

Summer 2007

## Second Class for the Second Time: How the Commercial Speech Doctrine Stigmatizes Commercial Use of Aggregated Public Records

Christine M. Shaffer

Follow this and additional works at: <https://scholarcommons.sc.edu/sclr>



Part of the [Law Commons](#)

---

### Recommended Citation

Christine M. Shaffer, The Impact of Medicaid Reforms & False Claims Enforcement: Limiting Access by Discouraging Provider Participation in Medicaid Programs, 58 S. C. L. Rev. 995 (2007).

This Note is brought to you by the Law Reviews and Journals at Scholar Commons. It has been accepted for inclusion in South Carolina Law Review by an authorized editor of Scholar Commons. For more information, please contact [digres@mailbox.sc.edu](mailto:digres@mailbox.sc.edu).

## **THE IMPACT OF MEDICAID REFORMS & FALSE CLAIMS ENFORCEMENT: LIMITING ACCESS BY DISCOURAGING PROVIDER PARTICIPATION IN MEDICAID PROGRAMS**

### **I. INTRODUCTION**

Approximately 42.5 million people depend on state Medicaid programs to provide payment for some or all of their health care services.<sup>1</sup> State Medicaid reform efforts and false claims enforcement aimed at controlling costs may limit beneficiaries' access to health care; by increasing the exposure of health care providers<sup>2</sup> to false claims liability, states may inadvertently cause the number of health care providers who are unwilling to accept Medicaid patients to increase. Failure to mitigate these burdens probably will result in the realization of the "very real threat that when a state cracks down too aggressively, providers—many of whom are underpaid anyhow—will quit the Medicaid program."<sup>3</sup>

In response to climbing health care costs, state and federal Medicaid reform efforts have intensified. Federal law now provides states with a number of options in structuring Medicaid programs. As a result, the structures of Medicaid programs have become increasingly complex; states' traditional administration of these programs by a single agency or contracted entity has given way to decentralized structures dominated by managed care organizations and private health plans.

The increasing complexity of Medicaid structures places additional burdens upon providers. Providers must comply with a variety of documentation, reporting, and reimbursement guidelines imposed by Medicaid agencies as well as Medicaid-contracted health plan administrators. Additionally, in light of reformers' intense focus on fraud and abuse by Medicaid providers, the complexity of the Medicaid structure may subject providers to a greater likelihood of false claims allegations for failure to adhere to regulations and guidelines. Given the already declining number of providers participating in Medicaid, the procedural requirements, combined with the potential liability

---

1. See EILEEN R. ELLIS ET AL., KAISER COMM'N ON MEDICAID AND THE UNINSURED, MEDICAID ENROLLMENT IN 50 STATES: JUNE 2005 DATA UPDATE 1 (2006), <http://www.kff.org/medicaid/upload/7606.pdf>.

2. In this Note, the term "provider" is used generally to refer to physicians, other health care practitioners (e.g., nurse practitioners), and health care institutions (e.g., hospitals).

3. Misha Segal, *Bleeding Dollars: Stanching the Flow of Misuse and Abuse Confronts a Hard Reality*, in SPECIAL REPORT ON MEDICAID: BRIDGING THE GAP BETWEEN CARE AND COST A20, A21 (2006), <http://www.pewcenteronthestates.org/medicaid.pdf>.

under state and federal false claims acts, may result in an exodus of providers from the Medicaid program.

This Note examines the potential decrease in Medicaid beneficiaries' access to care resulting from the combination of Medicaid reform measures and false claims enforcement. Part II provides an overview of state and federal reform measures designed to reduce Medicaid costs. The discussion includes a general overview of the Medicaid program and recently enacted federal legislation that increases the options available for structuring state programs and provides incentives to states for false claims enforcement. The overview also presents South Carolina's recent Medicaid reform measures and proposed false claims act.<sup>4</sup>

Part III analyzes the factors affecting Medicaid provider participation and the impact of false claims enforcement on participation. This part describes the implications of federal false claims enforcement in order to demonstrate the potential impact of substantially similar state false claims statutes. Because of the complexity of requirements governing providers participating in Medicaid programs, states' false claims enforcement efforts may contribute to the already declining number of providers accepting Medicaid patients.

Part IV suggests several measures for counteracting the potential decrease in Medicaid provider participation due to increased enforcement of state false claims laws. These measures include requiring health plans to disclose billing and reimbursement guidelines to health care providers, creating an ombudsman office within state Medicaid agencies to clarify program requirements, and providing an affirmative defense to providers who, in good faith, rely upon the guidance of Medicaid agencies and health plans. Part V briefly concludes.

## II. MEDICAID REFORM

Established by Title XIX of the Social Security Act, the Medicaid program provides payment for medical assistance for specified categories of people who lack sufficient income to obtain medically necessary health care services.<sup>5</sup> Federal law mandates Medicaid coverage for certain categories of people and allows states the option of providing coverage for other categories.<sup>6</sup> State and federal funds finance these benefits under state Medicaid programs.<sup>7</sup>

In 2007, the total cost for health care in the United States is projected to exceed two trillion dollars.<sup>8</sup> Combined state and federal Medicaid costs

---

4. Whether South Carolina's Medicaid reform measures will improve the quality of care or reduce costs is beyond the scope of this Note.

5. 42 U.S.C. § 1396 (2000).

6. 42 U.S.C. § 1396a(a)(10)(A) (2000 & Supp. III 2003). For a more extensive discussion of mandated and optional Medicaid categories and benefits, see BARRY R. FURROW ET AL., *HEALTH LAW* §§ 12-2 to -7 (2d ed. 2000).

7. 42 U.S.C. § 1396b (2000); *see also infra* note 34.

8. OFFICE OF THE ACTUARY, U.S. DEPT. OF HEALTH & HUMAN SERVS., NATIONAL HEALTH CARE EXPENDITURES PROJECTIONS: 2005–2015 tbl.1 (2005) (on file with author).

constitute 13.9% of total projected health care costs.<sup>9</sup> After peaking at a growth rate of 11.8% in 2001, growth in Medicaid spending has slowed each year and is projected to drop to 1.5% in 2006.<sup>10</sup> The decline in Medicaid spending growth is based primarily upon state Medicaid cost containment efforts.<sup>11</sup>

Managed care provides states with one method for Medicaid cost containment. “Managed care is a broad term that describes a variety of health care delivery system models that integrate the financing and delivery of health care within a system that seeks to manage the accessibility, cost, and quality of that care.”<sup>12</sup> Many managed care organizations (MCOs) contain costs by practices such as capitation, in which the MCO limits the amount of health care provided to patients and reimbursement paid to providers by paying providers a flat fee per patient for a given time period.<sup>13</sup> In general, states may require mandatory managed care enrollment for most categories of Medicaid beneficiaries so long as, among other requirements, the beneficiaries are able to choose from at least two managed care entities.<sup>14</sup> Currently, more than 63% of Medicaid beneficiaries nationally are enrolled in a managed care plan.<sup>15</sup>

9. *Id.* at tbl.3.

10. *Id.* Despite declines in both the national Medicaid annual growth rate and South Carolina’s total health care expenditure growth rate, South Carolina Medicaid’s annual growth rate has increased steadily since 2002. OFFICE OF THE ACTUARY, U.S. DEP’T OF HEALTH & HUMAN SERVS., HEALTH EXPENDITURES BY STATE OF PROVIDER: STATE-SPECIFIC TABLES, 1980–2004 (2006), <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf>. National Medicaid annual growth rates in personal health care expenditures for 2002, 2003, and 2004 were 10.4, 8.6, and 8.2%, respectively, and South Carolina total annual growth rates for the same years were 8.4, 7.9, and 7.7%, respectively. *Id.* By contrast, South Carolina Medicaid annual growth rates were 7.4, 8.8, and 9.0%, respectively. *Id.*

11. See OFFICE OF THE ACTUARY, U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 8. Following the expected implementation of state cost containment efforts, the average projected Medicaid growth rate for 2007 to 2015 is 8.6%. See *id.* at tbl.3.

12. THOMAS C. FOX ET AL., HEALTH CARE FINANCIAL TRANSACTIONS MANUAL § 11:2 (2006) (citation omitted), available at Westlaw Health Care Fin. Transactions Man. § 11:2; see also COLLEEN M. FLOOD, INTERNATIONAL HEALTH CARE REFORM: A LEGAL, ECONOMIC AND POLITICAL ANALYSIS 56 (2003) (“In general terms, managed care covers a variety of techniques whereby insurer/purchasers (be they public or private) seek to make health care providers sensitive to the costs and benefits of the services they supply or recommend to their patients.”).

13. See generally LAWRENCE O. GOSTIN ET AL., LAW, SCIENCE AND MEDICINE 624–26 (3d ed. 2005) (discussing the theories behind managed care and identifying several types of MCOs). In contrast to capitation, in a fee-for-service system providers receive payment for each service provided. *Id.* at 623–24.

14. 42 U.S.C. § 1396u-2(a)(1)(A), (3)(A) (2000). A state may not require Medicaid beneficiaries who are categorized as children with special needs, Medicare beneficiaries, or American Indians to enroll in managed care as a condition of receiving benefits. *Id.* at (a)(2).

15. FINANCE, SYSTEMS & BUDGET GROUP, U.S. DEP’T OF HEALTH & HUMAN SERVS., MEDICAID MANAGED CARE ENROLLMENT AS OF DECEMBER 31, 2005 (2006), <http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/Downloads/mmcp05.pdf>. Medicaid beneficiaries in forty-eight states, the District of Columbia, and Puerto Rico receive managed care. *Id.* Managed care has not penetrated the Medicaid programs in Alaska, Wyoming, or the Virgin Islands. *Id.* Approximately 14% of the more than 800,000 Medicaid beneficiaries in South Carolina receive managed health care. *Id.*

To further promote state innovation in the containment of Medicaid costs, Congress enacted the Deficit Reduction Act of 2005<sup>16</sup> (DRA). The DRA provides states with increased flexibility in structuring Medicaid programs. Specifically, states may increase cost-sharing and premium requirements for certain groups of Medicaid beneficiaries<sup>17</sup> and provide alternative benefit packages with reduced benefits to limited categories of beneficiaries.<sup>18</sup> In addition, the DRA enables the Secretary of the Department of Health and Human Services (DHHS) to permit payments to states for methods that increase the efficiency and effectiveness of providing medical assistance<sup>19</sup> and to authorize ten states to operate health opportunity account (HOA) demonstration programs.<sup>20</sup>

Following passage of the DRA, South Carolina's governor announced that the state would proceed with most of its plan for Medicaid reform.<sup>21</sup> The South Carolina Medicaid reform plan, Healthy Connections, offers five methods for providing medical assistance to qualified beneficiaries: pre-paid plans, primary care case management plans (PCCMs), an option-out program, health opportunity accounts, and traditional fee-for-service.<sup>22</sup> Healthy Connections

16. Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4, 4 (2006).

17. 42 U.S.C.A. § 1396o-1 (2006) (enacted as Deficit Reduction Act of 2005, Pub. L. No. 109-171, tit. VI(A), ch. 4, sec. 6041, 120 Stat. 4, 81-85 (2006)).

