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The False Claims Act and the Eroding Scientist in Healthcare Fraud Litigation

*Richard Doan, J.D.**

Imagine the following hypothetical: You're a physician, tired of the administrative hassles and politics of large hospital life. You and two of your medical school friends have opened up a small neighborhood clinic, "Corazon Medical, Inc." Your customer base consists almost entirely of elderly and low-income individuals who depend on Medicare and Medicaid for their healthcare needs. Although a fine physician, you are neither organized nor particularly knowledgeable about legal matters. Therefore, you delegate regulatory compliance and billing to your partners and medical technicians.¹ To your knowledge, your customers are happy and business is great—that is until you receive an ominous letter from the government.

The government letter reads, in part:

Corazon Medical, Inc. is under investigation for administering medical diagnostic tests by non-certified technicians, in violation of 42 C.F.R. § 410.33.² Monetary claims submitted to Medicare for these tests have been suspended.³ Should it be found that Corazon Medical has violated federal or state laws, regulations, or policies, your company may be subject to criminal and/or civil sanctions, including monetary fines and exclusion from the Medicare program.⁴

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1. See generally HOYT W. TORRAS, *HEALTH CARE FRAUD AND ABUSE: A PHYSICIAN'S GUIDE TO COMPLIANCE* 22 (2d ed. 2003).

2. 42 C.F.R. § 410.33(g)(1) (2009) (requiring that an independent diagnostic testing facility operate "its business in compliance with all applicable Federal and State licensure and regulatory requirements."). 42 C.F.R. § 410.33(g)(12). (2009) (requiring the facility "[h]ave the technical staff on duty with the appropriate credentials to perform tests.").

3. 42 C.F.R. § 410.33(h) ("[Centers for Medicare & Medicaid Services] will revoke a supplier's billing privileges if an [independent diagnostic testing facility] is found not to meet the standards in paragraph (g).").

4. John M. Degnan & Sally A. Scoggin, *Avoiding Health Care Qui Tam Actions*, 74 DEF. COUNS. J. 385, 385-86 (Oct. 2007); see also Robert Salcido, *The Government's Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457, 464 (Dec. 2003) (stating that "various United States Attorney's Offices would write to all healthcare entities . . . they believed were violating the FCA. The government's letters

Increasingly, the federal government's approach to this common hypothetical is to punish the healthcare providers.⁵ Administratively, the Centers for Medicare & Medicaid Services may revoke a Medicare or Medicaid provider's license.⁶ Judicially, the U.S. Attorney's Office may prosecute violations of criminal provisions under the False Claims Act (FCA).⁷ More likely, though, the U.S. Attorney's Office will bring suit to collect not only the government's money, but also to collect massive fines and interest.⁸ Under the rubric of anti-fraud enforcement, the government will endeavor to bankrupt your quaint, community clinic in a manner consistent with two maxims:

"Leave no stone unturned." In tackling problems arising out of Medicare and Medicaid claims, the U.S. government has made it clear that it will *not* tolerate fraud.⁹ It has pursued every imaginable cause of action against defrauders, from common law fraud and unjust enrichment, to violations of mail and wire fraud statutes.¹⁰

"Throw the book at them." Not only will the U.S. government pursue every legal remedy available, but it will also employ aggressive tactics in exacting emphatic punishments against defrauders.¹¹ It uses the FCA to penalize healthcare providers, large and small, with attention-grabbing fines.¹²

This paper addresses the federal government's expansive methods in tackling healthcare fraud, particularly in misapplying the FCA. Although tasked with the obligation of curtailing fraudulent submissions of Medicare and Medicaid claims, the U.S. government must also rein in the current trend of using the FCA against smaller medical providers. Part I of this paper provides a brief overview of the Medicare and Medicaid programs, as well as an outline of the claims submission process. Despite heavy regulation, this process is fraught with potential pitfalls for the unsophisticated medical provider and arguably invites the submission of false claims. Part II explores the FCA itself, including not only the statutory text but also the FCA's historical and modern-day purpose. As the

threatened these entities with treble damages and massive civil penalties.").

5. See Degnan & Scoggin, *supra* note 4, at 385; Salcido, *supra* note 4, at 458, 462.

6. See Degnan & Scoggin, *supra* note 4, at 386; 42 C.F.R. § 410.33(h).

7. Degnan & Scoggin, *supra* note 4, at 386.

8. *Id.* at 385-87; see Salcido, *supra* note 4, at 462.

9. See, e.g., Degnan & Scoggin, *supra* note 4, at 385-86.

10. See generally TORRAS, *supra* note 1, at 59-66, 70-71 (discussing statutes aimed at fraud, such as the Health Insurance Portability and Accountability Act (HIPAA), mail and wire fraud, civil monetary penalties and false statement statutes).

11. Degnan & Scoggin *supra* note 4, at 385-87; see Salcido, *supra* note 4, at 462.

12. See TORRAS, *supra* note 1, at 25; see also Degnan & Scoggin, *supra* note 4, at 385-87; see also Salcido, *supra* note 4, at 457.

FCA's original focus has ebbed in significance, the government has increasingly applied the FCA to circumstances that do not evince actual fraud. In doing so, federal courts have effectively eroded the statute's critical scienter¹³ requirement. Moreover, the FCA was recently amended under the authority of the Fraud Enforcement and Recovery Act of 2009 (FERA), which has made it even easier to establish liability. Part III criticizes the erosion of the scienter requirement and the government's overly broad interpretation of the FCA, especially in light of the fact that more appropriate equitable remedies are available. The common-law doctrines of "payment by mistake" and "unjust enrichment" adequately address the payment of non-fraudulent, albeit false, Medicare and Medicaid claims. Yet, the federal government pursues these appropriate remedies only in the alternative, essentially when the government fails under the FCA. Thus, Part IV of this paper argues for reform and calls for a clear delineation between remedial and punitive measures. In cases involving smaller medical providers, courts should strictly limit the FCA to instances where fraud is clearly manifest. Part V concludes this paper's analysis of the FCA.

I. HEALTH CARE AND FRAUD

A. Medicare Basics

Authorized under Title XVIII of the Social Security Act in 1965, the Medicare program was established to assist elderly and disabled Americans with their healthcare expenses.¹⁴

After a number of amendments, Medicare is now comprised of four parts.¹⁵ Part A provides insurance coverage to eligible beneficiaries¹⁶ for hospital stays and expenses¹⁷ associated with inpatient medical care.¹⁸

13. "Scienter" is the "degree of knowledge that makes a person legally responsible for the consequences of his or her act or omission." BLACK'S LAW DICTIONARY 1337 (8th ed. 2004).

14. EARL D. HOFFMAN, JR., BARBARA S. KLEES & CATHERINE A. CURTIS, BRIEF SUMMARIES OF MEDICARE & MEDICAID: TITLE XVIII AND TITLE XIX OF THE SOCIAL SECURITY ACT 5 (2007), available at <http://www.cms.hhs.gov/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2007.pdf>.

15. Medicare originally consisted of only Part A and Part B. Part C was later established through the Balanced Budget Act of 1997, and Part D was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. HOFFMAN, KLEES & CURTIS, *supra* note 14.

16. ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE 1-10 (2008) (explaining beneficiaries eligible for Part A Medicare coverage typically comprise those individuals age sixty-five and older or those persons with disabilities or end-stage renal disease.).

17. *Id.*

Completely distinct and independent, Part B of the Medicare program provides beneficiaries with outpatient care, typically physician services and medical supplies.¹⁹ Part C, adopted in 1997, grants expanded insurance coverage to allow Medicare beneficiaries the option of participating in private healthcare insurance plans,²⁰ including HMOs.²¹ Finally, Part D of the Medicare program assists beneficiaries with prescription drug costs.²²

In 2007, more than 44 million people participated in Part A, Part B, or both.²³ Overall, healthcare costs have increased significantly over the past few decades, and the costs are expected to continue to grow.²⁴ In 2006, Medicare expenditures reached \$408.3 billion.²⁵ Furthermore, as the nation's population ages over the next couple of decades, more and more individuals will be Medicare eligible, and the duration of their eligibility will likely increase.²⁶

B. Medicaid Basics

The Medicaid program, established under Title XIX of the Social Security Act, is a cooperative venture between the federal government and the states that provides help to low-income individuals and families who cannot afford the high costs of health care.²⁷

Medicaid is an entitlement program managed and partially funded by the states.²⁸ Through various statutes, regulations, and policies, however, the federal government has established broad national guidelines for the administration of state Medicaid programs.²⁹ In addition, the federal

18. MARK ALLEN KLEIMAN, *THE TANGLED WEB—A TRIAL LAWYER'S SURVIVAL GUIDE TO FEDERAL HEALTH CARE PROGRAMS* (July 2005), ATLA Annual Convention Reference Materials, Vol. 2, at 5.

