THE EMPIRE STRIKES BACK: A CRITIQUE OF THE BACKLASH AGAINST FRAUD AND ABUSE ENFORCEMENT

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I. INTRODUCTION

If there is any proposition on which all observers of our health care system agree, it is that Medicare and Medicaid fraud and abuse is morally wrong and fiscally harmful.[1] A recent poll conducted by the League of Woman Voters found that 65% of respondents believed that Medicare's biggest problems are waste, fraud and abuse.[2] Vice President Gore was the point person for the most recent White House health care fraud and abuse initiative, suggesting that toughness on fraud and abuse is recognized as a popular and noncontroversial political stance.[3] Congressional Republicans agree, and they have been equally vocal in condemning fraud and abuse and calling for vigorous action to stamp it out.[4] Even providers, often the ob-

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1. The focus of this Article is particularly on fraud and abuse enforcement in the Medicare, and to a lesser extent, the Medicaid programs. Much of the discussion presented in this Article, however, also applies to other government programs—indeed, to private sector fraud and abuse enforcement.

2. John A. McDonald, *Medicare Reform Effort Stalls, Panel Unable To Agree on Recommendations*, THE HARTFORD COURANT, Mar. 17, 1999, at A18.

3. *See Vice President Gore Announces New Efforts to Fight Health Care Fraud and Abuse*, U.S. NEWSWIRE, Mar. 25, 1999.

4. *See, e.g.*, Karen Gullo, *House Panel Looks at Government Waste*, ASSOCIATED PRESS, Feb. 10, 1999, *available in* 1999 WL 11926557 (citing hearing held by Rep.

jects of fraud and abuse enforcement, affirm their opposition in principle to fraud and abuse.[5] The American Medical Association's Principles of Medical Ethics, for example, require that physicians "shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception."[6]

It is, of course, not remarkable that Medicare and Medicaid fraud and abuse should be so uniformly condemned. Though fraud was not always regarded as a criminal offense by the Anglo-American common law, the criminalization of fraud has ancient roots.[7] Fraud has long been considered to be *malum in se*, subject to both civil and criminal sanctions.[8] Fraud against the federal government has been a criminal and civil offense since the Civil War,[9] and it is universally condemned as a drain on the federal treasury.[10] The prevalence of fraud and abuse in health care is frequently cited as a major factor in causing the high and rapidly growing level of health care expenditures in the United States.[11] Surveys conducted by the American Association of Retired Persons ("AARP") in 1995 and 1996 found that 87% of respondents believed that Medicare funding would be

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Dan Burton, R-Ind., Chair of the Committee on Government Reform and Oversight).

5. *See Are You Guilty Until Proven Innocent?: Tougher Rules on Fraud Enforcement Puts Providers on the Defense*, AMERICAN MED. NEWS, June 9, 1997, at 3.

6. AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS (1996) (visited Sept. 22, 1999) <http://www.ama.assn.org/ethic/pome.htm>.

7. *See* Gilbert Geis & Herbert Edelhertz, *Criminal Law and Consumer Fraud: A Sociological View*, 11 AM. CRIM. L. REV. 989, 989-96 (1973) (tracing the history of consumer fraud in the common law from 15th century antecedents).

8. *See* Geis & Edelhertz, *supra* note 7.

9. *See* Lisa Michelle Phelps, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1047 n.9 (1998).

10. *See* JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 1-3 to -10 (1993 & Supp. 1999). *Compare* Michael J. Davidson, *10 U.S.C. § 2408: An Unused Weapon in the Procurement Fraud Wars*, 26 PUB. CONT. L.J. 181, 181-84 (1997) (discussing the problem of fraud against the federal government in the related area of defense procurement fraud).

11. *See* MALCOLM K. SPARROW, LICENSE TO STEAL: WHY FRAUD PLAGUES AMERICA'S HEALTH CARE SYSTEM 1-2 (1996); Joseph A. Califano, Jr., *Rationing Health Care: The Unnecessary Solution*, 140 U. PA. L. REV. 1525, 1529 (1992); Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste and Abuse in Healthcare Spending*, 11 YALE J. ON REG. 455, 459 (1994).

adequate if fraud, waste and abuse could be eliminated.[12]

The popularity of the crusade against Medicare and Medicaid fraud and abuse is reflected in recent legislative and administrative initiatives. Both the 1996 Health Insurance Portability and Accountability Act ("HIPAA") and the 1997 Balanced Budget Act ("BBA") contain significant new Medicare and Medicaid fraud sanctions and enforcement provisions.[13] These statutes not only dramatically increase the scope of federal fraud and abuse jurisdiction (expanding it to cover fraud against any health care plan, public or private)[14] and the severity of federal sanctions (requiring, for example, permanent exclusion for a person convicted three times of a crime that could form the basis of a mandatory exclusion),[15] but they also generously fund a new Federal Fraud and Abuse Control Program ("Program").[16] This Program, established by the HIPAA,[17] is funded through a Health Care Fraud and Abuse Account established within the Medicare Trust Fund, into which criminal fines and civil penalties recovered under the fraud and abuse law, as well as additional appropriations, are being transferred.[18] For Fiscal Year ("FY") 1999, the Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") is expected to

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12. *See* Jill Bernstein & Rosemary Stevens, *Public Opinion, Knowledge, and Medicare Reform*, 18 HEALTH AFF., Jan.-Feb. 1999, at 185.

13. *See* Pub. L. No. 105-33, §§ 4301-4331, 111 Stat. 251 (1997); Pub. L. No. 104-191, §§ 200-250, 110 Stat. 1936 (1996) (statement in physicians' materials as to number of provisions); *see also* Ted Acosta & Howard J. Young, *The Health Insurance Portability and Accountability Act of 1996 and the Evolution of the Government's Anti-Fraud and Abuse Agenda*, 30 J. HEALTH & HOSP. L. 37 (1997) (discussing HIPAA provisions); Robert E. Hauberg, Jr. & W. Davis Frye, *Recent Healthcare Fraud Legislation: New Prosecutorial Tools or Congressional Pie in the Sky*, 31 J. HEALTH & HOSP. L. 23 (1998) (discussing HIPPA and BBA provisions).

14. 18 U.S.C. § 1347 (1994 & Supp. III 1997).

15. 42 U.S.C.A. § 1320a-7(c)(3)(G)(I) (West Supp. 1999).

16. *See* Pub. L. No. 104-191, § 201, 110 Stat. 1936 (1996); 42 U.S.C. § 1395i (1994 & Supp. III 1997). *See also* U.S. GEN. ACCOUNTING OFFICE, MEDICARE: HCFA'S USE OF ANTI-FRAUD-AND-ABUSE FUNDING AND AUTHORITIES (1998) (analyzing the HCFA's slow start in getting the Medicare Integrity Program underway).