18. § 1396u-7.

19. § 1396b(z)(1).

20. § 1396u-8. Generally, HOAs are "cash accounts for Medicaid enrollees that can be used to pay for medical expenses in order to meet the out-of-pocket costs associated with high deductible insurance plans. The insurance plans offered to Medicaid enrollees who volunteer to participate in the demonstrations will encompass all standard state Medicaid benefits." Press Release, Dep't of Health & Human Servs., CMS Solicits State Applications for Medicaid Health Opportunity Account Demonstrations (Jan. 10, 2007), <http://www.os.dhhs.gov/news/press/2007pres/20070110.html>. In January of 2007, the Centers for Medicare and Medicaid Services (CMS) began soliciting applications from states for the operation of HOA programs. Letter from Dennis G. Smith, Director, Centers for Medicaid and State Operations, to State Medicaid Directors (Jan. 10, 2007), <http://www.cms.hhs.gov/smdl/downloads/SMD011007.pdf>.

21. South Carolina Governor Mark Sanford, Recent News: Medicaid Reform Proposal to Be Implemented: Congressional Budget Bill Would Allow Most of 'SC Healthy Connections' to Go in Place Without Waiver (Feb. 2, 2006), <http://www.scgovernor.com/interior.asp?sitecontentid=7&newsid=707>.

22. S.C. DEP'T. OF HEALTH & HUMAN SERVS., SOUTH CAROLINA HEALTHY CONNECTIONS: MEDICAID TRANSFORMATION PLAN 21-27 (2006), [http://www.dhhs.state.sc.us/internet/pdf/SouthCarolinaHealthyConnectionsSeptember6\\_2006.pdf](http://www.dhhs.state.sc.us/internet/pdf/SouthCarolinaHealthyConnectionsSeptember6_2006.pdf). First, the prepaid health plan option allows beneficiaries to choose a managed care organization that is contracted with Medicaid and use their personal health accounts (PHAs) to pay the health plan premiums. *Id.* at 21-22. The second plan option, PCCM, requires beneficiaries to select a primary care physician, who will initially receive payment on a fee-for-service basis, to act as a "gatekeeper" to other services. *Id.* at 23. Under the option-out program, Medicaid beneficiaries are not considered traditional beneficiaries, but instead use their PHAs to pay for employer group health insurance. *Id.* at 24. Next, the health opportunity plan pilot allows beneficiaries to become consumers and purchase services directly from health care providers under traditional Medicaid fee schedules using their PHAs. *Id.* at 26. Finally, the categories of beneficiaries identified by Congress as exempt from managed care enrollment requirements, see *supra* note 14, will be required to remain in the traditional fee-for-service Medicaid program. S.C. DEP'T OF

promotes quality health care primarily by increasing health care competition and beneficiary cost accountability.<sup>23</sup>

In addition to Medicaid reform plans, federal and state efforts to intensify the focus on Medicaid fraud and abuse aim to reduce the costs of providing medical assistance. Traditionally, fraud and abuse efforts focused disproportionately on Medicare providers<sup>24</sup>; however, recent recognition of a significant likelihood of Medicaid fraud and abuse provided the stimulus for shifting focus to Medicaid providers.<sup>25</sup>

The most powerful weapon in the federal government's arsenal of fraud and abuse weapons is the civil False Claims Act (FCA).<sup>26</sup> Liability under the FCA extends to "[a]ny person who knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval."<sup>27</sup> Violation of the FCA is subject to \$5,500 to \$11,000 in penalties<sup>28</sup>

HEALTH & HUMAN SERVS., *supra*, at 27.

23. S.C. DEPT. OF HEALTH & HUMAN SERVS., *supra* note 22, at 4. South Carolina's original 1115 waiver proposal serves as the foundation for Healthy Connections. See S.C. DEPT. OF HEALTH & HUMAN SERVS., SOUTH CAROLINA HEALTHY CONNECTIONS, AN 1115 WAIVER PROPOSAL 5-7 (2005), <http://www.cms.hhs.gov/MedicaidStWaivProgDemoPGI/MWDL/list.asp> (follow "South Carolina Health Connections 1115" hyperlink; download "South Carolina Health Connections 1115"; then open the file "South Carolina Healthy Connections Proposal"). For criticisms of the proposal's premises, see JUDITH SOLOMON, CTR. ON BUDGET & POLICY PRIORITIES, STILL RISKY BUSINESS: SOUTH CAROLINA'S REVISED MEDICAID WAIVER PROPOSAL 5-10 (2006), <http://www.cbpp.org/1-11-06health.pdf>.

24. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-855T, MEDICAID FRAUD & ABUSE: CMS'S COMMITMENT TO HELPING STATES SAFEGUARD PROGRAM DOLLARS IS LIMITED 6-9 (2005) (concluding that, unlike CMS' oversight of Medicare fraud and abuse activities, CMS failed to allocate adequate resources to support states' Medicaid fraud and abuse efforts); see also ANDY SCHNEIDER, TAXPAYERS AGAINST FRAUD, REDUCING MEDICAID FRAUD: THE POTENTIAL OF THE FALSE CLAIMS ACT 35 (2003), <http://www.taf.org/publications/PDF/reducingmedicaidfraud.pdf> (discussing the greater number of settlements and larger recoveries in Medicare false claims cases as compared to Medicaid false claims cases).

25. Due to the size, growth, diversity, and open-ended federal funding of the Medicaid program, in 2003 the GAO added Medicaid to its list of programs at high risk for waste and exploitation. U.S. GEN. ACCOUNTING OFFICE, GAO-03-101, MAJOR MANAGEMENT CHALLENGES & PROGRAM RISKS: DEPARTMENT OF HEALTH AND HUMAN SERVICES 23-26 (2003). One of the key problem areas identified by the GAO included insufficient oversight of state efforts in identifying inaccurate Medicaid payments and Medicaid fraud and abuse. *Id.* at 26, 31 (citing U.S. GEN. ACCOUNTING OFFICE, GAO-02-300, MEDICAID FINANCIAL MANAGEMENT: BETTER OVERSIGHT OF STATE CLAIMS FOR FEDERAL REIMBURSEMENT NEEDED 12 (2002); U.S. GEN. ACCOUNTING OFFICE, GAO-01-662, MEDICAID: STATE EFFORTS TO CONTROL IMPROPER PAYMENTS VARY 28-29 (2001)).

26. 31 U.S.C. §§ 3729-3733 (2000); see JACK A. MEYER & STEPHANIE E. ANTHONY, TAXPAYERS AGAINST FRAUD, REDUCING HEALTH CARE FRAUD: AN ASSESSMENT OF THE IMPACT OF THE FALSE CLAIMS ACT 24, 92 (2001), <http://www.taf.org/publications/PDF/reducing.pdf>.

27. § 3729(a). Liability under the FCA also extends to other acts involving the payment of false or fraudulent claims, such as creating false records or statements and conspiring to defraud the government. § 3729(a)(2)-(7). For a historical overview of the FCA, see MEYER & ANTHONY, *supra* note 26, at 26-31.

28. § 3729(a). In response to the Inflation Adjustment Act of 1990, the Department of Justice changed the civil penalties regulations to allow the minimum penalty for violations of the FCA to rise from \$5,000 to \$5,500 and the maximum penalty from \$10,000 to \$11,000. 28 C.F.R. § 85.3 (2006).

for each false claim<sup>29</sup> and double or treble damages.<sup>30</sup> Since 1986, the Department of Justice (DOJ) has recovered \$15 billion from fraud and false claims settlements and judgments.<sup>31</sup> In fiscal year 2005, recoveries for health care fraud and false claims, primarily related to Medicare and Medicaid, constituted \$1.1 billion of the total \$1.4 billion recovered that year.<sup>32</sup>

To reduce fraud and abuse associated with the Medicaid program,<sup>33</sup> the DRA supplies a new incentive for states to enact false claims legislation. The DRA allows a state to recover an additional 10% of the state's share for recoveries received pursuant to a state law that prohibits the submission of false or fraudulent claims to the state's Medicaid program.<sup>34</sup> To qualify for the increased share of recovery, a state's law must meet several requirements:

(1) [E]stablish[] liability to the State for false or fraudulent claims described in [the FCA] with respect to [Medicaid

29. A claim includes "any request or demand [for payment] . . . if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse . . . any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c). Penalties are assessed based on the number of requests or demands for payment and not the individual items or services listed in each claim. *See United States v. Krizek*, 111 F.3d 934, 938–40 (D.C. Cir. 1997) (rejecting the government's argument that each code on a claim form constituted a separate false claim and remanding for recalculation of civil penalties based on the number of requests for payments, e.g., the number of claim forms submitted).

30. 31 U.S.C. § 3729(a).

31. Press Release, Dep't of Justice, Justice Department Recovers \$1.4 Billion in Fraud & False Claims in Fiscal Year 2005; More Than \$15 Billion Since 1986 (Nov. 7, 2005), [http://www.usdoj.gov/opa/pr/2005/November/05\\_civ\\_595.html](http://www.usdoj.gov/opa/pr/2005/November/05_civ_595.html). In addition to the DOJ, many state and federal agencies conduct investigations of Medicare and Medicaid fraud. ALICE G. GOSFIELD, MEDICARE AND MEDICAID FRAUD AND ABUSE §§ 6.1–6.10 (2006), *available at* MEDFRAUD (Westlaw) (identifying and discussing the roles of various entities in investigating Medicare and Medicaid fraud and abuse); *see also* AM. HEALTH LAWYERS ASS'N, FRAUD AND ABUSE: DO CURRENT LAWS PROTECT THE PUBLIC INTEREST? 14–15 (1999), *available at* [http://www.healthlawyers.org/Content/ContentGroups/Public\\_Interest2/Colloquiums\\_and\\_Reports/pi\\_fa\\_colloq99.PDF](http://www.healthlawyers.org/Content/ContentGroups/Public_Interest2/Colloquiums_and_Reports/pi_fa_colloq99.PDF) (describing regulation of fraud and abuse of the healthcare system by various government and private entities).

32. Press Release, Dep't of Justice, *supra* note 31.

33. The Congressional Budget Office estimates that enactment of state false claims acts will reduce Medicaid spending by \$334 million from fiscal year 2006 to 2015. CONG. BUDGET OFFICE, U.S. CONG., COST ESTIMATE, S. 1932 DEFICIT REDUCTION ACT OF 2005, at 36 (2006).

