

APPLYING THE FALSE CLAIMS ACT TO CHEMICAL AND
PHYSICAL RESTRAINT CASES: IS THE GOVERNMENT GOING
TOO FAR?

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On August 6, 2002, Jeanne W. Price, a 79-year-old Alzheimer's patient at the Central Montgomery Medical Center (CMMC), died while in a restraining device called a Posey vest. The CMMC staff used the restraint to keep Ms. Price from wandering the halls of the medical center by confining her in bed.¹ When the patient later attempted to get out of bed, she slipped off the side, causing the vest to tighten around her chest.² She soon died of asphyxiation. An attorney for the family stated that the patient may have been left unattended for up to an hour.³

The incident at CMMC prompted an investigation by the United States Department of Justice (DOJ) into the use of restraints on patients at CMMC. The investigation cited a systemic abuse of chemical and physical restraints, contrary to the standard of care set forth in the Medicare statute.⁴ Based on the findings, the DOJ issued subpoenas and threatened suit against CMMC for violations of the civil False Claims Act (FCA).⁵ In 2002, CMMC settled the case, agreeing to pay the federal government \$200,000, institute new

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1. Maryclaire Dale, *Montgomery Co. Hospital to Pay \$200,000 after Restraint Death*, LANCASTER INTELLIGENCER J., July 25, 2005.

2. *Id.*

3. *Id.*

4. Settlement Agreement between the Dep't of Justice and Central Montgomery Medical Center, <http://www.usdoj.gov/usao/pae/nursing/CMMCSettlementAgreement.pdf> [hereinafter Settlement]; 42 U.S.C. § 1395i-3(c)(1)(A)(ii) (2000). The relevant section of 1395i-3 reads:

Free from restraints. The right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Restraints may only be imposed—

(I) to ensure the physical safety of the resident or other residents, and

(II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

5. *Hospital Settles Case Over Conditions of Participation; Abuse of Restraints Cited*, Report on Medicare Compliance, ATLANTIC INFORMATION SERVICE, INC., Aug. 1, 2005.

standards, and submit itself to monitoring by an agreed-upon third party consultant.⁶

The deaths or injuries suffered by residents of nursing homes and hospitals provoke an emotive response from society. Inevitably, the public calls for retribution against the hospital or nursing home. Beginning with amendments to the civil False Claims Act in the 1980s that eased the burden of bringing claims against medical providers, the government began to use this statute to punish hospitals and nursing homes for claims of substandard care.⁷

However, the use of the FCA as it currently stands raises many policy problems, especially when applied to cases involving chemical and physical restraints. This article will examine the history and elements of the FCA and how it has been applied in the health care context. It will also analyze the benefits and drawbacks of using the FCA in health care cases, and determine how a court would decide a case based on the use of restraints. It will argue that, for a number of policy and procedural reasons, the FCA should not be extended to cover cases involving chemical and physical restraints. Finally, it will explore possible solutions to the policy problems raised by the Act and alternative means of obtaining justice.

HISTORY OF THE FCA

Known originally as “Lincoln’s Law,” the FCA was enacted in 1863 to deter and punish those who submitted false bills to the government for supplies never sent to Union troops and for overbilling of supplies actually sent.⁸ “For sugar it often got sand; for coffee, rye; for leather, something no better than brown paper; [and] for sound horses and mules, spavined beasts and dying donkeys. . . .”⁹ The original statute contained a *qui tam* provision to encourage private individuals, known as relators, to report alleged fraud to the government with the possibility of earning a reward in the form of a portion of the government’s winnings, usually around 15%.¹⁰ When a relator brings a *qui tam* action, the government is given sixty days to decide whether

6. Settlement, *supra* note 4.

7. Keith D. Barber, David B. Honig & Neal A. Cooper, *Prolific Plaintiff or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 IND. HEALTH L. REV. 131, 136 (2004).

8. 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, 159 (2003); Barber, *supra* note 7, at 136.

9. United States *ex rel.* Newsham v. Lockheed Missiles & Space Co., 722 F. Supp. 607, 609 & n.2 (N.D. Cal. 1989) (internal quotations omitted).

10. Barber, *supra* note 7, at 136.

it will intervene in the case and take over as the prosecution.¹¹ If the government does not intervene, the relator can still pursue a suit under the FCA.¹² However, if the government decides to enter the suit, the “relator’s direct involvement with the case virtually ceases.”¹³

Most early amendments to the FCA were unfriendly to the relator, and as a result, few *qui tam* actions were brought until the 1980s.¹⁴ The FCA was amended in 1986 to expand its scope, due to concerns over “rising government fraud, especially in the areas of defense contracting and health care benefits.”¹⁵ These amendments were designed to encourage *qui tam* relators by increasing the relator’s share of winnings to 25%-30% and enhance their ability to bring and assist in cases by lowering the burden of proof, increasing the penalties, and allowing a relator to stay in a suit even when the government intervened.¹⁶

ELEMENTS OF THE FCA

A FCA claim such as the cases against CMMC is brought under section (a)(1) of the FCA, which imposes liability on a person who “knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval is liable to the United States Government for a civil penalty. . . .”¹⁷ Courts have interpreted this section as five discrete elements: “(1) A claim (2) submitted to the U.S. government (3) which is false or fraudulent (4) with sufficient knowledge by the defendant of the falsity of the claim (5) constituting a negative and direct effect on the federal treasury.”¹⁸

A claim submitted to the U.S. government under the Medicare statute has been interpreted as a single submission form.¹⁹ If a provider misinterprets a

11. *Id.* at 138.

