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This Might Sting a Bit: Policing Skin Care in Nursing Facilities by Litigating Fraud

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NOTE

"THIS MIGHT STING A BIT": POLICING SKIN CARE IN NURSING FACILITIES BY LITIGATING FRAUD

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INTRODUCTION

> "You know where most folks die, Bernie?" Officer Feeney said one morning as Bernie walked to the park beside him.
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> "On the highway?" said Bernie.
>
> "Nope."
>
> "Airplanes?" Bernie guessed.
>
> The policeman shook his head. "Most people," he said, swinging his nightstick, "die in bed, which goes to show that bed is about the most dangerous place you can be."[1]

The situation is unsettling. We hear stories of bedsores the size of "dinner plates."[2] We hear of a little old man so mistreated by a nursing facility that he had over twenty-five bedsores, the majority of them at the most serious Stage IV level, which can be so deep as to expose bone.[3] One of his bedsores, about as wide as a cocktail napkin, "extended into his shoulder joint."[4] All of the bedsores contained black, dead tissue and stank of rot.[5] In addition, he "had a gangrenous left leg, and all five toes on his right foot were [dying] and in the process of falling off."[6]

Situations like this are preventable. However, an epidemic of poor skin care exists in our nation's nursing facilities. Poor skin care leads to unproductive and fraudulent use of federal funds, and litigating under the False Claims Act (FCA)[7] is an efficient, effective, and

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1 PHYLLIS REYNOLDS NAYLOR, THE BODIES IN THE BESSLEDORF HOTEL 3–4 (1986).

2 Diane K. Langemo et al., *The Lived Experience of Having a Pressure Ulcer: A Qualitative Analysis*, 13 ADVANCES SKIN & WOUND CARE 225 (2000), *available at* http://www.woundcare net.com/advances/articles/wcf210.htm.

3 David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANNALS HEALTH L. 147, 152–53 (1997). *See generally* National Pressure Ulcer Advisory Panel (NPUAP), *Pressure Ulcers Prevalence, Cost and Risk Assessment: Consensus Development Conference Statement*, DECUBITUS, May 1989, at 24, 25 (indicating that, in general, Stage 1 pressure ulcers present as redness and swelling that will not go away; Stage II–IV pressure ulcers present as an actual break or crater in the skin).

4 Hoffman, *supra* note 3, at 152.

5 *Id.*

6 *Id.*

7 31 U.S.C. §§ 3729–3733 (1994).

ing homes are among the sickest and most vulnerable populations in the nation."[21] Studies estimate that twenty percent of these nursing facility patients have pressure ulcers.[22] Extrapolating, by these estimates, roughly 320,000 of our most vulnerable members of society suffer from pressure ulcers. Sources estimate that upwards of 500,000[23] to 1.7 million people develop pressure ulcers annually.[24] Treating pressure ulcers annually costs from low estimates of $2.2 billion[25] or $7 billion[26] to a higher estimate by the Agency for Health Care Policy and Research (AHCPR) of $20 billion.[27] One estimate places at least $355 million of this cost in nursing facilities alone.[28] Complications from pressure ulcers, moreover, "account for 60,000 deaths in the United States every year."[29] The future seems to promise a growing infirm, elderly population vulnerable to pressure ulcers with no one to advocate for their proper care.[30]

Part I of this Note explores the statutory, regulatory, and case law milieu that allows the federal government to use the FCA to come to these patients' rescue. Effective use of the FCA would greatly alleviate the suffering of these patients while increasing the general quality of care in nursing facilities. To do so, the government must prosecute those nursing facilities that fail to provide proper care and bill the government for patient care falling outside of the specifications of care for which the government agreed to pay. Typically, the federal government contracts for products and services and then demands, as a condition of payment, that those products and services fall within a

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21 *Id.*

22 *See Pressure Ulcers: Prevention and Management*, 70 MAYO CLINIC PROCEEDINGS 789 (1995) (finding the incidence of pressure ulcers in two skilled nursing homes to be 23.9%); Wee Lock Ooi et al., *Nursing Home Characteristics and the Development of Pressure Sores and Disruptive Behavior*, 28 AGE & AGEING 45 (1999) (finding the overall incidence of pressure sores in high-risk homes to be 19.5%).

23 *See* James Hirshberg et al., *Osteomyelitis Related to Pressure Ulcers: The Cost of Neglect*, 13 ADVANCES SKIN & WOUND CARE 25, 29 (2000), *available at* http://www.woundcarenet.com/advances/articles/wc211.htm.

24 Langemo et al., *supra* note 2, at 225.

25 *Id.*

26 Cathy Thomas-Hess, *Pressure Ulcers: Keys to Prevention*, NURSING HOMES, May 1993, at 31, 31.

27 Hirshberg et al., *supra* note 23, at 25 ("This staggering amount includes hospitalization, durable medical equipment, home health care, nursing home care, physician management, and transportation.").

28 Miriam K. Jackobs, *The Cost of Medical Nutrition Therapy in Healing Pressure Ulcers*, TOPICS CLINICAL NUTRITION, Mar. 1999, at 41, 42 (citation omitted).

29 Thomas-Hess, *supra* note 26, at 31.

30 *Cf.* 1 SARAH N. WELLING ET AL., FEDERAL CRIMINAL LAW AND RELATED ACTIONS: CRIMES, FORFEITURE, THE FALSE CLAIMS ACT AND RICO § 14.3, at 546–47 (1998) (pointing out that the "ambiguous nature of medicine perpetuates . . . deference [to physicians]" and that this can harm naïve and unsuspecting victims).

arguably necessary tool for policing skin care and preventing bedsores in nursing facilities.[8]

Bedsores are a relatively simple physical ailment produced by mechanical force.[9] They result from unequal pressure, which is why clinicians call them pressure ulcers.[10] Pressure ulcers occur when a patient lies or sits in the same position for a very long time and a patient's bone, such as a hip or the pelvis, presses down against the mattress or sitting surface.[11] This pressure damages the underlying tissue[12] because it cuts off circulation to that tissue, resulting in a lapse in oxygen and nutrition, which leads to tissue death.[13] As with all necrotic tissue, i.e., dead flesh, it starts to rot, i.e., to ulcerate.[14] All people experience similar pressure when they sit or lie in the same position for too long and their hips ache or their rear ends fall asleep.[15] The difference is that healthy individuals shift their positions and alleviate the pressure before the tissue dies from lack of oxygen.[16] Infirm individuals, like those in nursing facilities, often cannot move on their own to relieve this pressure. Thus, they must rely on others, which leaves them vulnerable to pressure ulcers.[17]

The pressure ulcer problem—particularly in nursing facilities—is staggering. One source estimates that there are approximately "17,000 nursing homes in the United States with over 1.7 million beds."[18] "The federal government, through the Medicare and Medicaid programs, paid these homes nearly $28 billion in 1997"[19] and $39 billion in 1999.[20] Moreover, "[t]he 1.6 million elderly living in nurs-

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8 Although this Note focuses on bedsores (pressure ulcers), litigants could use the skeletal parts of this argument to police other infirmities like urinary and fecal incontinence, enteral feeding, malnutrition, and mental disabilities.

9 JOANN MAKLEBURST & MARY SIEGGREEN, PRESSURE ULCERS: GUIDELINES FOR PREVENTION AND NURSING MANAGEMENT 27 (2d ed. 1996) ("The unquestionable cause of pressure ulcers is compression of soft tissue sufficient to cause irreversible ischemia. Other siguificant contributions are shear, friction, excessive moisture, and possibly infection.").

10 *Id.* at 21.

11 *See id.* at 19–20.

12 AGENCY FOR HEALTH CARE POLICY & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 95-0653, PRESSURE ULCER TREATMENT, CLINICAL PRACTICE GUIDELINE, QUICK REFERENCE GUIDE FOR CLINICIANS, NO. 15, at 1 (1994).

13 MAKLEBURST & SIEGGREEN, *supra* note 9, at 19.

14 *Id.*

15 *See id.*

16 *Id.* at 20.

17 *See generally* AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 12, at 9–13 (dedicating an entire section to tissue load management—that is, relieving pressure in such a way as to prevent pressure ulcers).

18 Beth A. Klitch, *Big Stakes in Targeting Nursing Homes*, NURSING HOMES, Oct. 1998, at 15, 15 (citing data from 1997).

19 *Id.*

20 U.S. GEN. ACCOUNTING OFFICE, PUB. NO. GAO/HEHE-99-46, NURSING HOMES: ADDITIONAL STEPS NEEDED TO STRENGTHEN ENFORCEMENT OF FEDERAL QUALITY STANDARDS 1 (1999), *available at* http://www.gao.gov.

reasonable set of specifications.[31] In the case of pressure ulcers, it is the type and quality of skin care that must fall within certain specifications. The government does not intend to pay for skin care that fails to meet these specifications. If a provider charges for skin care that does not meet the specifications, such a charge is a false claim and is actionable under the FCA.[32] Part II of this Note demonstrates how the FCA can be used to police skin care in nursing facilities.

This Note focuses on pressure ulcers for two reasons. First, the Health Care Financing Administration's (HCFA's)[33] rules and regulations clearly specify that nursing facilities must heal any pressure ulcer present on a patient at the time of admission and must prevent any other pressure ulcers from developing, unless they are medically unavoidable.[34] These regulations fit cleanly and concisely into a false claims action. Second, this Note desires to raise awareness. It hopes to improve the quality of life of the elderly in nursing facilities through litigation and legal reform by presenting, directly and clearly, the unnecessary plight of those who suffer from pressure ulcers. It also intends to raise awareness about how the FCA can play a vital and necessary role in helping the government efficiently protect its interest in ensuring that patients receive the care they deserve and that nursing facilities use federal dollars properly.[35]

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31 *See* United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1488 (W.D. Okla. 1996); *see also* ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD § 1.03[2][iii], at 1-17 (2002) ("[F]ailure to provide necessary services . . . can become fraud if reimbursement is obtained upon the false representation that all necessary services have been provided." (citation omitted)). *But see id.* (stating that "claims of health care fraud based upon failure to provide necessary services may become extraordinarily complex" because they will often "implicate issues of medical decision-making, reasonable staffing choices, or other clinical issues").

32 *See Aranda*, 945 F. Supp. at 1488–89.

33 The Department of Health and Human Services recently changed the name of HCFA to the Centers for Medicare & Medicaid Services. *See* Ctrs. for Medicare & Medicaid Servs., *CMS: The Medicare, Medicaid, and SCHIP Agency*, *at* http://www.hcfa.gov (last visited Jan. 31, 2002). This Note, however, will still refer to the agency as HCFA for purposes of clarity.

34 42 C.F.R. § 483.25(c) (2000). *See generally* Lesley Ann Clement, *Litigating the Pressure Sore Case Against a Nursing Home*, NAELA Q. (Nat'l Acad. of Elder Law Attorneys, Inc., Tucson, Ariz.), Fall 1999, at 8, 10–11 (describing useful documents and procedures for tracking down facts during litigation to determine if a pressure ulcer was medically unavoidable); Paul W. Johnson & Veronica L. Armouti, *Pressure-Sore Litigation: An Overview*, 88 ILL. B.J. 336, 339–40, 343 (2000) (same).

35 Under the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b) (1994), individuals can also sue on behalf of the government to recover monies from false claims. This, in effect, makes every family member a watchdog capable of acting under the FCA to remedy their loved one's situation. *See, e.g.*, David J. Ryan, *The False Claims Act: An Old Weapon with New Firepower Is Aimed at Health Care Fraud*, 4 ANNALS HEALTH L. 127, 127 (1995) ("Once a figure of the Old West, the bounty hunter has appeared on the horizon in the fight against health care fraud. Armed with the False Claims Act (FCA), today's bounty hunter seeks out instances of fraud against Medicare and other federal programs." (citation omitted)). There is also no private cause of action under the Nursing Home Reform Act. *See* Robert

Pressure ulcers are an almost completely preventable and avoidable ailment.[36] As such, poor care and neglect[37] resulting in pressure ulcers unnecessarily inflict a gross amount of grief and suffering on hundreds of thousands of elderly citizens annually. Holding nursing facilities more strictly accountable for substandard skin care under the FCA would greatly benefit patients by both encouraging nursing facilities to provide quality care and deterring nursing facilities from allowing quality care to deteriorate.[38] Vigorously prosecuting nursing

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Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 141 (1999) (stating that using the FCA as an enforcement vehicle would create a private right to enforce the Nursing Home Reform Act).