17. William S. Painter et al., *1998 Recent Legislation, Cases, and Other Developments Affecting Healthcare Providers and Integrated Delivery Systems*, SD53 ALI-ABA 165 (1999).

18. *See* Pub. L. No. 104-191, § 201(k), 110 Stat. 1936 (1996); U.S. GEN. ACCOUNTING OFFICE, MEDICARE: HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM FINANCIAL REP. FOR FISCAL YEAR 1997, at 5 (1998) (tracing the contributions made to the Medicare Trust Fund for Fiscal Year 1997).

receive $90 to $100 million from this fund; the Department of Justice ("DOJ") civil and criminal divisions and U.S. Attorneys' offices, $32 million; the Federal Bureau of Investigation ("FBI"), $66 million; and the Health Care Financing Administration ("HCFA"), $550 to $560 million.[19]

Expansion of program funding and enforcement authority has predictably resulted in striking increases in enforcement activity. During FY 1998, the federal government netted $480 million in recoveries, filed 107 civil fraud cases, secured criminal convictions against 326 defendants, and excluded 3,021 providers.[20] During the previous year, FY 1997, the OIG and DOJ recovered $1.2 billion in fines, recoveries and penalties (including $517 million from three large cases), filed 89 civil fraud cases, secured convictions of 363 defendants, and excluded 2,700 individuals and entities for Medicare and Medicaid fraud.[21] Multimillion dollar settlements in fraud and abuse cases have become commonplace, including a $325 million settlement with Smith-Kline, a $255 million settlement with First American Health Care, and a $379 million settlement with National Medical Enterprises.[22]

Even though support of the general principle of rooting-out Medicare and Medicaid fraud is universal, there is a powerful and growing backlash among health care providers against the manner in which the Medicare and Medicaid fraud and abuse laws are being enforced. A recent American Hospital Association

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19. *See Final Federal Budget Package Includes More Than Money to Crack Down on Fraud*, 2 Health Care Fraud Rep. (BNA) 817 (1998). As will be explained more fully below, the OIG, DOJ and FBI (which is under the DOJ) bear the primary responsibility at the federal level for investigating Medicare and Medicaid fraud and abuse. *See infra* notes 339-42 and accompanying text. The HCFA administers the Medicare and Medicaid programs. Thomas A. Mesereau, Jr., *United States Code § 371: Conspiracy to Commit Fraud or Defraud the United States*, 1129 PLI/CORP. 281, 295 (1999).

20. *See* DEPARTMENT OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, 1998 ANNUAL REP. 2 (1999).

21. DEPARTMENT OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, 1997 ANNUAL REP. (1998) [hereinafter 1997 ANNUAL REP.]. Though full enforcement statistics are not yet available for FY 1998, the OIG has reported 3021 provider exclusions for 1998. DEPARTMENT OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., 1998 SEMIANNUAL REP. FOR APR. 1-SEPT. 30, at 6 (1997).

22. M.D. Krohn, Comment, *The False Claims Act and Managed Care: Blowing the Whistle on Underutilization*, 28 CUMB. L. REV. 443, 461 (1998).

Advocacy Paper, for example, accuses the DOJ of "us[ing] the False Claims Act as a blunt instrument to victimize hospitals who make innocent errors."[23] The paper continues, "every day, more hospitals and health systems receive Justice Department demand letters that require them to choose immediately between settlement and admitting fraud, or fighting the Department and incurring potentially enormous monetary penalties."[24] A 1998 Board of Trustees Report of the American Medical Association ("AMA") states, "we are extremely concerned that HCFA and the carriers have become overly aggressive in their pursuit of cost-containment initiatives in the guise of fraud and abuse or program integrity activities."[25] The AMA is "extremely troubled to see that the federal government's tactics have consistently taken a punitive approach with physicians, rather than one of education and prevention."[26] The American College of Physicians claims that the fraud and abuse laws "have created an atmosphere in which physicians feel that almost all of their behavior is suspect."[27] Finally, the American Association of Medical Colleges asserts that Physicians at Teaching Hospitals ("PATH"), a federal enforcement initiative program, is an "OIG program to coerce medical schools, hospitals and teaching physicians into forfeiting millions of dollars of fees billed in good faith by threatening punitive damages."[28]

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23. AMERICAN HOSP. ASS'N, ADVOCACY PAPERS FOR 1998 ANNUAL MEETING: YOUR MISSION ON CAPITOL HILL (last modified Jan. 20, 1998) <http://www.aha.org/repeal.html> [hereinafter ADVOCACY PAPERS].

24. *See* ADVOCACY PAPERS, *supra* note 23.

25. RANDOLPH D. SMOAK, JR., M.D., CHAIR, AMERICAN MED. ASS'N BD. OF TRUSTEES REP., MEDICARE FRAUD AND ABUSE I-98 (1998) [hereinafter BOARD OF TRUSTEES REP.].

26. *See* BOARD OF TRUSTEES REP., *supra* note 25, at 98.

27. American College of Physicians, *Understanding the Fraud and Abuse Laws: Guidance for Internists*, 128 ANN. INTERN. MED. 678 (1998). The Office of Inspector General responded to the American College of Physicians' ("ACP") assertions by noting that only 12 of the 261 convictions resulting from OIG investigations in 1998 involved doctors in their clinical practice. Only 42 of the 980 civil penalties imposed based on OIG investigations during the same period involved doctors, though three-quarters of a million doctors participate in Medicare. *Fraud and Abuse: IG Challenges Physicians To Give Examples of Harassment in Anti-Fraud Campaign*, Health Care Daily Rep. (BNA), Apr. 15, 1999, at 22, *available in* WL, 4/15/99 HCD d2 (noting that the IG challenged the ACP-ASIM to come up with specific incidents of harassment).