12. *Id.*

13. *Id.*

14. Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 459-60 (1998).

15. Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1467 n.1 (9th Cir. 1996) (citing S. REP. NO. 345, at 2-4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5267-69).

16. Meador & Warren, *supra* note 14, at 460; Robert Fabrinkant & Glenn Solomon, *Application of the Federal False Claims Act to Regulatory Compliance in the Health Care Industry*, 51 ALA. L. REV. 105 (1999).

17. 31 U.S.C. § 3729(a)(1) (2000).

18. Fabrinkant & Solomon, *supra* note 16, at 111; United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 695 (2d Cir. 2001).

19. United States v. Krizek, 111 F.3d 934, 938-39 (D.C. Cir. 1997).

rule or regulation and submits a number of bills with the same mistake for reimbursement, each bill will be subjected to a separate penalty.²⁰ The penalties are assessed as a set amount for each false claim (ranging from \$5,500 to \$11,000), plus three times the amount of damages to the government.²¹

However, a bill will only be subject to penalty if it is found to be false. Case law holds that falsity of a claim implies an attempt to deceive.²² However, the choice of bad methodologies may cross the line and render the providers' claim false.²³ Falsity in the health care context is most easily found where a bill for services not performed is submitted. Obviously, the non-performance of a service constitutes a false claim for reimbursement when the bill is presented to the government. However, falsity has also been found based on a theory of supplying worthless or substandard products.²⁴

To prove the products and care provided is substandard, the proponent of the false claim must show that the product or care was not worth the amount billed to Medicare.²⁵ In proving this, a proponent will rely on the standards set forth in the Omnibus Reconciliation Act of 1987, applicable to nursing homes under the Nursing Home Reform Act (NHRA), or the Conditions of Participation of the Medicare statute applicable to hospitals.²⁶ To participate in Medicare, all providers must submit applications stating that services were performed as billed and sign off on a clause recognizing that any misrepresentations will make the provider liable under the Medicare statute.²⁷ In *United States ex rel. Mikes v. Straus*, the Court found that by submitting bills, providers implicitly certify to the government that they are abiding by applicable statutes, rules, and regulations requiring the provision of appropriate quality of care and safety.²⁸ This theory of implied certification is used to find liability under the FCA for substandard care. If the court finds

20. Trunk, *supra* note 8, at 164.

21. 31 U.S.C. § 3729(a) (2000).

22. Wang v. FMC Corp., 975 F.2d 1412, 1420-21 ("The phrase 'known to be false' . . . does not mean 'scientifically untrue'; it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors. What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.")

23. *See id.*

24. Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57, 77 (1999).

25. Joan H. Krause, "Promises to Keep": *Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1379-80 (2002).

26. 42 U.S.C. § 1395i-3 (2000); 42 C.F.R. § 482.13 (2005).

27. 42 U.S.C. § 1395cc (2000).

28. 274 F.3d 687, 697-98 (2d Cir. 2001).

that a provider is not upholding its end of the deal under the NHRA or Conditions of Participation requirements for quality care, the court can find the provider liable under the FCA, since it has implicitly certified by presenting bills to the government. For example, in *United States v. NHC Health Care Corp.*, the court held, “[a]t some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient’s quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.”²⁹ Simply stated, the theory underlying a substandard care FCA case is that a provider who is not providing adequate care (as set forth in the NHRA and the Conditions of Participation) is submitting a false claim each and every time it presents a bill for substandard care to the government.

Additionally, a showing that a provider violated statutory or regulatory standards of care is evidence of the worthlessness of services, though not necessarily *per se* evidence.³⁰ Determination of falsity may turn on value of services provided.³¹ Applicable health care standards may include having sufficient numbers of staff, providing assistance in activities of daily living, providing wound care and disease monitoring, and preventing falls, bedsores, and weight loss.³²

Knowledge under the FCA includes actual knowledge, deliberate ignorance of the truth, and reckless disregard of the truth.³³ Reckless disregard of the truth has been interpreted as an extension of, and closely related to, gross negligence.³⁴ The proponent of a suit under the FCA is not required to prove specific intent.³⁵ By submitting a claim to Medicare, a provider is imputed with knowledge of all rules and regulations associated with making claims, and therefore has “few defenses to the knowledge requirement.”³⁶ Whether the knowledge of the amount and type of care given can be imputed to the provider is a difficult question. In *NHC Health Care Corp.*, the Court held that knowledge of substandard care can be imputed if a jury could find the nursing homes did not have a sufficient staff to properly

29. *United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051, 1056 (D. Mo. 2001).

30. *See id.* at 1056 n.4.

31. *See id.*

32. *See id.*

33. 31 U.S.C. § 3729(b) (2000).

34. *United States v. Krizek*, 111 F.3d 934, 941 (D.C. Cir. 1997).