36 *See, e.g.*, *AHCPR Guideline*, BROWN U. LONG-TERM CARE QUALITY ADVISOR, Mar. 31, 1997, at 4, 4 ("Most pressure ulcers can be prevented, and those stage one pressure ulcers that do appear need not worsen under most circumstances."), *available at* 1997 WL 9884335; Michael Kosiak, *Prevention and Rehabilitation of Pressure Ulcers*, DECUBITUS, May 1991, at 60, 62–68 ("Pressure ulcers are entirely preventable. They need not and should not occur."); Kenneth Olshansky, *Essay on Knowledge, Caring, and Psychological Factors in Prevention and Treatment of Pressure Ulcers*, 7 ADVANCES WOUND CARE 64, 64–65 (1994) (contending that "[Dr. Kosiak] is *absolutely* correct" and suggesting that "the major determinant of pressure ulcer development is not how sick the patient is, but how good the caregivers are" (emphasis omitted)). By contrast, Fabrikant and Solomon suggest that an absolutist view—proper care can prevent all pressure ulcers—does not comport with opinions of medical professionals in the field. *See* Fabrikant & Solomon, *supra* note 35, at 147 n.228. Citing MAKLEBURST & SIEGGREEN, *supra* note 9, at 14–15, Fabrikant and Solomon characterize the following as obvious misconceptions: all pressure ulcers develop because of poor nursing care, and all pressure ulcers are curable. Fabrikant & Solomon, *supra* note 35, at 147 n.228. Granted, Makleburst and Sieggreen do point out these misconceptions; however, Fabrikant and Solomon fail to elaborate on why Makleburst and Sieggreen label these statements as misconceptions. As far as "poor nursing," Makleburst and Seiggreen simply point out that "nurses" are not solely to blame for pressure ulcers; care from many providers in the continuum of care may contribute to pressure ulcers. MAKLEBURST & SIEGGREEN, *supra* note 9, at 14–15. Makleburst and Sieggreen also concede that not all pressure ulcers are preventable, but they provide examples demonstrating that they consider the unpreventable pressure ulcer a rarity, not the norm. Their examples of unpreventable pressure ulcers are not hundreds of thousands of patients bed-bound in nursing facilities; their examples are a patient in an extended coma, or a patient who fell at home and lay in the same position for a long period of time on a hard surface. *Id.* These patients, they say, *might* develop a pressure ulcer. *Id.* Saying that pressure ulcers are one hundred percent preventable might not comport with Makleburst and Sieggreen's statements, but saying that pressure ulcers are more than ninety-nine percent preventable most probably would.

37 Nat'l Citizens' Coalition for Nursing Home Reform, *Abuse and Neglect*, *at* http://www.nccnhr.org/public/50_156_450.cfm (last visited Jan. 25, 2002) (categorizing pressure ulcers and skin breakdown as both neglect and abuse).

38 *See* Hoffman, *supra* note 3, at 156; Mary DuBois Krohn, Comment, *The False Claims Act and Managed Care: Blowing the Whistle on Underutilization*, 28 CUMB. L. REV. 443, 468 (1998) ("What the FCA can do is uncover and deter fraudulent underutilization in federal managed care plans. Although this may be a limited role in the battle against managed care fraud, it is an extremely significant one."). *But see* Fabrikant & Solomon, *supra* note 35, at 106 ("From a policy perspective, the FCA is a poor and unnecessary weapon against substandard care. It is a poor weapon because it is far too blunt and because it simply makes no sense for federal prosecutors, no matter how well intentioned or expert, to establish clinical care norms."). Although Fabrikant and Solomon may be ultimately right in one respect—that the FCA can be a blunt weapon—its sheer power and deterrent capabil-

facilities for false claims when those facilities bill for care that fails to meet government specifications also benefits both the government[39] and the providers.[40] For example, the government could better trust that patients in nursing facilities would receive quality skin care, and providers would clearly understand what the government expects.[41] A provider would understand when the government will hold it accountable without being mandated by the government, in a "big brother" fashion, with respect to how it cares for its patients, provided it does so within agreed specifications.[42]

Currently, the United States Attorney's Office for the Eastern District of Pennsylvania, concentrating on nutrition and pressure ulcer care, has prosecuted four claims under this theory, which all ended in quick settlements: *United States v. Mercy Douglass Center Inc.*,[43] *United States v. City of Philadelphia*,[44] *United States v. Chester Care Center*,[45] and *United States v. GMS Management-Tucker, Inc.*[46] Significant scholarship exists on these cases and the bellwether effects of using the FCA to prosecute substandard care in nursing facilities.[47]

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ity can contribute greatly in deterring substandard care in powerful and wealthy multibillion-dollar enterprises like the nursing home industry.

39 Hoffman, *supra* note 3, at 156; *see also* Loretta Calvert, *The* Qui Tam *Provision of the False Claims Act: Congressional Missile or a Net Full of Holes*, 1998 ANN. SURV. AM. L. 435, 436 (1998) ("Unfortunately, the cost of government contractor corruption goes beyond poor quality goods or 'dollars and cents.' Corruption prevents the government from efficiently managing programs, 'erodes public confidence,' and poses 'not only a serious threat to human life but also to national security.'" (internal citations omitted)).

40 Barbara J. Gagel, *Health Care Quality Improvement Program: A New Approach (New Initiatives and Approaches in Health Care Quality)*, HEALTH CARE FINANCING REV., June 1, 1995, at 15, 20.

41 *Id.*; *see also* Constantinos I. Miskis & William F. Sutton, Jr., *Enforcing Quality Standards in Long-Term Care: The False Claims Act and Other Remedies*, FLA. B.J., June 1999, at 108, 111 (illustrating the benefit of clear expectations and standards for quality of care).

42 Gagel, *supra* note 40, at 17.

43 Consent Order and Judgment, No. 00-CV-3471 (E.D. Pa. July 14, 2000), *available at* http://www.usao-edpa.com/Invest/nursing/mercy2.pdf.

44 Settlement Agreement, No. 98-4253 (E.D. Pa. Aug. 14, 1998), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf.

45 Consent Order and Judgment, No. 98CV-139, 1998 U.S. Dist. LEXIS 4836 (E.D. Pa. Feb. 4, 1998).

46 Consent Order, No. 96-1271 (E.D. Pa. Mar. 6, 1996), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf.

47 *See, e.g.*, Hoffman, *supra* note 3; John R. Munich & Elizabeth W. Lane, *When Neglect Becomes Fraud: Quality of Care and False Claims*, 43 ST. LOUIS U. L.J. 27, 41 (1999) (discussing *United States v. GMS Management-Tucker, Inc.* and *United States v. Chester Care Center* and noting that in both cases, "[t]he government's case was sufficiently compelling and the risk for the provider so great that the parties settled on the day the complaint was filed"); Kathleen A. Peterson, Note, *First Nursing Homes, Next Managed Care?: Limiting Liability in Quality of Care Cases Under the False Claims Act*, 26 AM. J.L. & MED. 69, 74–81 (2000). *But see* Michael M. Mustokoff et al., *The Government's Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Ingenuity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANNALS HEALTH L. 137, 145 (1997) (arguing that undue expansion of the FCA by the government—not whether or

Significant scholarship also exists discussing the policy questions and problems associated with using the FCA to ensure quality care for nursing facility residents.[48] By building on the foundation of this scholarship and presenting specifics, we can move ahead with FCA cases based solely on the substandard treatment of pressure ulcers, i.e., substandard skin care, and make a marked difference in the skin care our elderly receive.

With sixty thousand elderly men and women dying annually because of complications from pressure ulcers, the problem has risen to epidemic proportions.[49] For comparison's sake, consider if, instead of the elderly, it were newborns dying by the tens-of-thousands from open wounds caused by their caregivers. Or consider the response if

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not quality of care for Medicaid patients should be protected—was the ultimate issue in *GMS Management-Tucker*). The authors of this article represented Tucker House II, the defendant nursing home in *GMS Management-Tucker*. *Id.* at 137.

48 *See, e.g.*, John T. Boese, *When Angry Patients Become Angry Prosecutors: Medical Necessity Determinations, Quality of Care and the* Qui Tam *Law*, 43 ST. LOUIS U. L.J. 53, 68–79 (1999) (discussing how managed care providers can lessen liability from disgruntled patients suing under the *qui tam* provision of the FCA); Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57 (1999) (discussing why health care fraud can be unusually difficult to prove); Fabrikant & Solomon, *supra* note 35, at 147–60 (arguing against using the FCA to punish care below the standards enumerated in regulations); Thomas Grande, *The False Claims Act: A Consumer's Tool to Combat Fraud Against the Government*, 12 LOY. CONSUMER L. REV. 129, 143–45 (2000) (discussing how false claims affect the quality and delivery of health services); David C. Hsia, *Application of* Qui Tam *to the Quality of Health* Care, 14 J. LEGAL MED. 301 (1993) (addressing false claims and the non-delivery of health care services); Terri D. Keville et al., *Recent Developments in Long-Term Care Law and Litigation*, 20 WHITTIER L. REV. 325, 341–44 (1998) (discussing the False Claims Act and long-term care); Munich & Lane, *supra* note 47, at 39–42 (analyzing three cases that used the FCA as a vehicle to improve quality of care); Mustokoff et al., *supra* note 47, at 144 (concluding that the FCA is an "exploding canister of a fraud statute" and the "statutory equivalent of a Saturday night special available to any gunslinger able to spell 'qui tam'"); Ryan, *supra* note 35, at 127 (pointing out the similarities between bounty hunters and litigants who use the FCA to fight health care fraud); Michael R. Dorfman, Note, *Qui Tam: Fighting the Uphill Battle Against Health Care Fraud*, 77 U. DET. MERCY L. REV. 927, 949–55 (2000) (discussing how *qui tam* suits under the FCA can help in the fight against health care fraud); Krohn, *supra* note 38, at 472 ("The FCA phenomenon is not a passing fad. As more companies settle FCA claims and cooperate with Government investigations, law enforcement officials must realize how pervasive health care fraud is and how effective the FCA is in detecting and deterring it."); Carolyn J. Paschke, Note, *The* Qui Tam *Provision of the Federal False Claims Act: The Statute in Current Form, Its History and Its Unique Position to Influence the Health Care Industry*, 9 J.L. & HEALTH 163, 186 (1994–95) (concluding that the False Claims Act "has potential to provide an additional service to the public by influencing the quality of care provided to Medicare and Medicaid recipients"); Peterson, *supra* note 47, at 88 (concluding that although cases permit plaintiffs "to bring quality of care suits under the FCA, based upon noncompliance with federal regulations," the best FCA defensive strategy will be for health care organizations to implement effective quality assurance programs); Patrick A. Scheiderer, Note, *Medical Malpractice as a Basis for a False Claims Action?*, 33 IND. L. REV. 1077, 1098 (2000) (arguing that the "FCA should not be used to help ensure that individuals who are provided government-funded health care receive quality health care").

49 Thomas-Hess, *supra* note 26, at 31.

instead of wounds that an individual must endure alone, pressure ulcers were a contagious affliction, threatening to harm all who encountered the afflicted. Over 1.5 million of our elderly live in nursing facilities.[50] Someone must protect them and their rights to be without unnecessary wounds in the twilight of their lives. This Note provides a vehicle by which to protect those rights, and hopefully, it provides a springboard by which others can pursue similar suits.[51]

I
THE LEGAL MILIEU TO POLICE SKIN CARE IN NURSING FACILITIES

A. Basic Parameters of the Milieu

A milieu of statutes,[52] agency regulations,[53] and agency research and action[54] creates a well-honed tool for policing skin care provided to nursing facility residents. The components of the milieu include: the Agency for Healthcare Research and Quality, the Nursing Home Reform Act (NHRA), the Health Care Financing Administration, and the False Claims Act. The Agency for Healthcare Research and Quality (AHRQ) provides the government with an opinion on what care is effective and efficient.[55] Its opinion forms a baseline for quality care

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50 *See* Klitch, *supra* note 18, at 15.

51 During my time as Director of Operations at Medical Resources, I had the opportunity to pursue this line of litigation—false claims and pressure ulcers—with several interested parties. Although I am no longer a part of these activities (mostly because of the time commitment of law school), I have kept in touch with my colleagues. When I wrote this Note, I knew of at least one corporation forming in the Southwest—and there may be more—that specifically aimed to sue nursing facilities via the *qui tam* provision of the FCA. Its main goal was to move forward from the foundation that Assistant U.S. Attorney Hoffman laid in the Eastern District of Pennsylvania, and to police conditions like pressure ulcers in nursing facilities.

52 *See, e.g.*, 42 U.S.C. § 1396r(b)(1)–(2) (1994) ("A nursing facility must . . . maintain the highest practicable physical, mental, and psychosocial well-being of each resident . . . ."); *id.* § 1320c-5(a)(1)–(2) ("It shall be the obligation of any health care practitioner . . . to assure . . . that services or items ordered or provided . . . will be provided economically and . . . will be of a quality which meets professionally recognized standards of health care . . . .").