34. 42 U.S.C.A. § 1396h(a) (2006). Because of the joint federal and state funding of the Medicaid program, states share with the federal government in Medicaid false and fraudulent claims recoveries. Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48,552, 48,552 (Aug. 21, 2006). Based on a state's per capita income, the federal medical assistance percentage (FMAP) determines the amount of federal funds a state receives for its Medicaid program. *Id.* Likewise, the FMAP determines the division of state and federal recoveries. *Id.* at 48,553. For example, the FMAP for South Carolina is 69.54%. Federal Financial Participation in State Assistance Expenditures, 70 Fed. Reg. 71,856, 71,857 (Nov. 30, 2005). Absent a state law meeting the provisions of the DRA, South Carolina would be entitled to 30.46% of Medicaid damages resulting from state actions recovered under the federal FCA, and the federal government would be entitled to 69.54% of Medicaid damage recoveries. *See* Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. at 48,553. Under a state false claims act meeting the DRA provisions, the state's portion of the recovery would equal 40.46% of the total recovery. *See id.*

expenditures] . . . (2) [C]ontain[] provisions that are at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in [the FCA]. (3) [C]ontain[] a requirement for filing an action under seal for 60 days with review by the State Attorney General. [and] (4) [C]ontain[] a civil penalty that is not less than the amount of the civil penalty authorized under [the FCA].<sup>35</sup>

If a state's false claims statute "meets the enumerated requirements on or after January 1, 2007, and the recovery from the action brought under the qualifying law is received by the State on or after January 1, 2007, the State will qualify for a 10 percent increase in its share of the amount recovered."<sup>36</sup>

Many states enacted false claims statutes prior to the passage of the DRA.<sup>37</sup> In response to the DRA's financial incentive, seventeen states,<sup>38</sup> including South Carolina,<sup>39</sup> introduced false claims bills. The federal Office of the Inspector General (OIG), in consultation with the Attorney General, determines whether a false claims statute meets the requirements of the DRA.<sup>40</sup>

Thus, after enactment of the DRA, two additional policies encourage states to fight the rising costs of Medicaid: flexibility in structuring the Medicaid program and increased incentives to enact and enforce state false claims statutes. In an effort to combat Medicaid costs and increase quality, South Carolina has implemented a reform plan that provides a variety of options for care to

35. 42 U.S.C.A. § 1396h(b). With respect to penalties, in determining whether a state's false claims law meets the requirements of the DRA, the OIG will only consider whether the false claims law contains penalty amounts that at least equal the *statutory* penalties of the FCA. Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. at 48,554 & n.2 (publishing the OIG's guidelines for determining whether a state law meets the requirements set forth in the DRA).

36. Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. at 48,553.

37. *Fraud and Abuse: Growth In State False Claims Laws Could Affect Settlements, Attorneys Say*, [2006] HEALTH CARE DAILY REPORT (BNA) (June 19, 2006) (noting that false claims laws in the District of Columbia, California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, Tennessee, Texas, and Virginia predated the DRA). In addition to the states identified, South Carolina also had a Medicaid false claims statute existing prior to the enactment of the DRA. Generally, South Carolina's current Medicaid false claims law prohibits the knowing and willful submission of a false claim to Medicaid. S.C. CODE ANN. § 43-7-60(B) (Supp. 2006). On top of imprisonment and fines for each false claim, the law permits the Attorney General to bring an action to recover treble damages and permits the court to impose civil penalties of \$2,000 per false claim. § 43-7-60(D), (E).

38. *Fraud and Abuse: Growth in State False Claims Laws Could Affect Settlements, Attorneys Say*, *supra* note 37.

39. S.B. 0082, 117th Gen. Assem., 1st Sess. (S.C. 2007). The bill, as filed, contains a qui tam provision. *Id.*

40. Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. at 48,553. For the OIG's review of specific state false claims laws, see Specific State Laws Reviewed by OIG, <http://oig.hhs.gov/fraud/falseclaimsact.html#1> (last visited Mar. 2, 2007). For a discussion of the OIG's review procedure, see *infra* note 102.



Medicaid beneficiaries. Efforts are also being made to enact a false claims statute in order to further reduce costs and combat Medicaid fraud and abuse.<sup>41</sup>

### III. SHIFTING BURDENS TO MEDICAID PROVIDERS

Despite the laudable aims of South Carolina's Healthy Connections plan, a resulting decrease in Medicaid beneficiaries' access to care may mitigate the projected increase in quality of care. The growing structural complexity of Medicaid combined with contemporaneous federal and state efforts to intensify the focus on Medicaid false claims may discourage provider participation in the Medicaid program.

This part analyzes the factors affecting the declining rate of Medicaid provider participation and the potential impact of false claims enforcement. The discussion focuses on concerns and implications of the federal False Claims Act (FCA) because the DRA requires that state statutes contain specific elements that are also present in the federal statute in order for a state to qualify for an increased share of recovery.

#### A. Provider Participation in the Medicaid Program

Historically, concerns regarding Medicaid provider participation<sup>42</sup> focused predominantly on low Medicaid reimbursement rates.<sup>43</sup> These concerns continue

41. See *supra* note 39 and accompanying text.

42. In the context of this Note, a "Medicaid-participating provider" refers to a provider who, "with respect to an individual enrolled in a fee-for-service program, . . . has entered into a participation agreement with the State for the provision of services to individuals entitled to benefits under the State plan, or with respect to an individual enrolled in an MCO [managed care organization], . . . has entered into an arrangement for the provision of services to enrollees of the organization under Medicaid." Letter from Dennis G. Smith, Director, Center for Medicaid and State Operations, to State Medicaid Directors, *supra* note 20, at 3.

43. In a 1990–1993 study, researchers sought to identify factors affecting full or limited participation in the Medicaid program. Janet D. Perloff et al., *Which Physicians Limit Their Medicaid Participation, and Why*, HEALTH SERVS. RES., April 1995, at 7, 8. The study focused on the effects of Medicaid reimbursement rates on providers' decisions to participate in the Medicaid program. *Id.* The results indicated that although higher Medicaid rates were associated with higher rates of full participation, to effect a significant change in Medicaid participation the Medicaid rates would have to increase an estimated 60%. *Id.* at 22. Regarding Medicaid managed care, the results indicated difficulties in increasing participation where the state refused to allow setting capitation rates above Medicare rates. *Id.* at 22–23. In addition, the researchers noted the flexibility afforded to providers under a fee-for-service system and that the payment of capitated fees by a managed care organization may adversely impact provider participation:

Historically, the fee-for-service system permitted providers to modulate their involvement with Medicaid in response to changing conditions such as rising practice costs, changes in payment level, and changes in demand. While this flexibility may limit access, it also preserves access by permitting continued involvement in the program at a level that is at the physician's discretion. Medicaid managed care contracts that require "fixed" participation—either by requiring that physicians participate fully, or by requiring that they accept a

to present a major deterrent to Medicaid provider participation. In 2004–2005, the number of physicians reporting that they would accept no new Medicaid patients increased to 21% from 19.4% in 1996–1997.<sup>44</sup> Despite increases in Medicaid payment rates and beneficiary enrollment,<sup>45</sup> 84% of providers refusing to accept new Medicaid patients cited low Medicaid reimbursement rates as a moderate or very important reason for limiting acceptance of Medicaid patients.<sup>46</sup> Typically, physicians refusing to accept new Medicaid patients are physicians who practice solo, in small groups, or metropolitan areas; receive from 1% to 9% of total revenue from Medicaid; and specialize in general internal medicine, family practice, and surgery.<sup>47</sup>

Another major factor, more recently emphasized, contributing to a decline in Medicaid provider participation is the difficulty in billing and receiving reimbursement from Medicaid and Medicaid-contracted plans. In 2004–2005, approximately 70% of physicians cited billing difficulties and paperwork requirements as reasons for not accepting new Medicaid patients,<sup>48</sup> and

---

predetermined number of patients—may limit this flexibility. This loss of flexibility may discourage physicians from entering into managed care arrangements, making implementation of these arrangements more difficult and leading to unintended reductions in access as physicians formerly available to at least some Medicaid eligibles decline any involvement with the programs. The consequences of requiring fixed participation in Medicaid managed care are not well understood, and the effects of such consequences on access to care should be examined closely in states enrolling Medicaid eligibles into managed care.

*Id.* at 23; see also Sidney D. Watson, *Medicaid Physician Participation: Patients, Poverty, and Physician Self-Interest*, 21 AM. J.L. & MED. 191, 194–202 (1995) (discussing the impact of low payment rates on provider participation and suggesting that states seek other “financial incentives” to entice providers to participate in the Medicaid program); Peter Cunningham & Jessica May, *Medicaid Patients Increasingly Concentrated Among Physicians*, TRACKING REP. NO. 16 (Ctr. for Studying Health Sys. Change, Washington D.C.), Aug. 2006, at 1 <http://www.hschange.com/CONTENT/866/866.pdf> (“Medicaid payment rates, which are considerably lower than physician payment rates under Medicare or private insurance, historically have deterred physician participation in Medicaid.”).

44. Cunningham & May, *supra* note 43, at 1. Additionally, 14.6% of physicians in both 2000–2001 and 2004–2005 reported that they derived no revenue from Medicaid, a rise from 12.9% in 1996–1997. *Id.* The number of physicians accepting no new Medicaid patients is much higher than the number of physicians reporting refusal to accept other patients: in 2004–2005, 4.3% of physicians reported that they were not accepting new privately insured patients, and 3.4% reported that they were not accepting new Medicare patients. *Id.*

45. *Id.* at 1.

46. *Id.* at 3.

47. *Id.* at 2, 3. Solo practitioners and physicians practicing with a single partner reporting acceptance of no new Medicaid patients increased from 29.0% in 1996–1997 to 35.3% in 2004–2005. *Id.* at 3. Likewise, from 1996–1997 to 2004–2005 small group practices limiting acceptance of new Medicaid patients rose from 16.2% to 24.0%. *Id.* at 3 tbl.4. Contrary to the decreased participation of solo practitioners and small groups, the participation of institutional providers increased slightly. *Id.* at 2–3 tbl.4. Despite the shift in provision of care to Medicaid patients, solo practitioners and small groups received 41.7% of Medicaid revenue compared to 30.5% by institutional providers. *Id.* at 2, 5 supp. tbl.2.

48. *Id.* at 3, 5 supp. tbl.2.

approximately two-thirds cited late payments as a contributing factor.<sup>49</sup> Common billing issues include down-coding<sup>50</sup> and retrospective denials of services.<sup>51</sup> Examples of burdensome paperwork requirements include “clinical time stealers” such as clinically irrelevant documentation required to support medical necessity and the level of a service billed.<sup>52</sup>

In spite of federal efforts to simplify health care administration for both health care providers and health plans, vast differences persist in documentation and reporting guidelines for health plans. Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA),<sup>53</sup> in part to standardize electronic transmissions in health care in order to reduce health care costs.<sup>54</sup> DHHS, acting with authority vested by HIPAA, adopted standardized code sets for reporting health care services.<sup>55</sup> At the same time, however, DHHS refused to adopt standard guidelines for all but one of the medical services code sets, citing numerous “practical barriers” such as inconsistent definitions of codes.<sup>56</sup> Thus,

49. *Id.* at 3, 5 supp. tbl.2.

50. Down-coding by a health plan includes reducing the code billed for a service to a code of lesser value. *See* REPORT OF THE COUNCIL ON MED. SERV., AM. MED. ASS'N, PHYSICIANS' EXPERIENCES WITH RETROSPECTIVE DENIAL OF PAYMENT AND DOWN-CODING BY MANAGED CARE PLANS 3 (2000), <http://www.ama-assn.org/ama/upload/mm/372/i00cms5.doc>. Health plans often perform down-coding without review of the medical record. *Id.*

51. *Id.* at 2–3. Retrospective denials involve the denial of payment for services already provided to a patient. *Id.* at 1.

