) no more than 40 percent of gross revenue can come from referrals or business generated by investors; (7) the entity cannot make loans (including loan guarantees) to an investor in a position to generate referrals or business; and (8) dividends and other payments must be proportional to the capital each investor has contributed. *Id.* § 1001.952(a)(2)(i)–(viii).

164. *Id.* § 1001.952(a)(2)(i), (vi).

165. *Id.* § 1001.952(3)(i)(A).

166. *Id.* § 1001.952(n).

167. *Id.* § 1001.952(n)(1)–(9).

168. *Id.* § 1001.952(o).

### III. PREVENTING UNILATERAL WHISTLEBLOWER CLAIMS AGAINST CERTAIN RURAL PROVIDERS

As illustrated above, rural health care providers routinely face financial difficulties. To account for the context in which rural providers operate, policymakers have established programs and legal or regulatory exceptions specific to rural providers. One area where the law applies equally to rural providers as other providers, however, is in relation to claims brought by whistleblowers under the FCA. DOJ policy expressly directs government attorneys to take into account the impact on a community's access to care in determining how or whether to pursue a civil FCA case.<sup>169</sup> This policy does not apply to whistleblowers, who are free to pursue such cases unilaterally where the government chooses not to intervene.

From the preceding discussion, several things are clear. First, providers in rural, underserved areas operate in a financially unstable environment and rely on a variety of federal programs. The expense and burden of defending what may be a meritless civil FCA claim may present a substantial difficulty for such providers who are relatively unsophisticated<sup>170</sup> compared to larger organizations in more populous areas, have slim operating margins, and cannot afford insurance that clearly covers FCA liability and defense costs. Second, unilateral whistleblower FCA actions play a very minimal role in recovering wrongfully obtained government funds from health care providers. Because of this reality, Congress should consider amending the statute to permit civil FCA whistleblower claims against rural providers in underserved areas, such as HPSAs and MUA/Ps, to proceed only if the government intervenes.<sup>171</sup>

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169. Holder, *supra* note 43.

170. One empirical study found that managers at larger health care organizations generally found governmental billing compliance guidance material more understandable. Daniel P. Lorence & Ibrahim Awad Ibrahim, *Identifying Barriers to Billing Compliance*, 30 J. HEALTH CARE FIN. 49, 60 (2003); *see also* COMMITTEE ON THE FUTURE OF RURAL HEALTH CARE, QUALITY THROUGH COLLABORATION: THE FUTURE OF RURAL HEALTH 100 (2005), *available at* [http://www.nap.edu/catalog.php?record\\_id=11140](http://www.nap.edu/catalog.php?record_id=11140) (“Traditionally, many rural health administrators have backgrounds in clinical or technical fields and have learned management skills on the job.”).

171. This Article focuses primarily on why Congress should amend the FCA in this regard. However, twenty-eight states currently have state false claims act under which a whistleblower could bring claims in relation to Medicaid and other health programs involving state funding. *See, e.g., State False Claims Act Reviews*, OFFICE OF INSPECTOR GEN., <http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp> (last visited Sept. 4, 2013). States that enact FCAs that are substantially similar to the federal civil FCA—including the whistleblower provisions—receive a larger share of misappropriated Medicaid funds recovered under such statutes. *See* 42

This change would have little or no impact on cases where there is evidence that a provider engaged in egregious conduct,<sup>172</sup> as a private whistleblower with insider information would still have the same opportunity and financial incentives to bring the claim. The only difference is that such a claim would only be able to move forward if the government's attorneys choose to intervene after reviewing the sealed complaint and conducting an initial investigation.<sup>173</sup> In other cases, however, government attorneys may discover through this early investigation that a whistleblower's claims are based on a misinterpretation of billing regulations<sup>174</sup> or are simply a disgruntled former employee's attempt to retaliate against the defendant.<sup>175</sup> In such cases, government attorneys would be able to

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U.S.C. § 1396h (2006). This Article's argument for limiting the scope of whistleblower provisions against rural providers applies equally to both the federal FCA and analogous state FCAs.

172. One commentator presents a similar argument in relation to academic teaching hospitals: "No one could dispute that hardship or not, fraudulent institutions should be aggressively investigated and relentlessly prosecuted. However, the internal and social costs of such investigations are high, and care should be taken so that the mystique of the health care fraud law enforcement machine does not seduce the regulator into becoming a hunter when there is no prey." Bucy, *supra* note 42, at 50.
173. Several commentators have proposed a similar statutory reform to all cases brought under the FCA, not just those involving providers in designated underserved rural areas. *See generally* J. Randy Beck, *The False Claims Act and the English Eradication of Qui Tam Legislation*, 78 N.C. L. REV. 539, 637–41 (2000); Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 332–37 (2007).
174. The United States Court of Appeals for the District of Columbia Circuit, in a *qui tam* FCA outside the health care context, perhaps best summed up the concern that a *qui tam* litigant may erroneously interpret "confusion" about ambiguous regulations as conduct violating the FCA, stating:

Forty years ago Jimi Hendrix trilled his plaintive query: "Is this love, baby, or is it . . . [just] confusion?" In this False Claims Act case, we face a similar question involving a mortgage subsidy program initiated in that era: Is this fraud, or is it . . . just confusion?