35. *Id.*

36. *Trunk*, *supra* note 8, at 163; *Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 63-64 (1984).

care for residents under the terms of its Medicare agreement.³⁷ The Court maintained that the FCA “allows a jury to find knowledge based on deliberate indifference or reckless disregard for the truth,” and acknowledged that this conclusion could be inferred from evidence of shortages in the staff and the neglect of the residents.³⁸ The Court subsequently held:

an entity who is charging the Government for a minimum amount of care provided to its residents should question whether understaffing might lead to undercare. The knowledge of the answer to that question is charged to the Defendants when they submitted their Medicare and Medicaid claim forms. In other words, a jury could reasonably find that NHC should have known if they were failing to provide all necessary care . . . at the time they submitted their claims for reimbursement.³⁹

In a physical and chemical restraint case under the FCA, the government (or the relator) must prove all five elements of a FCA case. The proponent of the suit must show that the provider submitted a claim for reimbursement to the government.⁴⁰ The proponent of the suit will also have to prove that the claim is false, typically by showing that the use of restraints by the provider was not in compliance with the NHRA or the Conditions of Participation.⁴¹ The knowledge element is usually easy to prove, as most providers who receive reimbursements from Medicare are imputed with the knowledge of the statute, rules, and regulations.⁴² However, the proponent will have to prove that the provider knew or should have known about the abuse of restraints.⁴³ Since an abuse of restraints would mean that the government is paying for a higher quality of care than the patient is receiving, a negative effect on the federal treasury can be implied.

PENALTIES

Under the FCA, each false claim is fined between \$5,000 and \$10,000—the exact amount is left to the judge’s discretion—plus three times the amount of damages that the government sustains due to the false claim.⁴⁴ However, in 1999, the DOJ issued a final rule that the initial fine is increased to \$5,500

37. See *NHC Health Care Corp.*, 163 F. Supp. 2d at 1058.

38. *Id.*

39. *Id.*

40. See *Fabrinkant*, *supra* note 16, at 111; *Straus*, 274 F.3d at 695.

41. *Id.*

42. *Id.*

43. *Id.*

44. 31 U.S.C. § 3729(a) (2000).

to \$11,000 for each false claim made to the government.⁴⁵ While in many health care claims the actual damage to the government may be pennies, an initial penalty of at least \$5,000 per claim filed means that the fine to the provider can be astronomical.⁴⁶ Since the Medicare statute has its own liability provision, a provider can also be liable and subject to a separate penalty under provisions in the Medicare statute for a false claim for reimbursement.⁴⁷

THE FCA AS APPLIED TO HEALTH CARE CASES

Since the 1980s, the FCA has been used by imaginative federal prosecutors to punish and deter a wide array of crimes, including health care fraud.⁴⁸ One of the first successful substandard care suits by the federal government was *United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.*, in which the DOJ brought a FCA action against a psychiatric hospital.⁴⁹ The government alleged that “appropriate precautions were not taken and that physical injury to and sexual abuse of patients occurred because of inadequate conditions, such as understaffed shifts, lack of monitoring equipment, and inappropriate housing assignments.”⁵⁰ Therefore, the government maintained that the failure of the defendant to provide a safe and quality environment violated the FCA.⁵¹ This violation of the FCA rested on the facility’s implied certification that the billings presented to the government complied with the Medicaid statutes and regulations in submitting bills under the program.⁵² The court agreed with the government and found that defendant violated the FCA by submitting bills for

45. 28 C.F.R. § 85.3 (2006); John T. Boese, *Can Substandard Medical Care Become Fraud? Understanding an Unfortunate Expansion of Liability Under the Civil False Claims Act*, THE BRIEF, Summer 2000, at 30.

46. 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, 142-43 (2001).

47. 42 U.S.C. § 1320a-7b; 42 U.S.C. § 1395i-3(b)(3)(B)(ii).

48. See, e.g., *Cook County v. United States ex rel. Chandler*, 538 U.S. 119 (2003) (holding that FCA suits may be brought against local governments); *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914 (7th Cir. 2005) (allowing a *qui tam* suit under the Higher Education Act); *United States ex rel. Ali v. Danie, Mann, Johnson & Mendenhall*, 355 F.3d 1140 (9th Cir. 2004) (allowing suit to proceed for false claims submitted to FEMA).

49. 945 F. Supp. 1485 (W.D. Okla. 1996).

50. *Id.* at 1488.

51. See *id.* at 1487-88.

52. *Id.* at 1487.

procedures that were not performed to the standard of care set forth in the Medicare statute.⁵³

Reasoning similar to *Aranda* was applied in a consent decree between the DOJ and GMS Management-Tucker, Inc. for care given in the Tucker House Nursing Home.⁵⁴ The U.S. government filed a complaint against GMS Management-Tucker, Inc. due to reports of poor wound care and malnutrition at the Tucker Home under the theory that the care given was below the standard set in the NHRA.⁵⁵ The allegations of false claims arose from the accounts of three patients in the home who all lost extreme amounts of weight and developed severe decubitus ulcers (bedsores).⁵⁶ The NHRA requires nursing homes that receive Medicare payments to abide by standards such as maintaining or enhancing the quality of life of residents, providing adequate nutrition and wound care, and providing for the physical and psychological well-being of residents.⁵⁷ The theory advanced by the government was that the nursing home signed off on an agreement with the government certifying that the care provided comported with the bills submitted.⁵⁸ The government alleged when the nursing home sought reimbursement for services that did not meet the statutory standard of care, it was submitting claims in violation of the FCA.⁵⁹ In February of 1996, the owners and operators of the nursing home agreed to a \$600,000 penalty to settle the claim and entered into a consent order that mandated monitoring and reporting by all facilities owned by GMS-Tucker.⁶⁰

In the CMMC case, the government utilized the same theory of liability as earlier cases to address the use of chemical and physical restraints.⁶¹ The government relied on the implied certification theory, maintaining that the medical center agreed to abide by the Conditions of Participation of the Medicare statute when it submitted bills for reimbursement.⁶² According to the government, when CMMC overused chemical and physical restraints and

53. *Id.*

54. See David R. Hoffman, *The Federal False Claims Act As a Remedy to Poor Care*, FALSE CLAIMS ACT AND *QUI TAM*, Q. REV., July 1996, at 17, 21-22 (citing Complaint, United States v. GMS Management-Tucker, Inc., Civ. A. No. 96-1271 (E.D. Pa. 1996)).