28. AMERICAN ASS'N OF MED. COLLEGES, HEALTH CARE: CONCERNS AND RECOM-

Even federal judges occasionally bridle at the government's exercise of its enforcement authority. Judge Sporkin of the District Court of the District of Columbia recently chided the government for seeking "astronomical" damages against a "fine physician" in an False Claims Act case, asserting that the government's pursuit of the doctor was "reminiscent of Inspector Javert's quest to capture Jean Valjean in Victor Hugo's *Les Miserables.*"[29]

The anguished cries of providers have reached the ears of Congress. Amendments that would have seriously limited enforcement under the False Claims Act ("FCA") enjoyed strong bipartisan support in the 105th Congress.[30] Bills introduced in both the Senate and House in early 1998 had bipartisan sponsors—Thad Cochran (R.-Miss.) and Ernest Hollings (D.-S.C.) sponsored the Senate bill, and Bill McCollum (R.-Fla.) and William Delahut (D.-Mass.) sponsored the House.[31] At one point, the House bill had 120 co-sponsors.[32] In the end, this legislation failed to pass, but the 1998 Budget Bill did contain provisions requiring the General Accounting Office ("GAO") to oversee the continuing implementation of policies adopted by the OIG and DOJ to respond to provider criticisms,[33] and congressional interest in this issue remains strong.[34]

The issues raised by the provider backlash against federal fraud and abuse enforcement are important. Has fraud and abuse enforcement gone too far? Should the fraud and abuse laws only be enforced against those conventionally thought of as "true criminals," or is it appropriate to enforce fraud and abuse sanctions against "legitimate providers" too? Is it good policy to use the fraud and abuse laws to assure compliance with complex

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MENDATIONS REGARDING THE PHYSICIANS AT TEACHING HOSPITALS (PATH) INITIATIVE (last modified Jun. 12, 1997) <http://www.aamc.org/hlthcare/path/concerns.htm> [hereinafter PATH INITIATIVE].

29. United States v. Krizek, 7 F. Supp. 2d 56, 60 (D.D.C. 1998).

30. *See* S. 2007, 105th Cong. (1998); H.R. 3523, 105th Cong. (1998).

31. *See* S. 2007; H.R. 3253.

32. *Opponents of Legislation Aimed at Amending FCA Cite Increase in Fraud*, 2 Health Care Fraud Rep. (BNA) 338 (1998).

33. *See* Pub. L. No. 105-277, tit. I, § 118, 112 Stat. 2681 (1998). These policies are discussed below at *infra* notes 386-88 and accompanying text.

34. Kurt Eichenwald, *Changes in Rules on Prosecution of Hospitals Erode Bill's Support*, N.Y. TIMES, June 14, 1998, at 1.

and technical billing requirements or to ensure the quality of care provided by health care professionals and institutions? How much weight should be given to the complaints of providers that they are being punished for innocent misinterpretations of their program obligations? Even if it is appropriate to use the fraud and abuse laws to enforce program obligations, can the application of the severe sanctions provided by the civil false claims be justified? Is it ever appropriate to go further and use criminal sanctions (or program exclusion) to accomplish this objective? Finally, are providers in fact coerced into extortionate settlement agreements because the fraud and abuse laws deny them adequate procedural protections? Does the FCA's authorization of *qui tam* enforcement unfairly expose providers to unjust and oppressive demands? In the end, what is proper fraud and abuse enforcement process and policy?

These are the themes of this Article. We begin with a brief overview of the fraud and abuse laws to illustrate the breadth and depth of sanctions available to fraud and abuse enforcers. Second, we examine the types of conduct currently addressed by fraud and abuse enforcement. Next, we introduce and evaluate provider criticisms of fraud and abuse enforcement:

- that the sanctions provided by the fraud and abuse laws are disproportionately severe;
- that the Medicare and Medicaid program requirements enforced by these laws are so complex that providers who misconstrue them cannot be faulted and in particular, should not be subjected to the severe sanctions of the fraud and abuse laws; and
- that providers are denied the right to defend themselves under the fraud and abuse laws and are vulnerable to being coerced into oppressive settlements.[35]

We conclude with our own recommendations as to how the issues raised by providers might be addressed without compromising the essential role of fraud and abuse enforcement.

Throughout our discussion, we will focus on fraud and abuse enforcement within the Medicare program. Of course, fraud and abuse affects other government health care programs as well. Most of the laws and sanctions that apply to Medicare also ap-

35. *See supra* notes 23-31 and accompanying text.

ply to Medicaid and other federally-funded programs. Medicare is, however, the largest federal health care program.[36] In Medicaid, the second largest federally-funded program,[37] fraud and abuse laws are often enforced by state prosecutors.[38] For the sake of simplicity, therefore, our discussion will be limited in most instances to Medicare fraud and abuse.

II. FRAUD AND ABUSE ENFORCEMENT AUTHORITIES AND REMEDIES

The multiplicity and diversity of federal health care fraud and abuse enforcement provisions is truly remarkable.[39] First, a range of criminal authorities address fraud and abuse.[40] Most specifically, it is a felony to knowingly and willfully make false statements or representations to secure payments or benefits in a federal or state health care program, to fraudulently conceal information affecting eligibility for a benefit or payment in such programs, or to convert program payments or benefits intended for another.[41] It is also a felony to knowingly and willfully pay, offer, solicit or receive remuneration (bribes or kickbacks) for furnishing or arranging to furnish federally-financed health care services.[42] More generally, it is a felony to defraud any public or private health care benefit program, to embezzle or steal money from such a program, or to willfully obstruct an investigation of a federal crime committed against such a program.[43] Most criminal prosecutions for health care fraud are not, however, brought under specific health care fraud prohibitions, but

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36. Richard S. Foster, *The Financial Status of Medicare*, 113 PUBLIC HEALTH REPS., 110 (1998).

37. Shari G. Kleinev et al., *Health Care Fraud*, 36 AM. CRIM. L. REV. 773, 775 (1999).

38. *See, e.g.*, NATIONAL ASS'N OF ATTORNEYS GEN., MEDICAID FRAUD REP. 2 (1997).

39. *See* TIMOTHY S. JOST & SHARON DAVIES, MEDICARE AND MEDICAID FRAUD AND ABUSE §§ 2-2, 2-3, 2-5 (1998) (including recent summaries of these laws); Aaron M. Altschuler et al., *Health Care Fraud*, 35 AM. CRIM. L. REV. 841, 842-43 (1998).

40. *See* Pamela H. Bucy, *Crimes by Health Care Providers*, 1996 U. ILL. L. REV. 589, 591-647 (1996).

41. 42 U.S.C. § 1320a-7(a), (b) (1994 & Supp. II 1997).

42. *Id.* § 1320a-7b(b).

43. 18 U.S.C. § 1347 (1994 & Supp. III 1997).

rather, they are brought under more general federal statutes that prohibit the knowing presentation of false or fraudulent claims to the United States,[44] the making of false or fraudulent statements or representations to the United States,[45] and the use of the mail or electronic communications to commit frauds.[46] Federal prosecutors tend to favor these statutes because these prosecutors—and the judges before whom fraud and abuse cases are tried—are more familiar with these statutes than with the newer, more specific Medicare and Medicaid fraud statutes.[47] Finally, health care criminal charges are often supplemented by even more generic charges of aiding and abetting, conspiracy, Racketeer Influenced and Corrupt Organizations Act ("RICO") violations, money laundering, obstruction of justice or tax evasion.[48]

Despite the availability of a range of criminal authorities that address health care fraud, the DOJ has increasingly relied on a civil statute, the federal civil False Claims Act ("civil FCA"),[49] for penalizing Medicare fraud.[50] The FCA provides that one who knowingly presents a false or fraudulent claim or makes a false statement to the United States to get a false or fraudulent claim paid is liable for treble damages, plus civil penalties of $5,000 to $10,000 per claim.[51] Health care providers tend to file large numbers of small claims, often amounting to thousands of claims over the course of a year.[52] If any significant percentage of these are false, penalties claimed against

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44. 18 U.S.C. § 287 (1994).