53 *See, e.g.*, 42 C.F.R. § 483.25 (2000) ("Quality of care").

54 *E.g.*, AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 12; *see also, e.g.*, Consent Order and Judgment, United States v. Chester Care Ctr., No. 98CV-139, 1998 U.S. Dist. LEXIS 4836, at *21 (E.D. Pa. Feb. 4, 1998) (incorporating Agency for Health Care Policy and Research clinical practice guidelines into a consent order and judgment involving a facility charged with substandard care); Settlement Agreement, United States v. City of Philadelphia, No. 98-4253 (E.D. Pa. Aug. 14, 1998) (incorporating Agency for Health Care Policy and Research clinical practice guidelines into a settlement agreement involving a facility charged with substandard care), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf.

55 145 CONG. REC. E2526 (daily ed. Nov. 19, 1999) (statement of Rep. Bliley) ("[T]he agency's mission [is] to become the focal point for supporting federal health care research and quality improvement activities.").

in federal programs, i.e., the threshold for professional standards of quality.[56] The NHRA requires that providers give care that meets professional standards of quality.[57] This statutory language represents a minimum specified standard that the provider must fulfill in order to participate in, or contract with, federal healthcare programs.[58] The government requires providers to make sure that the care they provide is economical.[59] Every time providers bill HCFA, they certify that the health care services they provide "will be of a quality which meets professionally recognized standards of health care."[60] Therefore, if a provider provides patients with substandard care, but certifies that it provided quality care, that mistruth potentially triggers liability under the FCA.[61]

This argument not only protects the federal treasury from false claims, but it also allows the government, in federally funded healthcare programs like Medicare and Medicaid, to police the minimum standard of care with the FCA.[62] Ultimately, liability under the FCA should decrease the amount of government funds squandered in payments for substandard care.[63] As courts find more nursing facilities

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56 *See, e.g.*, Am. Med. Dirs. Ass'n, *Pressure Ulcers* (1996), *available at* http://www.guideline.gov; Univ. of Iowa Gerontological Nursing Interventions Research Ctr., *Treatment of Pressure Ulcers* (1997), *available at* http://www.guideline.gov; Univ. of Iowa Gerontological Nursing Interventions Research Ctr., *Prevention of Pressure Ulcers* (1997), *available at* http://www.guideline.gov. These practice guidelines are all adapted from previous AHCPR Clinical Guidelines.

57 42 U.S.C. § 1396r(b)(4)(A) (1994).

58 *See* United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1488 (W.D. Okla. 1996) ("Statutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider's failure to meet such standards is a ground for exclusion from the program.").

59 42 U.S.C. § 1320c-5(a)(1) (1994); *see also* United States *ex rel.* Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass. 2000) ("[T]he entitlement to Medicare reimbursement depends upon fulfilling an obligation to perform services economically . . . ." (citing 42 U.S.C. 1320c-5(a)(1) (1994))).

60 42 U.S.C. § 1320c-5(a)(2) (1994).

61 Hoffman, *supra* note 3, at 156 ("If long-term care facilities exhibit gross negligence in the provision of care to our elderly, and we, the taxpayers, are paying for this care through the Medicare and Medicaid programs, simply stated, there is the potential for False Claims Act liability."); *see also* Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732 (7th Cir.) ("[A] claim can be false or fraudulent if the speaker offers a misleading half-truth."), *cert. denied*, 528 U.S. 1038 (1999); United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1155 (W.D. Mo. 2000) ("[A] health care provider can be held to have impliedly certified that it will comply with the relevant standard of care as set forth in the regulations and statutes if that standard of care lies at the core of the parties' agreement."); United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1048 (S.D. Tex. 1998) ("[S]ubmission of such claims for services that were statutorily ineligible for payment under the Medicare Act constitutes a false claim . . . .").

62 *See* Hoffman, *supra* note 3, at 156; *see also* S. REP. No. 99-345, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269 ("[T]he False Claims Act is a . . . powerful tool in deterring fraud.").

63 *See* S. REP. No. 99-345, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269; *see also* Hoffman, *supra* note 3, at 156 ("The . . . False Claims Act is another weapon available to the

liable, the quality of care should increase because liability will have a two-fold effect. First, offending nursing facilities will increase the quality of skin care they provide. Second, non-offending nursing facilities will not allow their quality of skin care to deteriorate.

B. The Nursing Home Reform Act of 1987

When considering federal action to increase patient care in general, and to eradicate pressure ulcers in particular, it is important for the statutory framework to support and mandate a higher standard of care. Congress passed the Omnibus Budget Reconciliation Act of 1987 on December 21, 1987, which President Reagan subsequently signed into law on December 22, 1987.[64] Title IV, subtitle C of that Act comprises the Nursing Home Reform Act of 1987.[65] Part 2 of the NHRA concentrates on improving nursing facilities in the Medicaid program.[66] In general, this Act requires nursing facilities[67] to protect and respect residents' rights[68] and to promote residents' quality of life.[69] The Act also requires that resident care meet "professional standards."[70]

1. *Congressional Purpose Behind the NHRA*

Congress wanted to respond to a regnlatory scheme that failed to adequately protect nursing facility residents.[71] Before the NHRA,

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government to combat inappropriate behavior, and it will be pointed at those who choose profits over good care, neglect over concern, and greed over compassion when caring for nursing home residents.").

64 Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 (codified in scattered sections of the U.S.C.).

65 *Id.* §§ 4201–4218, 101 Stat. at 1330-160 to 1330-220 (codified as amended in scattered sections of 42 U.S.C. (1994 & Supp. V 1999)).

66 *Id.* § 4211, 101 Stat. at 1330-182 (codified as amended at 42 U.S.C. §§ 1396r, 1396r-3, 1396s (1994 & Supp. V 1999)).

67 "Nursing home" is a common, everyday term for a long-term care facility. The government uses the more precise terms of "Skilled Nursing Facility" and "Nursing Facility" to differentiate between the programs most common in long-term care. Skilled Nursing Facilities provide long-term acute (critical or life-threatening) care under the Medicare program. 42 U.S.C. § 1395i-3 (1994 & Supp. V 1999). Nursing Facilities provide non-acute (institutional daily assisted living) care under the Medicaid program. *Id.* § 1396r (1994 & Supp. V 1999). The federal government provides funds for both Medicare and Medicaid. Medicare is solely federally funded, *id.* § 1395i-1 (1994), whereas Medicaid receives a mix of federal and state monies, *see generally id.* §§ 1396–1396v (laying out the statutory framework of the Medicaid program).

68 *Id.* § 1396r(c) (1994 & Supp. V 1999).

69 *Id.* § 1396r(b)(1) (1994) ("A nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.").

70 *Id.* § 1396r(d)(4)(A) (Supp. V 1999) ("A nursing facility must operate and provide services in compliance with all Federal, State and local laws and regulations . . . and with accepted professional standards and principles . . . .").

71 *See* 133 CONG. REC. 17,612 (1987) (statement of Rep. Stark).

Medicare and Medicaid participation standards focused on whether the facility could provide the type of care required—for example, whether the nursing facility staff were trained and equipped to heal and prevent pressure ulcers. As part of the NHRA, Congress shifted the focus of the participation standards instead to the quality of care actually provided—for example, whether the nursing facility actually healed and prevented ulcers.[72] Congress intended to curb a trend in "shockingly deficient" care that could greatly exacerbate a patient's medical problems and in some instances lead to death.[73] The legislators wanted to reverse the fact that, at the time, there were more "'poor-quality'" homes than "'very good homes.'"[74]

Congress further intended that the legislation protect federal funds. Forty percent or more of all Medicaid dollars come from the federal government.[75] The NHRA increased enforcement procedures to protect these funds by expanding state and federal governments' powers to terminate Medicare participation agreements with, or to stop payments for new patients to, those facilities that failed to comply with the reforms.[76]

The NHRA grew out of a House resolution introduced by Representative Dingell in May 1987.[77] This resolution directly addressed many of the deficiencies in the nursing facility industry that the Institute of Medicine unmasked in its 1986 report, *Improving the Quality of Care in Nursing Homes*.[78] Specifically, the Institute recommended—and the resolution adopted the recommendation—that federal programs should stress quality of care, which includes skin care to maintain skin integrity, and that residents' rights and quality of life should become prerequisites for facilities to participate in the Medicaid program.[79]

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72 *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 20, at 5.

73 *See* 133 CONG. REC. 17,612 (1987) (statement of Rep. Stark).

74 *Id.* at 11,299 (statement of Rep. Waxman) (quoting a 1986 study by the Institute of Medicine); *see infra* note 79 and accompanying text.

75 *Id.*

76 *See* 42 U.S.C. § 1396r(h)(1)(B), (2)(A)(i), (3)(C)(i) (1994); *see also* U.S. GEN. ACCOUNTING OFFICE, *supra* note 20, at 5–8 (showing that the 1987 Omnibus Budget Reconciliation Act expanded denial-of-payment sanctions for nursing facilities).

77 *See* H.R. 2270, 100th Cong. (1987).

78 INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES (1986).

79 R. Bruce Gebhardt, *National Academy of Sciences Report on Nursing Home Regulation*, NURSING HOMES, May–June 1986, at 18, 18–19. Later, HCFA further defined these rights to include maintaining one's dignity, making one's own choices—including choices about health care—and the ability to communicate with personnel within the facility and with others outside the facility. 42 C.F.R. § 483.15 (2000). Quality of life also includes allowing the resident to participate in activities at the facility, *id.* § 483.15(c)–(d), accommodating her needs, *id.* § 483.15(e), and providing a safe and clean environment, *id.* § 483.15(h).

2. *Relevant Provisions of the NHRA*

Of particular interest is the fact that the NHRA expressly conditions payment on provision of quality care. First, the Act mandates that each state establish a method to deny payment for substandard care of any patient admitted to a nursing facility.[80] Second, it specifies that the Secretary of Health and Human Services can deny further payments to a state for inadequate care furnished by a nursing facility.[81] Both of these provisions specifically contain the phrase "denial of payment."[82]

By providing for the denial of payment for substandard care, the NHRA helps protect against a specific type of evil: the mistreatment or substandard treatment of nursing facility residents.[83] If a statute creates a remedy for a specific type of evil, that remedy may also address comparable evils.[84] Consequently, the NHRA also protects against a comparable, related evil: pilfering federal funds by providing care that does not meet the statutory standards.[85] Therefore, the "denial of payment" language allows the federal government to require a nursing facility to provide quality care before the government will pay for that care.[86]

3. *Consequences of the NHRA*

Over time, Congress began to see some benefit from the NHRA. In 1995, one sponsor hailed it as a law that "provide[s] for the most basic and minimum standard of care for the most frail and most vulnerable among us."[87] He quoted improvements such as a fifty-percent reduction in dehydration problems and thirty thousand fewer patients with pressure ulcers.[88] Current data, however, point to the need for better enforcement of quality-of-care requirements. By 2030, estimates project that the number of people in the United States aged

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80 42 U.S.C. § 1396r(h)(2)(A)(i) (1994).

81 *Id.* § 1396r(h)(3)(C)(i).

82 *Id.* § 1396r(h)(2)(A)(i), (3)(C)(i).

83 *See* 133 CONG. REC. 11,299 (1987) (statement of Rep. Waxman).

84 *Cf.* Oncale v. Sundowner Offshore Servs., Inc., 523 U.S. 75, 79 (1998) ("[S]tatutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.").

85 *Cf.* 42 U.S.C. § 1320c-5(a) (1994) (demonstrating a general concern that all providers and facilities receiving payment from federal programs must provide care economically and within professional standards of quality).

86 *See id.*; *see also* Munich & Lane, *supra* note 47, at 46 ("If . . . compliance . . . is a prerequisite to obtaining a government benefit, false certifications of compliance may create liability." (footnote omitted)).

87 141 CONG. REC. 27,512 (1995) (statement of Sen. Pryor).

88 *Id.* at 27,514 (statement of Sen. Pryor).

sixty-five years and older will exceed 70 million.[89] While HCFA—the agency charged with implementing the NHRA—has made strides in oversight, it cannot yet ensure that nursing facilities fully comply with federal standards.[90]

For example, from January 1997 to October 1998, out of approximately 17,000 facilities, officials cited 2809 nursing facilities for inadequate attention to prevent pressure ulcers, 1171 for failure to provide adequate nutrition, and 510 for failure to maintain a resident's dignity.[91] In addition, government studies demonstrate that sanctions only induce temporary compliance: in a study of seventy-four homes referred to HCFA for sanctions, sixty-nine were again referred for sanctions during a follow-up inspection.[92] Current enforcement mechanisms, therefore, inadvertently send the message to noncompliant nursing facilities that continued or repeated noncompliance "carries few consequences."[93] These statistics and findings indicate that HCFA and the federal government would greatly benefit from enforcement tools beyond the sanctions provided for in the NHRA.[94] The False Claims Act is the necessary tool with the power to fill that void.