55. *Id.* at 17.

56. *Id.*

57. 42 U.S.C. § 1395i-3 (2000).

58. See Hoffman, *supra* note 54, at 17.

59. *Id.*

60. *Id.* at 20-22.

61. See Settlement, *supra* note 4, at 1.

62. *Id.*

continued to present bills to Medicare, it was submitting claims for substandard care, and therefore violated the FCA.⁶³

BENEFITS OF USING THE FCA IN THE HEALTH CARE ARENA

One of the main arguments made in favor of the use of the FCA against hospitals and nursing homes is that it reimburses the government for funds that were improperly obtained by providers. In 2001 alone, the Office of the Inspector General estimated that Medicare wrongly overpaid providers by approximately \$12 billion.⁶⁴ Since the *qui tam* amendments of 1986, the government has been able to recoup almost \$8 billion.⁶⁵

Proponents of the use of the FCA against providers also claim that the ability for individuals with any information on possible FCA violations to bring suit against a provider facilitates the government's capacity to address problems.⁶⁶ Under the *qui tam* provision, anyone who possesses original inside information has standing to bring suit against the provider.⁶⁷ Since many of the victims of the substandard care are unable to bring suit due to logistical or competency concerns, the *qui tam* provision allows friends or family of the victim, or staff of the hospital or nursing home to bring suit. Therefore, the FCA allows individuals who are not the victims themselves to address standard of care violations.

Along with allowing non-victims of substandard care to bring suit, the FCA allows suits to be brought in situations where state law actions would fail. For example, under state tort law claims, the individual bringing suit must be able to prove at least negligence on the part of the provider in order to win.⁶⁸ Proving negligence may be challenging because of the requirement of demonstrating proximate causation. With most of the victims of substandard care being ill or incompetent, proving that a provider's

63. *Id.*

64. Krause, *supra* note 25, at 1366-67 (citations omitted).

65. Fried, Frank, Harris, Shriver & Jacobson LLP, *Qui tam* FCA Statistics, <http://www.ffhsj.com/quitam/fcastats.htm> (last modified Nov. 20, 2003).

66. See Krause, *supra* note 46, at 209 ("Courts . . . expressly acknowledge that laws such as the FCA serve a punitive, deterrent function as well as a remedial one.").

67. See 31 U.S.C. §§ 3729, 3730(b) (2000).

68. See Angela Snellenberger Quin, *Imposing Federal Criminal Liability on Nursing Homes: A Way of Deterring Inadequate Health Care and Improving the Quality of Care Delivered?*, 43 ST. LOUIS U. L.J. 653, 682-83 (1999); see also Jennifer N. Phan, *The Graying of America: Protecting Nursing Home Residents by Allowing Regulatory and Criminal Statutes to Establish Standards of Care in Private Negligence Actions*, 2 HOUS. J. HEALTH L. & POL'Y 297, 314-21 (2002).

substandard care led to the harm to the victim by way of the victim's testimony is difficult. Also, many times the victim is not in a condition where he or she would be able to bring suit. Many victims do not have access to outside assistance, nor do they have the requisite mental capacity to bring a suit alone.⁶⁹ Under the FCA, the relator, and not the victim, must only show that the care given was not up to par with the relevant statute.

Furthermore, the high penalties that are mandated by the FCA serve as a strong deterrent to hospitals and nursing homes. Under the theory of deterrence, a provider will be sure that it is following the standards set out in federal statute to avoid the enormous penalties under the Act. As stated by Assistant U.S. attorney David Hoffman, "the use of the False Claims Act is another weapon available to the government to combat inappropriate behavior, and it will be pointed at those who choose profits over good care. . . ."⁷⁰ Therefore, the use of the FCA may also encourage nursing homes and hospitals to provide quality care to avoid the threat of penalties.

Proponents of using the FCA against health care providers point to examples such as the one from Chippenham Manor Nursing Home, a large nursing home located in Richmond, Virginia. The home was threatened with FCA action due to its alleged substandard care, including patients with "spontaneous skin breakdowns," and staffing and supplies shortages.⁷¹ Shortly after the threat, the home settled with the government.⁷² In the settlement, the home agreed to pay \$275,000 to the government. However, instead of the money going into the Medicare trust as it has with other cases, the bulk of the money was put toward an approved "restorative plan" to fix the problems.⁷³ During informal interviews, both residents and staff of the facility agree that Chippenham has improved since the settlement. However, this type of recycling of fines, namely, the use of the settlement money to fund the improvement of the provider, is exceedingly rare.⁷⁴

69. See Michael L. Rustad, *Heart of Stone: What is Revealed About the Attitude of Compassionate Conservatives Toward Nursing Home Practices, Tort Reform, and Noneconomic Damages*, 35 N.M. L. REV. 337, 344-46, 353-54 (2005).

70. David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Facilities*, 6 ANNALS HEALTH L. 147, 156 (1997).

71. *Monitors See Gains at Nursing Home that Used False-Claims Fines to Fix Problems*, Report on Medicare Compliance, ATLANTIC INFORMATION SERVICE, INC., Sept. 11, 2003, at 1.