19. FABRIKANT, *supra* note 17, at 1-11.

20. HOFFMAN, KLEES & CURTIS, *supra* note 14. Part C is more commonly referred to as the Medicare Advantage program, but prior to 2003, it was called the Medicare+Choice program. *Id.*

21. KLEIMAN, *supra* note 18, at 10.

22. HOFFMAN, KLEES & CURTIS, *supra* note 14.

23. *Id.* at 6.

24. *See id.* at 3-4.

25. *Id.* at 15.

26. *See* Steve Calfo, Jonathon Smith & Mark Zezza, *Last Year of Life Study*, CTRS. FOR MEDICARE & MEDICAID SERVS., OFFICE OF THE ACTUARY, 3, http://www.cms.hhs.gov/ActuarialStudies/downloads/Last_Year_of_Life.pdf.

27. HOFFMAN, KLEES & CURTIS, *supra* note 14; *see also* 42 U.S.C. § 1396-1 (Supp. 2009) (editorially transferred from 42 U.S.C. 1396 by Pub. L. No. 111-3 (2009)).

28. *See* HOFFMAN, KLEES & CURTIS, *supra* note 14, at 16. Each state sets its own eligibility requirements, the scope of services covered, and the rate of payment. As a result, Medicaid provisions vary widely by state, including their designations. *Id.*

29. *Id.*

government contributes a significant amount, at least fifty percent of a state's contribution, to fund Medicaid.³⁰ It also reimburses all, or nearly all, of a state's expenditures for select Medicaid programs and services.³¹ These federally matched funds and reimbursements enable state Medicaid programs to assist low-income residents with an array of healthcare services, such as inpatient and outpatient care, vaccinations, physician services, laboratory testing, pregnancy and pediatric care, and rehabilitation services.³²

In terms of expenditures, state Medicaid programs have grown considerably over the years.³³ In 2004, nearly fifty-nine million people participated in state Medicaid programs.³⁴ The federal and state costs of administering the programs constitute nearly fourteen percent of total healthcare expenditures in the United States.³⁵ As the nation's population ages, long-term health care through Medicaid will become increasingly important and increasingly expensive.³⁶

C. Claims Submission & Reimbursement

The Centers for Medicare & Medicaid Services (CMS) is the federal agency that oversees the administration of the Medicare and Medicaid programs.³⁷ CMS contracts with outside organizations (known as "carriers" or "intermediaries") to handle the processing of Medicare claims.³⁸

To receive reimbursement for submitted claims, a healthcare provider³⁹

30. KLEIMAN, *supra* note 18, at 1. The exact amount reimbursed by the federal government is calculated using each state's per capita income. HOFFMAN, KLEES & CURTIS, *supra* note 14, at 21.

31. *Id.* (explaining the federal government reimburses 100 percent of the costs associated with the Qualifying Individuals program and for services provided through the Indian Health Service. It reimburses the states ninety percent of expenses used for family planning services.).

32. *Id.* at 19-20.

33. PAMELA H. BUCY ET AL., HEALTH CARE FRAUD 1-10 n.31 (1999).

34. *Id.* at 1-17.

35. See 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, 996-97 (2007).

36. In 2004, the average Medicaid cost per beneficiary for nursing home care was \$24,475, compared with a \$2,400 average for an adult beneficiary who did not require nursing home care. HOFFMAN, KLEES & CURTIS, *supra* note 14, at 22-23.

37. The Centers for Medicare and Medicaid Services [hereinafter CMS] falls within the Department of Health and Human Services. CMS was formerly known as the Health Care Financing Administration. *Id.* at 2.

38. *Id.* at 14.

39. In this paper, health care or medical "provider" includes those providers listed in 42 U.S.C. §§ 1395x(s) and (u) (2006) (e.g., physicians, durable medical equipment suppliers, medical testing facilities, and nursing homes), as well as "any other person or organization

must apply for enrollment in the Medicare or Medicaid program through CMS.⁴⁰ If CMS accepts the application, the provider is issued a 10-digit National Provider Identifier (NPI) number to be used for billing and identification.⁴¹ Once validated and enrolled, the provider may then submit reimbursement claims for medical services and supplies provided to eligible Medicare or Medicaid beneficiaries.⁴²

Claim processing procedures and rules vary with each program. For instance, hospitals and other institutional service providers under Medicare Part A are reimbursed using a predetermined amount based on the beneficiary's medical diagnosis.⁴³ The federal government, however, reimburses Medicare Part B services and supplies on a "fee for services" basis, which is capped using a fee schedule.⁴⁴ State Medicaid programs typically follow a vendor payment system, in which the state pays or pre-pays the provider directly for services and supplies.⁴⁵ The federal government then reimburses a part of the state's expenditures.⁴⁶

Prior to a medical provider obtaining reimbursement, however, it must properly submit a claim to the government via carriers and intermediaries.⁴⁷ First, the provider must fill out and submit a claim form.⁴⁸ In addition to basic provider information, such as the NPI, the form should also include the appropriate CPT⁴⁹ and ICD-9 codes.⁵⁰ The CPT codes identify the type of service or supplies rendered by the provider,⁵¹ while the ICD-9 codes identify the reason for the services or supplies.⁵² Medical providers should

who furnishes, bills, or is paid for health care in the normal course of business." 45 C.F.R. § 160.103 (2010).

40. See generally CMS: MEDICARE PROVIDER-SUPPLIER ENROLLMENT, <http://www.cms.gov/MedicareProviderSupEnroll> (last visited Dec. 5, 2010).

41. See CMS, *The Who, What, When, Why & How of NPI: Information for Health Care Providers* (August 2006), available at http://www.cms.hhs.gov/MedicareProviderSupEnroll/downloads/EnrollmentSheet_WWWWH.pdf.

42. See *id.*

43. BUCY ET AL., *supra* note 33, at 1-11.

44. The fee schedule is established by a scale known as the Resource-Based Relative Value Scale. *Id.* at 1-12.

45. HOFFMAN, KLEES & CURTIS, *supra* note 14, at 21.

46. See *id.*

47. See *id.* at 14.

48. TORRAS, *supra* note 1, at 183.

49. The American Medical Association's Physician's Current Procedural Terminology (CPT). CMS, MEDICARE CLAIMS PROCESSING MANUAL: CHAPTER 23 – FEE SCHEDULE ADMINISTRATION AND CODING REQUIREMENTS 26 (October 26, 2007), available at <http://www.cms.hhs.gov/manuals/downloads/clm104c23.pdf> [hereinafter CLAIMS PROCESSING MANUAL].

50. TORRAS, *supra* note 1, at 183.

51. *Id.* at 244.

52. *Id.*

use the ICD-9 codes reflecting the “highest degree of specificity” with respect to the descriptions of symptoms or diagnoses.⁵³ These codes are used in part to determine coverage and payment amounts.⁵⁴

When a CMS carrier or intermediary receives provider claims for reimbursement, it usually reviews them with an automated computer claims processing program.⁵⁵ During this prepayment audit, CMS rejects claims that are likely incorrect or medically unnecessary.⁵⁶ In addition, CMS carriers and intermediaries conduct post-payment audits on a routine basis to investigate suspicious claims that have already been paid out.⁵⁷

Carriers and intermediaries also have their own fraud departments that review and investigate suspicious claims.⁵⁸ When they discover evidence of fraud or abuse by a provider, they refer the case to the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS).⁵⁹ The OIG intensifies the investigation and determines whether or not to move forward with administrative, civil, or criminal sanctions.⁶⁰ If the OIG finds that prosecution is warranted, it presents the case to the Department of Justice (DOJ) to pursue criminal and/or civil penalties against the provider.⁶¹

*D. Healthcare Fraud and Abuse*⁶²

The Problem. Without a doubt, fraud and abuse continue to plague America’s healthcare system. For example, a recent CMS experiment in South Florida and Los Angeles uncovered significant fraud involving suppliers of durable medical equipment.⁶³ In South Florida alone, the

53. CLAIMS PROCESSING MANUAL, *supra* note 49, at 7.

54. *Id.* at 6.

55. TORRAS, *supra* note 1, at 183.

56. *Id.* at 184.

57. *See generally id.* at 186, 190-92 (outlining an example of the post-payment audit process).

58. *Id.* at 175.

59. *Id.* at 175-76.

60. *Id.*

61. TORRAS, *supra* note 1, at 176-77.

62. In this paper, the terms “fraud” and “abuse” are used together to describe noncompliance with Medicare and Medicaid laws by healthcare providers. However, the terms are distinct and should not be construed as interchangeable. “Fraud” (as a non-legal concept) can be viewed as an “intentional deception or misrepresentation that someone makes, knowing it is false, that could result in the payment of unauthorized benefits.” *Id.* at 5. In contrast, “abuse” can be considered those “actions that are inconsistent with sound medical, business, or fiscal practices.” *Id.* (quoting CIGNA HEALTHCARE, JURISDICTION C SUPPLIER MANUAL: CHAPTER 14 – FRAUD AND ABUSE 2-3 (2010)).