U.S. *ex rel.* K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 981 (D.C. Cir. 2008); *see also* U.S. *ex rel.* Williams v. Renal Care Group, 696 F.3d 518, 531 (6th Cir. 2012) (holding that a Medicare provider did not act in "reckless disregard" when it "followed industry practice in trying to sort through ambiguous regulations").

175. *See, e.g.*, David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 COLUM. L. REV. 1244, 1275 ("While *qui tam* relators are sometimes championed as moralistic heroes courageously fighting corporate malefactors, FCA opponents paint a far less flattering portrait. *Qui tam*'s opponents cast relators as vengeful former employees who use the FCA as leverage in garden-variety employment disputes.").

prevent the whistleblower from pursuing the claim on their own and thereby shield the provider from incurring potentially excessive defense costs. This change would also promote the DOJ's policy of considering an underserved rural "community's interest in access to adequate health care along with any other relevant concerns" in pursuing FCA cases.<sup>176</sup>

Such an amendment would make the determination of whether or not to intervene much more significant in cases involving rural providers. However, it would also provide government attorneys greater ability to assure continued access to care in underserved areas. In light of the various programs and regulatory exemptions that apply only to rural providers in underserved areas, such a change would not be unprecedented. Indeed, the various Stark and AKS exceptions and safe harbors that apply only to rural providers illustrate how, even in the context of health care fraud and abuse prevention, policymakers recognize the context within which rural providers operate. Such a change in the FCA is analogous to the policy objective of shielding providers at FQHCs from malpractice liability in state court. As explained above, the HRSA has stated that shielding FQHCs from such malpractice liability relieves those facilities from the obligation to purchase malpractice insurance, thereby freeing up federal grant funds to serve more patients. Similarly, to the extent that a rural provider's FCA liability exposure can be limited to only cases the government deems worth pursuing, additional federal grant funds and enhanced Medicare payments can be dedicated to serving patients rather than defending FCA claims.

Such a policy change would add a measure of stability to the financial insecurity rural providers often confront. Considering how heavily rural providers rely government programs for funding, such a change may be particularly beneficial.<sup>177</sup> It may increase the relative attractiveness of rural practice.<sup>178</sup> Drawing upon empirical studies investigating how reimbursement rates impact access to care, one commentator concluded that "increased costs associated with unpredictable exposure to damages and litigation costs . . . may have a negative impact on access to healthcare."<sup>179</sup>

As noted above, publicly available DOJ statistics do not specify how many FCA claims brought in the health arena are against rural provid-

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176. Holder, *supra* note 43.

177. See Matthew, *supra* note 121, at 462 ("[P]roviders serving the urban and rural poor are especially at risk of becoming the target of the government's fight against fraud due to the large numbers of Medicare and Medicaid patients who they serve.").

178. The "little financial reward" associated with practicing in rural areas is among the causes cited for physician shortages in rural areas. *Id.* at 461.

179. *Id.* at 464-65.

ers,<sup>180</sup> and it is unclear how often rural providers are named in such lawsuits.<sup>181</sup> But it is clear from existing data that unilateral whistleblower FCA claims account for a very small proportion of total FCA recoveries. Considering this situation, requiring the government to intervene in order for a *qui tam* action against a rural provider to proceed would likely have little or no appreciable impact on DOJ and OIG enforcement efforts. Conversely, such a policy change would by no means be a silver bullet in addressing access to care shortfalls in rural areas of the United States. Yet it would add a small measure of additional security to struggling rural health care providers and prevent the possibility that one would face a substantial financial hardship.

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180. Public access to additional and more specific empirical data would facilitate an informed analysis as to whether the argument presented here would detrimentally impact FCA recoveries. As one commentator put it, “One reason litigation politics have become so dysfunctional in recent decades is a lack of empirical data that can inform public debate.” Engstrom, *supra* note 175, at 1318–19. Although Professor Engstrom provides an in-depth empirical analysis of *qui tam* based on a variety of factors, this analysis focuses primarily on the characteristics of the *qui tam* relator and the relator’s attorney; it does not detail characteristics of the defendant such as health care provider type or size. *Id.* at 1286–1305.

181. Considering the slim financial resources rural providers often have, however, even a small number of such cases could have a detrimental impact on access to care in underserved rural areas.