52. *See* Alice G. Gosfield, *The Doctor-Patient Relationship as the Business Case for Quality: Doing Well by Doing Right*, 37 J. HEALTH L. 197, 203 (2004).

One of the most frustrating aspects of the current practice environment for most physicians is the time they must devote to irrelevant documentation. The documentation demands of evaluation and management codes (E/M), the failure to comply with which can lead to false claims exposure, has nothing to do with the clinical treatment of the patient. This documentation has been developed purely for post-payment auditing purposes to verify that the level of code and the reimbursement associated with it were appropriate to the service. Similarly, the documentation of the medical necessity of specific services in the course of treatment is neither necessary nor clinically useful, but is required primarily for post-payment auditing.

*Id.*

53. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936, 1936, 2103 (1996) (codified as amended in scattered sections and titles 26, 29, and 42).

54. HIPAA § 261, 110 Stat. at 2021.

55. *Id.* 50,312, 50,370 (Aug. 17, 2000) (codified at 45 C.F.R. § 162.1002 (2006)).

56. *Id.* at 50,323. The American Medical Association (AMA), creator and distributor of one of the adopted standard code sets, Current Procedural Terminology (CPT), responded with the following concerns and proposal:

The AMA believes that standard implementation guidelines for code sets are essential for uniform national application of the code sets. If standard guidelines for medical code sets were adopted, many attachments would be eliminated. If health plans and physicians are permitted to implement and interpret medical data code sets as they see fit, the purpose of administrative simplification will not be achieved. An important part of administrative simplification and reduced regulatory hassle certainly includes the simplification and uniformity of instructions for the coding of health care services. The overwhelming amount of

health plans retain great discretion in the imposition of documentation and reporting requirements upon providers of health care.

As the options for providing medical assistance diversify and the number of managed care plans increases, the billing and reimbursement complexities associated with the Medicaid program also increase.<sup>57</sup> Shifting from centralized claims processing and administration to administration by multiple plans by way of a variety of options distributes burdens to Medicaid-participating providers by requiring providers to adhere to the unique requirements of each health plan.<sup>58</sup> Instead of encountering billing issues and reporting requirements with one entity, Medicaid providers face these issues with each Medicaid-contracted health plan.<sup>59</sup> Thus, in order to assess the impact of the South Carolina Medicaid reform plan upon the provision of care to beneficiaries, it is necessary to examine the implications of placing additional burdens upon providers. While Medicaid reforms may result in improved quality of care and reduced costs, access to care by Medicaid beneficiaries may be limited if providers elect to avoid the requirements imposed by Medicaid and its contracted health plans.

### *B. Focusing Fraud and Abuse Efforts on Medicaid Providers*

The current Medicaid environment stresses the importance of identifying fraud and abuse by Medicaid providers, and the FCA will undoubtedly play an essential role in this effort.<sup>60</sup> Furthermore, the financial incentives provided to states enacting false claims acts suggests that states will mimic the federal government's utilization of the federal FCA.<sup>61</sup> Combined, the complexity of

---

paperwork to which physicians are subject would be significantly reduced if coding guidelines were standardized within electronic transactions. The AMA believes that the CPT guidelines and instructions should be specified as a national standard for implementing CPT codes.

Mary L. Kuffner, Am. Med. Ass'n, Statement of the American Medical Association to the Workgroup on Electronic Data Interchange Regarding HIPAA Implementation Issues 6 (January 27, 2004), <http://www.wedi.org/cmsUploads/pdfUpload/eventsPresentationInformation/pub/ACF2161.pdf>.

57. See *supra* note 22 and accompanying text.

58. See, e.g., *supra* text accompanying note 56. But cf. S.C. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 22, at 21 ("To create a value based delivery system, the role of the state must move from the myopic function of processing individual claims to a management approach that moves the whole system toward quality.").

59. See *infra* text accompanying notes 65 and 66.

60. See *supra* text accompanying notes 26 and 33–34.

61. John Gibeaut, *Seeking the Cure: With Health Care Fraud Rampant, States Are Urged to Pass Their Own False Claims Acts, But Foes Warn of Windfalls for Plaintiffs Lawyers*, A.B.A. J., October 2006, at 44, 46.

With health care fraud as the No. 1 drain on federal and state treasuries, supporters can't see how any state can reject an offer that's as good as the one Congress made in the Deficit Reduction Act. Supporters say the federal False Claims Act's success virtually ensures similar accomplishments at the same level.

*Id.* at 46; see also 42 U.S.C.A. § 1396(h)(b) (2006) (identifying provisions that must be included in a state false claims act to qualify for an increased percentage of recovery).

reporting and documentation requirements for Medicaid providers and the breadth of the FCA and state false claims laws act as powerful disincentives for Medicaid participation. Thus, even if the Medicaid reform plan attains its goals of higher quality of care and reduced Medicaid costs, the cumulative effect of false claims enforcement and administrative complexities may prove too great for providers.

### 1. *Complexity: Setting the Stage for False Claims Allegations*

Discussions of the current health care environment inevitably refer to it as complex. For example, one court referred to the Medicare regulations as “technical, complex, and numerous.”<sup>62</sup> Commentators echo the sentiment. “[T]here are many uncertainties about the billing requirements imposed on providers, and doubtless, there are instances when well-meaning individuals with billing responsibilities are simply unable to parse these complexities.”<sup>63</sup> Another commentator concisely stated that “the current environment is simply too complex.”<sup>64</sup>

Medicaid, by its nature, imposes a far more complex environment upon health care providers than even Medicare. Because of the flexibility afforded to states in administering their Medicaid programs, state Medicaid programs vary greatly in terms of administration and enforcement. “Medicaid, like Medicare, is a huge and complex program. Unlike Medicare, however, Medicaid is not just one program with fairly uniform national rules. Instead, Medicaid is effectively 51 different programs with eligibility, benefits, reimbursement, and administrative policies that vary widely within broad federal guidelines.”<sup>65</sup> Moreover, differences also exist in the policies of managed care organizations within a single Medicaid plan.<sup>66</sup> Therefore, Medicaid reform measures that

---

62. *United States v. Chen*, No. 2:04-cv-00859-PMP-PAL, 2006 U.S. Dist. LEXIS 35845, at \*24 (D. Nev. May 30, 2006); *see also* *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 770 (N.D. Tex. 2003) (noting the complexities of Medicare coding and billing).

63. Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 294 (1999) (footnote omitted).

64. Gosfield, *supra* note 52, at 209 (advocating simplifying requirements imposed on health care providers).

65. SCHNEIDER, *supra* note 24, at 36–37. In addition to the Medicaid programs for each state and the District of Columbia, Medicaid programs exist for Puerto Rico and American Samoa, Guam, Northern Mariana Islands, and Virgin Islands. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-04-707, MEDICAID PROGRAM INTEGRITY: STATE AND FEDERAL EFFORTS TO PREVENT AND DETECT IMPROPER PAYMENTS 4 (2004).

66. Carolyn Buppert, *Billing For Nurse Practitioner Services: Guidelines for NPs, Physicians, Employees, and Insurers*, 4 MEDSCAPE NURSES, 2002, [http://www.medscape.com/viewarticle/422935\\_print](http://www.medscape.com/viewarticle/422935_print) (“Medicaid reimbursement is further complicated by the fact that many Medicaid recipients are enrolled in managed care plans. Managed care plans’ policies on reimbursement differ from the state and federal rules governing reimbursement when the patient is not enrolled in managed care.”).

distribute administrative responsibilities to other entities will result in increased complexity of the system.

## 2. *False Claims Basics*

As reforms reshape the structure of Medicaid programs, the FCA continues to hold providers within its grasp. In an FCA action, the government, or the relator,<sup>67</sup> must prove the following three elements by a preponderance of the evidence<sup>68</sup>:

(1) that the defendant caused to be presented to the United States a false *or* fraudulent claim for payment or that the defendant made, used, or caused another to make or use a false statement or document; (2) that the defendant did so for the purpose of obtaining payment from the government or approval of a claim against the government; and (3) that the defendant knowingly presented a claim that was false or fraudulent.<sup>69</sup>

The FCA reaches not only those who submit false claims directly to the federal government, but also those who submit claims to Medicaid agencies and contracted health plans.<sup>70</sup> “Thus, claims submitted to private insurers who administer the Medicare or Medicaid programs on behalf of the government are covered.”<sup>71</sup>

---

67. See *infra* text accompanying note 91.

68. 31 U.S.C. § 3731(c) (2000).

69. *United States v. Rogan*, 459 F. Supp. 2d 692, 716–17 (N.D. Ill. 2006) (citation omitted).

70. Donald H. Caldwell, Jr., *Qui Tam Actions: Best Practices For Relator's Counsel*, 38 J. HEALTH L. 367, 369 (2005) (noting that the FCA applies to Medicaid claims if federal funds provide a portion of the payment); see also Shelley R. Slade, *False Claims Act May Reach Managed Care Organizations*, HEALTHCARE FIN. MGMT. MAG. (Jan. 2002), [http://www.findarticles.com/p/articles/mi\\_m3257/is\\_1\\_56/ai\\_82067681/print](http://www.findarticles.com/p/articles/mi_m3257/is_1_56/ai_82067681/print); (discussing the scope of the FCA in the context of managed care); GOSFIELD, *supra* note 31, at § 5:10 (stating that the FCA's definition of a claim extends to claims submitted by a provider to a Medicare or Medicaid managed care organization).

The potential for false claims liability exists despite the prevalence of Medicaid managed care arrangements involving a fixed, or capitated, payment to the managed care organization in which a provider is enrolled. See SCHNEIDER, *supra* note 24, at 18–20 (discussing the types of fraud and abuse in capitation and fee-for-service arrangements). The general view is that risk-based managed care arrangements create the incentive to underutilize services, *id.* at 20, while fee-for-service creates an incentive to overutilize services and submit more claims for higher payments, *id.* at 18–19. However, managed care organizations may or may not pay providers on a capitated basis. *Id.* at 19–20. Some providers continue to receive payments on a fee-for-service basis. *Id.*; see also Gosfield, *supra* note 52, at 205–06 (discussing incentives created by fee-for-service and capitated payments).

71. Caldwell, *supra* note 70, at 369–70.

A variety of acts beyond submitting claims for services not performed<sup>72</sup> may result in the submission of a false claim and subject a provider to potential liability under the FCA. Other less obvious grounds for false claims allegations include violations of the anti-kickback and Stark laws<sup>73</sup> and “reverse false claims.”<sup>74</sup> The most controversial false claims actions, however, allege billing misrepresentations and failure to adhere to regulations and billing guidelines<sup>75</sup> as the basis for establishing the knowing submission of a false claim. These false claims actions are controversial because the regulations and guidelines that providers must follow are complicated and often ambiguous. Common examples of these types of false claims cases include those based on allegations of upcoding,<sup>76</sup> unbundling,<sup>77</sup> and false certifications of medical necessity.<sup>78</sup>

---

72. Mark H. Schlein & Chris Barry-Smith, Am. Health Lawyers Ass’n, State Attorneys General: A Dynamic Force in Health Care Fraud Enforcement (Sept. 26, 2004), *available at* WL AHLA-PAPERS P09260418 (noting that submitting claims for services or goods not provided constitutes a common false claims allegation).