63. U.S. Dep’t of Health & Human Servs., *HHS Fact Sheet: Medicare Provider Enrollment Demonstration Involving Suppliers of Durable Medical Equipment, Prosthetics,*

Medicare billing privileges of 634 providers were revoked after a federal contractor conducted investigations of 1,472 suppliers.⁶⁴ And in 2006, as part of its White Collar Crime Program, the FBI investigated 2,423 cases of healthcare fraud, which resulted in 534 criminal convictions.⁶⁵ These statistics demonstrate that healthcare fraud remains a drain on the national treasury.⁶⁶ Some estimates of federal funds lost to fraud and abuse reach ten percent of the nation's total healthcare costs.⁶⁷

Factors. What exactly drives so many medical providers to defraud the government? Health care is particularly prone to fraud and abuse.⁶⁸ A number of factors contribute to the high levels of fraud and abuse in the U.S. healthcare system. Economics, for one, plays a pivotal role. As healthcare demand continues to rise, the supply of qualified medical providers and the amount of government spending may not keep up with the nation's healthcare needs. This rising demand creates an incentive, for both medical providers and beneficiaries, to "bend the rules" when necessary.⁶⁹

Key characteristics of the healthcare system lend themselves to fraud and abuse.⁷⁰ For instance, Medicare and Medicaid beneficiaries often do not have full knowledge of the necessary medical care they need, and the bulk of their medical costs are covered by the government.⁷¹ Consequently, beneficiaries lack motivation to monitor costs or question their providers about services that may not have been medically necessary.⁷² Furthermore, the government reimbursement structure invites certain types of fraud.⁷³ Fee-for-service reimbursement systems, such as with Medicare Part B, make it easy for providers to misrepresent their services, to bill for services that were not performed, and to accept referral kickbacks.⁷⁴ Capitated systems, on the other hand, encourage entities, like HMOs, managed care

Orthotics and Supplies (DMEPOS) in High-Risk Areas, July 2, 2007 at 1.

64. *Id.*

65. Degan & Scoggin, *supra* note 4, at 386.

66. See BUCY ET AL., *supra* note 33, at 1-4.

67. *Id.* at 1-3.

68. *Id.*

69. See *id.* at 1-20 - 1-23.

70. See generally KLEIMAN, *supra* note 18, at 2 (describing specially fraudulent schemes in Medicaid and Medicare).

71. See Memorandum from the Volume-and-Intensity Response Team, Office of the Actuary, to the Chief Actuary, CMS (Aug. 13, 1998), available at <http://www.cms.hhs.gov/ActuarialStudies/downloads/PhysicianResponse.pdf>.

72. See *id.*

73. See Timothy S. Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 251-54 (1999).

74. See BUCY ET AL., *supra* note 33, at 1-20 - 1-21.

organizations, and insurers, to maximize profits, and thereby, provide incentives to unlawfully cut costs and supplement revenue.⁷⁵

Another major factor contributing to fraud and abuse, especially in the claims submission process, is the sheer complexity of the Medicare and Medicaid systems.⁷⁶ Medicare has been described as an “amazing array . . . of reporting, coding, and billing rules.”⁷⁷ One commentator lamented on the voluminous regulations and the “complete alphabet soup” of government agencies, programs, and intricacies involved in providing healthcare services.⁷⁸ The complexity of health care related statutes, regulations, rules, and policies is particularly problematic in distinguishing between fraud and mistake. Providers can easily manipulate complex rules, such as procedures for ICD-9 coding, to submit improper claims.⁷⁹ If caught, they may feign ignorance and confusion, blaming the complex system.⁸⁰ Nonetheless, even critics of this “complexity defense” concede that well-meaning providers do in fact make legitimate mistakes as a result of program complexities.⁸¹

Types of fraud and abuse. Healthcare fraud and abuse come in many forms; however, instances of fraud and abuse often fall within one of the following categories:⁸²

1. **“Mischarge” cases.** The most common cases of healthcare fraud involve the mischarging of claims to the government.⁸³ In these cases, medical providers either bill for services that were never

75. *Id.* at 1-21 - 1-22; *see also* Jost & Davies, *supra* note 73, at 253-54.

76. *See* Leonard C. Homer, *If Successor Liability Under the Medicare Program Is Inevitable: Due Diligence Issues That May Be the Basis for False Claims Act and Medicare Program Penalty Liability*, in HEALTH CARE FRAUD & ABUSE: HOW TO NAVIGATE THE COMPLIANCE PROCESS 57, 57 (Paul R. DeMuro ed., 1999).

77. *Id.*

78. KLEIMAN, *supra* note 18, at 1.

79. *See* TORRAS, *supra* note 1, at 273.

80. *See* Jost & Davies, *supra* note 73, at 294.

81. *See, e.g., id.* at 293-94. The authors argue that fraud abuse laws do not permit penalties for unintentional conduct. *Id.* at 294-95. This argument essentially dismisses Medicare and Medicaid complexity as a legitimate defense “in light of the rigorous intent obligations imposed by law.” *See id.* at 303. I would argue, however, that the intent requirements are not so rigorous in practice. As this paper later explores, the federal government arguably has an available remedy on the gamut of intent obligations. *See* discussion *infra* Parts II.E, III. The authors also posit that the complexity problem is actually overstated, considering the specialized practices and sophisticated billing systems used by modern healthcare providers. *See* Jost & Davies, *supra* note 73, at 303-04.

82. JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 1-40 (Aspen Publishers 3d ed. vol. 1, 2008) [hereinafter CIVIL FALSE CLAIMS]. Mr. Boese includes a fifth category of false claims, the “substandard product or service” case, which essentially falls within the category of “mischarge” cases. *See id.* at 1-40, 1-42.1.

83. *Id.* at 1-40.

rendered or overcharge the government for medical services or supplies.

2. “False negotiation” cases. Referred to by some courts as “frauds-in-the-inducement,” false negotiation cases arise from situations in which a provider makes false statements to induce the government to enter into a contract for services or supplies.⁸⁴
3. “False certification” cases. These cases, as exemplified in the Introduction’s hypothetical controversy with Corazon Medical, Inc., involve healthcare providers making false certifications of compliance with statutory and regulatory requirements for reimbursement to the government.⁸⁵ *United States ex rel. Mikes v. Strauss*, for example, is a “false certification” case concerning the quality of care in a nursing home.⁸⁶ The defendants allegedly performed spirometry procedures in violation of the American Thoracic Society’s guidelines.⁸⁷ Due to complex and voluminous rules and regulations, false certification cases are especially problematic.
4. “Reverse false claim” cases. Reverse false claims occur when a provider makes a false statement in order to avoid paying the government what it owes, in violation of § 3729(a)(1)(G) of the FCA.⁸⁸

Efforts to reduce fraud. The driving force behind the government’s efforts to reduce healthcare fraud is, of course, money. As mentioned above, healthcare fraud and abuse results in a significant loss of public funds. Additionally, the massive healthcare expenditures spurred the government to try and contain program costs.⁸⁹ Through its anti-fraud efforts, the government has recovered enormous sums of money.⁹⁰ One estimate has the government recovering \$15 for every \$1 spent on FCA-

84. *Id.*

85. *Id.* at 1-42.

86. *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 692 (2d Cir. 2001).

87. *Id.*

88. 31 U.S.C. § 3729(a)(1)(G) (2006); see CIVIL FALSE CLAIMS, *supra* note 82, at 1-42.2, 2-8 (discussing § 3729(a)(7) of the FCA prior to the FERA amendments, which expressly established a reverse false claim provision).

89. See Shaffer, *supra* note 35, at 996-98.

90. John T. Boese, *Can Substandard Medical Care Become Fraud? Understanding an Unfortunate Expansion of Liability Under the Civil False Claims Act*, 29 BRIEF 30 (2000) [hereinafter *Can Substandard Medical Care Become Fraud?*]. In 2001, the federal government recovered \$1.22 billion in Medicare and Medicaid anti-fraud enforcement efforts. Stephanie L. Trunk, *Sounding the Death Toll for Health Care Providers: How the Civil False Claims Act Has a Punitive Effect and Why the Act Warrants Reform of Its Damages and Penalties Provision*, 71 GEO. WASH. L. REV. 159, 161 (2003).

related litigation.⁹¹ These gains serve to encourage the expansion of enforcement actions as well as the scope of anti-fraud laws.⁹²

Multiple facets of the U.S. government responded to the healthcare problem with increased attention on fighting fraud. Congress has passed legislation and numerous amendments to reduce fraud and punish transgressors more severely, including the FCA, the Health Insurance Portability and Accountability Act of 1996,⁹³ the Program Fraud Civil Remedies Act of 1986,⁹⁴ and mail and wire fraud statutes.⁹⁵ The OIG issued annual work plans, model compliance programs, fraud alerts, advisory opinions, guidelines, and news releases.⁹⁶ For its part, the DOJ designated healthcare fraud as a top priority.⁹⁷

Although fraud enforcement efforts have historically focused on Medicare, the federal government has sought more action against Medicaid fraud.⁹⁸ In February 2006, Congress passed § 6031 of the Deficit Reduction Act (DRA).⁹⁹ This legislation creates a monetary incentive for states to enact their own false claims legislation to battle Medicaid fraud.¹⁰⁰ The DRA also requires healthcare providers receiving \$5 million or more in Medicaid payments to establish a compliance program to reduce fraud.¹⁰¹

But what about small-business providers who are not required to have compliance programs (and probably cannot afford to establish one anyway)? Even absent compliance programs, they will still be fully liable for submitting false claims. Small-business providers will suffer most from the harsh effects of anti-fraud laws, such as the potentially devastating monetary fines imposed by the FCA.