C. The Health Care Financing Administration

While the Nursing Home Reform Act of 1987 provides the foundation for the government's quality-care policies for nursing facilities, the Health Care Financing Administration provides the detailed regulations that manipulate and implement this policy. Congress created HCFA in 1977 to bring the main federal health care programs—Medicare and Medicaid—under one management umbrella.[95] Medicaid is a joint federal and state program; each state runs its own program,

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89 Admin. on Aging, U.S. Dep't of Health & Human Servs., *Profile of Older Americans: 2000*, *available at* http://www.aoa.dhhs.gov/aoa/stats/profile/default.htm.

90 U.S. GEN. ACCOUNTING OFFICE, *supra* note 20, at 2.

91 *Id.* at 3, 11 tbl.4.

92 *See id.* at 13.

93 *Id.* at 23.

94 In general, it is important to note that the NHRA does not contain a private cause of action. Only the federal government, through administrative actions, can bring an action against a deficient nursing facility. However, the *qui tam* provision of the FCA creates an avenue for a private cause of action in which private litigants can sue deficient nursing facilities for substandard care. *See* Fabrikant & Solomon, *supra* note 35, at 141; *see also* Pamela H. Bucy, *Civil Prosecution of Health Care Fraud*, 30 WAKE FOREST L. REV. 693, 757 (1995) (concluding that a "mix of civil and administrative remedies [including the FCA] created to combat health care fraud is unique, but it is especially appropriate for a field such as health care which is heavily regulated and in which criminal prosecution is difficult").

95 HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. HCFA-02135, STRATEGIC PLAN (1998), *available at* http://www.hcfa.gov/about/agency/sp/sp_final.htm.

and the federal government supplies the majority of the funding as well as some supervision.[96] Spending in the Medicaid program has risen from $3.9 billion in 1968 to more than $178 billion in 1998.[97] In 1996, Medicaid cost approximately $163 billion, of which the federal government paid $92 billion, or about 55 percent.[98] In general, HCFA is the "single largest purchaser of health care in the world."[99] It pays for approximately one-third of the entire annual health care bill in the United States.[100]

HCFA realizes its stature in the market and its responsibilities to many beneficiaries.[101] As a result, it has set improving management over its public funds, improving care, and "protect[ing] beneficiaries from substandard care" as some of its main priorities and objectives.[102] In order to facilitate these goals, HCFA seeks to prosecute substandard care using "all legal remedies available."[103] In the last four to five years, by "aggressive enforcement" of statutes and regulations, HCFA has recovered approximately $1.9 billion.[104] The False Claims Act is a necessary component to continue and greatly enhance this recovery trend. HCFA also acknowledges that these successes come from cooperating with other Health and Human Services agencies, such as the Agency for Health Care Policy and Research,[105] and federal law enforcement officials.[106]

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96 *Medicare Fraud and Abuse: Hearing Before the Subcomm. on Oversight and Investigations and Subcomm. on Health & Env't of the House Commerce Comm.*, 106th Cong. (1999) (testimony of Penny Thompson, Program Integrity Director, and Rhonda Hall, Medicaid Fraud & Abuse National Coordinator, Health Care Financing Admin.), *available at* http://www.hcfa.gov/testmony/1999/991109.htm.

97 Heath Care Fin. Admin., *Medicaid Alliance for Program Safeguards, at* http://www.hcfa.gov/medicaid/fraud (last visited Jan. 31, 2002).

98 Press Release, Health Care Financing Administration, Fact Sheet (Feb. 1997), *available at* http://www.hcfa.gov/facts/f9702b.htm (last visited Jan. 31, 2002).

99 *Medicare Program: Improper Payments & Fraud: Statement for the Record to the Health Task Force of the House Budget Comm.*, 106th Cong. (2000) (statement of Office of Inspector General, Dep't of Health & Human Servs.), *available at* http://www.oig.hhs.gov/testimony/00712fin.htm.

100 *See Medicare Waste, Fraud & Abuse: Hearing Before the Subcomm. on Labor, Health and Human Servs., Education of the Senate Appropriations Comm.*, 106th Cong. (2000) (statement of June Gibbs Brown, Inspector General, Dep't of Health & Human Servs.), *available at* http://oig.hhs.gov/testimony/00309fin.htm.

101 *See* HEALTH CARE FIN. ADMIN., *supra* note 95.

102 *Id.*

103 *Id.*; *see also* 42 C.F.R. § 1001.701 (2000) (allowing the Office of Inspector General to exclude a provider from federal health care programs for furnishing substandard services and items); *id.* § 1001.901 (allowing the Office of Inspector General to exclude any provider for submitting false claims).

104 Press Release, U.S. Dep't of Health & Human Servs., A Comprehensive Strategy to Fight Health Care Waste, Fraud and Abuse (Mar. 9, 2000), *available at* http://www.hhs.gov/news/press/2000pres/20000309a.html.

105 *See* HEALTH CARE FIN. ADMIN., *supra* note 95, at 13.

106 *See* Press Release, *supra* note 104, at 1.

HCFA promulgates specific rules and regulations that outline the standards which a nursing facility must meet in order to participate in the Medicaid program.[107] The regulations require a nursing facility to protect and promote the rights of each resident[108] and address matters of quality of life[109] and quality of care.[110] These rights include the right of every resident to retain her dignity, make her own choices—including about her care—and to be able to communicate with personnel within the facility and others outside the facility.[111] The Nursing Home Reform Act also mandates, and HCFA regulations specifically state, that nursing facilities must provide quality care.[112] The HCFA regulations explain in some detail what quality of care entails.[113] Quality care ensures a resident's ability to perform daily living tasks, including bathing, toiletting, and eating, will not decline unless decline is unavoidable.[114] It secures good nutrition, cleanliness, and requires the facility to attend to urinary incontinence.[115] Most importantly, quality care mandates that an entering patient without pressure ulcers will not develop pressure ulcers unless they are clinically unavoidable, and that the facility will treat a patient's pressure ulcers at the time of admission and prevent new ulcers from forming.[116] In sum, the nursing facility must demonstrate that it can provide quality care and then demonstrate that it has continued to provide for all the residents' needs before it can participate in the program and receive federal funds for the specific care it provided.

D. The Agency for Healthcare Research and Quality

Congress created the Agency for Healthcare Research and Quality to provide the best information to other federal agencies in order to establish a minimum threshold for proper care of federally funded patients. To understand these purposes fully, it is important to examine the history of the Agency for Health Care Policy and Research, which became the AHRQ, and the development and eventual criticism of the Clinical Practice Guidelines.

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107 42 C.F.R. § 483.1(b) (2000) ("The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as . . . a nursing facility in the Medicaid program.").

108 *Id.* § 483.10.

109 *Id.* § 483.15.

110 *Id.* § 483.25.

111 *Id.* § 483.15.

112 *Id.* § 483.25.

113 *See generally id.* ("Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.").

114 *Id.* § 483.25(a)(1).

115 *Id.* § 483.25(a)(3), (d), (i).

116 *Id.* § 483.25(c).

1. *Genesis in the Agency for Health Care Policy and Research*

In 1989, via the Omnibus Budget Reconciliation Act, Congress established the Agency for Health Care Policy and Research.[117] The legislators designed the agency to be the resident expert on health care quality issues[118]—like pressure ulcers. The agency was to research quality, effectiveness, and the outcome of the health care provided throughout the nation to try to improve health care services and policy in the United States.[119] Ultimately, Congress envisioned an agency with "enhanced stature" comparable in "scientific prominence" to the National Institutes of Health.[120]

To facilitate its mission, Congress authorized the AHCPR to compile and publish clinical practice guidelines and health care standards.[121] These guidelines were to include treatment and medical-condition-specific information for quality review purposes.[122] The agency was to develop these guidelines through consensus-building with prominent health care professionals and to base the guidelines upon the best available information and research.[123] The AHCPR's creators intended that the gnidelines would translate extensive federal research into information that clinicians could use.[124] By 1995, the agency had published nineteen guidelines,[125] including two on pressure ulcers.[126]

While many clinicians still welcome guidelines—and their possible proliferation over widely used sources like the Internet—as a genuine improvement in medicine that provide physicians with

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117 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103(a), 103 Stat. 2106, 2189 (codified as amended at 42 U.S.C. § 299 (Supp. V 1999)).

118 *See* 135 CONG. REC. E2107 (daily ed. June 13, 1989) (statement of Rep. Waxman); *see also* 141 CONG. REC. 14623 (1995) (statement of Sen. Rockefeller) ("Congress gave AHCPR the following mission: 'to enhance the quality, appropriateness and effectiveness of health care service and access to such services . . . .'" (quoting sec. 6103, § 901(b), 103 Stat. at 2189 (codified as amended at 42 U.S.C. § 299(b) (Supp. V 1999)))).

119 *See* 42 U.S.C. § 299(b) (1994 & Supp. V 1999); *see also* 141 CONG. REC. 14623 (1995) (statement of Sen. Rockefeller) (discussing the agency's mission and accomplishments).

120 135 CONG. REC. E2107 (daily ed. June 13, 1989) (statement of Rep. Waxman).

121 42 U.S.C. §§ 299a-1(a)(1), 299b-1(a) (1994 & Supp. V 1999).

122 135 CONG. REC. E2107 (daily ed. June 13, 1989) (statement of Rep. Waxman).

123 *Id.*; *see* 42 U.S.C. § 299b-1(b)(1) (1994) (current version at 42 U.S.C. § 299b (Supp. V 1999)).

124 *See* 135 CONG. REC. E2107 (daily ed. June 13, 1989) (statement of Rep. Waxman).

125 *Reauthorization of the Agency for Health Care Policy and Research: Hearing Before the Subcomm. on Health and Env't of the House Comm. on Commerce*, 106th Cong. 24 (1999) (testimony of John M. Eisenberg, Administrator, Agency for Health Care Policy and Research) [hereinafter *Hearing*].

126 *See* AGENCY FOR HEALTH CARE POLICY & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 92-0047, PRESSURE ULCERS IN ADULTS: PREDICTION AND PREVENTION, CLINICAL PRACTICE GUIDELINE NO. 3 (1992), *available at* http://hstat.nlm.nih.gov/tempfiles/is/tempD14990.html; AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 12.

authoritative sources grounded in substantial research,[127] critics refer to practice guidelines as "cookbook" medicine.[128] These guidelines, however, arguably represent a burgeoning consensus in the health care community that guidelines can define and measure minimum standards for quality care.[129] For example, other federal health agencies like the Health Care Financing Administration use these guidelines in reviewing expenditures in quality assurance programs.[130] Currently, HCFA does not promulgate its own treatment guidelines, but it does disseminate AHCPR clinical practice guidelines.[131] HCFA builds indicia of quality care from the guidelines—such as not placing a patient with an open pressure ulcer in a bubbling whirlpool where the jets can act as a water knife and remove any healing new-growth tissue[132]—and, when appropriate, uses those indicia to promulgate minimum treatment conditions for participating in Medicare and Medicaid.[133] Specifically, HCFA states that it "distribute[s] Agency for Health Care Policy and Research guidelines on pain management, pressure ulcer treatment, depression in primary care, and urinary incontinence to nursing homes."[134]

2. *Evolving into the Agency for Healthcare Research and Quality*

a. *The Halt in Promulgation of Practice Guidelines*

Despite these practical successes and because of criticism,[135] the Agency for Health Care Policy and Research eventually decided to stop producing guidelines.[136] In 1999, the agency's administrator empbasized that he did not envision the AHCPR setting national standards or mandating national clinical practices.[137] Rather, he envisioned the agency acting as a "science partner," providing the evidentiary research that others within the profession could use to develop the necessary practice guidelines.[138]

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127 Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?*, 25 AM. J.L. & MED. 403, 404 (1999).

128 *Id.* at 411–12.

129 *See, e.g.*, Gagel, *supra* note 40, at 17.

130 *Id.*; *see also* Agency for Healthcare Research & Quality, AHRQ Pub. No. 00-P016, *Medicare Uses of AHRQ Research: Translating Research into Practice* (Jan. 2000) (finding that AHRQ and AHCPR research helps to make "the Medicare program a prudent purchaser of high-quality care"), *available at* http://www.ahrq.gov/research/tripmedi.htm.