45. 18 U.S.C. § 1001 (1994 & Supp. III 1997).

46. 18 U.S.C. §§ 1341, 1343 (1994).

47. *See* JOST & DAVIES, *supra* note 39, § 2-2.

48. *Id.*

49. 31 U.S.C. § 3729 (1994). The number of civil health care fraud investigations pending in U.S. Attorneys' Offices increased from 270 in 1992 to 3471 at the end of FY 1998. The number of civil health care fraud cases filed increased from 60 in 1995 to 107 in 1998. U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD REP. FISCAL YEARS 1995 & 1996, at 6-15 (1997). Leon Aussprung, *Fraud and Abuse: Federal Civil Health Care Litigation and Settlement*, 19 J. LEG. MED. 1, 5 (1998).

50. Pamela H. Bucy, *Civil Prosecution of Health Care Fraud*, 30 WAKE FOREST L. REV. 693, 695 (1995).

51. 31 U.S.C. § 3729.

52. Hospitals and health systems, for example, file in aggregate about 200,000 Medicare claims a day. *See Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 105th Cong. (1997) (statement of the American Hosp. Ass'n) (last modified Oct. 23, 1997) <http://www.aha.org/ar/wm_1023.html>.

providers can literally run into hundreds of millions of dollars.[53] Nevertheless, since civil FCA penalties are civil rather than criminal,[54] civil FCA defendants are not afforded the protections that criminal procedure routinely offers criminal defendants (including the beyond a reasonable doubt standard of proof).[55] Thus, the civil FCA provides an attractive alternative to prosecutors who believe that a provider's conduct warrants a severe sanction but at the same time would prefer to avoid the rigorous procedural burdens imposed by the criminal process.[56] The civil FCA also authorizes *qui tam*, "whistleblower," enforcement, affording persons with inside knowledge of fraud and abuse the oppotunity to sue a provider in hopes of recovering a bounty of between 15% and 30% of the total civil FCA judgment or settlement, thereby encouraging private enforcement to supplement and stimulate public prosecutions.[57]

Finally, federal fraud and abuse statutes also provide for an array of administrative sanctions. The most serious administrative penalty from the perspective of most providers is exclusion from participation in federal and state health care programs.[58] Exclusion from federal and state programs for at least five years is mandatory in four situations, including, most notably, conviction of a felony criminal offense related to the delivery of an item or service paid for by a federal or state health care program.[59] The Inspector General may also, at her discretion, bring exclusion proceedings based on sixteen other grounds, including license suspension or revocation and failing to disclose information to the DHHS as required by law.[60] For many pro-

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53. *See supra* note 52 and accompanying text.

54. *See* United States *ex rel.* Marchus v. Hess, 317 U.S. 537, 539-42 (1943).

55. 31 U.S.C. § 3731(c) (1994) (providing that proof must be "by a preponderance of the evidence"). This provision was added by the 1986 amendments, as some courts had held that proof under the FCA needed to be by clear and convincing evidence. United States v. Ueber, 303 F.2d 462, 463 (6th Cir. 1962); BOESE, *supra* note 10, at 5-91.

56. *See* Bucy, *Civil Prosecution of Health Care Fraud*, *supra* note 50, at 756-57.

57. 31 U.S.C. § 3730 (1994).

58. *See* Julie Johnsson, *Are You Guilty Until Proven Innocent? Tougher Rules on Fraud Enforcement Put Providers on the Defensive*, AM. MED. NEWS, June 9, 1997, at 1 (noting that Medicare fraud cases are often settled because providers cannot risk being excluded from Medicare participation).

59. 42 U.S.C. § 1320a-7(a) (1994 & Supp. III 1997).

60. *Id.* §§ 1320a-3, 1320a-5 (1994); *id.* § 1320a-7(b) (1994 & Supp. III 1997).

viders who are dependent on Medicare, the five year mandatory exclusion can be the most devastating consequence of a criminal fraud and abuse conviction, which may otherwise result in little or no prison time.[61] Finally, the Medicare and Medicaid statutes specify at least eighty situations in which civil money penalties can be administratively imposed.[62] Most of these authorities are rarely, if ever, used, though they provide one more vehicle for pursuing fraudulent or abusive conduct.[63]

III. THE ROLE OF FRAUD AND ABUSE ENFORCEMENT IN POLICING THE MEDICARE PROGRAMS

It is useful for heuristic purposes to divide the targets of fraud and abuse enforcement into two groups, though in reality the boundary between them is often far from clear. First, there are individuals and enterprises who provide no useful goods or services to federal health care program beneficiaries and whose sole or primary purpose for participating in these programs is to obtain money through fraud. Health care is a trillion dollar industry, and it attracts the same petty criminals and sophisticated criminal enterprises that are drawn to easy cash elsewhere.[64] These individuals and entities are indisputably the legitimate focus of law enforcement attention; they are not our

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61. *See* Howard E. O'Leary, *Regulating Health Care Costs Through Fraud Enforcement*, 62 DEF. COUNS. J. 211, 220-21 (1995) (discussing the severe effect of program exclusions and the need to avoid convictions to avoid exclusion); Johnsson, *supra* note 58, at 1. *See, e.g.*, Travers v. Shalala, 20 F.3d 993, 995-98 (9th Cir. 1994) (imposing mandatory exclusion upon doctor who was placed in deferred sentencing program after nolo contendre plea); Hein v. Inspector Gen., [1993 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 41,366 (D.A.B. Feb. 26, 1993) (excluding dentist for five years based on an "Alford" plea in which he pleaded not guilty but accepted conviction and sentence to community service and restitution).

62. JOST & DAVIES, *supra* note 39, §§ 2-5, 5-4.

63. Recent amendments to the Medicare and Medicaid administrative penalty provisions, for example, provide for penalties for upcoding, 42 U.S.C. § 1320a-7(a)(1)(A) (1994 & Supp. III 1997), and for the billing of medically unnecessary care, *id.* § 1320a-7(a)(1)(E). Upcoding and billing for unnecessary services are also, of course, already covered by the criminal, *see id.* § 1320a-7(a), (b), and civil, *see* 31 U.S.C. § 3729 (1994), False Claims Acts.