73. In general, the anti-kickback statute prohibits soliciting, receiving, and offering of payment for referrals of individuals to persons for services that are paid by federal health programs. 42 U.S.C. § 1320a-7b(b) (2000 & Supp. III 2003). Subject to specific exceptions, the Stark laws prohibit physicians from referring Medicare or Medicaid patients for certain services to entities with which the physician or an immediate family member has a financial relationship. 42 U.S.C. § 1395nn(a)–(h) (2000 & Supp. III 2003). Many courts recognize that violations of the anti-kickback or Stark laws may form the basis of false claims allegations. *See, e.g.,* United States *ex rel.* Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 238 F. Supp. 2d 258, 266 (D.D.C. 2002) (holding that allegations of Stark and anti-kickback violations are sufficient to support a claim under the FCA); *see also* Jonathan L. Diesenhaus & Laura F. Laemmle, *Enforcement of Health Care Kickback Prohibitions Through the Civil False Claims Act: Recent Trends*, U.S. ATTY’S’ BULL. (U.S. D.O.J. Executive Office for U.S. Attorneys, Washington D.C.), Sept. 2005, at 36, 39–42, *available at* [http://www.usdoj.gov/usao/eousa/foia\\_reading\\_room/usab5305.pdf](http://www.usdoj.gov/usao/eousa/foia_reading_room/usab5305.pdf) (discussing theories of FCA liability for anti-kickback and Stark violations).

74. Reverse false claims typically include allegations that a recipient of government payments engaged in conduct to avoid paying money owed to the government. GOSFIELD, *supra* note 31, § 5:10; *see, e.g.,* Cantrell *ex rel.* United States v. N.Y. Univ., 326 F. Supp. 2d 468, 470–71 (S.D.N.Y. 2004) (holding that “underreporting of monies owed to the government” by a federally-funded defendant constituted a cognizable “reverse false claim” under the FCA).

75. *See In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 351 (D. Conn. 2004) (“[T]here have been numerous cases imposing FCA liability, and even criminal false claims liability, based on violations of Medicare manual provisions.”), *rev’d in part on other grounds sub nom.* United States v. Baylor Univ. Med. Ctr., 469 F.3d 263, 263, 265 (2d Cir. 2006).

76. *See, e.g.,* Cantrell, 326 F. Supp. 2d at 469 (alleging that reporting a code to Medicare representing complex evaluation services for administration of vaccines in a clinical trial constituted upcoding and false claims). “Upcoding” reflects the practice of using a billing code that provides a higher payment rate than the billing code that actually reflects the service furnished to the patient.” Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8990 n.15 (Feb. 23, 1998). The problem with false claims allegations of upcoding are that “there are no federal statutes or regulations describing proper coding procedures or standards for [codes] that are completed on the form.” Robert Salcido, *The Government’s Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457, 477 (2003). The ambiguities in coding have allowed the government to “augment[] its FCA recoveries” by applying different standards in reviewing claims. *Id.* at 479.

[T]he OIG will identify conditions . . . that are difficult to diagnose and that can exist even when clinical evidence does not support the condition. When the

In addition to submitting or causing the submission of a “false” claim, the FCA requires that a person knowingly submit or cause to be submitted a false claim.<sup>79</sup> Under the FCA, knowingly means that a person “(1) has actual

---

physician documents the condition, the OIG looks beyond the physician documentation to the clinical evidence to evaluate whether the claim was correctly coded. Alternatively, when the physician does not precisely document the condition, but the condition is supported clinically, the government rejects the claim on the grounds that the physician did not document the record.

*Id.*

77. “‘Unbundling’ is the practice of submitting bills piecemeal or in fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together and therefore at a reduced cost.” Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. at 8990 n.20. The CMS created the National Correct Coding Initiative (NCCI) to analyze the appropriateness of medical service codes when billed with other codes to Medicare. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL CORRECT CODING INITIATIVE POLICY MANUAL FOR MEDICARE SERVICES vii (2005) (Version 12.3), <http://www.cms.hhs.gov/NationalCorrectCodInitEd/Downloads/manual.zip> (download the file “manual.zip”; open the file “INTROfinal.doc”). “Unfortunately, NCCI is not designed to handle the myriad of code combinations in the commercial and Medicaid population.” TEX. ASS’N OF HEALTH PLANS, POSITION ON THE STANDARDIZATION OF CODE SETS, BUNDLING EDITS AND LOGIC 10 (2004), [www.tahp.org/advocacy.cfm](http://www.tahp.org/advocacy.cfm) (follow “Our Issues” hyperlink, then follow “standardized coding” hyperlink to download document). Other than Medicare, most health plans utilize commercial code edits that are rarely made available to providers. See Am. Med. Ass’n, Testimony Before the National Conference of Insurance Legislators Health Insurance Meeting, Bringing Fairness and Transparency to Health Plan Payer Contracting and Payment Processes 3, 11 (July 8, 2005) (discussing the “black box” mentality of health plans that refuse to disclose reimbursement policies), [http://www.ama-assn.org/ama1/pub/upload/mm/378/ncoil\\_testimony.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/378/ncoil_testimony.pdf).

78. Timothy P. Blanchard, “Medical Necessity” Determinations—A Continuing Healthcare Policy Problem, 37 J. HEALTH L. 599, 604 (2004) (discussing standards for determining medical necessity, and noting that the Medicare and Medicaid statutes fail to define medical necessity).

Today, the question of “medically necessary” is compound. It is in part a medical science and in part a political or societal decision (what “necessary” services are “reasonable” for taxpayers or members of an insurance risk pool to shoulder?). “Medical necessity is rarely defined, largely unexamined, generally misunderstood and idiosyncratically applied in medical and insurance practice.”

*Id.* (quoting *Medical Necessity: From Theory to Practice, Hearing on Examining Issues with Regard to the Delivery of Necessary Health Care in the United States Before the Committee on Health, Education, Labor and Pensions*, 106th Cong. 32 (1999) (statement of Linda A. Bergthold, Project Director, Decreasing Variation in Medical Necessity Decision Making at the Center for Health Policy, Stanford University)). For example, the only direction supplied by the Medicare statutes is that payment may not be made unless services are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A) (2000). If no national policy governs the service, Medicare contractors typically make medical necessity decisions on a case-by-case basis or in the formulation of local policies. Blanchard, *supra*, at 606–07. Similarly, state Medicaid agencies may place “appropriate limits” on medical necessity, but neither the federal Medicaid statutes nor the regulations provide a definition of medical necessity. *Id.* at 600 (quoting 42 C.F.R. § 440.230(d) (2004)). Despite the general lack of standards and definitions for medical necessity, providers may be held liable under the FCA for falsely certifying the medical necessity of services on claim forms. *Id.* at 604–05; see, e.g., *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. at 347 (holding that the submission of claim forms implicitly certified that services were “reasonable and necessary” and that claims for services that were not reasonable and necessary were legally false).

79. 31 U.S.C. § 3729(a) (2000).



knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.”<sup>80</sup> Thus, courts and commentators commonly assert that the FCA excludes honest mistakes such as those due to negligence or inadvertence.<sup>81</sup> While the FCA requires that a person knew of the claim’s falsity, “no proof of specific intent to defraud is required.”<sup>82</sup>

In defending against false claims allegations, providers often challenge the falsity and knowledge elements of the FCA.<sup>83</sup> The government’s failure to identify a violation of a regulation, rule, or standard may preclude a finding of falsity.<sup>84</sup> Furthermore, in the case of an ambiguous regulation, rule, or standard, a provider is more likely to prevail in challenging the knowledge element when the provider adheres to a reasonable interpretation of the regulation, rule, or standard.<sup>85</sup> A provider’s reliance on the instructions of a government entity in submitting and receiving payment for a claim may provide an additional defense to the FCA’s scienter requirement where “the government knows of the defendant’s practices and notwithstanding that knowledge pays on the defendant’s claims.”<sup>86</sup>

Despite these possible defenses to falsity and knowledge, concern and uncertainty exist due to the vast number of regulations, rules, and standards governing health care providers. In light of providers’ duty to familiarize

80. 31 U.S.C. § 3729(b) (2000).

81. *See, e.g.,* Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1478 (9th Cir. 1996) (quoting United States *ex rel.* Anderson v. N. Telecom, Inc., 52 F.3d 810, 815 (9th Cir. 1995)) (stating that the FCA requires more than an “innocent mistake or mere negligence”); *Health Care Initiatives Under the False Claims Act that Impact Hospitals: Hearing Before the Subcomm. on Immigration and Claims of the H. Comm. on the Judiciary*, 105th Cong. 16 (1998) (statement of Lewis Morris, Assistant Inspector General for Legal Affairs, Office of Inspector General, Department of Health and Human Serv) (asserting that “contrary to what some critics may have said, billing errors due to simple negligence, mistakes, or inadvertence are not actionable under the False Claims Act”); Jost & Davies, *supra* note 63, at 294 (arguing that the scienter requirement of the FCA “distinguish[es] between those who mistakenly transgress billing requirements or other restrictions and those who know that they are, or are reckless as to the chance that they may be, violating the law but act anyway”).

82. 31 U.S.C. § 3729(b).

83. Salcido, *supra* note 76, at 488–93 (discussing possible defenses to the FCA elements of falsity and knowledge).

84. *Id.* at 488–89 & n.148 (citing numerous cases in which a plaintiff’s failure to identify a defendant’s non-compliance with a rule or regulation precluded a finding of falsity).

85. *Id.* at 490; *see, e.g.,* United States v. Medica-Rents Co., 285 F. Supp. 2d 742, 771–75 (N.D. Tex. 2003) (precluding a finding of the FCA’s requisite scienter where “considerable confusion” surrounded the appropriate reporting of medical equipment and the defendant possessed a good faith belief that the code used was appropriate and adhered to the instructions of a Medicare carrier).