72. See *id.*

73. *Id.*

74. *Id.*

PROBLEMS WITH USING THE FCA IN THE HEALTH CARE ARENA

A number of problems arise when the FCA is used as a sword against health care providers. The most glaring are the practical problems of the astronomical fines imposed by the FCA on providers who are already struggling to stay afloat, and the strong incentives placed on provider to give up their cases and settle. Furthermore, the NHRA and the Conditions of Participation are written in aspirational legislative language that does not translate well to real-world practice. Apart from the practical problems, a number of theoretical problems also emerge when the FCA is taken out of its original context.

The most obvious problem with using the FCA as a punishment to nursing homes and hospitals that are allegedly falling under the appropriate standard of care is that the fines imposed upon the providers can be ruinous. For most providers, operating on razor-thin profit or, in the case of many community hospitals, no profit, the imposition of the penalties will gravely affect their ability to continue to care for their patients.⁷⁵ Many of the providers who are subject to FCA action are “dependant on federal funding . . . [and] face the Herculean task of improving quality of care and strictly complying with burdensome regulations, all while government reimbursement rates are diminishing.”⁷⁶ The enormous FCA penalties have the potential to shut down facilities. “While closing the doors of a facility providing ‘inferior’ services is beneficial to the residents, bankrupting the facilities and the consequential damage that could occur from transferring the residents may not be the appropriate ends to justify the means.”⁷⁷ In *Northern Health Facilities, Inc. v. United States*, the court held that the risk of “‘transfer trauma’ resulting in severe psychological, emotional, and physical damage due to this closure” to the residents of the facility was substantial and should be a weighty consideration when a facility closure may occur.⁷⁸

75. John T. Boese, *Can Substandard Medical Care Become Fraud? Understanding an Unfortunate Expansion of Liability under the Civil False Claims Act*, THE BRIEF, Summer 2000, at 30.

76. *Id.*

77. David A. Bohm, *Striving for Quality Care in America’s Nursing Homes: Tracing the History of Nursing Homes and Noting the Effect of Recent Federal Government Initiatives to Ensure Quality Care in the Nursing Home Setting*, 4 DEPAUL J. HEALTH CARE L. 317, 343 (2001).

78. 39 F. Supp. 2d 563, 571 (D. Md. 1998). Though it mentioned the problems of transfer trauma, the court denied the nursing home’s petition for a temporary restraining order to enjoin the government from terminating its Medicare participation because it found the Secretary of State had the sole discretion for termination.

Although the Court is compelled to reach the conclusion that Secretary Shalala through HCFA had

FCA litigation and penalties, even if they do not force a facility to close, may threaten the adequacy of resources available to the facility to dedicate to patient care and improve quality of care.⁷⁹ The seemingly elegant solution for providers of dropping out of the Medicare program is usually a financially impossible undertaking, as many hospital and nursing home residents are covered by Medicare and the facilities depend on the reimbursements.⁸⁰

Problems arise even if the provider settles the FCA claim with the government. Most of the FCA cases against hospitals and nursing homes end in settlement, as the provider may favor a lesser financial burden and a reduced risk settling the claim outside of court.⁸¹ Therefore, the providers are often induced to settle with the government, even when they have a good chance of winning, because their potential liability is so great. The government accedes to settlement because “the FCA only provides leverage for the government to recoup money in its current thrust under health care fraud and abuse initiatives,” and with settlement, the government is guaranteed some type of remuneration.⁸² Healthcare providers have argued that the power the government has in generating settlements is coercive, stunningly similar to extortion.⁸³ Apart from the providers paying the government for claims that they might win, the high rate of settlement discourages clarification in the law.

[S]ettlement removes many factual and legal issues from judicial scrutiny, it precludes a provider from arguing a range of issues that are crucial both to the development of FCA jurisprudence and to the underlying regulatory policy . . . [w]hat results . . . is an amorphous collection of quasi-legal guidance with no precedential value, on which the government will happily rely in future enforcement efforts.⁸⁴

the authority to terminate Greenbelt’s participation in the Medicare program, the Court wishes to express its concerns about the fairness of this action. The Court believes that this is an inequitable result. From all indications, Greenbelt entered into the Consent Order in good faith. The Temporary Manager and the Federal Monitor have just recently begun the work necessary to correct the deficiencies cited by the respective agencies. Although the agencies argue that the conditions at Greenbelt have become worse, not better, since January, the Court believes that the Temporary Manager has not had sufficient time to address the problems.

Id. at 577.

79. Boese, *supra* note 75, at 30-31.

80. *Id.*

81. Bohm, *supra* note 77, at 342-43; *see also* Boese, *supra* note 75, at 31 (“[A]ttempts by *quit tam* relators to litigate quality of care issues under the False Claims Act have been almost universally rejected by courts, whereas those initiated by the government have all settled to date.”).

82. Bohm, *supra* note 77, at 343.

83. Krause, *supra* note 46, at 205.

84. *Id.* at 205-06.

Another major problem with using the FCA in health care cases is that the standards set out in the NHRA and the Conditions of Participation are at best aspirational, and at worst vague and unrealistic. The standards laid out by the government are “general requirements but are not specific as to the content of those requirements.”⁸⁵ Even the *Aranda* court in upholding the use of the FCA against a hospital noted that “[i]t may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its services meet ‘professionally recognized standards for health care.’”⁸⁶ Thus, under the FCA, the government is able to penalize providers with huge sums of money under statutes that are subjective and unclear.

Furthermore, “[t]he mere specter of allowing health care quality issues to form the basis of an FCA prosecution is a federal court’s nightmare.”⁸⁷ That is, if a FCA case reaches court instead of settling, judges will have the duty of determining the proper standards of care, rather than health professionals. Because no concrete guidance nor precedent exists in this area, judges will have free reign in setting standards of health care.