64. *See* Stephen J. Hedges, *The New Face of Medicare: Organized-Crime Involvement with Medicare*, U.S. NEWS & WORLD REP., Feb. 2, 1998, at 46-52; Malcolm K. Sparrow, *Fraud Control in the Health Care Industry: Assessing the State of the Art*, NAT'L INST. OF JUST. RES. IN BRIEF, Dec. 1998, at 1.

concern here.

It would be a mistake, however, to think of fraud and abuse enforcement only—or even primarily—in terms of this group of perpetrators. An equally important, perhaps more important, function of fraud and abuse enforcement is to police the behavior of a second group—genuine providers, suppliers and professionals who provide real goods and services to program beneficiaries, but who, in doing so, respond improperly to the incentives built into the payment systems of our public health care financing programs.[65] This category of fraud and abuse enforcement is our concern here.

Health care systems must inevitably pay providers in one way or another. By virtue of their structure, payment systems unavoidably provide incentives for certain kinds of provider behavior—for example, the provision, of more, or of higher quality, or of more cost-effective health care goods and services.[66] Payment systems are often consciously designed to promote such goals.[67] If the incentives of payment systems are the engines that propel provider performance, however, fraud and abuse enforcement is the rails and brakes that direct proper payment practices and restrain providers' misconduct.

When Medicare was established in the mid-1960s, it adopted the cost- and charge-based fee-for-service payment methods commonly used by Blue Cross and Blue Shield plans at the time.[68] Over the past three decades, Medicare has become much more sophisticated in paying for health care goods and services—developing its own per case, per diem, and per service payment systems. These systems are still, however, fundamentally fee-for-service systems; they still pay providers or professionals for delivering distinct units of health care services.[69]

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65. *See* JOST & DAVIES, *supra* note 39, § 2-1.

66. *See, e.g.*, Thomas Bodenheimer & Kevin Grumbach, *Reimbursing Physicians and Hospitals*, 272 JAMA 971 (1994).

67. *Id.* at 971-75 (discussing commonly used methods for paying doctors and hospitals and the effects of such payments).

68. *See* Timothy S. Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 85 (1999).

69. Currently only about 15% of Medicare beneficiaries receive care through capitated-managed care plans; the rest remain in fee-for-service Medicare. *See generally* John K. Iglehart, *The American Health Care System, Medicare*, 340 NEW ENG. J. MED. 327 (1999) (discussing the structure of Medicare payment); *see also* DAVID G. SMITH, PAYING FOR MEDICARE: THE POLITICS OF REFORM 181-200 (1992) (de-

Fee-for-service payment creates incentives for providers to (1) maximize the volume of profitable goods and services for which they bill and (2) maximize profit per service by billing for the highest payment rate available for a service, while at the same time minimizing the amount expended in providing the service.[70] Thus, the optimal strategy for a hospital paid on a diagnosis-related group ("DRG") per-case basis would be to maximize admissions of Medicare patients covered by profitable DRGs, bill for the most complex DRGs permitted, and minimize the costs of delivering care.[71]

Service volume can be maximized both through legitimate and illegitimate means. The most socially beneficial strategy for maximizing volume is to develop a reputation for providing high quality care at a reasonable price and a large base of satisfied patients.[72] Referral of patients may also be legitimately increased by gaining the respect and recognition of professionals who are in positions to refer patients.[73] But claims volume can also be increased through illegitimate means: paying bribes and

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scribing the design of the current Medicare hospital and physician reimbursement systems).

70. *See* CAM DONALDSON & KAREN GERARD, ECONOMICS OF HEALTH CARE FINANCING: THE VISIBLE HAND 32-35 (1993) (describing the incentives created by fee-for-service payments); Uwe Reinhardt, *Hipocrates and the "Securitization" of Patients*, 277 JAMA 1850 (1997); Bodenheimer & Grumbach, *supra* note 66, at 971-75.

71. *See* Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 YALE J. ON REG. 499, 509-13 (1990).

72. This is, of course, what happens in competitive markets under ideal conditions. *See* DONALDSON & GERARD, *supra* note 70, at 15. The strategy of managed competition, the heart of the Clinton health reform plan, is based on trying to improve competition in the health care industry, primarily through creating information and facilitating consumer choice, to make this provider strategy more common and rewarding. *See* Alain C. Enthoven, *The History and Principles of Managed Competition: Why Managed Care Has Failed to Contain Health Costs*, 14 HEALTH AFF. 27-28 (1995).

73. The key role of physicians in acting as patients' agents in making health care purchasing decisions has long been recognized. *See generally* Kenneth Arrow, *Uncertainty and The Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 949-51 (1963). Since physicians control about 70% of health care spending and, in particular, control admission to health care institutions, quality and price-based competition for their attention and allegiance is an important and legitimate form of competition. MICHAEL D. ROSKO & ROBERT W. BOYLES, THE ECONOMICS OF HEALTH CARE: A REFERENCE HANDBOOK 82 (1988); Mark Pauley, *Is Medical Care Different?*, FEDERAL TRADE COMM'N, COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 19 (1978).

kickbacks for referrals, billing for "gang visits" to nursing homes or for unnecessary care or for goods and services not in fact provided, "unbundling" codes to increase the volume of services billed, or forging prescriptions and certifications to support bills from non-physician providers or suppliers.[74]

Similarly, the profitability of providing goods and services can be enhanced both properly and improperly. Medicare providers are entitled to try to make a profit by claiming the most financially advantageous code appropriate for a service and minimizing their costs through legitimate efficiencies and economies.[75] Some providers, however, maximize their profit per service instead through illegitimate upcoding, underservice (such as premature discharge when services are paid on a per-case basis), inflated cost reports where payments are cost-related, or cuts in expenditures that undermine quality (such as understaffing).[76]

Though fee-for-service payment systems have historically dominated Medicare, this may not be true much longer. Increasingly, Medicare beneficiaries have moved from fee-for-service to at-risk managed care organizations ("MCO"s), and the Balanced Budget Act of 1997 attempts to increase this movement radically through the Medicare & Choice program.[77] Recent congressional proposals would increase this movement away from fee-for-service medicine by turning Medicare into a premium support program that would assist in purchasing private insurance for

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74. *See* PAMELA H. BUCY, HEALTH CARE FRAUD: CRIMINAL, CIVIL AND ADMINISTRATIVE LAW §1.03[2][a] (1996 & Supp. 1999); JOST & DAVIES, *supra* note 39, § 1-5; Pamela H. Bucy, *Health Care Reform and Fraud by Health Care Providers*, 38 VILL. L. REV. 1003, 1008-15 (1993); *see also* Office of Inspector General, Fraud Alert, Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 Fed. Reg. 1813, 1815 (1999); OFFICE OF INSPECTOR GEN., ORDERING MEDICARE EQUIPMENT AND SUPPLIES: PHYSICIAN PATIENT RELATIONSHIPS 12 (1999).