91. Degnan & Scoggin, *supra* note 4, at 386.

92. See *Can Substandard Medical Care Become Fraud?*, *supra* note 90, at 30.

93. The Health Insurance Portability and Accountability Act extends anti-fraud enforcement efforts to encompass offenses against private payers. TORRAS, *supra* note 1, at 60.

94. 31 U.S.C. §§ 3801-3812 (2006). The Program Fraud Civil Remedies Act focuses on smaller false claims violations and allows for slightly lighter damages than the False Claims Act. CIVIL FALSE CLAIMS, *supra* note 82, at 1-43.

95. 18 U.S.C. §§ 1341-1343 (2006).

96. Paul R. DeMuro & John D. Whipple, *Government's Current Compliance Initiatives – 1999*, in HEALTH CARE FRAUD & ABUSE: HOW TO NAVIGATE THE COMPLIANCE PROCESS 11, 18-19 (Paul R. DeMuro ed., 1999).

97. Nicole A. Berryman, *Health Care Fraud*, 38 AM. CRIM. L. REV. 915, 915 (2001).

98. Shaffer, *supra* note 35, at 999.

99. Michael A. Igel, *A Perfect 10: The Deficit Reduction Act of 2005 Provides Incentive for Florida to Amend Its Own False Claims Act Legislation*, 81 FLA. B.J. 23, 23-24 (2007).

100. *Id.*

101. 42 U.S.C. § 1396a(a)(68)(A)-(B) (Supp. 2009).

II. THE FALSE CLAIMS ACT

In its fight against healthcare fraud and abuse, the U.S. government wields a potent statutory weapon: the False Claims Act.¹⁰² Critics have characterized the U.S. government's increased use of the FCA against the healthcare industry as a mechanism "to bully"¹⁰³ providers and to "inflict a death blow on already struggling healthcare institutions."¹⁰⁴ Some commentators, on the other hand, view it as an "undeniably beneficial" tool to combat the dangers of healthcare fraud.¹⁰⁵ Regardless of one's perception, the reality is that the FCA, as employed against unsophisticated healthcare providers, is merciless in its enforcement.

A. Elements of the FCA

At its core, the FCA establishes civil liability against a healthcare provider who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

...

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . .¹⁰⁶

These provisions can be broken down into the following elements:¹⁰⁷

Knowing.¹⁰⁸ The FCA's scienter requirement mandates, as a general

102. Shaffer, *supra* note 35, at 999.

103. See Trunk, *supra* note 90, at 160.

104. Can Substandard Medical Care Become Fraud?, *supra* note 91, at 30.

105. Raegan A. McClain, *The Government, the Legislature and the Judiciary—Working Towards Remediating the Problems With the Civil False Claims Act: Where Do We Go From Here?*, 10 ANNALS HEALTH L. 191, 242 (2001).

106. 31 U.S.C. § 3729(a) (2006).

107. Courts are split over whether a showing of damages is a required element under the FCA and is therefore not included. See *Can Substandard Medical Care Become Fraud?*, *supra* note 91, at 31.

108. The scienter requirement is explored in more detail in Part II, Subpart E, below.

rule, that a defendant know, in some way, that the claim was false.¹⁰⁹

Presentment. For liability to attach under Subsection (a)(1)(A) of the FCA, an actual presentment of the false claim must be made.¹¹⁰ Presentment, though, is not required under Subsections (a)(1)(B) or (G).¹¹¹

To the U.S. government. The false or fraudulent claims must be made to the federal government before liability attaches. Courts, however, have held that claims submitted to state-managed Medicaid programs constitute a presentment to the U.S. government.¹¹² Furthermore, government agents, including federal agencies like CMS and government contractors like CMS carriers and intermediaries, fall within the FCA's scope.¹¹³

Of a claim. Prior to FERA, the FCA defined a "claim" as "any request or demand, whether under a contract or otherwise, for money or property."¹¹⁴ The FERA amendments redefined "claim" to include any claim regardless of whether or not the United States has title to the money or property. Thus, healthcare providers' claims for reimbursement under either Medicare or Medicaid are actionable FCA claims.

That is false or fraudulent. The terms "false" and "fraudulent" are not defined by the FCA. Generally, though, to be held liable under the FCA, a defendant must have submitted a claim that is in fact false.¹¹⁵ In addition, a "materiality" element must be shown. For pre-FERA claims, the falsity of the claim must be material to the government's decision to pay or approve the claim.¹¹⁶ The FERA amendments, however, explicitly defined

109. See *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 938 F. Supp. 399, 402 (S.D. Tex. 1996), *aff'd in part, vacated and remanded in part*, 125 F.3d 899 (5th Cir. 1997); see also Ann DesRuisseaux, A New Form of Abuse in the Health Care Field: The Federal Government's Abuse of the FCA in Pursuing Medicare and Medicaid Fraud and Abuse 6 (1999) (outlining the elements of a FCA claim) (unpublished LL.M. thesis, University of Houston Law Center) (on file with O'Quinn Law Library, University of Houston Law Center).

110. *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671 (2008) (with respect to § 3729(a) of the pre-FERA FCA); see also *United States ex rel. Sterling v. Health Ins. Plan of Greater N.Y., Inc.*, No. 06 Civ. 1141 (PAC) 2008 WL 4449448, at *3 (S.D.N.Y. Sep. 30, 2008).

111. *Allison Engine Co.*, 553 U.S. at 671; *Sterling*, 2008 WL 4449448, at *3.

112. See *United States ex rel. Davis v. Long's Drugs, Inc.*, 411 F. Supp. 1144, 1149 (S.D. Cal. 1976) (holding that California's Medicaid program qualified for federal funds and had substantial contacts with the federal government although the program was entirely state-run); see *United States ex rel. Putnam v. E. Idaho Reg'l Med. Ctr.*, 696 F. Supp. 2d 1190, 1200 (D. Idaho 2010).

113. See 31 U.S.C. § 3729(a)(1)(E) (2006); but see *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 491 (D.C. Cir. 2004) (reasoning that Amtrak cannot be considered part of the Government, despite having received sizeable government subsidies and being a "mixed-ownership government corporation").

114. 31 U.S.C. § 3729(b)(2)(A).

115. CIVIL FALSE CLAIMS, *supra* note 82, at 2-8.

116. See *id.* at 2-158.6 – 2-158.7; but see *United States ex rel. Longhi v. Lithium Power*

“material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”¹¹⁷ This definition, therefore, relaxes the materiality requirement, making it easier for the government to establish liability under the FCA.

B. *Qui Tam Provision*¹¹⁸

The most controversial aspect of the FCA is the *qui tam*¹¹⁹ provision. This unique feature of the statute enables third parties, known as “relators,” to sue suspected defrauders on behalf of the federal government.¹²⁰ When a relator initiates a *qui tam* action, the government may opt to either intervene or allow the relator to pursue litigation on its own.¹²¹ In exchange for their roles as fraud enforcement substitutes, relators are entitled to a percentage of the recovery from a successful suit, including settlement awards.¹²² If the government intervenes, the relator is apportioned “at least 15 percent but not more 25 percent of the proceeds” resulting from the lawsuit; if the government declines to intervene, the relator can recover between 25 percent and 30 percent of the proceeds.¹²³ These potentially large monetary sums serve as powerful incentives for relators to bring suit.¹²⁴ The Fifth Circuit in *United States ex rel. Foulds v. Texas Tech Univ.* even acknowledges that the FCA “provides for what can amount to massive rewards for” relators.¹²⁵

One of the major criticisms of the *qui tam* provision is that the FCA does not require relators to possess direct or independent knowledge of wrongdoing before bringing suit.¹²⁶ As such, relators can sue based solely

Techs, 575 F.3d 458, 468-70 (5th Cir. 2009) (holding that a statement is material if it has the potential to influence the government’s payment decision).

117. 31 U.S.C. § 3729(b)(4).