The *qui tam* provision has its own drawbacks for use in the health care area. With a possibility of gaining up to 30% of the winnings and little discouragement to bring all claims, a relator has the incentive to bring suit against providers, even where there is little evidence or de minimis violations. The FCA attempts to deter such behavior by relators by awarding attorney’s fees to the defendant when “the Government does not proceed with the action and the person bringing the action conducts the action . . . [and the] defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.”⁸⁸ As interpreted by the Ninth Circuit Court, “[a]n action is clearly frivolous when the result is obvious or the appellant’s arguments of error are wholly without merit. An action is clearly vexatious or brought primarily for purposes of harassment when the plaintiff pursues the litigation with an improper purpose, such as to annoy or embarrass the defendant.”⁸⁹ However, this finding is difficult to establish in a suit against

85. Fabrikant & Solomon, *supra* note 16, at 141.

86. United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs., 945 F. Supp. 1485, 1488 (W.D. Okla. 1996).

87. Michael M. Mustokoff, Jody A. Werner & Michael S. Yecies, *The Government’s Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Ingenuity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANN. HEALTH L. 137, 142 (1997).

88. 31 U.S.C. § 3730(d)(4) (2000).

89. Pflingston v. Ronan Eng’g Co., 284 F.3d 999, 1006 (9th Cir. 2002) (citations omitted).

a health care provider as the standards that the suits are brought under (the NHRA and the Conditions of Participation) are vague and aspirational.

Another troubling problem with prosecuting health care providers under the FCA is the potential for an “uncoordinated effort” by governmental agencies to “subject[] [the provider] to multiple assaults for the same conduct. . . .”⁹⁰ Because of the enforcement provisions in NHRA, a nursing home can be subject to double liability. Consequently, a particularly troubling result was reached in *Northern Health Facilities v. United States*.⁹¹ Both the DOJ and the Health Care Financing Agency (now the Centers for Medicare and Medicaid Services) brought suit against Greenbelt Nursing and Rehabilitation Center (Greenbelt) for violations of the FCA and violations of the NHRA, respectively. The court upheld the uncoordinated attempt by the two federal agencies when it denied injunctive relief from termination from Medicare under the NHRA, even after the nursing home entered into a settlement agreement with the DOJ to pay penalties and improve its quality of care.⁹² Though the court found that the imposition of penalties under the NHRA after entering into the consent decree with the DOJ was unfair and against the public interest, the court held that both agencies had a right to sue Greenbelt under the repetitive statutes.⁹³

A theoretical concern about the use of the FCA in the health care context is that it is being used to punish and deter offenders.⁹⁴ However, the FCA is a civil statute. Society uses criminal law, not civil law, to punish and deter conduct.⁹⁵ One scholar has argued that

[w]hile the criminal law has little reason to fear overdeterrence . . . within its appropriate domain, the same cannot be said of civil laws such as the FCA. The overextension of punitive prohibitions is most troubling when the underlying violation is essentially a regulatory offense, or noncompliance with one of the growing number of regulations promulgated by administrative agencies.⁹⁶

90. Boese, *supra* note 75, at 31.

91. 39 F. Supp. 2d 563, 566-67 (D. Md. 1998).

92. *Id.* at 577.

93. *Id.*

94. Vermont Agency of Natural Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 784-85 (2000) (holding that treble damages are punitive in nature).

95. Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 YALE L.J. 1795, 1796 (1992) (“the criminal law is meant to punish, while the civil law is meant to compensate”).

96. Krause, *supra* note 46, at 209 (internal quotations omitted).

Finally, one must look to the original intent of the law. The FCA was written to deter false billings to the federal government during the Civil War. The authors of the statute were concerned with overpaying for artillery and receiving useable supplies for the Union troops. The statute has now been taken out of its original context of straightforward billing and put into the fuzzy realm of quality of care in health care facilities. Since the federal government already has statutes in place to prosecute facilities directly for poor quality of care, such as the NHRA, using an out of place Civil War relic to punish providers seems, at best, duplicative.

APPLYING THE FCA TO PHYSICAL AND CHEMICAL RESTRAINT CASES

The case against CMMC for restraining Ms. Price up to the moment of her death never generated a formal complaint, nor did it go through any type of litigation procedures. Therefore, its precedential value is non-existent. A court receiving a FCA suit based solely on the alleged overuse of chemical and physical restraints would be writing on practically a blank slate. The major question for a restraints-only suit would involve how a court would merge with or distinguish from the *Aranda* model.

However, in *Aranda*, the court did not have to delve deeply into health care standards because the facility's care was glaringly and unreasonably poor. The patients at the facility were under little supervision, which lead to physical and sexual abuse.⁹⁷ Since *Aranda* and *NHC Healthcare Corp.*, which followed *Aranda*'s holding without expansion or distinction, were the first and only cases where a federal court addressed the merits of a quality of care claim under the FCA, the door is wide open for a case in which the court would have to interpret standards of care with respect to restraints.

The major reason for the employment of chemical and physical restraints on patients in hospitals and nursing homes is to promote patient safety and prevent falls.⁹⁸ Falls and their related injuries are the reason behind many lawsuits against these providers.⁹⁹ Though patients who fall may sue the nursing home or hospital for negligently failing to use proper restraints, the provider must make sure not to over-restrain patients. Therefore, the provider

97. United States *ex rel.* *Aranda v. Cmty. Psychiatric Ctrs.*, 945 F. Supp. 1485, 1488 (W.D. Okla. 1996).

98. Julie A. Braun & Elizabeth A. Capezuti, *The Legal and Medical Aspects of Physical Restraints and Bed Siderails and Their Relationship to Falls and Fall-Related Injuries in Nursing Homes*, 4 DEPAUL J. HEALTH CARE L. 1, 7 (2000).