75. *See, e.g.*, Lave, *supra* note 71, at 509 (discussing prospective hospital payment).

76. *See* JOST & DAVIES, *supra* note 39, § 1-5; Bucy, *Health Care Reform and Fraud By Health Care Providers*, *supra* note 74, at 1015-20; *Fraud and Abuse: Health Care Enforcement Efforts Moving in New Direction, Sheehan Says*, Health Care Daily Rep. (BNA), July 1, 1998, at d9, *available in* WL 7/1/98 HCD d9 (describing use of fraud and abuse laws to address problems of underservice in managed care) [hereinafter *New Direction*].

77. *See* MEDICARE PAYMENT ADVISORY COMM'N, CONTEXT OF A CHANGING MEDICARE PROGRAM 5-6 (1998).

beneficiaries.[78] Under both the risk-based MCO and the premium support alternatives, payment is essentially capitated.[79] Public programs pay health plans or providers on a risk-adjusted per-beneficiary basis rather than on a per-service basis.[80] The risk of exposure for increased costs is shifted from Medicare to the MCO, insurer or provider.[81]

Capitated systems create incentives for insurers and MCOs to maximize covered populations (especially healthy populations), minimize risk exposure, minimize costs, and seek supplemental income. As in fee-for-service medicine, profits in capitated systems can be made legitimately and illegitimately.[82] Covered populations can be maximized legitimately by developing a reputation for providing conscientious service and competent care, or they can be maximized illegitimately through fraudulent recruiting practices or by offering kickbacks to persons who can steer beneficiaries to the plan.[83] Instead of legitimately managing risk, MCOs can illegitimately avoid risk through "cherry-picking," illegally disenrolling the sick, and by shifting the provision of service to any carve-outs specified in a plan.[84] Costs can be minimized legitimately through efficient operation, but they can be minimized also through illegitimate underservicing of patients and underpaying of providers.[85] In addition, MCOs can illegitimately attempt to increase their income by collecting improper supplemental premiums from bene-

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78. *See* John Breaux, *Premium Supports Can Help*, USA TODAY, Jan. 13, 1999, at 14A; Gail R. Wilensky & Joseph P. Newhouse, *What's Right? What's Wrong? What's Next?*, 18 HEALTH AFF. 92, 100-05 (1999).

79. *See, e.g.*, Bodenheimer & Grumbach, *supra* note 66.

80. *See* Lisa I. Iezzoni et al., *Paying More Fairly for Medicare Capitated Care*, 339 NEW ENG. J. MED. 1933 (1998); Wilensky & Newhouse, *supra* note 78, at 103-04.

81. *See* Frances Miller, *Capitation and Physician Autonomy*, 6 HEALTH MATRIX 89 (1996).

82. *See* Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?*, 31 GA. L. REV. 373, 385-93 (1997) (arguing that if payment systems are risk-adjusted, the optimal strategy would be to minimize risk exposure at any particular level of adjusted risk and to avoid any risk categories that are not profitable).

83. *See id.* at 387-89.

84. *See id.*; *Fraud and Abuse: Kickbacks, Managed Care, Patient Dumping Top IG Enforcement Agenda, Official Reports*, Health Care Daily Rep. (BNA), Mar. 27, 1998, at d4, *available in* WL 3/27/98 HCD d4.

85. Davies & Jost, *supra* note 82, at 385-87; Krohn, *supra* note 22, at 445-48.

ficiaries or by obtaining kickbacks from suppliers, such as drug manufacturers.[86]

Moreover, changing from a fee-for-service to a capitated payment system does not necessarily eliminate the fraud and abuse risks inherent in fee-for-service systems if the rate paid to MCOs or insurers is in any respect related to the payments the MCOs or insurers make to providers.[87] MCOs or insurers themselves often pay providers on a fee-for-service basis for providing direct goods and services to patients.[88] These MCOs and insurers are potential victims of the same abuses to which fee-for-service Medicare is currently subject. Capitation simply moves the risks of fraud and abuse downstream.

Provider responses to the incentives offered by public health care financing program payment structures cannot always easily be categorized as legitimate or illegitimate. Rather, they lie along a continuum ranging from beneficial to inexcusable. At one end of this continuum is appropriate and efficient conduct, such as increasing the number of patients served through successful quality- and service-based competition or decreasing costs through increased productivity. Further along the continuum are what might be called "enthusiastic" responses to incentives. These include responses that the designers of the incentive system perhaps did not contemplate, but they are not yet beyond the bounds of either reasonableness or manageability.[89] To illustrate, in most of the years since Medicare first adopted DRG

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86. *Fraud and Abuse: Philadelphia Prosecutors Investigate Fraud in Drug Formularies, Questionable HMO Denials*, Health Care Daily Rep. (BNA), June 29, 1998, at d5, *available in* WL 6/29/98 HCD d5.

87. Until the Balanced Budget Act of 1997, DHHS regularly entered into cost-based contracts with MCOs. 42 U.S.C. § 1395mm(h) (Supp. III 1997); *see also* Merrile Sing et al., *The Consequences of Paying Medicare Managed Care Plans Their Costs*, 35 INQUIRY 210 (1998). Medicare cost-reimbursement MCOs are being phased out under the BBA, and they will be eliminated after 2002. 42 U.S.C. § 1395mm(h)(5).

88. *See* Davies & Jost, *supra* note 82, at 390-91.

89. "Enthusiastic coding" has long been recognized as a factor in Medicare. One commentator noted that, prior to the recent increased government surveillance of providers, inconsistency in government interpretation of program requirements and lax oversight led to a situation in which "some institutions must have gotten the message that if they were not upcoding or over-serving to enhance their Medicare reimbursements they were the only ones around not doing so." Connie R. Curran, *Whose Needs are Being Met?*, 15 NURSING ECON. 233, 278 (1997).

per-case reimbursement, and in particular following the years in which the DRG system was extensively modified, DRG case-mix complexity has increased, presumably in part because providers are assigning more remunerative codes than they had previously used in order to make up for income otherwise lost.[90] Medicare has primarily addressed this phenomenon, however, not through vigorous efforts to stamp out such "upcoding," but rather by decreasing the amount paid per case.[91] The system can accommodate a reasonable amount of gaming.

Following the continuum across the boundary between legal and illegal reactions to incentives, one comes to responses that are properly characterized as fraud and abuse: excessive and illegal upcoding, unbundling, provision of unnecessary care, cherry-picking, underservice, or provision of care of substandard quality.[92] At the far end of the spectrum, one crosses another boundary and enters the world of fraudulent enterprises, plain and simple—entities that bill for goods and services never rendered or that provide no goods and services at all. The territory of activity that falls between the borders that bound permitted (though sometimes dubious) responses to incentives and outright fraudulent enterprises has increasingly become the domain of fraud and abuse enforcement.