118. See generally CIVIL FALSE CLAIMS, *supra* note 82 at 4-9 – 4-316 (discussing an in-depth analysis of *qui tam* litigation under the FCA).

119. “*Qui tam*” (pronounced “kwi tam”) is a short-form version of the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which translates to “who as well for the king as for himself sues in this matter.” BLACK’S LAW DICTIONARY 1282 (8th ed. 2004).

120. CIVIL FALSE CLAIMS, *supra* note 821, at 1-4 - 1-5.

121. *Id.* at 4-9 – 4-19.

122. *Id.* at 4-201.

123. 31 U.S.C. §§ 3730(d)(1)-(d)(2) (1995).

124. Degnan & Scoggin, *supra* note 4, at 385.

125. *United States ex rel. Foulds v. Tex. Tech Univ.*, 171 F.3d 279, 282 (5th Cir. 1999) (stating that plaintiff “seeks to collect a Texas-sized reward based on her allegations of over 400,000 false claims (which could generate fines of between \$5,000 and \$10,000 each) and over \$20 million in overpayments (which § 3279(a) would treble).”).

126. Todd J. Canni, *Who’s Making False Claims, the Qui Tam Plaintiff or the Government Contractor? A Proposal to Amend the FCA to Require That All Qui Tam*

on suspicion, speculation, or even a “scintilla of knowledge.”¹²⁷

Because of this low threshold, small healthcare providers are especially vulnerable to *qui tam* actions. Medicare and Medicaid beneficiaries, former and current employees, acquaintances, competitors, et al., can file complaints without having any direct knowledge of a single false claim having been submitted.¹²⁸ Unlike large hospitals, community clinics (and comparable medical providers) do not have the hundreds of thousands, or millions of dollars, needed to adequately defend against FCA suits.¹²⁹ They would be forced to quickly capitulate and settle, despite the absence of any meaningful evidence. The alternative, unfortunately, is to face the even stiffer penalties from a negative FCA judgment.

C. FCA Damages

The potential damages to a healthcare provider found in violation of the FCA can be astounding. Liability for a provider found to knowingly have submitted a false Medicare or Medicaid claim, is “a civil penalty of not less than \$5,000 and not more than \$10,000, plus three times the amount of damages which the Government sustains.”¹³⁰ These penalties are assessed *per claim* submitted.¹³¹ Considering that each drug prescription filled by a pharmaceutical provider may be viewed as a separate claim, the penalties can, and often do, multiply rapidly.¹³²

For the small, struggling, or newly-formed medical providers, these mounting damages can realistically run them out of business.¹³³ Accordingly, commentators and healthcare institutions have criticized the

Plaintiffs Possess Direct Knowledge, 37 PUB. CONT. L. J. 1, 2 (2007).

127. *Id.* at 2, 14.

128. See Degnan & Scoggin, *supra* note 4, at 387.

129. *Id.* at 386-87; See Joan H. Krause, *Twenty-Five Years of Health Law Through the Lens of the Civil False Claims Act*, 19 ANNALS HEALTH L. 13, 15 (2010).

130. See 31 U.S.C. § 3729(a)(1) (2006). The government must show that its losses were actually sustained as a result of the falsity of the claim. *United States v. Thomas*, 709 F.2d 968, 972 (5th Cir. 1983). In other words, the government “should recover, as *single* damages, the amount it actually paid *minus* the amount it would have paid had the claim not been false.” See CIVIL FALSE CLAIMS, *supra* note 82, at 3-5. In 1999, the monetary penalties allowed under the FCA was adjusted upwards to a minimum of \$5,500 and a maximum of \$11,000 per claim, to reflect inflation. 28 C.F.R. § 85.3(a)(9) (2010).

131. See 31 U.S.C. § 3729; see also *United States ex rel. Foulds v. Tex. Tech Univ.*, 171 F.3d 279, 282 (5th Cir. 1999) (stating that claims can generate fines between \$5,000 and \$10,000 dollars each).

132. See Edward P. Lansdale, *Used As Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 NEW ENG. L. REV 159, 177-78 (Fall 2006).

133. See *Can Substandard Medical Care Become Fraud?*, *supra* note 90, at 30.

FCA's damages provision as exorbitant.¹³⁴ Defendants have even challenged the constitutionality of assessed damages, contending that the FCA violates the Excessive Fines Clause of the Eighth Amendment.¹³⁵ In contrast, supporters of the FCA defend the government's ability to levy heavy fines as an "optimal deterrence" against future fraud.¹³⁶ These two viewpoints stand at opposite sides in a battle of statutory interpretation: the determinative question being whether the FCA serves a remedial or punitive purpose.¹³⁷

D. History and Purpose

The remedial versus punitive debate must begin with a look back at the initial passage of the FCA. Congress passed the FCA in 1863 to counter the actions of unscrupulous government contractors, and President Lincoln signed the bill into law at the height of the Civil War.¹³⁸ The FCA was enacted with the principal goal of "stopping the massive frauds perpetrated by large [private] contractors."¹³⁹

The overarching purpose of the FCA, as a tool to combat government contracting fraud, remains today. But whether the FCA achieves this purpose through restitution or deterrence and punishment remains an issue of contention. The Supreme Court's majority decision in *United States ex rel. Marcus v. Hess* succinctly emphasized the FCA's original purposes.¹⁴⁰ Justice Black wrote for the majority:

[O]ne of the chief purposes of the Act, which was itself first passed in war time, was to stimulate action to protect the government against *war frauds*.

...

We think the chief purpose of the statutes here was to provide for *restitution* to the government of money taken from it by fraud, and the device of double damages plus a specific sum was chosen to make sure that the government would be made completely whole.¹⁴¹

134. Trunk, *supra* note 90, at 161-62.

135. *Id.* at 169-71.

136. See Jost & Davies, *supra* note 73, at 266-69.

137. Trunk, *supra* note 91, at 171.

138. CIVIL FALSE CLAIMS, *supra* note 82, at 1-6.

139. Vt. Agency of Natural Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 781 (2000) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)).

140. See *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547-48 (1943).

141. *Id.* at 547-51 (*emphasis added*) (commenting on 31 U.S.C. § 3729(a)(1)(G) (2006), the FCA now calling for treble damages); *but see* S. REP. NO. 99-345, at 9 (1986), *reprinted*

Along similar lines, another federal court concluded that the FCA's damages provision was "meant by Congress to reflect a fair ratio to damages in order to make sure the government would be made completely whole."¹⁴²

The FCA has since been amended three times, in 1943, 1986, and most recently in 2009.¹⁴³ The 1943 amendments limited the scope of the FCA's *qui tam* provision because of the "parasitical actions" of relators at the time.¹⁴⁴ The 1986 amendments reversed course, however, and provided greater monetary incentives to relators.¹⁴⁵ The Congressional record accompanying the 1986 amendments stated the legislative intent behind strengthening the FCA as: "[t]he purpose of S. 1562, the False Claims Reform Act, is to enhance the Government's ability to recover losses sustained as a result of fraud against the Government."¹⁴⁶ In laying the background for the amendments, the record later reasons, "[a]lthough the Government may also pursue common law contract remedies, the False Claims Act is a much more powerful tool in deterring fraud."¹⁴⁷ The Supreme Court seemed to concur with that assessment when it concluded in *Vt. Agency of Natural Res. v. United States ex rel. Stevens* that FCA damages are "essentially punitive in nature."¹⁴⁸ In analyzing the post-FERA FCA provisions, particularly § 3729(a)(1)(B), at least one federal court has concluded that the "FCA's statutory scheme is punitive in purpose and effect"¹⁴⁹

Not everyone agrees, however, that the damages provision is punitive. In the *Vt. Agency* decision, Justice Stevens, joined in his dissent by Justice Souter, declined to characterize the damages as punitive.¹⁵⁰

in 1986 U.S.C.C.A.N. 5266, 5274 ("The False Claims Act is intended to reach all fraudulent attempts. . . . A false claim for reimbursement under the Medicare, Medicaid, or similar program is actionable under the act").

142. *Peterson v. Richardson*, 370 F. Supp. 1259, 1267 (N.D. Tex. 1973).

143. See generally CIVIL FALSE CLAIMS, *supra* note 82, at 1-12 – 1-17; Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (2009); 31 U.S.C. § 3729(a) (2006).

144. *Lansdale*, *supra* note 132, at 169.

145. *Id.* at 170.

146. S. REP. NO. 99-345, at 1.

147. *Id.* at 4.

148. See *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-85 (2000) (reasoning that the Supreme Court's earlier suggestions that FCA damages were remedial were based upon the double damages allowed, as opposed to the modern FCA's treble damages, which demonstrate an intent to punish and deter).

149. *United States ex rel. Baker v. Cmty. Health Sys., Inc.*, No. 05-279 WJ/WDS, 2010 LEXIS 51545, at *19 (D. N.M. Mar. 19, 2010).