86. Salcido, *supra* note 76, at 492 & n.156 (citations omitted); *see also* United States v. Southland Mgmt. Corp., 326 F.3d 669, 682 & n.8 (5th Cir. 2003) (noting that the “government knowledge defense” provides “a means by which the defendant can rebut the government’s assertion of the ‘knowing’ presentation of a false claim. Inevitably, the extent of the government’s knowledge is also bound up with whether the claim itself was false.”).

themselves with the requirements of government programs,<sup>87</sup> the sheer number of these requirements may effectively subject providers to a standard of negligence for false claims:

[P]roviders are held responsible for being familiar with the huge volume of published manuals and regulations governing the provision of health care services to government program beneficiaries, and the billing for such services. The government is likely to deem the submission of bills contrary to such requirements to be in “reckless disregard” of such requirements, even if the requirements were not actually known to the person or persons responsible for the submission of the bill. Given the vast quantity of regulatory material applicable to government health care programs, the government’s position in such matters can in effect create a negligence standard for providers, the violation of which subjects them not only to restitution but, under the federal False Claims Act, to possible treble damages and to immense fines.<sup>88</sup>

Several additional aspects of the FCA and patterns in false claims cases pose potential barriers to provider participation in the Medicaid program. First, the FCA authorizes qui tam (also called “whistleblower”<sup>89</sup>) actions.<sup>90</sup> In a qui tam action, a plaintiff, known as a relator,<sup>91</sup> files a complaint under seal and serves a copy of the complaint along with a “written disclosure of substantially all material evidence and information the person possesses” to the government.<sup>92</sup> During the time the complaint is under seal, the government investigates the allegations, and the defendant is not notified of the qui tam action.<sup>93</sup> After investigating the complaint, the government may or may not elect to intervene.<sup>94</sup> A relator may pursue false claims allegations if the government elects not to intervene.<sup>95</sup> In general, if the government chooses to intervene, the relator

---

87. *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 328 (D. Conn. 2004), *rev'd in part on other grounds sub nom.* United States v. Baylor Univ. Med. Ctr., 469 F.3d 263, 263 (2d Cir. 2006) (quoting United States v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001)).

88. Russell Hayman, *Voluntary Disclosure*, in HEALTH CARE FRAUD & ABUSE 193, 198 (Practising Law Institute 1999).

89. The whistleblower provision of the FCA protects an employee from wrongful discharge or discrimination for initiating a qui tam action, 31 U.S.C. § 3730(h) (2000). For a general discussion of this provision, see Caldwell, *supra* note 70, at 383–85.

90. 31 U.S.C. § 3730. For a discussion of the procedural aspects of qui tam actions and the interaction between a relator and the government, see generally Caldwell, *supra* note 70, at 374–85.

91. See SCHNEIDER, *supra* note 24, at 24.

92. § 3730(b)(2).

93. *Id.* A complaint must remain under seal for a minimum of sixty days. *Id.* The government may move to extend the time period a complaint remains under seal. § 3730(b)(3).

94. § 3730(b)(4)(A)–(B).

95. § 3730(b)(4)(B).

recovers a minimum of 15% to a maximum of 25% of the proceeds and reasonable expenses and attorneys' fees.<sup>96</sup> If the government elects not to intervene, the relator recovers a minimum of 25% to a maximum of 30% of the proceeds and reasonable expenses and attorneys' fees.<sup>97</sup>

From fiscal year 1987 to 2005, qui tam actions resulted in recoveries totaling more than \$9.6 billion of the total \$15 billion recovered in false claims settlements and judgments.<sup>98</sup> While described as an essential tool in identifying health care fraud and abuse,<sup>99</sup> the financial incentives to "whistleblow" raise concerns about the accuracy of false claims allegations and the motivations underlying qui tam actions. For example, "[f]undamental misunderstanding of the extent of the relator's knowledge can cause the government to expend its resources investigating, only to find, after a long goose chase, that there is no case."<sup>100</sup> Additionally, some commentators believe that some potential whistleblowers may seek and evaluate jobs based on the likelihood of discovering wrongdoings in hopes of reporting to the government and obtaining a portion of the recovery.<sup>101</sup>

Though the government retains the right under the FCA to dismiss qui tam cases,<sup>102</sup> the government rarely applies the brakes in qui tam actions.<sup>103</sup> These concerns carry over to actions brought pursuant to state false claim acts because of the possibility that state false claims laws will also include qui tam provisions.<sup>104</sup> In fact, qui tam actions brought pursuant to state false claims laws

96. § 3730(d)(1). If the court finds that an action is based primarily on information other than that provided by the relator, the relator receives a maximum of 10% of the recovery. *Id.* For an analysis of the FCA and factors affecting a relator's share of recovery, see Paul D. Scott, Am. Bar Ass'n Ctr. for Continuing Legal Educ., *The Civil False Claims Act and Qui Tam Enforcement* (November 28–30, 2001) available at Westlaw N02CFCB ABA-LGLED H-1.

97. § 3730(d)(2).

98. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-320R, *INFORMATION ON FALSE CLAIMS ACT LITIGATION: BRIEFING FOR CONGRESSIONAL REQUESTERS* 5 (2006).

99. *See, e.g.*, SCHNEIDER, *supra* note 24, at 33 (discussing findings that show Medicaid qui tam relators provide information resulting in the discovery of otherwise unidentifiable fraud and abuse).

100. Caldwell, *supra* note 70, at 385.

101. *See* Schlein & Barry-Smith, *supra* note 72.

102. In qui tam cases in which the government intervenes, the government may dismiss a qui tam action over the objections of a relator so long as the relator is provided notice of the motion for dismissal and an opportunity for a hearing on the motion. 31 U.S.C. § 3730(c)(2)(A) (2000). Some courts have held that the government may seek dismissal without intervening. Scott, *supra* note 96 (citing *Juliano ex rel. U.S. v. Fed. Asset Disposition Ass'n*, 736 F. Supp. 348, 351 (D.D.C. 1990), *aff'd*, 959 F.2d 1101, 1101 (D.C. Cir. 1992)); *see also* *Ridenour ex rel. U.S. v. Kaiser-Hill Co.*, 397 F.3d 925, 933–35, 940 (10th Cir. 2005) (holding that prior intervention is not necessary for dismissal of a qui tam action brought pursuant to the FCA and noting other courts that have similarly held or stated the same in dicta) (citations omitted), *cert. denied*, 126 S. Ct. 341, 341 (2005).

103. Scott, *supra* note 96 (The government "rarely exercises the power . . . to dismiss [FCA] cases without the consent of the relator.").

104. Under the DRA, for a state to increase its share of a recovery by an additional 10%, the provisions of a state's false claims act must be "at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described" in the FCA. 42 U.S.C.A. § 1396h(b)(2) (2006). The DRA tasks the U.S. DHHS's Office of Inspector General (OIG), together with the Attorney

may result in a greater cause for concern due to the potential for greater recovery.<sup>105</sup>

The inherent pressures exerted by the FCA compel most providers to settle false claims cases.<sup>106</sup> The potential for astronomical penalties and damages constitutes a major factor in inducing settlements of false claims allegations.<sup>107</sup> In most false claims actions, providers settle because of the potential liability and the threat of a mandatory five-year exclusion from any federal health care program, even if they believe the case is defensible.<sup>108</sup> Furthermore, the costs of litigation<sup>109</sup> and the threat of negative publicity<sup>110</sup> may cause settlement to appear as the only feasible option to many health care providers. The coercive nature of settlement agreements for false claims allegations not only impacts the immediate provider, but also deprives other providers of interpretations of law essential to preventing and defending a false claims suit.<sup>111</sup> Thus, FCA enforcement pushes providers in an endless cycle of allegations and settlements

General, with determining if state laws meet the requirements. 42 U.S.C.A. § 1396h(a) (2006). The inclusion of provisions more restrictive than those specified in the FCA may result in a determination that a state law fails to meet the effectiveness requirement. Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48,552, 48,554 (Aug. 21, 2006). The OIG evaluates a state's law on a case-by-case basis and considers whether it includes specific provisions relating to qui tam actions, such as procedural aspects and percentage shares at least as generous to the relator as the federal FCA. *Id.* at 48,553–54.

105. See Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. at 48,553 (noting that in actions brought pursuant to the FCA, qui tam relators may receive a portion of the federal share of recovery, but not the state's share of recovery; however, relators in qui tam actions brought pursuant to state false claims laws typically stand to recover a portion of the state's recovery.) By appending a state false claims action to a federal FCA action under the theory of pendant jurisdiction, it should be possible for a relator to recover a portion of both the federal and state recoveries. See GOSFIELD, *supra* note 31, at § 6.10; see also, SCHNEIDER, *supra* note 24, at 37 ("The financial incentives and procedural opportunities for whistleblowers to identify and prosecute Medicaid fraud are significantly stronger in states with their own false claims acts than in states without such acts.").

106. Leon Aussprung, *Fraud and Abuse: Federal Civil Health Care Litigation and Settlement*, 19 J. LEGAL MED. 1, 17 (1998) (asserting that most institutions settle rather than risk litigation); Schlein & Barry-Smith, *supra* note 72.

107. See Schlein & Barry-Smith, *supra* note 72; see *supra* text accompanying notes 28–30.

108. Schlein & Barry-Smith, *supra* note 72.

109. The FCA provides that the defendant will bear the burden of "reasonable expenses" and "reasonable attorneys' fees and costs" of a successful relator. 31 U.S.C. § 3730(d)(1) (2000); see also Keith D. Barber et al., *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 IND. HEALTH L. REV. 131, 172 (2004) ("The government's abusive investigation practices do not have small consequences. They disrupt the provision of health care services by forcing providers to divert often-substantial resources, time, and human capital to respond.").

110. See Aussprung, *supra* note 106, at 46–49 (noting the importance of providers' reputations and suggesting methods to minimize negative publicity).

111. See 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, 146 (2001) ("Because settlements do not include detailed judicial findings regarding intent, it is unclear whether providers choose to settle allegations where they honestly believe the regulations to be unclear." (footnote omitted)).

without providing a solid ground on which other providers can stand to prevent or defend false claims allegations.<sup>112</sup>

### 3. *Enforcing the False Claims Act*

Past enforcement efforts by the federal government illustrate the concerns about the effects of enforcing the federal FCA and state false claims acts in an increasingly complex health care industry. Enforcement of the FCA throughout the 1990s brought to light the array of regulations and guidelines imposed upon health care providers.<sup>113</sup> Seemingly brushing aside concerns about the number of regulations and guidelines, the federal government pursued investigations that brought strong criticisms from the health care industry.<sup>114</sup> The responsive outcries from health care providers and organizations<sup>115</sup> eventually led to the development of investigatory guidelines for false claims.<sup>116</sup> While these guidelines signify the government's recognition of the need for uniform

112. See Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 273 (2004) ("Private litigation, in particular, can interfere with necessary regulation by diverting limited government resources, generating unfavorable precedent, and damaging regulators' relationships with the industry.").

113. See, e.g., *Health Care Initiatives Under the False Claims Act that Impact Hospitals: Hearing Before the Subcomm. on Immigration and Claims of the H. Comm. on the Judiciary*, *supra* note 81, at 58 (prepared statement of William L. Lane, President, Holy Family Hospital and Medical Center) (arguing against the "inappropriateness of using the False Claims Act for addressing hospital billing—errors which largely are the result of hundreds of pages of law, thousands of pages of regulations and interpretations of those regulations which differ widely among the more than forty fiscal intermediaries that administer the Medicare payment program for the federal government across the country").

114. See, e.g., Aussprung, *supra* note 104, at 27 (discussing the health care industry's criticisms of the OIG's Physicians at Teaching Hospitals (PATH) audits).

115. See, e.g., *Health Care Initiatives Under the False Claims Act that Impact Hospitals: Hearing Before the Subcomm. on Immigration and Claims of the H. Comm. on the Judiciary*, *supra* note 81, at 48 (prepared statement of Gordon M. Sprenger, Executive Officer, Allina Health Systems) (stating that "the government has engaged in a massive recovery project based on no statutory or regulatory basis").