131 Gagel, *supra* note 40, at 20.

132 AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 12, at 15–16.

133 *See id.*

134 Gagel, *supra* note 40, at 20–21.

135 Furrow, *supra* note 127, at 411–12.

136 *See Hearing, supra* note 125, at 8 (testimony of John M. Eisenberg, Administrator, Agency for Health Care Policy and Research).

137 *See id.*

138 *Id.*

Congress agreed with this sentiment of limiting the agency's promulgation of future practice guidelines. On December 6, 1999, President Clinton signed the Healthcare Research and Quality Act of 1999 (HRQA)[139] into law.[140] The HRQA continued funding for the Agency for Health Care Policy and Research but renamed it the Agency for Healthcare Research and Quality.[141] The HRQA refocused the mission of the agency and cemented the agency's position as the expert on quality care.[142] The agency's mission was now to enhance the "quality, appropriateness, and effectiveness of health services" through the promotion and dissemination of scientific research.[143] Congress hoped that synthesizing and disseminating scientific information, not specific clinical practice guidelines, would improve health care.[144] Congress specifically stated that the AHRQ would no longer develop clinical practice guidelines.[145] Congress did not rescind, however, any of the existing guidelines—including those on pressure ulcers. Instead, the HRQA charges the agency with providing evidence to physicians, permitting physicians to develop guidelines without having the federal government dictate how they practice medicine.[146]

b. *The AHRQ's New Role in Research*

Although it blunted the agency's power to promulgate practice gnidelines, Congress did intend that the HRQA strengthen the role of the new Agency for Healthcare Research and Quality. It would allow the agency "a critical role as the hub and driving force for the Federal government's quality improvement efforts."[147] As the "hub" for the federal government's quality assurance programs, the AHRQ serves to inform and define health care standards within federal programs.

The HRQA does limit, however, the AHRQ's powers to set broad-reaching national standards of care. The HRQA directly and repeatedly states that the agency shall not mandate national standards. For instance, the HRQA specifically states that the "[a]gency shall not mandate national standards of clinical practice or quality health care

139 Healthcare Research and Quality Act of 1999, Pub. L. No. 106-129, 113 Stat. 1653 (codified as amended at 42 U.S.C. §§ 299–299c-7 (Supp. V 1999)).

140 *See* President's Statement on Signing the Healthcare Research and Quality Act of 1999, 35 WEEKLY COMP. PRES. DOC. 2524 (Dec. 13, 1999) [hereinafter *President's Statement*].

141 *Id.* at 2524.

142 *See id.*

143 42 U.S.C. § 299(b).

144 *See id.* § 299(b)(2).

145 *See* 42 U.S.C. § 299a(e)–(f) (mandating that the AHRQ not set national standards). *But see Hearing, supra* note 125, at 3 (prepared statement of Rep. Green, Member, Subcomm. on Health & Env't) ("[T]here is a great potential upside to having an agency solely dedicated to improving and updating the 'best practices' standards for care.").

146 142 CONG. REC. 11,712 (1996) (statement of Rep. Thomas).

147 H.R. REP. No. 106-305, at 16 (1999).

standards."[148] Also, the HRQA states that it should not be construed "to imply that the [a]gency's role is to mandate a national standard or specific approach to quality measurement and reporting."[149] Therefore, it is quite certain that Congress intended the AHRQ to dictate neither national standards of care nor measurement or reporting standards that mandate how nursing facilities, hospitals, and other providers must treat all patients. However, overreaching national standards of care are quite different from minimum standards for federal health care programs. The AHRQ is the proper body to help define the standards of health care for which the federal government, i.e., the consumer, should lawfully pay.

To determine and set these minimum standards, the HRQA specifically created the AHRQ as the lead agency, the "hub" in quality improvement in federal healthcare programs.[150] Because of the government's compelling need to manage federal health care programs more efficiently, Congress intended this expertise to radiate out and inform arrangements such as government health care contracts.[151] Ensuring the appropriate use of health care services is especially critical to Congress's efforts "to manage its [health care] programs more effectively and efficiently."[152] Part of that viability includes ensuring that nursing facilities provide care that meets "professional standards of quality,"[153] and the AHRQ is in the best position to inform that effort.

c. *Reconciling Congressional Intent*

The friction in this conclusion, however, resides in reconciling one congressional intent with another. On one hand, Congress intended to limit the Agency for Healthcare Research and Quality by forbidding it to mandate *national* standards of care.[154] On the other hand, to ensure cost-efficient use of federal resources, Congress mandated that the AHRQ coordinate all research related to "quality measurement and quality improvement activities undertaken and supported by the Federal Government."[155] The critical question is how can an agency coordinate quality measurement and quality im-

148 42 U.S.C. § 299a(e).

149 *Id.* § 299a(f).

150 *President's Statement, supra* note 140, at 2524; *see also* 42 U.S.C. § 299b-6(a) (setting forth the AHRQ's general mandate to "strengthen the management of Federal health care quality improvement programs").

151 *See* H.R. REP. No. 106-305, at 17.

152 *See id.*

153 42 U.S.C. §§ 1395i-3(b)(4)(A), 1396r(b) (1994).

154 *Id.* § 299a(e)–(f) (Supp. V 1999).

155 *Id.* § 299b-6(a)(1).

provement activities, but not mandate national standards to properly measure or to encourage improvement?

The answer lies in defining the scope of the agency's authority. Congress did not intend the AHRQ to set a national policy that told every doctor or clinician how to practice medicine.[156] Congress intended, however, that the agency set at least minimum standards for federal programs.[157] A physician or other clinician who wants to treat patients in federal programs should not expect to be paid from the federal coffers for care that the AHRQ finds inefficient or ineffective.[158]

Allowing the agency to define a minimum level of acceptable care for federal programs does not negate the Healthcare Research and Quality Act of 1999; rather, it fulfills the purpose of the statute.[159] The Act emphatically prevents the agency from mandating a single, national, uniform method of treatment by which every clinician must treat her patients.[160] In contrast, Congress intended the HRQA to fill the federal government's compelling need for information to ensure the viability of federal health care programs.[161] To this end, Congress wanted to promote a "renewed and reinvigorated" agency that, in a non-regulatory way, would be an expert in clinical care.[162] Other agencies like the Health Care Financing Administration follow this lead and already use the AHRQ's expertise to set guidelines for conditioning nursing facility participation in federal programs.[163] Allowing federal agencies to use AHRQ guidelines and expertise as a minimum standard of acceptable care in federal health care programs while still allowing myriad other treatments does not negate the HRQA by man-

156 *See* H.R. REP. No. 106-305, at 23 ("The Committee clearly intends that the [AHRQ] . . . should inform public policy, not make public policy.").

157 *See id.* at 17 ("[T]he Federal government has a compelling need for information that will help it to manage its programs more effectively and efficiently . . . .").

158 *See, e.g.*, Consent Order and Judgment, United States v. Chester Care Ctr., No. 98CV-139, 1998 U.S. Dist. LEXIS 4836, at *6–*8 (E.D. Pa. Feb. 4, 1998) (allowing settlements when a nursing facility agreed to perform wound care according to AHCPR guidelines); Consent Order, United States v. GMS Mgmt.-Tucker, Inc., No. 96-1271 (E.D. Pa. Mar. 6, 1996), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf.

159 *Cf.* N.Y. State Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 419–20 (1973) ("We cannot interpret federal statutes to negate their own stated purposes."); County of Wilson v. Nat'l Bank, 103 U.S. 770, 778 (1880) ("What is implied in a statute is as much a part of it as what is expressed."); Colo. Health Care Ass'n v. Colo. Dep't of Soc. Servs., 842 F.2d 1158, 1171 (10th Cir. 1988) (explaining that statutes should be interpreted to effectuate, not negate, congressional intent). *But see* Bates v. United States, 522 U.S. 23, 29 (1997) (reiterating that the Supreme Court "ordinarily resists reading words or elements into a statute that do not appear on its face").

160 *See* 42 U.S.C. § 299a(e)–(f).

161 *See* H.R. REP. No. 106-305, at 17–18 (1999).

162 *Id.* at 18.

163 *See* Gagel, *supra* note 40, at 20.

dating national standards. Instead, it brings to life one purpose of the statute—enhancing the cost-benefit ratio in federal health care programs—without reaching a result that the statutory language bars.

E. The False Claims Act

Although aggressive policing of payments in federal health care by sanctions and other methods has produced $1.9 billion in savings over the last four to five years,[164] estimated federal treasury losses to fraud approach $100 billion annually, or approximately $400 to $500 billion over the same time period.[165] The wide disparity between these two statistics indicates the need for a much more stringent approach to recover the remaining 99.8%. The False Claims Act is that tool.

In 1863, Congress adopted and President Abraham Lincoln signed into law the FCA[166] to deal with widespread fraud—such as "broken rifles, lame horses, and useless ammunition"[167]—that Civil War defense contractors perpetrated on the federal government.[168] In general, Congress intended that the FCA cover all claims submitted to the federal government for money, property, or services.[169] The FCA allows the government to recover triple the amount wrongly paid out, and between $5,000 and $10,000 in penalties for each claim.[170] The most common type of false claim occurs when a contractor charges the government for goods or services that the contractor did not actually provide, or "provided in violation of contract terms, specification, statute, or regulation."[171]

In an effort to reinvigorate the FCA and better allow the government to police claims, Congress enacted the False Claims Amend-

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164 *See* Press Release, *supra* note 104.

165 MALCOM K. SPARROW, LICENSE TO STEAL: WHY FRAUD PLAGUES AMERICA'S HEALTH CARE SYSTEM 2 (1996) (citing data from a Government Accounting Office report).

166 31 U.S.C. §§ 3729–3733 (1994) (originally enacted as Act of Mar. 2, 1863, 12 Stat. 696 ("An Act to prevent and punish Frauds upon the Government of the United States")).

167 132 CONG. REC. H22,339 (daily ed. Sept. 9, 1986) (statement of Rep. Berman); Marc S. Raspanti & David M. Laigaie, *Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act*, 71 TEMP. L. REV. 23, 24 (1998).

168 CONG. GLOBE, 37th Cong., 3d Sess. 952 (1863) (statement of Sen. Howard); S. REP. No. 99-345, at 8 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273.

169 *See* S. REP. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. at 5274; *see also* United States v. Neifert-White Co., 390 U.S. 228, 233 (1968) (stating that the FCA extends to "all fraudulent attempts to cause the Government to pay out sums of money"). *But see* United States v. McNinch, 356 U.S. 595, 599 (1958) ("[T]he False Claims Act was not designed to reach every kind of fraud practiced on the Government."); United States *ex rel.* Weinberger v. Equifax, Inc., 557 F.2d 456, 460 (5th Cir. 1977) ("The penal nature of the [FCA] requires careful scrntiny to see if the alleged misconduct violates the statute.").

170 31 U.S.C. § 3729(a).

171 S. REP. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. at 5274.

ments Act of 1986.[172] Proponents of the amendments intended to give the government "help—lots of help—to adequately protect the Treasury against growing and increasingly sophisticated fraud."[173]

1. *Elements of an FCA Claim*

The False Claims Act creates liability for any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval."[174] In false claim litigation, courts look to see if the government has successfully proved all of the necessary elements: a claim, falsity, and knowing conduct or scienter.[175] The Fourth Circuit also requires that the falsity be material to the claim,[176] and many other courts have explicitly or implicitly followed the Fourth Circuit's lead.[177]

An FCA claim is a request, even a partial request, for money or property from the federal government.[178] Simply stated, submitting a bill for fraudulent conduct with intent to induce payment from the United States gives rise to a claim.[179]

Although the FCA does not specifically define falsity, courts have defined the term in different ways. One court defined falsity as "a

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172 Pub. L. No. 99-562, 100 Stat. 3153 (1986) (codified as amended at 31 U.S.C. §§ 3729–3733 (1994)); *see* S. REP. No. 99-345, at 2, *reprinted in* 1986 U.S.C.C.A.N. at 5266–67; *see also id.* at 4, *reprinted in* 1986 U.S.C.C.A.N. at 5269 ("Although the government may also pursue common law contract remedies, the False Claims Act is a much more powerful tool in deterring fraud.").

173 132 CONG. REC. 20,535 (1986) (statement of Sen. Grassley).

174 31 U.S.C. § 3729(a). For the purposes of this discussion, this Note will treat all false claim complaints as if the federal government brought them; however, it is important to note that 31 U.S.C. § 3730(b) allows a private citizen to sue on the government's behalf.