150. See *Vt. Agency*, 529 U.S. at 801-02.

E. The Eroding Scienter Requirement

Despite the FCA's original purpose as a remedial measure to combat contractor fraud, the federal government has increasingly manipulated the statute in aggressive and unconventional ways.¹⁵¹ As detailed above, it has provided greater incentives for *qui tam* actions and expanded enforcement efforts to diverse industries, including health care. In doing so, and perhaps driven in part by the attention-grabbing recoveries, the government gradually eroded the FCA's scienter requirement. It sought to continuously push the outer limits of what constitutes a "knowing" presentment of false claims.¹⁵²

As contemplated by the first enactment of the FCA, liability attaches only when a healthcare provider "knowingly" submits a false or fraudulent claim to the government.¹⁵³ Innocent mistakes, negligent actions, and flawed reasoning are purportedly not actionable under the FCA.¹⁵⁴ The 1986 amendments, however, lowered the FCA's scienter requirement.¹⁵⁵ Subsequently, neither actual knowledge nor a specific intent to defraud the government is required to establish liability.¹⁵⁶ Beyond actual knowledge, the FCA's definition of "knowingly" expanded to include: (1) the deliberate ignorance and (2) reckless disregard of the falsity of the claim.¹⁵⁷

Deliberate Ignorance. Even without actual knowledge, a medical provider may be liable under the FCA based on "deliberate ignorance" of Medicare or Medicaid regulations.¹⁵⁸ A provider that is "willfully blind" to regulations and the consequences of misconduct, can be found deliberately ignorant.¹⁵⁹ Proving deliberate ignorance requires evidence that the provider purposely avoided learning of, or blinded itself to, the falsity of the submitted claims.¹⁶⁰ Thus, before FCA liability can attach, the government (or a *qui tam* plaintiff) must show, by a preponderance of the evidence, two things: first, that the provider had reason to believe its actions may have been unlawful; and second, that the provider purposely failed to investigate these suspicions.¹⁶¹

151. See *Can Substandard Medical Care Become Fraud?*, *supra* note 90, at 30.

152. See *Trunk*, *supra* note 90, at 164.

153. 31 U.S.C. § 3729(a)(1) (2006).

154. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681-82 (5th Cir. 2003).

155. See *CIVIL FALSE CLAIMS*, *supra* note 82, at 1-18-1-19.

156. 31 U.S.C. § 3729(b)(1).

157. *Id.*; see also *Southland*, 326 F.3d at 681-82.

158. See *United States v. Erikson*, 75 F.3d 470, 481 (9th Cir. 1996).

159. See *id.*

160. *Id.*; *United States v. Lara-Valesquez*, 919 F.2d 946, 950-51 (5th Cir. 1990) (defining "deliberate ignorance" in the context of a criminal jury charge).

161. See *Erikson*, 75 F.3d at 481.

Reckless Disregard. A healthcare provider may also be liable under the FCA based on a “reckless disregard” of a submitted claim’s falsity.¹⁶² Federal courts are not perfectly aligned when applying the reckless disregard standard. Most courts, following the D.C. Circuit’s lead in *United States v. Krizek*, construed reckless disregard as equivalent to “aggravated gross negligence” or “gross negligence plus.”¹⁶³ The Eighth Circuit, in a case predating the 1986 amendments to the FCA’s scienter requirement, approached the “knowing” element in a similar, but different, fashion: “The question here then would be whether the defendants’ ‘clumsiness’ or ‘carelessness and foolishness in the extreme’ constitute conduct that the court can deem to create sufficient knowledge or awareness under the False Claims Act to be civilly actionable.”¹⁶⁴ Whether this “extreme carelessness” standard is the equivalent of gross negligence or the more stringent gross negligence-plus standard remains unclear.

Gross negligence has been characterized as a conscious indifference to a high risk that harm would result from an act or omission.¹⁶⁵ For instance, gross negligence under Texas state law has two elements: (1) objectively, the act or omission must involve an extreme degree of risk, and (2) “the actor must have actual, subjective awareness of the risk involved, but nevertheless proceed in conscious indifference”¹⁶⁶ In Pennsylvania, gross negligence has been construed to mean the “lack of slight diligence or care,” “a conscious, voluntary act or omission in reckless disregard of a legal duty,” and “a form of negligence where the facts support substantially more than ordinary carelessness, inadvertence, laxity, or indifference.”¹⁶⁷

Although gross negligence (without more) is supposedly not actionable under the FCA,¹⁶⁸ many FCA cases apply what appears to be an ordinary gross negligence standard and not the heightened *Krizek* gross negligence plus standard purportedly adopted by most Circuits. For example, in *United States ex rel. Kosenske, M.D. v. Carlisle HMA, Inc.*, the district court cited

162. 31 U.S.C. § 3729(b)(1)(A)(iii) (2006).

163. *United States v. Krizek*, 111 F.3d 934, 941-42 (D.C. Cir. 1997) (stating that the standard for reckless disregard is, at a minimum, an extreme version of ordinary negligence); *United States ex rel. Longhi v. Lithium Power Techs.*, 513 F. Supp. 2d 866, 876 (S.D. Tex. 2007).

164. *United States v. Coop. Grain and Supply Co.*, 476 F.2d 47, 56 (8th Cir. 1973).

165. *Helms v. Universal Atlas Cement Co.*, 202 F.2d 421, 423 (5th Cir. 1953); see *Crowder v. Am. Eagle Airlines, Inc.*, 118 Fed. App’x 833, 840-41 (5th Cir. 2004) (applying the gross negligence standards of both Texas and Louisiana common law).

166. *Transp. Ins. Co. v. Moriel*, 879 S.W.2d 10, 23 (Tex. 1994).

167. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 2010 WL 1390661, at *7 n.7 (M.D. Pa. 2010) (citations omitted).

168. *United States ex rel. Ervin and Assocs., Inc. v. Hamilton Sec. Grp.*, 298 F. Supp. 2d 91, 101 (D.D.C. 2004).

to the *Krizek* decision in determining the *qui tam* relator “must show that defendants acted with aggravated gross negligence.”¹⁶⁹ Despite this, the court proceeded to define ordinary gross negligence and performed a factual analysis based on this standard, essentially equating reckless disregard with gross negligence.¹⁷⁰

In *United States v. Mack*, the District Court for the Southern District of Texas applied the *Krizek* “gross negligence plus” standard¹⁷¹ and held that the defendant demonstrated a reckless disregard for the falsity of the claim by failing to adequately supervise his billing staff.¹⁷² To reach its conclusion, the court considered a number of factors: (1) the defendant’s knowledge of prior deviant billings, (2) his failure to hire full-time staff, (3) his failure to properly train the part-time staff, and (4) his failure to read or require that his staff read the Medicaid manual that set out provider requirements.¹⁷³ These negligent actions, viewed in the aggregate, met the *Krizek* “gross negligence plus” standard for reckless disregard.¹⁷⁴ The actions evidenced the defendant’s conscious indifference to the high risk of false claims.¹⁷⁵

In *United States v. Stevens*, the District Court for the Western District of Kentucky granted the government summary judgment against a defendant who completely delegated the Medicare reimbursement claims process to his billing manager (and father-in-law). Based on its reading of *Krizek*, the court held that the defendant, even though he may not have had any actual knowledge of the clinic’s billing practices, was required to take reasonable steps to ensure the accuracy of the claims for reimbursement. The court concluded that Dr. Stevens “utterly failed” to ensure the accuracy of the claims, comparing his inaction with the defendant’s in *Krizek*.¹⁷⁶ The *Stevens* case, among others, approaches the scienter requirement almost in a way that transfers the burden of proof to the defendant.¹⁷⁷ Although the FCA requires the government (or *qui tam* relator) to establish the “knowing” element, courts have treated defendants’ excuses and assertions

169. *Kosenske*, 2010 WL 1390661 at *7.

170. *Id.* at *7 - 9.

171. *See* *United States v. Mack*, No. 98-1488, 2000 WL 33993336, at*5 (S.D. Tex. May 16, 2000) (explaining that “the billing provider must manifest, at a minimum “an extreme version of ordinary negligence” in the submission of false claims.”) (citing *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997)).

172. *Id.* at *7.

173. *See id.*

174. *See id.*

175. *See id.*

176. *United States v. Stevens*, 605 F. Supp. 2d 863, 868-69 (W.D. Ky. 2008).

177. *See id.*; *See also* *UMC Electronics Co. v. United States*, 43 Fed. Cl. 776, 794 (Fed. Cl. 1999).

of lack of knowledge like an affirmative defense, further eroding the FCA's scienter requirement.