Fraud and abuse enforcement has long addressed improper provider responses to fee-for-service incentives, such as upcoding, unbundling, billing for unnecessary goods and services, or inflated cost reports.[93] In the late 1990s, the enforcement initiatives challenging this conduct have become much more extensive, aggressive and organized. National enforcement ini-

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90. MEDICARE PAYMENT ADVISORY COMM'N, REP. TO CONGRESS: MEDICARE PAYMENT POLICY 58 (1999); OFFICE OF INSPECTOR GEN., INSPECTOR GENERAL'S REP. ON THE HEALTH CARE FIN. ADMIN., 1996 FIN. REP. (1997). There are also a number of studies showing that physicians increase the volume and complexity of their billing in response to fee reductions. Winnie C. Yip, *Physician Response to Medicare Fee Reductions: Changes in the Volume of Coronary Artery Bypass Graft (CABG) Surgeries in the Medicare and Private Sectors*, 17 J. HEALTH ECON. 675 (1998).

91. *See, e.g.*, MEDICARE PAYMENT ADVISORY COMM'N, REP. TO CONGRESS: MEDICARE PAYMENT POLICY II 52-53 (1998) [hereinafter MEDICARE PAYMENT POLICY II].

92. *See, e.g.*, Bucy, *Health Care Reform and Fraud by Health Care Providers*, *supra* note 74, at 1008-15; Bucy, *Civil Prosecution for Health Care Fraud*, *supra* note 50, at 693-95.

93. JOST & DAVIES, *supra* note 39, § 2-1.

tiatives, such as the PATH audits, the lab unbundling project, the DRG window project, and others, have brought the full power of the DOJ and the OIG into play in confronting abusive provider billing practices.[94]

Fraud and abuse enforcement challenges to improper relationships among providers and professionals have also become more determined. Provider attempts to increase the volume of patient referrals through the use of bribes and kickbacks have long been illegal but in recent years have been confronted much more aggressively by fraud and abuse enforcers.[95]

At the close of the 1990s, moreover, fraud and abuse enforcement has moved beyond challenging improper billing practices to challenge other abusive provider conduct. As noted above, providers can often increase profitability by limiting the resources they expend to provide care of adequate quality to program beneficiaries.[96] To be eligible to receive Medicare payment, a provider must meet minimum program certification requirements.[97] A provider that fails to meet program requirements cannot legally claim Medicare payment; therefore, a provider that represents that it is entitled to payment without meeting these requirements is making a false claim or statement.[98] Public payment programs have, of course, systems for overseeing compliance with requirements related to quality or

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94. Chris Serb, *Compliance Best Defense Against Medicare Fraud for Hospitals & Health Networks*, Sept. 5, 1997, at 50, *available in* WL 9/5/97 HHNTWK 50 (discussing the Dep't of Health & Human Services' three primary probes: (1) the clinical laboratory investigation to determine whether labs are upcoding procedures or unbundling, (2) the DRG window project to examine whether providers billed for a patient's follow-up services within 3 days of discharge, and (3) the PATH project, which examines whether senior doctors received payments for services that were actually performed by residents at teaching hospitals).

95. JOST & DAVIES, *supra* note 39, ch. 3.

96. *See* 1997 ANNUAL REP., *supra* note 21, at 8, 11-12; Leon Aussprung, *Fraud and Abuse: Federal Civil Health Care Litigation and Settlement*, 19 J. LEGAL MED. 1, 29-30 (1998).

97. Nursing Homes, for example, must meet extensive statutory and regulatory requirements. 42 U.S.C.A §§ 1395i-3, 1396r (West 1992 & Supp. 1999); 42 C.F.R. pt. 483 (1998).

98. United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997), *on remand*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998); *see* David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANNALS OF HEALTH L. 147, 156 (1997); *Fraud and Abuse: Health Care Enforcement Efforts Moving in New Direction*, *supra* note 76, at d9.

adequacy of goods and services.[99] Nursing homes, for example, are inspected by the states.[100] However, these programs have been notoriously ineffective in addressing quality problems.[101] In the recent past, therefore, fraud and abuse enforcers have begun to try their hand at deterring this inappropriate provider behavior.[102]

Recent escalation of fraud and abuse enforcement is having dramatic effects. In 1998, Medicare costs rose only by 1.5%, the lowest growth rate in the history of the program.[103] During the first six months of FY 1999, the cost of the Medicare program actually dropped $2.6 billion.[104] Analyses of these developments gave direct credit to fraud and abuse enforcement as an important factor in containing cost growth.[105] The level of intensity of the DRG case-mix, which has increased in most years, stayed stable in 1998.[106] In the same year, moreover, the HCFA financial audit found that the number of improperly paid Medicare claims dropped from $23.6 billion to $12.6 billion, 7% of total Medicare payments.[107] Fraud and abuse enforcement

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99. *See* 42 U.S.C.A. § 1395i-3.

100. *See id.* § 1395i-3(B)(i) (requiring that registered nurses inspect such facilities and allowing for inspection by state officials in the event falsification is discovered).

101. *See, e.g.*, U.S. GEN. ACCOUNTING OFFICE, NURSING HOMES: ADDITIONAL STEPS NEEDED TO STRENGTHEN ENFORCEMENT OF FEDERAL QUALITY STANDARDS (1999) (including one of the most recent reports on this topic); U.S. GEN. ACCOUNTING OFFICE, NURSING HOMES: COMPLAINT INVESTIGATION PROCESSES OFTEN INADEQUATE TO PROTECT RESIDENTS (1999); DEPARTMENT OF HEALTH & HUMAN SERVS. & OFFICE OF INSPECTOR GEN., QUALITY OF CARE IN NURSING HOMES: AN OVERVIEW (1999) [hereinafter OIG: NURSING HOMES]; U.S. GEN. ACCOUNTING OFFICE, CALIFORNIA NURSING HOMES: CARE PROBLEMS PERSIST DESPITE FEDERAL AND STATE OVERSIGHT (1998) (including recent reports documenting this problem).

102. OIG: NURSING HOMES, *supra* note 101, at 12.

103. Robert Pear, *'98 Medicare Growth Slowest Since Program Began in '65*, N.Y. TIMES, Jan. 12, 1999, at A1.

104. Laurie McGinley, *Usual Enemies Trade Roles in Medicare-Funds Battle*, WALL ST. J., May 11, 1999, at A24.

105. *See* Pear, *'98 Medicare Growth Slowest since Program Began in '65*, supra note 103, at A1; McGinley, *supra* note 104, at A24.