99. *Id.* at 1.

is put into a precarious situation between being the target of negligence suits and FCA suits for substandard care due to overuse of restraints.

Both the NHRA and the Conditions of Participation contain provisions dealing with the use of chemical and physical restraints on patients.¹⁰⁰ The NHRA mandates the

right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Restraints may only be imposed (I) to ensure the physical safety of the resident or other residents, and (II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used. . . .¹⁰¹

The Conditions of Participation are more detailed, but carry the same theme that restraints are only to be used in the least restrictive manner and only on the directions of a physician.¹⁰² These provisions were written in response to

100. 42 U.S.C. § 1395i-3(c)(1)(A)(ii) (2000); 42 C.F.R. § 482.13(e)-(f) (2005).

101. 42 U.S.C. § 1395i-3(c)(1)(A)(ii).

102. 42 C.F.R. § 482.13(e)-(f) (2005). The text of this provision reads:

(e) Standard: Restraint for acute medical and surgical care.

(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.

The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

evidence that nursing homes and hospitals were leaving patients restrained for

- (f) Standard: Seclusion and restraint for behavior management.
- (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term “restraint” includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient’s body that he or she cannot easily remove that restricts freedom of movement or normal access to one’s body. A drug used as a restraint is a medication used to control behavior or to restrict the patient’s freedom of movement and is not a standard treatment for the patient’s medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.
- (2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient’s physical safety and less restrictive interventions have been determined to be ineffective.
- (3) The use of a restraint or seclusion must be—
- (i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;
 - (ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:
 - (A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).
 - (B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient’s treating physician.
 - (C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.
 - (D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.
 - (iii) In accordance with a written modification to the patient’s plan of care;
 - (iv) Implemented in the least restrictive manner possible;
 - (v) In accordance with safe appropriate restraining techniques; and
 - (vi) Ended at the earliest possible time.
- (4) A restraint and seclusion may not be used simultaneously unless the patient is—
- (i) Continually monitored face-to-face by an assigned staff member; or
 - (ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.
- (5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.
- (6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.
- (7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient’s death is a result of restraint or seclusion.

days at a time, mainly for convenience due to understaffing problems.¹⁰³ Particularly in the nursing home context, anecdotes about perpetually restrained patients with decubitus ulcers so deep that an observer could see bone were common.¹⁰⁴

In CMMC, the government maintained that the overuse of chemical and physical restraints fell into the “substandard care” category of FCA cases. That is, the case would fall into the theory in *Aranda* that the government is not getting what it is paying for when it reimburses providers who use restraints in violation of the standards set forth in the NHRA and Conditions of Participation. Under a claim for substandard care, the government would have to show that the provider knowingly submitted a claim that was false, and that the claim adversely affected the Treasury.¹⁰⁵

Even if the government could prove that the claim was submitted knowingly, the problem with this type of case arises in the term “false.” With respect to chemical and physical restraint cases, what is interpreted to constitute falsity is exceedingly important to the outcome of the case. To determine falsity, the deciding court will be faced with the task of interpreting the standards of conduct set forth in the NHRA and the Conditions of Participation. The District Court in *Aranda* stated that even though the standards are vague, a court should not be barred from determining that an FCA violation exists.¹⁰⁶ Therefore, a court faced with a chemical or physical restraint case will likely follow this precedent and decide on the merits.

The deciding court will be challenged with the duty of examining the facts of the case and determining if the facts fit within the standard of care. In an egregious case of restraint, especially where no physician orders existed, a court could easily decide in favor of the government. However, in a closer case, the court would have to be making decisions that are normally left to a physician. (How long should restraints be used? What type of restraint is the least restrictive for a patient’s condition? Is the patient a danger to himself or to others?) The outcome of the case would be dependent on the answers to the above questions and other similar ones. Thus, the inquiry would be fact-intensive and, “as a practical matter, the deck is stacked in the defendant’s

103. See Herbert Neil Wigder & Mary S. Matthews, *Restraints*, EMEDICINE, Nov. 7, 2005, <http://www.emedicine.com/emerg/topic776.htm>.

104. See Mark Thompson, *Fatal Neglect in Possibly Thousands of Cases, Nursing Home Residents are Dying From a Lack of Food and Water and the Most Basic Level of Hygiene*, TIME, Oct. 27, 1997, at 34.

105. 31 U.S.C. § 3729 (2000).

106. United States *ex rel.* *Aranda v. Cmty. Psychiatric Ctrs.*, 945 F. Supp. 1485, 1488 (W.D. Okla. 1996).

favor: while the government's proof is likely to consist of experts who merely review patient files, the defendant can offer detailed recollections of each patient's special circumstances."¹⁰⁷ Therefore, if a close case would avoid settlement, the provider would probably be able to prevail on the merits.

POLICY REASONS AGAINST USING THE FCA TO PROSECUTE RESTRAINT CASES

The fact-intensive nature of a close restraint case brings up a major issue: Should judges be making decisions that are normally left to physicians? The standards of care set out in the NHRA and the Conditions of Participation are well meaning, but give the individuals who work in nursing homes and hospitals very little guidance in day-to-day activities. Where the government mandates are unclear, it does not seem fair or reasonable to impose high penalties for technical non-compliance. "The phrase 'known to be false' . . . does not mean 'scientifically untrue'; it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors."¹⁰⁸ Therefore, if a facility used restraints believing them to be in the best interest of a patient and under a physician's orders, and submitted bills to the government for the care, the facility should not be punished.