In *United States ex rel. Schaefer v. Conti Medical Concepts, Inc.*, another FCA case out of the Western District of Kentucky, the district court correctly declined to grant summary judgment for the government. Despite the complicated coding system for back braces involved and the lack of any evidence of actual knowledge of coding errors on the part of the defendants, the government sought liability under the FCA, relying on the decisions in *Krizek* and *Stevens*. The court, however, distinguished those cases in determining the facts at issue did not warrant summary judgment.¹⁷⁸

Conti Medical Concepts, Inc., in particular, is a case representing an alarming trend by the government to pursue negligent, or even grossly negligent, actions as fraud.¹⁷⁹ Due to a multitude of factors—be it program complexity, inexperience, lackadaisical attitudes, or even sheer stupidity—healthcare providers, especially those in small practices and businesses, may make a number of mistakes and bad judgments that could lead to the submission of false claims. Because the FCA is meant to address fraudulent actions against the government, however, innocent mistakes and negligence are not sufficient to hold a Medicare or Medicaid provider liable.¹⁸⁰ Thus, poor business acumen, including mere noncompliance with CMS regulations and the failure to properly train one's staff, is not enough for FCA liability.¹⁸¹ The penalties are simply too harsh to justify. Rather, the provider must have submitted a false or fraudulent claim knowingly—that is, with actual knowledge, deliberate ignorance, or reckless disregard of the claim's falsity.¹⁸²

F. The FERA Amendments

In addition to the eroding scienter requirement, amendments to the FCA in 2009 have further inched the FCA towards becoming a general anti-fraud statute.¹⁸³ The Fraud Enforcement and Recovery Act (FERA) was passed and signed into law on May 20, 2009.¹⁸⁴ The primary purpose of FERA

178. *United States ex rel. Schaefer v. Conti Med. Concepts, Inc.*, No. 3:04-CV-400-H, 2009 WL 5104149, at *4-6 (W.D. Ky. Dec. 17, 2009).

179. *See id.*

180. *See United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681-682 (5th Cir. 2003).

181. *See id.*

182. 31 U.S.C. § 3729(b)(1) (2006).

183. *See Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008) (warning that the FCA is not an all-purpose antifraud statute).

184. Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (2009).

was to combat the financial and mortgage-related frauds that led to the economic crisis in 2008.¹⁸⁵ Healthcare fraud was not the principal concern. In fact, the statement issued by President Obama regarding FERA does not mention healthcare fraud at all: “These legislative enhancements will help the Department of Justice to combat mortgage fraud, securities and commodities fraud, and related offenses, and to protect taxpayer money that has been expended on recent economic stimulus and rescue packages.”¹⁸⁶

Nonetheless, FERA amended the FCA to make it a more effective tool against government fraud in general, including healthcare fraud. The FERA amendments renumbered several provisions of the FCA, altered the statutory language, and added or redefined certain terms.¹⁸⁷ These amendments expressly established, *inter alia*, a new, less cumbersome standard for the “materiality” element of an FCA claim and the court-invented reverse false claim.¹⁸⁸ Arguably, though, the primary goal of the FERA amendments to the FCA was to address the liability issues surrounding government contractors and subcontractors.¹⁸⁹

These amendments may have been necessary to effectively enforce against fraud perpetrated by large financial institutions at the root of the economic crisis or by those unscrupulous defense contractors taking advantage of the conflicts in Afghanistan and Iraq. However, application of the FERA amendments to small medical providers is unnecessary and without justification. The primary concerns that drove FERA into law—namely, mortgage and financial fraud—are simply not relevant to health clinics, suppliers of durable medical equipment, or other small healthcare providers. Likewise, the ability of subcontractors to escape liability under the pre-FERA FCA has little application to the world of small medical providers. Courts have already established that claims for Medicaid payments are subject to the FCA.¹⁹⁰ Small medical providers are also unlikely to enter into the kinds of complicated subcontracting arrangements

185. *See id.*; see S. REP. NO. 111-10, at 2 (2009), reprinted in 2009 U.S.C.C.A.N. 430, 432-433.

186. Press Release, White House, Pres. Barack Obama, (May 20, 2009) (2009 WL 1398364).

187. For example, subsection 3729(a) was stricken and replaced with subsections 3729(a)(1) and (2); the language “to get a false or fraudulent claim paid or approved by the Government” in old § 3279(a)(2) was stricken and the terms “claim,” “obligation,” and “material” were redefined in § 3729(b). Pub. L. No. 111-21, at 1621-23.

188. *See supra* Part II.A.

189. S. REP. NO. 111-10, at 4 (stating that “[t]he effectiveness of the False Claims Act has recently been undermined by court decisions which limit the scope of the law and, in some cases, allow subcontractors paid with Government money to escape responsibility for proven frauds”).

190. *United States ex rel. Putnam v. E. Idaho Reg’l Med. Ctr.*, 696 F. Supp. 2d 1190, 1195-96 (D. Idaho 2010).

that the FERA amendments address.¹⁹¹ Moreover, subcontractors would still be liable to the government for fraudulent claims under alternative remedies to the FCA—remedies that are much more appropriate in scale to the unsophisticated healthcare provider.

III. ALTERNATIVE REMEDIES

Healthcare providers that make multiple mistakes and perform negligently should by no means benefit from the dereliction of their duties as Medicare and Medicaid participants. In these circumstances (e.g., *United States v. Mack*), though, the government should refrain from employing the FCA. Employing the FCA would certainly deter similar actions in the future, but it would also inflict massive penalties. For many smaller providers, FCA damages could serve as a “death blow” to their businesses, even though they never committed actual fraud.¹⁹² Instead, the government should seek to recoup its losses through alternative remedies, specifically federal common-law doctrines.

Federal law applies to cases involving the rights of the United States under a national program such as Medicare or Medicaid.¹⁹³ Furthermore, the U.S. government can recover funds “wrongfully, erroneously, or illegally” paid to healthcare providers.¹⁹⁴ Federal courts have, thus, recognized two theories for the government to recover funds that were wrongfully, erroneously, or illegally paid out to providers: the common-law doctrines of “unjust enrichment” and “payment by mistake.”¹⁹⁵

A. Federal Doctrine of Unjust Enrichment

The federal government may sue for equitable relief under the theory of “unjust enrichment” to recover funds wrongfully or illegally paid to a Medicare or Medicaid provider.¹⁹⁶ To establish unjust enrichment, the government must show that: (1) it had a reasonable expectation of payment, (2) the participant should reasonably have expected to pay, or (3) society’s reasonable expectations of person and property would be defeated by nonpayment.¹⁹⁷ Restitution for unjust enrichment, however, is available

191. See *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665-67 (2008); see S. REP. NO. 111-10, at 10.

192. See *Can Substandard Medical Care Become Fraud?*, *supra* note 90, at 30.

193. See *United States v. Vernon Home Health*, 21 F.3d 693, 695 (5th Cir. 1994).

194. See *LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989) (citing *United States v. Wurts*, 303 U.S. 414, 415 (1938)).

195. *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 776-77 (N.D. Tex. 2003).

196. See *Heller v. Fortis Benefits Ins. Co.*, 142 F.3d 487, 495 (D.C. Cir. 1998) (allowing reimbursement for ERISA payments).

197. *United States ex rel. Roberts v. Aging Care Home Health, Inc. (Aging Care I)*, 474

only when no legal contract exists between the parties and when other remedies are inadequate.¹⁹⁸ Generally, Medicare and Medicaid participation agreements do not create a contractual relationship between providers and the federal government.¹⁹⁹ Instead, these agreements create statutory rights under their respective programs.²⁰⁰

B. Payment-by-Mistake Doctrine

In the alternative, the U.S. government may sue to recover its erroneous payments through the doctrine of “payment by mistake.” Regardless of a statutory remedy, the government is entitled to recover funds it paid “under an erroneous belief which was material to the decision to pay.”²⁰¹ The government can recover funds from those parties who received reimbursements directly or from third parties who “participated in and benefited from the tainted transaction.”²⁰² Federal district courts have applied this “payment by mistake” doctrine when it is shown that: “(1) payments were made (2) under the belief that they were properly owed; (3) that belief being erroneously formed; and (4) the mistaken belief was material to the decision to pay.”²⁰³ Furthermore, the government need not show that the parties acted knowingly or that they were unjustly enriched.²⁰⁴

In establishing a mistaken payment, the critical question is whether or not the erroneous belief was material to the decision to pay.²⁰⁵ Courts answered this question by holding that the government is entitled to recover funds when it would not ordinarily pay a party due to statutory or regulatory noncompliance.²⁰⁶ In *United States v. Mead*, for instance, the Court of

F. Supp. 2d 810, 820 (W.D. La. 2007) (citing *Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990)).

198. *Medica-Rents Co.*, 285 F. Supp. 2d at 777; *United States ex rel. Zissler v. Regents of the Univ. of Minn.*, 992 F.Supp. 1097, 1112 (D. Minn. 1998); see also *Coop. Benefit Adms., Inc. v. Ogden*, 367 F.3d 323, 335 (5th Cir. 2004) (holding that the federal common law doctrine of unjust enrichment should be applied as a “gap” filler if statutory remedy exists and is inapplicable where the statutory text is specific and clear).