175 PROCUREMENT FRAUD COMM., AM. BAR ASS'N, QUI TAM LITIGATION UNDER THE FALSE CLAIMS ACT 14 (Howard W. Cox & Peter B. Hutt II eds., 2d ed. 1999) [hereinafter QUI TAM LITIGATION]; *see also* United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1487 (W.D. Okla. 1996) ("The essential elements of a claim . . . are: (1) submission of a claim for payment . . . ; (2) falsity or fraudulence of the claim; and (3) 'knowing' action, which means acting either with actual knowledge of information or in deliberate ignorance or reckless disregard of the truth or falsity of information.").

176 *See* United States *ex rel.* Berge v. Bd. of Trs. of the Univ. of Ala., 104 F.3d 1453, 1459 (4th Cir.), *cert. denied*, 522 U.S. 916 (1997).

177 QUI TAM LITIGATION, *supra* note 175, at 21 & n.53 (citing cases requiring materiality).

178 31 U.S.C. § 3729(c); QUI TAM LITIGATION, *supra* note 175, at 14–16; *cf.* United States v. Neifert-White Co., 390 U.S. 228, 233 (1968) (stating that the FCA extends "beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay sums of money").

179 *See, e.g.*, United States *ex rel.* Pogne v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (holding that the plaintiff must show that "Defendants engaged in the fraudulent conduct with the purpose of inducing payment from the government" in order to bring an FCA claim).

lie."[180] Another found the relevant test for falsity to be whether the claimant omitted or misstated material facts and that the claimant intended the omission or statement to deceive.[181] In the realm of health care, courts have found falsity to exist when the provider fails to comply with statutes and regulations and that failure is at the core of the agreement between the provider and the government.[182]

The FCA specifically defines "knowing" and "knowingly" to mean a person either has "actual knowledge," acts in "deliberate ignorance of the truth or falsity," or acts in "reckless disregard" of the veracity of the information.[183] Furthermore, "no proof of specific intent to defraud is required."[184]

Finally, although materiality does not appear in the statute, the Fourth Circuit has explicitly recognized such an element, and several other circuit and district courts have agreed either expressly or implicitly.[185] In general, materiality means that the information supplied influenced agency action.[186] In other words, the falsity led the government to pay the claim.[187]

2. *Using the FCA to Police Skin Care*

The False Claims Act allows the federal government to push aggressively to reclaim fraudulently disbursed money.[188] For example,

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180 Wang *ex rel.* United States v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992).

181 Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732 (7th Cir.), *cert. denied*, 528 U.S. 1038 (1999).

182 *See* United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1156 (W.D. Mo. 2000) ("Knowingly submitting claims against the United States for Medicare and Medicaid services not actually performed clearly violates the FCA."); *see also* United States *ex rel.* Mikes v. Straus, 84 F. Supp. 2d 427, 435 (S.D.N.Y. 1999) (mentioning that implied false cerification exists only if statutory compliance is "at the core" of the agreement between the contractor and the government, and that the government would have refused to pay had it been aware of the noncompliance).

183 31 U.S.C. § 3729(b); *see also NHC Healthcare*, 115 F. Supp. 2d at 1153 ("The purpose of this particular definition of 'knowing' was to avoid the claimants who bury their heads in the sand and purposefully submit in ignorance a false claim."); S. REP. No. 99-345, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272 (wanting to prevent ostrich-like behavior by which a corporate officer could claim no actual knowledge because she simply did not want to know).

184 31 U.S.C. § 3729(b); *see also NHC Healthcare*, 115 F. Supp. 2d at 1153 (discussing briefly this lack of scienter).

185 QUI TAM LITIGATION, *supra* note 175, at 21 & n.53.

186 *Id.* at 22.

187 *See* United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) ("[F]alse *certification* of compliance . . . creates liability [under the FCA] when certification is a prerequisite to obtaining a government benefit."); *see also* United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (stating that the plaintiff must show that the defendant "engaged in the fraudulent conduct with the purpose of inducing payment from the government").

188 *See* John Phillips & Janet Goldstein, *The False Claims Act in Practice*, *in* QUI TAM: BEYOND GOVERNMENT CONTRACTS 469, 474–80 (PLI Litig. & Admin. Practice Series, Litig. Course Handbook Series No. H-456, 1993).

the government can reclaim funds paid to a health care facility for a defined level of care when the patient received less.[189] Providing less than what the government paid for is an underutilization claim, so named because the provider underutilized the amount the government paid the facility to care for a patient.[190] The government can also seek recovery when a provider implies that its services meet all standards and requirements under federal law, but they actually do not.[191] Such a claim is false by implied certification,[192] because if the government conditions payment on a facility certifying it has complied with all applicable statutes, then noncompliance with those statutes is a false claim.[193]

Assistant United States Attorney David Hoffman of the Eastern District of Pennsylvania, concentrating on nutrition and pressure ulcer care, has successfully prosecuted four claims under this theory: *United States v. Mercy Douglass Center Inc.*,[194] *United States v. City of Phila-*

189 *See, e.g., NHC Healthcare*, 115 F. Supp. 2d at 1156 (finding that the government pled a proper cause of action under the FCA against a nursing facility providing substandard care); *see also, e.g.*, Consent Order, United States v. GMS Mgmt.-Tucker, Inc., No. 96-1271 (E.D. Pa. Feb. 21, 1996) (approving settlement in a case where the government brought a false claim action on the theory that nursing facility patients received care below the level for which the government had paid), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf; John M. Parisi, *A Weapon Against Nursing Home Fraud and Abuse*, TRIAL, Dec. 1999, at 48 (describing recent use of the FCA to help ensure quality care in nursing facilities).

190 *See* Katherine E. Harris, *Fraud and Abuse: EMTALA, Nursing Homes, Quality of Care Seen as Top Health Fraud Topics in 2000*, BNA's Health Care Daily Rep. (BNA) D-10 (Jan. 12, 2000) ("[T]he rise of managed care and capitated payments has led to the to the risk of underntilization, where providers allegedly limit their expenditures to maximize their profits."); *see also* Ryan, *supra* note 35, at 149 (describing an underutilization claim in these terms: "Providers who are compensated with capitated payments may be tempted to curtail treatment or even fail to perform necessary services since providing those services will yield no additional compensation"). Nursing facilities are typically analogous to both managed care and capitated payments because a large number of states choose to use a per diem or similar case mix reimbursement platform for their nursing facilities. Ctrs. for Medicare & Medicaid Servs., *Medicaid Payments for Nursing Facility Services*, *at* http://www.hcfa.gov/medicaid/ltc10.htm (last visited Feb. 14, 2002).

191 *See* United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1487–1488 (W.D. Okla. 1996); *cf.* Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000) ("Permitting FCA liability based on a false certification of compliance with a government contract, whether the certification is expressed or implied, is consistent with the legislative history of the 1986 Amendments to the FCA." (citation omitted)).

192 *See, e.g.*, Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429, 434 (1994) (stating that payment vouchers represented an implied certification of continued adherence to participation requirements for a federal government contract program), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

193 *E.g.*, United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997).

194 Consent Order and Judgment, No. 00-CV-3471 (E.D. Pa. July 14, 2000), *available at* http://www.usao-edpa.com/Invest/nursing/mercy2.pdf.

delphia,[195] *United States v. Chester Care Center*,[196] and *United States v. GMS Management-Tucker, Inc.*[197] On March 6, 1996, in *GMS Management-Tucker*, the district court entered two consent orders settling the false claims suit brought by Hoffman for $600,000.[198] The complaint alleged that the patients under GMS Management-Tucker's care suffered from malnutrition, dehydration, pressure ulcers, and gangrene in some instances.[199] The frail old man described in the opening paragraphs of this Note with bedsores the size of "dinner plates"[200] lived in this nursing facility. He had more than twenty-five bedsores, the majority of which were deep enough so as to expose muscle and bone.[201] One of his bedsores, about the same diameter as a compact disc, "extended into [his] shoulder joint."[202] All of the bedsores contained rotting tissue.[203] In response to this horrific but all-too-common situation, the consent orders specifically addressed wound care needs at the facility, mandating that wound care meet and exceed Agency for Health Care Policy and Research clinical practice guidelines.[204]

In *United States v. Chester Care Center*, the district court entered a Consent Order and Judgment for $500,000.[205] In *United States v. City of Philadelphia*, the facility agreed to settle for $50,000.[206] Most recently, in *United States v. Mercy Douglass Center Inc.*, the defendants agreed to settle for $80,000.[207] All of these suits focused on liability

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195 Settlement Agreement, No. 98-CV-4253 (E.D. Pa. Aug. 14, 1998), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf.

196 Consent Order and Judgment, No. 98CV-139, 1998 U.S. Dist. LEXIS 4836 (E.D. Pa. Feb. 4, 1998).

197 Consent Order, No. 96-1271 (E.D. Pa. Mar. 6, 1996), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf; Hoffman, *supra* note 3, at 147; Peterson, *supra* note 47, at 74–75.

198 Consent Order, *GMS Mgmt.-Tucker* (No. 96-1271), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf.

199 Complaint at 8–9, *GMS Mgmt.-Tucker* (No. 96-1271), *available at* http://www.usao-edpa.com/Invest/nursing/gms2.pdf.

200 Langemo et al., *supra* note 2.

201 Hoffman, *supra* note 3, at 152.

202 *Id.*

203 *Id.*

204 *Id.* at 154–55.

205 Consent Order and Judgment, No. 98CV-139, 1998 U.S. Dist. LEXIS 4836, at *3 (E.D. Pa. Feb. 4, 1998).

206 Settlement Agreement at 33, United States v. City of Philadelphia, No. 98-4253 (E.D. Pa. Aug. 14, 1998), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf. The Settlement Agreement also required an additional allocation of $15,000 for a project to improve quality of life at the facility. *Id.*

207 Consent Order and Judgment at 3, United States v. Mercy Douglass Ctr. Inc., No. 00-CV-3471 (E.D. Pa. July 14, 2000), *available at* http://www.usao-edpa.com/Invest/nursing/mercy2.pdf.

same facilities are often part of multimillion-dollar nursing facility chains with enough financial resources to buy competent and aggressive advocacy.

II

HARNESSING THIS LEGAL MILIEU'S POTENTIAL TO POLICE SKIN CARE IN NURSING FACILITIES

Using this milieu of statutes, regulations, and case law, we can eradicate or nearly eradicate pressure ulcers in nursing facilities. The Nursing Home Reform Act of 1987 mandates that nursing facilities, in order to get paid, must provide care that meets professional standards of quality.[214] The Health Care Financing Administration, as part of its duties in administering the Medicare and Medicaid programs, must implement the NHRA. In addition, federal law designates the Agency for Healthcare Research and Quality as an expert on the quality of federal health care.[215] Therefore, the government can use the AHRQ's expert information to supplement HCFA rules and regulations in a manner that defines professional standards of quality to fully implement Congress's intent in enacting the NHRA.[216] Once defined, professional standards of quality represent a minimum threshold, i.e., a set of viable contract specifications.[217] Pressure ulcer care that fails to meet that threshold is substandard,[218] and this delineation provides the government with a method to quickly separate quality skin care for which it will pay from substandard skin care for which it will not pay.[219] The government contracted for quality skin care, meaning skin care that meets the minimum threshold, not substandard care.[220] Any bill that a nursing facility knowingly submits to the government for payment for health care products and skin care services of a quality less than that for which the government contracted has submitted a false claim punishable under the False Claims Act.[221]

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214 42 U.S.C. §§ 1396r, 1396r-3, 1396s (1994 & Supp. V 1999); *see supra* Part I.B.

215 *See* 42 U.S.C. § 299 (Supp. V 1999); *supra* Part I.D.

216 *See* 145 CONG. REC. E2526 (daily ed. Nov. 19, 1999) (statement of Rep. Bliley).

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

218 *Cf.* 42 U.S.C. § 1320a-7(b)(6)(B) (1994) (providing that the Secretary may exclude anyone who furnishes patient services "of a quality which fails to meet professionally recognized standards of health care"); *id.* § 1320c-5(a)(2) (stating that health care providers must assure that patient services "will be of a quality which meets professionally recognized standards of health care"); *Aranda*, 945 F. Supp. at 1488 (holding that "a provider's failure to meet . . . [quality of care] standards is a ground for exclusion from the program").

219 *See* Lakeland Continuing Care Ctr., No. C-97-070, Dec. No. CR683 (Dep't of Health & Human Servs., Departmental Appeals Bd., Civil Remedies Div.), July 18, 2000, *available at* http://www.hhs.gov/dab/decisions/cr683.html.

220 *See* Gagel, *supra* note 40, at 16.