116. In 1998, the Deputy Attorney General issued a memorandum specifying guidelines for false claims investigations. Memorandum from Eric C. Holder, Jr., Deputy Attorney Gen. to all United States Attorneys, all First Assistant United States Attorneys, all Civil Health Care Fraud Coordinators in the Offices of United States Attorneys, and all Trial Attorneys in the Civil Division Commercial Litigation Section, *Guidance on the Use of the False Claims Act in Civil Health Care Matters* (June 3, 1998), <http://www.usdoj.gov/dag/readingroom/chcm.htm>. The guidelines were issued to ensure enforcement of the FCA in a "fair and even-handed manner." *Id.* Before making false claims allegations, the guidelines direct the government to evaluate whether there is a "sufficient legal and factual predicate for proceeding." *Id.* The government must first determine whether a false claim exists by analyzing all relevant regulations and guidance. *Id.* Then the government must assess whether the provider "knowingly" submitted the false claim, considering actual or constructive notice of regulations or policies; clarity of the regulations; magnitude or pervasiveness of the false claims; existence of a compliance program and efforts to comply with billing rules; "past remedial efforts"; reliance on guidance issued by a program or its agents; and prior audits putting a provider on notice. *Id.*

enforcement measures, the effectiveness of the guidelines in preventing inappropriate false claims actions is debated.<sup>117</sup>

The recent Medicare case *United States v. Prabhu*<sup>118</sup> supports the apprehension of Medicaid providers about potential false-claims liability for noncompliance with a multitude of regulations, rules, and standards. Despite the physician's good faith efforts to comply with ambiguous Medicare regulations and standards, the federal government aggressively pursued an FCA action.<sup>119</sup> While the action was ultimately dismissed, *Prabhu* is a paradigmatic example of false claims enforcement sending a fatal blow to providers participating in government programs; the FCA action caused the physician to cease providing services that substantially benefitted his patients.<sup>120</sup>

In *Prabhu*, the government alleged the physician knowingly submitted false claims to Medicare in violation of the FCA.<sup>121</sup> The government claimed that the physician had billed for pulmonary rehabilitation services that were not covered by Medicare, billed for pulmonary tests without performing services required in billing the code or documenting a written report, and billed for medically unnecessary services.<sup>122</sup> The court held as a matter of law that the government failed to produce sufficient evidence upon which a jury could reasonably find that the defendant physician knowingly submitted false claims in violation of the FCA and granted the defendant physician's motion for summary judgment, dismissing the case with prejudice.<sup>123</sup>

The court held, as to the coverage of pulmonary rehabilitation services and the billing of the services with a code for simple stress tests, that the government had failed to prove a violation of any rule, regulation, or standard.<sup>124</sup> The evidence established that from 1981 to 2000 Medicare explicitly recognized the coverage of pulmonary rehabilitation in a variety of publications and continued to pay for pulmonary rehabilitation; the government's expert acknowledged the coverage of pulmonary rehabilitation services in a variety of jurisdictions and settings, and the Medicare carrier's Medical Director confirmed the absence of any policy that prohibited the billing of pulmonary rehabilitation component services.<sup>125</sup> Most notably, both the Medicare carrier's Medical Director and the government's own expert agreed that Medicare coverage had always extended to

---

117. Krause, *supra* note 111, at 139 (noting that while the health care industry remains concerned about the DOJ's compliance, "Congress appears satisfied"); see also Robert Salcido, *supra* note 76, at 465–66 (identifying three projects with national scope that the DOJ initiated without designating them as "national initiatives" as specified by the investigatory guidelines).

118. 442 F. Supp. 2d 1008, 1008 (D. Nev. 2006).

119. *Id.* at 1010–11, 1030.

120. *Id.* at 1010, 1023.

121. *Id.* at 1010.

122. *Id.* at 1011.

123. *Id.* at 1026.

124. *Id.* at 1027.

125. *Id.* at 1012–14.

pulmonary rehabilitation component services such as pulmonary stress tests.<sup>126</sup> In addition, the government “failed to prove falsity as a matter of law, by failing to dispute the overwhelming evidence that [the physician] was following the instructions provided by the Medicare carrier in billing for pulmonary stress tests as part of his rehabilitation program.”<sup>127</sup> The court stressed that over a period of thirteen years, the physician and his billing service had repeatedly contacted the Medicare carrier for guidance, and the carrier had never informed the physician that it had changed its policy, never transmitted any provider notices that prohibited the billing practice, such as bulletins or flyers, and never denied the physician’s claims that would have indicated the government’s advice had changed.<sup>128</sup>

Regarding the government’s allegations that the code representing a simple stress test required the physician to perform additional services and a written report, the court concluded that “the government’s interpretation of the CPT [c]ode for [the] test is wrong.”<sup>129</sup> In concluding that the government failed to prove the falsity of the claims, the court relied upon guidance issued by the AMA, which published the code, “expressly refuted” the government’s claim and the fact that the government’s own expert agreed with the guidance.<sup>130</sup> As to the written report, the court concluded that the government failed to establish the falsity of the claim because the medical director of the Medicare carrier conceded that this requirement did not exist, and the carrier had never issued any policy requiring a written report for a simple stress test.<sup>131</sup>

The court went on to hold that even if the court had found that some of the claims were false, the government failed to prove that the physician knowingly submitted a false claim<sup>132</sup> because the regulations were ambiguous, the physician’s billing practice was consistent with a reasonable interpretation of the regulations, and the physician and his staff believed in good faith that the interpretation was proper.<sup>133</sup> The court stated that when a person’s “conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance,” the person does not “knowingly” submit a false claim.<sup>134</sup> In this area that government agents admitted was “rife with confusion,” the physician made good faith efforts to comply with program requirements and billing rules.<sup>135</sup>

126. *Id.* at 1014.

127. *Id.* at 1027.

128. *Id.* From 1991 to 2004, Medicare representatives confirmed the appropriateness of the physician’s billing. *Id.* at 1017–20. The physician sought confirmation of his billing during an on-site visit to his office, in numerous telephone conversations, in a meeting between the physician’s billing supervisor and Medicare’s provider relations representative, and by a panel of speakers at a Medicare seminar. *Id.*

129. *Id.* at 1028.

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* at 1029.

134. *Id.*

135. *Id.* at 1030.

In addition, the court relied upon the physician's compliance with instructions for submitting claims, the carrier's advice to bill for the test, and the government's awareness of the physician's practices during the 1990s because of an "extensive criminal and civil investigation."<sup>136</sup> Thus the court concluded:

Under these circumstances, . . . the Government cannot demonstrate that the Defendant knowingly submitted false claims. It would be simply *irrational* for any person subjected to the level of scrutiny to which [the physician] was subjected to knowingly submit any claim that was questionable or borderline, let alone flat-out wrong."<sup>137</sup>

Relating to the government's allegations of medically unnecessary services and insufficient documentation, the court concluded that the physician's claims were not false as a matter of law.<sup>138</sup> Because the government had not identified violation of any controlling rule, regulation, or standard, since neither CMS nor the Medicare carrier articulated any such guidelines,<sup>139</sup> the certification of medical necessity on the claim form was "literally true," and the government failed to establish the falsity of the claims as a matter of law.<sup>140</sup> The court reasoned that the claims were in fact clinically necessary because the physician documented his determination that the patients would benefit from additional treatment, and the government failed to establish falsity by not providing any clinical evidence that the services were not medically necessary.<sup>141</sup>

Regarding documentation, the claims were not false because no articulated, objective standard existed to determine the appropriate documentation required, and the physician's documentation fell "within the range of reasonable medical and scientific judgment regarding how to document the medical necessity of pulmonary rehabilitation services."<sup>142</sup> The court concluded that the services were not knowingly submitted in violation of the law because ambiguity existed in how the services should be documented; the alleged low error rate demonstrated, at most, inadvertent conduct or an honest mistake;<sup>143</sup> and the government's case

---

136. *Id.* During the 1990s, a criminal investigation by the Federal Bureau of Investigation (FBI), the OIG, and Nevada's Medicaid Fraud Control Unit (MFCU) placed the physician's Medicare and Medicaid billings under intense scrutiny. *Id.* at 1023. "Despite this detailed review, the undisputed evidence show[ed] that DOJ never questioned the simple stress test claims." *Id.* The DOJ withdrew its intervention in the *qui tam* suit in 1995 "without receiving any payment as settlement [and] thereby effectively acknowledging that its case lacked merit." *Id.*

137. *Id.* at 1031.

138. *Id.* at 1032.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.* at 1032.

143. *Id.* at 1034.



“made no economic sense” because the physician lost money in providing the pulmonary rehabilitation services.<sup>144</sup>

#### 4. *Implications of False Claims Enforcement*

Despite the dismissal of the false claims action against the physician in *Prabhu*, the government’s suit had a damaging effect: “[A]s a direct result of this lawsuit, [the physician] ceased providing pulmonary rehabilitation to his patients.”<sup>145</sup> Thus, the “rare victory”<sup>146</sup> for providers in *Prabhu* demonstrates that even vindication by the courts does not mitigate the consequences of the increasing complexity of the health care industry.

Absent the extraordinary facts under which the government alleged false claims in *Prabhu*, uncertainty remains as to the circumstances under which a provider would prevail in a suit based on false claims allegations. For example, many courts have adopted the theory that government knowledge and approval of a provider’s conduct negates the scienter element of the FCA.<sup>147</sup> However, the defense fails where the government does not have “full knowledge” of material facts surrounding the conduct.<sup>148</sup> For instance, in *United States v. Chen*,<sup>149</sup> a provider argued the government knowledge defense based on Medicare’s review and approval of three claims for payment.<sup>150</sup> The court denied<sup>151</sup> a motion to reconsider its refusal to grant summary judgment<sup>152</sup> because the government established a material issue of fact as to thirty-six similar claims filed subsequent to the carrier’s approval.<sup>153</sup> In addition, a material issue of fact was created as to the government’s knowledge because Medicare had relied on information submitted by the provider in approving the previous three claims.<sup>154</sup> Therefore,

144. *Id.* at 1035. The physician “lost substantial money” by providing these services to his patients but stated that he had provided the services because of the “substantial health benefit his patients obtained.” *Id.* at 1023.

145. *Id.* at 1023.

146. Amy Lynn Sorrel, *Court Vindicates Nevada Doctor in Latest Twist of Fraud Case*, AM. MED. NEWS, Sept. 4, 2006, available at <http://www.ama-assn.org/amednews/2006/09/04/gvsb0904.htm> (“Physicians are often forced to settle such disputes with the government, even when they believe they are acting appropriately, because the financial stakes are so high.”).

147. *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (joining the 2nd, 7th, 9th, and 10th circuits in holding “that the government’s knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation”).

148. *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 920–21 & n.14 (4th Cir. 2003) (rejecting a contractor’s “government knowledge” defense to the scienter requirement of the FCA where the Department of Energy approved a subcontract based on less than “full knowledge,” but continued to pay invoices after becoming aware of the falsity of the certification).