199. See *Medica-Rents Co.*, 285 F. Supp. 2d at 777 (citing *Mem’l Hosp. v. Heckler*, 706 F.2d 1130, 1136 (11th Cir. 1983)).

200. *Aging Care I*, 474 F. Supp. 2d at 820.

201. *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970) (citing *United States v. Wurts*, 303 U.S. 414, 415-16 (1938)).

202. *LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989) (citing *Mead*, 426 F.2d at 124).

203. *Medica-Rents Co.*, 285 F. Supp. 2d at 776 (quoting *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1316 (W.D. Okla. 1998)).

204. See *Mead*, 426 F.2d at 125; see also *Mt. Vernon Co-op. Bank v. Gleason*, 367 F.2d 289, 291 (1st Cir. 1966).

205. See *Mead*, 426 F.2d at 124.

206. See *id.*; see also *United States ex rel. Roberts v. Aging Care Home Health, Inc.*

Appeals for the Ninth Circuit held the defendants were liable for repayment because the government paid them under the mistaken belief that the defendants had complied with regulations promulgated by the Department of Agriculture.²⁰⁷ Had the government known about the defendants' noncompliance, it would have paid out a much smaller amount of money.²⁰⁸ Similarly, the Louisiana District Court in *United States ex rel. Roberts v. Aging Care Home Health, Inc.* granted the government's motion for partial summary judgment for payment by mistake.²⁰⁹ The court held that the defendants' certifications of statutory compliance were false and, therefore, material to the government's decision to pay.²¹⁰ In *Aging Care*, however, the statute in question expressly conditioned payment on compliance with all of its provisions.²¹¹

C. Damages Under the Common Law Doctrines

Under the doctrines of unjust enrichment and payment-by-mistake, the federal government is entitled to recover public funds wrongfully or erroneously paid out (i.e., restitution).²¹² And unless explicitly precluded by statute, pre-judgment and post-judgment interest may be applied at the court's discretion.²¹³ However, because these doctrines are equitable remedies, punitive damages may not be assessed.²¹⁴

With unjust enrichment and payment-by-mistake theories, the healthcare provider may reduce restitution damages by the amount of those services or supplies it would have been entitled to had the claim been submitted correctly.²¹⁵ Of course, in false certification cases, any amount of reimbursement received from the government would be subject to restitution; thus, the provider would have to return the full amount that the government paid on the claim, plus interest.²¹⁶ Nonetheless, paying

(*Aging Care I*), 474 F. Supp. 2d 810, 819 (W.D. La. 2007).

207. *Mead*, 426 F.2d at 124.

208. *See id.*

209. *Aging Care I*, 474 F. Supp. 2d at 819.

210. *Id.*

211. *Id.*

212. *Id.* at 819, 821.

213. *Id.* at 821 (granting the government post-judgment interest under 28 U.S.C. § 1961(a), but denying pre-judgment interest because of the government's delay in intervening, the complexity of the legal issues, and the lengthy duration of the proceedings).

214. *See id.*

215. *See United States v. Nazon*, No. 93 C 5456, 1993 WL 410150, at *3 (N.D. Ill. Oct. 14, 1993). *See, e.g., Martin v. Phillips*, 440 A.2d 1124, 1126 (N.H. 1982).

216. *Id.* (explaining that "Nazon . . . was barred from receiving [federal funds] as a result of his exclusion from Medicare. . . . Even if Nazon provided top-notch medical services, he was not entitled to Medicare reimbursement . . .").

restitution to the government is a much more lenient and acceptable sanction than the treble damages and fines under the FCA.

For example, in *Aging Care II* the Louisiana District Court determined that, under the FCA, it “is required to award treble damages” and interest, resulting in total fines against the defendant of \$4,665,011.64.²¹⁷ The court then calculated that, under either an unjust enrichment or payment-by-mistake theory, the defendant would have had to reimburse the government only \$427,503.88.²¹⁸ Similarly, in *United States v. Rogan* the North Carolina District Court concluded that the defendant, under the FCA, was required to pay \$64,259,032.50, whereas the government would only have been entitled to \$16,864,677.50, plus interest, under a payment-by-mistake theory (referred to in that case as a “mistake-of-fact” claim) or at least \$10,000,000 under an unjust enrichment theory.²¹⁹

IV. RECOMMENDATION

The federal government cannot reasonably expect unsophisticated healthcare providers to navigate the maze of 15,000 Medicare regulations,²²⁰ 400 pages of Medicare laws, thousands of pages of CMS literature, 7,000 CPT codes,²²¹ and 51 idiosyncratic state Medicaid programs.²²² The government, nevertheless, imposes a duty on providers to know the applicable laws.²²³ Increasingly, failure to comply with these voluminous laws and regulations translates to an automatic finding of “reckless disregard” for a provider’s obligations under Medicare or Medicaid.²²⁴ Having so easily established the scienter requirement, the government will proceed to sue the provider under the FCA, even though fraud was never actually committed. This expansive use of the FCA results in penalties far exceeding the harm done, and it should be curtailed.

In prosecuting future FCA actions against smaller healthcare providers, the federal government should take into account the following concerns:

- (1) the complexity of the nation’s healthcare system,
- (2) the incentives for relators to abuse the FCA’s *qui tam* provision for personal gain,

217. *United States ex rel. Roberts v. Aging Care Home Health, Inc. (Aging Care II)*, No. 02-2199, 2008 WL 2945946, at *11 (W.D. La. Jul. 25, 2008).

218. *Id.*

219. *United States v. Rogan*, 459 F. Supp. 2d 692, 727-28 (N.D. Ill. 2006).

220. KLEIMAN, *supra* note 18, at 1.

221. Jost & Davies, *supra* note 73, at 262.

222. Shaffer, *supra* note 35, at 1006.

223. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001).

224. *Id.*

- (3) the potentially devastating effects of FCA sanctions on small-business providers,
- (4) the disagreement over whether the FCA serves a remedial or punitive purpose,
- (5) the unwarranted erosion of the FCA's scienter requirement, and
- (6) the availability of more equitable remedies.

Accordingly, I propose a simple recommendation to the Justice Department: strictly limit application of the FCA to instances where fraud is evident, and apply equitable remedies for recovery of public funds when false claims were "unknowingly" submitted.

In its anti-fraud enforcement efforts, the government must clearly delineate the line between remedial and punitive actions. If it seeks to punish and deter the submission of false or fraudulent claims, it should pursue damages under the FCA. To ensure that only true defrauders are punished (as opposed to those providers lost in the jumble of regulations), the government must strictly apply the FCA's scienter requirement. Essentially, the "reckless disregard" standard should be interpreted as "gross negligence plus" and not as the less stringent standard used in *United States v. Mack*.²²⁵

In circumstances of provider negligence, mistake, confusion, or just poor judgment, the federal government should pursue restitution under the theories of "unjust enrichment" and "payment by mistake." The loss of government reimbursement (plus interest) should serve notice to healthcare providers to improve their business practices. Yet, without the FCA's harsh penalties, unsophisticated medical providers would still be able to operate and offer their services to Medicare and Medicaid beneficiaries.

V. CONCLUSION

In support of the False Claims Act, President Lincoln described the impetus for eliminating fraud against the government: "Worse than traitors in arms are the men who pretend loyalty to the flag, feast and fatten on the misfortunes of the Nation while patriotic blood is crimsoning the plains of the South and their countrymen are mouldering [sic] in the dust."²²⁶

Undoubtedly, the FCA has been an effective tool against private contractors seeking to cheat the U.S. Treasury of public funds; too effective, perhaps. Since the Civil War years, the government has expanded the scope of the FCA considerably. Originally enacted as a remedial measure, the

225. *United States v. Mack*, No. Civ.H-98-1488, 2000 WL 33993336, at *7 (S.D. Tex. May 16, 2000).

226. Trunk, *supra* note 90, at 159-60.

FCA now functions to deter and punish more than to restore. The federal government has recovered huge sums of money from FCA actions. The government once enlisted the FCA to battle war profiteers, but in recent decades, the focus has shifted to the healthcare industry, particularly Medicare and Medicaid providers.

Alas, the government has aggressively pushed the FCA's limits, effectively eroding the "knowledge" requirement in the statute. It has done so despite the existence of equitable remedies that more appropriately make the government whole. The government's expansive enforcement efforts under the FCA now even reach providers that make simple billing errors or negligently fail to comply with complex regulations. Many of these providers cannot afford the expense of litigation, and many more cannot survive the excessive penalties mandated by the FCA.

The use and interpretation of a statute naturally evolves over time. But, if the government continues on its path to expand the scope of the FCA, even President Lincoln, if alive today, would barely recognize this formidable statute, once known as "Lincoln's Law."