221 QUI TAM LITIGATION, *supra* note 175, at 17–18 & n.28 (citing United States *ex rel.* Eaton v. Kansas Healthcare Investors, II, L.P., 22 F. Supp. 2d 1230, 1232 (D. Kan. 1998);

for false claims resulting from providing substandard care.[208] All of the settlements also mandated that the facility provide wound care, i.e., pressure ulcer care, equal to or greater than that enumerated in the Agency for Health Care Policy and Research clinical practice guidelines.[209] The suits, moreover, also demonstrate that even going after single facilities rather than large, sweeping national nursing facility chains can make a marked difference in the lives of the elderly.

3. *Criticisms of Using the FCA as a Tool to Deter Health Care Fraud*

Critics charge that the type of false claims litigation that Hoffman pursues is unfair or untenable. Some warn that such suits might "inflict a death blow on already struggling health care institutions."[210] Others claim that the FCA is a "poor and unnecessary weapon against substandard care" because "it is far too blunt and because it simply makes no sense for federal prosecutors, no matter how well intentioned . . . , to establish clinical care norms."[211] Critics suggest that "[a]chieving theoretically possible levels of care in chronically debilitated patient populations with scanty resources and an inadequate workforce is simply unrealistic."[212] Ultimately, they claim that "using the FCA to fill in gaps in quality regulation dilutes the force of the [FCA], generates complaints about fairness, and may ultimately lead the health care industry to question the legitimacy of the government's anti-fraud efforts."[213]

These criticisms, however, smack of hyperbole and misplaced concern. Rather than focusing on the problems that patients face, the criticisms seemingly blame the patient for somehow touching off a new breed of unfair victimization, or unreal expectations at best, by the federal government. They shift the focus from the frail and elderly—who most often do not have an advocate other than the government and could benefit from strict policing of care—and instead bewail the hardship of the facility. They ask us to insulate facilities from the consequences of providing substandard care. Yet, these

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208 *Id.*; Settlement Agreement, *City of Philadelphia* (No. 98-4253), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf; Consent Order and Judgment, *Chester Care Ctr.* (No. 98CV-139), 1998 U.S. Dist. LEXIS 4836, at *3.

209 Consent Order and Judgment at 6, *Mercy Douglass* (No. 00-CV-3471), *available at* http://www.usao-edpa.com/Invest/nursing/mercy2.pdf; Settlement Agreement at 18, *City of Philadelphia* (No. 98-4253), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf; Consent Order at 6, United States v. GMS Mgmt.-Tucker, Inc., No. 96-1271 (E.D. Pa. Mar. 6, 1996), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf; Consent Order and Judgment, *Chester Care Ctr.* (No. 98CV-139), 1998 U.S. Dist. LEXIS, at *5.

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

211 Fabrikant & Solomon, *supra* note 35, at 106.

212 Boese, *supra* note 210, at 30.

213 Joan H. Krause, *Medical Error as False Claim*, 27 AM. J.L. & MED. 181, 197 (2001).

A. Pressure Ulcers (Bedsores)

As discussed above, pressure ulcers represent a significant national health concern. More than 1.7 million people develop them annually.[222] In general, practitioners classify pressure ulcers by set criteria. Practitioners working with the National Pressure Ulcer Advisory Panel developed a staging system that the medical community and the Agency for Health Care Policy and Research have adopted as the universal classification schema.[223] This system classifies pressure ulcers into four stages, with Stage I ulcers being rather benign and Stage IV ulcers being the most advanced, i.e., the affected area decays to the point of exposing muscle and bone.[224] However, pressure ulcers, with proper attention and care, are an almost completely preventable and avoidable ailment.[225] As such, the poor care and neglect[226] that result in pressure ulcers unnecessarily inflict a great amount of grief and suffering on hundreds of thousands of elderly people annually.

Evidence demonstrates that this malady has considerable human and economic costs.[227] The life-threatening complications that arise from pressure ulcers, including infection and sepsis,[228] claim tens of thousands of lives in the United States each year.[229] Moreover, with almost ten baby boomers turing fifty years old per minute, the future promises a greater at-risk population.[230] As of last year, studies esti-

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United States v. Chester Care Ctr., No. 98CV-139, 1998 U.S. Dist. LEXIS 4836 (E.D. Pa. Feb. 4, 1998); *Aranda*, 945 F. Supp. at 1487–88.

222 Langemo et al., *supra* note 2, at 225.

223 Nat'l Pressure Ulcer Advisory Panel, *NPUAP Statement on Reverse Staging of Pressure Ulcers* (Sept. 1995), *at* http://www.npuap.org/positn2.htm (last visited Oct. 29, 2001).

224 *See id.* Stage I ulcers show up as abnormal red areas that will not briefly turn white and then back to red when a caregiver gently presses on the affected area, indicating lack of blood flow. Stage II ulcers present themselves as partial-thickness skin loss, meaning an actual break or tear in the skin occurs involving the epidermis, dermis, or both. Stage III ulcers manifest full-thickness skin loss, meaning the ulcer extends through the epidermis and dermis into the fatty tissue underneath, but not into muscle tissue. Stage IV ulcers extend all the way down into the muscle tissue and can even extend into bones and joints. *Id.*; MAKLEBURST & SIEGGREEN, *supra* note 9, at 58–59.

225 *See* Kosiak, *supra* note 36, at 62 ("Pressure ulcers are entirely preventable. They need not and should not occur.").

226 Nat'l Citizens' Coalition for Nursing Home Reform, *supra* note 37 (categorizing pressure ulcers and skin breakdown as both neglect and abuse).

227 *See supra* notes 2–51 and accompanying text.

228 Sepsis is "a poisoned state caused by the absorption of pathogenic microorganisms and their products into the bloodstream." WEBSTER'S NEW WORLD DICTIONARY OF AMERICAN ENGLISH 1223 (Victoria Neufeldt & David B. Guralnik eds., 3d College ed. 1991); *see also* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE PAYMENTS FOR SEPTICEMIA 2 (1999) ("Septicemia (blood poisoning) can result from bacteria infecting the bloodstream in various ways. It is a very serious infection which can rapidly lead to septic shock and death."), *available at* http://oig.hhs.gov/oei/reports/a356.pdf.

229 Thomas-Hess, *supra* note 26, at 31.

230 *See* Hirshberg et al., *supra* note 23, at 29.

mate that over one-fifth of the nation is over the age of sixty-five.[231] Many expect the number of pressure ulcers to increase by thirty percent in the next decade, "when 70 million Americans become eligible for Medicare."[232] As this demographic ages, the future of its skin care remains questionable, increasing its susceptibility to abusive and neglectful caregivers.[233]

In general, to neglect a nursing facility resident means that the health care practitioner fails to prevent harm or danger and does not avert or alleviate pain.[234] The practitioner's neglect could include improperly positioning the body, failing to provide proper nutrition or fluids, failing to take residents to the toilet, or letting residents sit in soiled disposable briefs[235]—all of which can lead to a loss of dignity and pressure ulcers.[236] Practitioner abuse, however, means intentionally causing harm or pain, including knowingly providing substandard care which the practitioner knows will probably not prevent or alleviate pressure ulcers.[237] In sum, pressure ulcers often signal neglect or abuse.[238]

B. The Nursing Home Reform Act, Health Care Financing Administration, and Pressure Ulcers

To implement the quality-of-care, quality-of-life,[239] and professional standards[240] required by the Nursing Home Reform Act, the Health Care Financing Administration promulgated detailed and specific regulations regarding the quality of care[241] and quality of life[242] of nursing facilities residents. HCFA promulgated a regulation specifically regarding pressure ulcers, which states that "the facility *must* ensure" that any entering resident "without pressure sores does not develop pressure sores unless the individual's clinical condition dem-

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231 *Id.*

232 *Id.*

233 *Cf.* 141 CONG. REC. 27,512 (1995) (statement of Sen. Pryor) (stating that fifty percent of nursing home residents have no living relative to advocate or monitor their care, and that in 2020, approximately 3.6 million Americans will be in nursing homes); *Forecasting Elder Care Trends for the 21st Century*, U.S.A. TODAY NEWSVIEW, SPECIAL NEWSLETTER EDITION, Aug. 2000, vol. 129, at 6 ("[T]his country must undergo a dramatic overhaul if we are to care for the 13,000,000 people who will need caregiver assistance by the year 2020.").

234 *See* Nat'l Citizens' Coalition for Nursing Home Reform, *supra* note 37.

235 *Id.*

236 AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 126.

237 *Id.*

238 *See* Thomas S. Harmon, *Ordinary People Can Spot Signs of Elder Abuse*, TAMPA TRIB., May 15, 1999, at 15.

239 *See* 42 U.S.C. § 1396r(b)(1), (b)(4)(A) (1994).

240 *Id.* § 1396r(d)(4)(A) (1994 & Supp. V 1999).

241 42 C.F.R. § 483.25 (2000).

242 *Id.* § 483.15.

onstrates that they were unavoidable."[243] Developing pressure ulcers, however, should be the rare exception not the norm.[244] The regulation also states that "the facility must ensure" that any resident with "pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing."[245] In particular, the language "must ensure"[246] indicates that preventing new—and properly treating existing—pressure ulcers is mandatory for the nursing facility, not optional.[247] This is an example of specific statutes and regulations governing the standards that a nursing facility must meet in order to participate in the Medicaid program.[248] Because courts recognize that Medicaid requires minimum standards, the government should take punitive action if a nursing facility fails to meet these standards, such as excluding that provider from Medicaid[249] and aggressively pursuing that nursing facility under the False Claims Act.

C. The Agency for Healthcare Research and Quality's Efforts Regarding Pressure Ulcers

Federal agencies have also been vigilant regarding pressure ulcers. In the early 1990s the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality, published two clinical practice guidelines to improve and ensure continuity of pressure ulcer care: *Pressure Ulcers in Adults: Prediction and Prevention*[250] and *Pressure Ulcer Treatment.*[251] The agency worked hard to ground these gnidelines in the best available science, reviewing 45,000 abstracts and some 1700 papers[252] in order to fulfill the original congressional intent of translating the best research into relevant

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243 *Id.* § 483.25(c) (emphasis added); *see also* Johnson & Armouti, *supra* note 34, at 340 (stating that plaintiffs' lawyers argue that "nursing homes must adhere to HCFA regulations to be reimbursed by the federal government for . . . Medicaid residents").

244 *See* Kosiak, *supra* note 36 and accompanying text.

245 42 C.F.R. § 483.25(c).

246 *Id.*

247 *Cf.* Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 35 (1998) (stating that "the mandatory 'shall' . . . normally creates an obligation impervious to judicial discretion").

248 42 C.F.R. § 483.1(b). This provision similarly applies to the Medicare program. *Id.*

249 *See, e.g.*, United States *ex rel.* Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485, 1488 (W.D. Okla. 1996) ("Statutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider's failure to meet such standards is a ground for exclusion from the program."). *But see* Boese, *supra* note 210, at 30 ("Achieving theoretically possible levels of care in chronically debilitated patient populations with scanty resources and an inadequate workforce is simply unrealistic.").

250 AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 126.

251 AGENCY FOR HEALTH CARE POLICY & RESEARCH, *supra* note 12.

252 Frank A. Cervo et al., *Pressure Ulcers: Analysis of Guidelines for Treatment and Management*, GERIATRICS, Mar. 2000, at 55, 56.

information for practitioners.[253] HCFA, in turn, disseminated these pressure ulcer guidelines, and others, to nursing facilities.[254] In 1995, because of the prominence of these guidelines in the nursing facility industry, the American Medical Directors Association, a national professional organization composed of and representing physicians who practice in nursing facilities, adapted these clinical practice guidelines on treating pressure ulcers.[255] Congress subsequently curtailed the AHCPR from developing any further clinical practice guidelines.[256] However, the practice guidelines on pressure ulcers continue to be a strong indicator of a minimum standard of care for treating pressure ulcers on nursing facility residents.

In *United States v. Mercy Douglass Center Inc.*,[257] *United States v. City of Philadelphia*,[258] *United States v. Chester Care Center*,[259] and *United States v. GMS Management-Tucker, Inc.*,[260] the government insisted that the settlement agreements with the nursing facilities include the facilities' promises to provide pressure ulcer care according to AHCPR clinical practice guidelines. The settlement agreements between the Department of Justice and nursing facilities in Pennsylvania during the 1990s strongly indicate that the federal government uses the guidelines as a measuring stick for the minimum acceptable level of pressure ulcer care.

D. Using the False Claims Act to Enhance Pressure Ulcer Care

Combining the federal statutes and regulations regarding pressure ulcers with False Claims Act litigation can meaningfully change the quality of skin care in nursing facilities. However, critics may argue that Congress designed the FCA solely to protect federal funds and not to police compliance with statutes or regulations.[261] Typi-

253 *See* 135 CONG. REC. E2107 (daily ed. June 13, 1989) (statement of Rep. Waxman).