149. No. 2:04-CV-00859-PMP-PAL, 2006 U.S. Dist. LEXIS 53329 (D. Nev. July 31, 2006).

150. *Id.* at \*6–7.

151. *Id.* at \*9.

152. *Id.* at \*1.

153. *Id.* at \*7.

154. *Id.* at \*8.

reliance upon a health plan's approval and payment does not immunize a provider from false claims allegations and liability; it may only provide a defense.

Because of the persisting confusion created by regulations, rules, and standards, providers may continue to settle false claims allegations:

Compared to "bad actors" engaged "in raw fraud," legitimate providers whose activities fall within a regulatory gray area might well be more likely to fear the untoward effects of a fraud suit, and hence more likely to settle. If so, this would have the perverse effect of relieving the government of its burden of proof in precisely those cases in which the protection afforded by the intent requirement is most important. There is a danger that such settlements will completely deter not "raw" fraud, but rather the basic provision of health care services where billing requirements are unclear—putting anti-fraud enforcement in direct conflict with the goal of providing necessary medical care to patients.<sup>155</sup>

Furthermore, enforcement efforts such as those in *Prabhu* send a message to providers that despite a provider's good faith efforts to comply, the government may pursue false claims actions. It is unlikely that many providers could withstand the scrutiny endured by the physician in *Prabhu* after thirteen years of efforts to comply with program requirements.

#### IV. BALANCING THE BURDENS

The complexity of the health care industry, especially in the Medicaid program, creates an increased risk of potential false claims allegations. In light of the reimbursement and reporting issues presently creating a disincentive for providers to continue caring for Medicaid patients, failure to minimize the burdens imposed upon health care providers may adversely impact beneficiaries' access to care. States that elect to enact false claims statutes should protect against the potential decrease in Medicaid providers and beneficiaries' access to care.

Guidance provided by the efforts of states, health care organizations, and commentators suggests three measures that may mitigate the potential harmful effects of Medicaid reform and false claims enforcement on provider participation in the Medicaid program. Combined, these measures may encourage healthcare providers to participate in the Medicaid program by increasing financial certainty regarding Medicaid payments and protecting providers from baseless false claims litigation.

---

155. Krause, *supra* note 111, at 208.

First, South Carolina and other states should enact a law requiring the disclosure of all billing and reimbursement information by health plans to health care providers. This law should require health plans, including Medicaid health plans, to disclose “*what they pay and how they pay*.”<sup>156</sup> For example, Texas law requires health maintenance organizations to provide, within thirty days of a request, a “description and copy of the coding guidelines, including any underlying bundling, recoding, or other payment process and fee schedules applicable to specific procedures that the physician or provider will receive under the contract.”<sup>157</sup> Contracts must also require that providers receive notification of changes in billing or coding policies at least ninety days before they become effective, prohibit retroactive application of policies, and allow providers to terminate the contract within thirty days of receiving notice of changes.<sup>158</sup> Not only should state law require the provision of payment policies and fee schedules upon request by contracted providers, health plans should also be required to supply these policies to providers contemplating contracting with health plans.

The provision of payment policies to health care providers prior to contracting and upon request would serve four fundamental purposes. First, the provision of payment and coding policies would allow providers to assess the financial costs of providing specific services to Medicaid patients. If policies exist, providers should be supplied with this information prior to contracting; providers should not discover after-the-fact that the services they intended to provide are not financially feasible because of policies that reduce or eliminate payment of specific services.

Second, contracts that include provisions requiring disclosure upon request would prevent health plans from using these provisions as a negotiating strategy. In particular, the disclosure requirements would protect small groups and solo practitioners who may, individually, lack the Medicaid patient base to leverage inclusion of these disclosure requirements. By requiring these provisions through statute, providers may not feel compelled to decline Medicaid participation in fear of discovering adverse payment policies.

Third, as noted by one court, disclosure of such information is necessary for health care providers in determining the accuracy of payments and the contractual obligations of health insurance plans.<sup>159</sup> Substantial time and

---

156. Am. Med. Ass’n, Testimony Before the National Conference of Insurance Legislators Health Insurance Meeting, Bringing Fairness and Transparency to Health Plan Payer Contracting and Payment Processes 2 (July 8, 2005).

157. TEX. INS. CODE ANN. § 843.321(a)(1)–(2) (Vernon 2006).

158. § 843.32(a)(3)–(4).

159. Med. Ass’n of Ga. v. Blue Cross & Blue Shield of Ga., Inc., 536 S.E.2d 184, 186 (Ga. Ct. App. 2000)

Without such fee information, there is no way for doctors to calculate for themselves whether they have been fully paid for a particular service under the plan. While the doctors agreed to abide by Blue Cross’ rules and regulations, and while they agreed to allow Blue Cross to make changes to the reimbursement plan

resources could be wasted in determining if ambiguous or undisclosed contractual obligations are being met; instead, those resources should be focused on patient care.

Finally, in addition to increasing providers' certainty regarding payment, supplying health care providers with this information would aid in the prevention of inadvertent billing misrepresentations and failures to comply with program requirements. Even with compliance programs and regular audits, providers can do little to identify deviations from health plan policies if the policies are not timely and fully disclosed to providers. The provision of policies to providers would enable providers to identify and prevent "false" claims before there is an allegation of falsity that may be based upon policies never disclosed to health care providers.

Laws requiring the disclosure of more information to providers are insufficient alone to counteract the potential impact upon Medicaid providers; South Carolina should also enact measures to ensure that providers receive clear information, not simply more information.<sup>160</sup>

In the absence of meaningful standards and useful guidance from a payor, a physician is often presented with a choice among the following unacceptable actions: assuming risk of nonpayment if a payor deems the service not to be covered; furnishing a service only if the patient provides a commitment to pay if the service is not covered . . . ; or not furnishing or recommending the service.<sup>161</sup>

Even if a provider chooses to assume the risks of nonpayment in performing a service, providers may not be as willing to assume the risk of payment; that is, providers may choose not to perform a service at all in order to avoid false claims allegations and the possibility of civil penalties and double or treble damages.<sup>162</sup> Therefore, South Carolina should create an ombudsman office within the state Medicaid agency that would allow providers to seek clarification of program requirements without fear of liability.<sup>163</sup> Given the prevalence of managed care within Medicaid, a state's ombudsman program should provide guidance for both Medicaid and Medicaid managed care plans. Either in the presence of a multitude of ambiguous policies or the lack of applicable policies,

---

rules, the doctors never agreed to allow Blue Cross to keep its fee schedules and methods for determining fees secret. Such information is critical to the doctors so that they can ensure that Blue Cross is fulfilling its obligations under the contracts.

*Id.*

160. See Krause, *supra* note 111, at 213 (arguing that consistent and legitimate FCA enforcement requires clarification of regulatory "gray areas").

161. Blanchard, *supra* note 78, at 620 (footnote omitted).

162. See *supra* text accompanying notes 106–110.

163. See AM. HEALTH LAWYERS ASS'N, *supra* note 31, at 34.

fear of false claims liability should not force providers into withholding or discontinuing services simply because they have been unable to obtain useful clarifying guidance.

An ombudsman program would provide an avenue for providers to seek advice and clarification while remaining anonymous. Because of anonymity, more providers may be willing to come forward and address potential false claims. More importantly, an ombudsman program would allow providers to receive guidance to resolve ambiguity or issues not directly addressed by Medicaid and Medicaid health plans. Given the variations between Medicaid and each health plan's provisions, providers should not be required to wait for false claims allegations in order to discern whether the government considers a claim to be false. Both the federal and state false claims acts are inappropriate tools for defining the falsity of claims. Settlements provide little guidance to other providers, and the costs of false litigation, both monetary and in terms of access to care, are too great to ignore the potential for resolution of the problem by creating a voluntary program that provides guidance and clarification.

Finally, South Carolina's false claims statute should entitle providers "to an affirmative defense in false claims cases in which they can establish their good faith reliance" on the advice of a government program or health plan.<sup>164</sup> While many courts and commentators have asserted that the scienter requirement of the FCA prevents *convictions* under the FCA for "honest mistakes,"<sup>165</sup> *United States v. Prabhu* illustrates that providers may face false claims *allegations* for "honest mistakes" in spite of good faith efforts to comply with program requirements.<sup>166</sup>

There are rules that are really confusing and where doctors can't get direction. And we've had [doctors who have] gone through hell based on these kind of [FCA allegations], and I'd just encourage a balance there. It's very hard to deal with. You've got to get the bad guys, but there ought to be a process. You need to be thinking about a process for deciding when a case is not meritorious and then dropping it.<sup>167</sup>

States considering enacting a false claims statute should keep in mind that while many provisions of the federal FCA must be included within the state statute in order to qualify, the state law need not adopt all provisions of the FCA.

---

164. Jost & Davies, *supra* note 63, at 315.

165. See *supra* note 81 and accompanying text.

166. *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1030 (D. Nev. 2006).

167. *Reauthorization of the U.S. Department of Justice: Executive Office for U.S. Attorneys, Civil Division, Environment and Natural Resources Division, Executive Office for U.S. Trustees, and Office of the Solicitor General: Hearing Before the Subcomm. on Commercial and Administrative Law of the H. Comm. on the Judiciary*, 109th Cong. 83 (2006) (statement of Rep. Chris Cannon, Chairman, Subcomm. on Commercial and Administrative Law).

Including affirmative defenses for good faith reliance upon the advice of health plans and government knowledge reinforces the requisite “knowingly” scienter.

Of course, affirmative defenses for good faith reliance and government knowledge will not completely prevent the negative consequences of false claims allegations themselves. For example, false claims allegations will probably affect providers’ reputations, and providers will incur legal costs in responding to the allegations; however, these affirmative defenses, if successful, would allow a provider to more quickly dispose of a false claims action. These defenses may be particularly useful in defending against qui tam actions that have continued despite government refusal to intervene. Because qui tam plaintiffs have a significant monetary incentive to bring false claims actions and may not be aware of providers’ efforts to comply, providers should be allowed to respond with the government’s own advice and awareness to defeat these actions. In addition, these cases may provide an incentive for the state government to elect not to intervene in a qui tam action, or, one would hope, to seek dismissal of the qui tam action.

Providing an affirmative defense for providers who rely upon the advice of government programs or health plans would supply providers with the assurance necessary to avoid settling claims and prevent prosecutors from pursuing meritless claims based solely upon ambiguous regulations, rules, or standards and the opinion of an “expert.”

## V. CONCLUSION

Medicaid reform efforts combined with increased focus on fraud and abuse in the Medicaid program seek to reduce the costs of the Medicaid program. False claims allegations and prosecutions may adversely affect Medicaid beneficiaries’ access to care by pressuring providers to refuse to participate in the Medicaid program. To counteract the cumulative effect of false claims enforcement in a complex health care industry, South Carolina and other states should develop measures to encourage open communication between Medicaid health plans and providers, provide clarification of ambiguous regulations and guidance, and protect Medicaid providers that are making good faith efforts to comply with program requirements.

*Christine M. Shaffer*