As stated above, the FCA was not designed to deal with health care claims, and it should *not* be used in chemical and physical restraint cases, at least not in its current form. Due to the *qui tam* provision, it is exceedingly easy for a relator to bring a suit alleging overuse of restraints. Because the standards set forth in the statutes are so vague, a relator has every incentive to bring a suit on the chance it would settle or a court would find for the government. Therefore, resources that should be going toward patient care are spent fending off what amounts to frivolous claims. Furthermore, even if a facility is using the restraints properly, it has a large incentive to settle the suit before the action ever reaches court. As judges would be interpreting the standards, many providers fear losing suit even when they are medically correct in their use of restraining devices. Here again, resources that should be used within the facility are diverted.

107. Joan H. Krause, *Medical Error as False Claim*, 27 AM J.L. & MED. 181, 196-97 (2001) (explaining why a case applying the FCA to medical errors would probably lose).

108. *Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992) (citations omitted).

RECOMMENDED SOLUTIONS

Nursing home and hospital patients always have the ability to bring suit under state law claims such as medical malpractice, fraud, and battery. Many states have enacted legislation making inadequate care, abuse, and neglect crimes.¹⁰⁹ These causes of action may not necessitate a vulnerable segment of society to bring suit against the facility in charge of its care, as many states are requiring the staff of hospitals and nursing homes to bring forward possible cases of abuse and neglect.¹¹⁰

Furthermore, scholars and some states are turning to a theory of absolute liability when dealing with elder abuse.¹¹¹ According to one scholar, “[i]n cases involving defendants who violate . . . laws protecting vulnerable groups, courts have held these statutes to be essentially strict liability provisions requiring defendants to safeguard such individuals from foreseeable harm. To allow common law defenses would undermine the legislative purpose in enacting these laws.”¹¹² Therefore, in the states that uphold absolute liability for vulnerable populations, defenses such as contributory negligence and assumption of risk will not apply.

With the sheer magnitude of problems raised by the FCA when applied to health care cases, it should no longer be utilized in this area. The problem of overcharging Medicare can be managed under the Medicare statute, and the problem of substandard care can be handled under state law, especially if all states adopt mandatory reporting provisions. However, because of the emotional response to inferior nursing home and hospital care and a general feeling of “needing to do something,” the FCA will probably continue to be applied to these cases. In this situation, the FCA should be modified to take into account that it is now used for health care in addition to its original intent of war supplies. The best across-the-board solution is to add a separate provision to cover the burgeoning field of health care claims. This new provision would apply to all providers who are qualified to receive

109. Snellenberger Quin, *supra* note 68, at 682-86.

110. *See, e.g.*, ARIZ. REV. STAT. ANN. § 46-454 (2006); FLA. STAT. § 415.1034 (2005); OKLA. STAT. tit. 43A, § 10-104 (2005); UTAH CODE ANN. § 76-5-111.1 (2005); VT. STAT. ANN. tit. 33, § 6903 (2005).

111. Thelen v. St. Cloud Hosp., 379 N.W.2d 189, 193-94 (Minn. Ct. App. 1985); Kent v. County of Hudson, 245 A.2d 747, 757 (N.J. Super. Ct. App. Div. 1968); RESTATEMENT (SECOND) OF TORTS § 483 cmt. c (1965); Seymour Moskowitz, *Saving Granny from the Wolf: Elder Abuse and Neglect—The Legal Framework*, 31 CONN. L. REV. 77, 154-57 (1998). Other states, while not calling it absolute liability, will refuse to impose contributory negligence on the part of the elderly person. *See, e.g.*, Powell v. Parkview Estate Nursing Home, Inc., 240 So. 2d 53, 57 (La. Ct. App. 1970).

112. Moskowitz, *supra* note 111, at 155.

reimbursement from the government under the Medicare program and actually submit bills for reimbursement. It would retain the same definitions for knowledge and falsity as the original Act, but would provide for different penalties. The provision would first set a minimum amount that the claim submitted must exceed before penalties are imposed, so that providers are not punished for claims that are off by pennies. Under the new provision, however, providers whose claims are under the statutory minimum will receive warnings and may be penalized after a specified number of warnings on the same mistake. The damages recoverable by the government would also be decreased substantially, and at least 90% of the money recovered would have to be put into a trust fund for the provider to aid it in improving its services. Providers who are cited for using an excessive amount of physical and chemical restraints will be required to use a majority of the trust money to hire more well-qualified staff.

If a statutory solution is not feasible, or in conjunction with a new statutory provision, courts should be given more discretion in setting the penalties under the FCA. Since each claim, which may only have deprived the government of pennies, is a separate false claim, providers are subject to huge penalties with the \$5,500 minimum fine per claim. Instead of mandating an initial penalty, judges should be given discretion in setting the fines *and* how they should be later spent. By having a lower risk of financial ruin, providers will be more willing to avoid settlement.

Moreover, the burden of proof should be raised so that the government would have to prove the falsity of the claim by more than a mere preponderance of the evidence. Since this statute has already been acknowledged as a hybrid civil and criminal statute, raising the burden to clear and convincing evidence or something similar in effect should not be controversial.

CONCLUSION

The restraint of nursing home and hospital patients raises an emotional response from individuals and instigates a call for the government to “do something” to punish and deter providers. However, punishing providers through the FCA as it currently stands is causing more problems than it is solving.