254 Gagel, *supra* note 40, at 20–21.

255 Press Release, Agency for Health Care Policy & Research, U.S. Dep't of Health & Human Servs., AMDA Adapting AHCPR Clinical Practice Guidelines for Use in Long Term Care Facilities (Sept. 5, 1995), *at* http://ahcpr.gov/news/pres/adapting.htm.

256 *See* 42 U.S.C. § 229a(e) (Supp. V 1999) ("The Agency shall not mandate national standards of clinical practice . . . ."); *see also* 142 CONG. REC. 11712 (1996) (statement of Rep. Thomas) ("[The AHCPR] announced last month that it will no longer directly support the development of clinical practice guidelines.").

257 Consent Order and Judgment, No. 00-CV-3471 (E.D. Pa. July 14, 2000), *available at* http://www.usao-edpa.com/Invest/nursing/mercy2.pdf.

258 Settlement Agreement, No. 98-CV-4253 (E.D. Pa. Aug. 14, 1998), *available at* http://www.usao-edpa.com/Invest/nursing/pnh4.pdf.

259 Consent Order and Judgment, No. 98CV-139, 1998 U.S. Dist. LEXIS 4836, at *6–*8.

260 Consent Order at 6, No. 96-1271 (E.D. Pa. Mar. 6, 1996), *available at* http://www.usao-edpa.com/Invest/nursing/gms3.pdf and http://www.usao-edpa.com/Invest/nursing/tucker.pdf.

261 *See, e.g.*, United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999) ("[T]he FCA is not an appropriate vehicle for policing technical compliance

cally, the government contemplates that civil monetary penalties or exclusion from the program—both authorized by Medicaid statutes—will be the primary mechanisms for correcting the problem of poor skin care, but a backlog of administrative appeals hampers efficient policing in this manner.[262]

When the federal government conditions payment of federal funds on compliance with federal statutes, however, a nexus develops that allows derivative policing of whether or not the contractor complies with that federal statute.[263] When a regulation requires care that prevents or properly treats pressure ulcers, allowing a resident to develop a pressure ulcer or failing to treat an existing ulcer violates the statute, fails to meet payment conditions, and thus creates a false claim.[264]

These claims for substandard pressure ulcer care meet all of the necessary elements in the FCA.[265] Liability under the FCA attaches when nursing facility personnel knowingly present a false claim[266] for payment when the falsity is intended to induce payment from the federal government.[267]

The bills that a nursing facility submits to the federal government fall within the definition of a claim.[268] A nursing facility contracts with the federal government for a per diem payment, i.e., the facility submits a claim of a flat rate for each day the facility houses the resident.[269] In return, the facility agrees, as required by statute, to main-

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with administrative regulations."); United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1512–13 (M.D. Tenn. 1996) (stating that "the False Claims Act . . . was designed to protect the Federal treasury" and "not intended to operate as a stalking horse for enforcement of every statute, rule, or regulation").

262 *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 20, at 3.

263 *See, e.g.*, United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1036 (S.D. Tex. 1998); *see also* Boese, *supra* note 210, at 30 (discussing indications "that the government will increase its use of the False Claims Act to address quality of care deficiencies").

264 *Cf. Thompson*, 20 F. Supp. 2d at 1048 (finding that submission of claims for services that are "statutorily ineligible for payment under the Medicare Act constitutes a false claim").

265 The elements are: (1) a claim, (2) falsity, (3) knowledge, and sometimes (4) materiality. *See supra* Part I.E.1.

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

267 *See* United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1512–13 (M.D. Tenn. 1996).

268 *Cf.* United States v. Cherokee Implement Co., 216 F. Supp. 374, 375 (N.D. Iowa 1963) (defining a claim as "a demand for money or for some transfer of public property or disbursement of public funds").

269 United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000); *see also Aranda*, 945 F. Supp. at 1488 (explaining that "[i]t may be easier for a maker of widgets to determine whether its product meets contract specifications than for a [health care provider] to determine whether its services meet 'professionally recognized standards for health care' . . . ." but that "a problem of measurement should not . . . bar

tain and enhance the resident's quality of life,[270] including preventing and properly treating pressure ulcers.

In order to meet the element of knowledge, the practitioner need not have "actual knowledge" that allowing a pressure ulcer to develop is substandard care and thus statutorily ineligible for payment. Rather, the government must demonstrate only that the practitioner acted in "deliberate ignorance" or reckless disregard of the truth.[271] Nursing facility personnel, moreover, have an affirmative duty to read the pertinent statutes, regulations, and practice guidelines and not to act in ignorance of such statutes, regulations, and guidelines.[272]

In order to demonstrate falsity, the government must show that the claim was a mistruth.[273] Each nursing facility certifies that the information on each bill is true, that the facility understands payment comes from federal and state funds, and that it understands that making false statements or concealing a material fact violates federal law.[274] Preventing pressure ulcers from developing and properly treating patients who have pressure ulcers when admitted become prerequisites to receiving Medicaid funds for providing skin care.[275] The government conditions payment on the facility preventing and treating those pressure ulcers. If the provider directly or indirectly conceals the pressure ulcers, or does not treat the pressure ulcers as regulations[276] and statutes[277] require, the claim becomes a statutorily ineligible false claim.[278] When a nursing facility submits such a claim and falsely certifies that skin care complied with all applicable statutes and regulations—claiming that the facility prevented and properly

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. . . an FCA claim [for] substandard health care services . . . ."). *But see* Boese, *supra* note 210, at 34 (discussing *Aranda* and arguing that "[w]hat the court failed to recognize is that human qualities, including the 'highest practicable level' of 'psychosocial well-being,' are inherently subjective unlike engineering specifications").

270 *NHC Healthcare*, 115 F. Supp. 2d at 1153.

271 31 U.S.C. § 3729(b) (1994); *see NHC Healthcare*, 115 F. Supp. 2d at 1153 ("The purpose of this particular definition of 'knowing' was to avoid the claimants who bury their head in the sand . . . .").

272 *Cf.* United States v. Coop. Grain & Supply, 476 F.2d 47, 55 (8th Cir. 1973) ("The applicant for public funds has a duty to read the regulations or be otherwise informed of the basic requirements of eligibility.").

273 *Cf.* Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732 (7th Cir. 1999) ("[A] claim can be false or fraudulent if the speaker offers a misleading half-truth."), *cert. denied*, 528 U.S. 1038 (1999).

274 *See* HEALTH CARE FIN. ADMIN., FORM HCFA-1500 (12-90), HEALTH INSURANCE CLAIM FORM, at 2, *available at* http://www.hcfa.gov/medicare/edi/1500-90.pdf.

275 *See NHC Healthcare*, 115 F. Supp. 2d at 1155.

276 *See* 42 C.F.R. § 483.25(c) (2000).

277 *See* 42 U.S.C. § 1396r(b)(1), (d)(4)(A) (1994 & Supp. V 1999).

278 *Cf.* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1048 (S.D. Tex. 1998) ("[S]ubmission of . . . claims for services that were statutorily ineligible for payment under the Medicare Act constitutes a false claim . . . .").

treated pressure ulcers when it did not—this false implied-certification provides the requisite falsity.[279]

Lastly, if the case requires direct or indirect materiality, the litigant need only show the falsity was "critical to the decision to pay."[280] Essentially the question rests in a "but for" posture—that is, but for the lie, the misleading statements, or the half-truths about properly caring for pressure ulcers, would the federal government have paid the claim?[281] If the answer is "no," then the falsity induced the payment—the very essence of a false claim.[282]

E. The Potential Impact of the FCA as a Policing Tool

Approximately 300,000 nursing facility patients suffer from pressure ulcers at any given time.[283] Conservatively assuming only fifty percent of these are preventable pressure ulcers,[284] that would mean that 150,000 residents have received substandard skin care that led to pressure ulcers. This calculation translates into 150,000 potential false claims per month presented to the federal government for payment. At a cost of $5,000 to $10,000 per false claim,[285] industry-wide penalties alone—not including recovery of three times the amount of these claims[286]—could run between $75 and $150 million per month.

The magnitude of this liability could quickly attract the attention of any single nursing facility or chain. For example, in a single, one-hundred-bed nursing facility, assuming only a ten percent pressure ulcer incidence rate, one would find, on any given day, ten patients

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279 *See NHC Healthcare*, 115 F. Supp. 2d at 1155 ("[A] health care provider can be held to have impliedly certified that it will comply with the relevant standard of care as set forth in the regulations and statutes if that standard of care lies at the core of the parties agreement."); *see also* Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000) ("Permitting FCA liability based on a false certification of compliance with a government contract, whether the certification is expressed or implied, is consistent with the legislative history of . . . the FCA." (citation omitted)); *Thompson*, 125 F.3d at 902 ("[W]here the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation."); Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429, 433–34 (1994) (finding a false claim when a construction company submitted vouchers with fraudulent claims to a federal small business program because each voucher's submission implied continued adherence to the program's participation requirements), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

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

281 *See* United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (discussing that the fraudulent conduct must be intended to induce the payment from the government).

282 *See Ab-Tech*, 31 Fed. Cl. at 434.

283 *See supra* note 22 and accompanying text.

284 *See* discussion *supra* note 36.

285 *See* 31 U.S.C. § 3729(a) (1994).

286 *Id.*

with pressure ulcers.[287] Conservatively estimating that one-half of those pressure ulcers were medically unavoidable leaves five patients with medically avoidable pressure ulcers. Aside from the amount of the claims,[288] a single facility could be liable for penalties alone of $25,000 to $50,000 per month ($5,000 or $10,000 × 5 patients), or $300,000 to $600,000 per year. This significant amount should be enough to make any individual facility sit up and take notice, and will likely motivate nursing facilities to provide better skin care, thereby reducing the number of pressure ulcers.

For a nursing facility chain, the liability would be argnably more significant. A chain of 100 one-hundred-bed nursing facilities would have 10,000 beds chain-wide, and a conservative estimate of a ten percent rate of pressure ulcer occurrence would mean that on any given day, the nursing facility chain would have 1000 patients with pressure ulcers. Even if one-half of those pressure ulcers were medically unavoidable, 500 avoidable pressure ulcers would remain. From penalties alone under the FCA, that nursing facility chain would have potential liability of $2.5 million to $5 million per month ($5000 or $10,000 × 500 patients), or $30 million to $60 million per year. This large potential liability would also significantly motivate nursing facilities to provide proper skin care.

CONCLUSION

In sum, pressure ulcers are unnecessary wounds that lead to a great amount of unnecessary suffering,[289] or in some cases, to the demise of an afflicted individual.[290] Unfortunately, nursing facilities, which cater to the oldest, most frail, and most vulnerable members of our society,[291] tend to have more than their fair share of patients with pressure ulcers.[292] Although traditional avenues of policing compliance—sanctions and exclusions—have brought some progress, it is not nearly enough.[293]

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287 *See* Ooi et al., *supra* note 22, at 47 (finding an 11.4% overall incidence rate of pressure sores in low-risk nursing facilities).

288 *See, e.g.*, AM. HEALTH CARE ASS'N, NATIONAL DATA ON NURSING FACILITIES (pointing out that in 1995, the average daily Medicaid reimbursement rate for a nursing facility was approximately $85 per day), *at* http://www.acha.org/who/profile4.htm (last visited Jan. 31, 2002). If one assumes slight increases over the intervening six years, one can infer that daily reimbursement rates for nursing facilities are currently about $100 per day per patient, or about $3,000 for the average month. If the federal government successfully sues the nursing facility under the FCA, the government would also recover a portion of this payment for each patient with avoidable pressure ulcers. This award would be tripled because the FCA allows for treble damages. 31 U.S.C. § 3729(a).

289 *See* Langemo et al., *supra* note 2.

290 *See* Thomas-Hess, *supra* note 26, at 31.

291 *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 20, at 1.

292 *See id.* at 11.

293 *See id.* at 3.

By providing for significant potential liability, the False Claims Act provides a meaningful and aggressive method to prevent pressure ulcers in a large, vulnerable elderly population. Federal statutes and regulations require that nursing facilities not allow pressure ulcers to develop or deteriorate unless medically unavoidable. Pressure ulcers, however, are an almost completely avoidable problem. Therefore, the majority of nursing facilities that allow pressure ulcers to develop or deteriorate violate statutes and regulations. As a result, they are providing substandard care. Billing the federal government for such substandard care is a false claim and is therefore subject to significant liability under the FCA. The federal government should use the FCA to police skin care in nursing facilities because the potential liability is so great that the facilities will take serious notice. Nursing facilities, moreover, should take notice because the large majority of pressure ulcers are preventable. When you are old, frail, and alone, with few to advocate on your behalf, being in bed at the mercy of your caregiver should not be the most dangerous place to be.