106. *See* MEDICARE PAYMENT POLICY II, *supra* note 91, at 58-60.

107. *Fiscal Year 1998 Financial Statement Audit: Hearing on Financial Management Before the Information and Technology Subcomm. of the House Comm. on Gov't Reform and Gov't Management*, 106th Cong. 3-5 (1999) (statement of June Gibbs Brown, Inspector General); Robert Pear, *Improper Medicare Payments Fall, But Still Cost $12 Billion*, N.Y. TIMES, Feb. 10, 1999, at A15 (noting that $9.3 billion was attributed to upcoded claims or claims for unnecessary treatment, $2.1 billion to documentation discrepancies, and $1.2 billion to non-covered services or other errors,

officials claim that these statistics show that providers are becoming more cautious in their billing because of concern about fraud and abuse enforcement and that this caution is having an effect on program expenditures.[108]

IV. THE BACKLASH AGAINST FRAUD AND ABUSE ENFORCEMENT

As fraud and abuse law enforcers have become more aggressive and creative in policing the payment practices of genuine providers, providers have begun to fight back, often quite pugnaciously. The primary grievances of providers protesting the expanding scope and severity of fraud and abuse enforcement are threefold. First, they complain that fraud and abuse sanctions are too severe, i.e., they assert that prosecutors impose, or at least threaten, enormous and punitive fraud and abuse sanctions for trivial offenses.[109] Second, they protest that Medicare program requirements are too complex and unclear and that sanctions are being imposed in situations where providers have made good faith attempts to comply with program requirements but have simply misunderstood the requirements or understood them differently than did the government.[110] And finally, they object that there is, in reality, no practical way to resist the demands of fraud and abuse enforcers—that providers are vulnerable to unfair and abusive coerced settlements.[111]

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with 39% of the improper claims being submitted by hospitals, 26% by physicians and 13% by home health agencies).

108. Pear, *Improper Medicare Payments Fall, But Still Cost $12 Billion*, *supra* note 107, at A15. Additional examples of the deterrence can also be found. After several durable medical equipment ("DME") suppliers were convicted of fraudulently misrepresenting the nature of lymphedema pumps supplied to Medicare recipients, claims for the pumps dropped by 92%, saving Medicare $76.2 million in one year. OFFICE OF INSPECTOR GEN., MEDICARE ALLOWANCES FOR LYMPHEDEMA PUMPS (1998) (last modified July, 1998) <http://www.dhhs.gov/progorg/oei>.

109. *See supra* notes 27-28 and accompanying text.

110. *See supra* notes 25-28 and accompanying text.

111. *Supra* note 28 and accompanying text.

A. Grievance #1: The Penalties are Too Severe

The provider concern regarding the severity and proportionality of sanctions is a serious one. As noted above, the civil FCA provides for both treble damages and penalties of $5,000 to $10,000 per claim.[112] There is little legislative history as to the intent of Congress in adopting these penalties, but the provisions seem to have been intended both to deter false claims and statements and to cover the costs the government incurs in investigating and prosecuting false claims.[113] In the health care program context, however, providers protest that they result in overkill.

In traditional false claims contexts, such as fraud in defense contracting, the per claim penalties do not become a major issue because the contracts result in a relatively small number of relatively large claims.[114] Health care providers, however, typically submit a steady stream of small claims, resulting, in the aggregate, in enormous volumes of claims.[115] Hospitals may submit hundreds of claims a day.[116] A computer error or a mis-

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112. 31 U.S.C. § 3729 (1994).

113. *See* United States v. Stocker, 798 F. Supp. 531, 536 (E.D. Wis. 1992).

114. *See, e.g.*, Hughes Aircraft v. United States *ex rel.* Schumer, 520 U.S. 939 (1997) (illustrating the most recent Supreme Court FCA case in which the plaintiff sought a judgment of $150 million for a $50 million overcharge, but per claim penalties were not mentioned as an element of recovery); United States v. Bornstein, 423 U.S. 303 (1976) (holding defense subcontractor liable for three penalties for three false shipments of falsely marked electron tubes to prime contractor).

115. *See* U.S. GEN. ACCOUNTING OFFICE, APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES 3 (1998). Medicare processed over 900 million claims in 1997. *See* U.S. GEN. ACCOUNTING OFFICE, HCFA MANAGEMENT: AGENCY FACES MULTIPLE CHALLENGES IN MANAGING ITS TRANSITION TO THE 21ST CENTURY 3 (1999).

116. In aggregate, hospitals file about 200,000 claims a day, according to the American Hospital Association ("AHA"). *See supra* sources accompanying note 52. The HCFA's review of claims at the University of Pennsylvania hospital covered 1.4 million claims over a six-year period. *See* PATH INITIATVE, *supra* note 28. Provider advocates often exaggerate this point, however. One very common version of this complaint begins with the assertion that the average hospital files 200,000 claims a day. *See* Dan Freedman, *Hospitals Seek Relief From Medicare Fraud Investigations*, SAN ANTONIO EXPRESS-NEWS, May 3, 1998, at A4; *Fraud and Abuse: Federal Prosecutors in Texas Back off Operation Bad Bundle Due to Data Problems*, Health Care Daily Rep. (BNA), Nov. 23, 1998, at d3, *available in* WL 11/23/98 HCD d3 [hereinafter *Operation Bad Bundle*]; *Fraud and Abuse: DOJ Ready to Work With Hospitals to Tone Down Harsh FCA Demand Letter*, Health Care Daily Rep. (BNA), Apr. 29,

understanding of coding requirements can result in thousands of erroneous claims being filed over a reasonably short period of time. Even if individually quite small, when the amounts wrongly claimed are trebled, and the number of claims is multiplied by $5,000 to $10,000, astronomical sums are quickly reached. Two hundred $50 false claims, for example, could result in sanctions of between $1,030,000 and $2,030,000. The practice of statistical extrapolation makes the threat of enormous civil sanctions even more real. Suppose, for example, that an investigator reviews 400 out of a universe of 4000 claims of $50 each and finds twenty of the 400 claims to be false. Utilizing statistical extrapolation techniques, a prosecutor might conclude that 200 of the 4,000 claims were false, warranting, again, a penalty between one and $1,000,000 to $2,000,000 based on the twenty false claims actually identified.[117]

For many providers, the threat of program exclusion is even more ominous than the possibility of multi-million dollar penalties.[118] This is particularly true of providers and professionals who depend on Medicare because they specialize in the care of the elderly and disabled (hospices, home health agencies and nursing homes) or because the elderly and disabled constitute a significant share of their caseload (hospitals, internists

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1998, at d4, *available in* WL 4/29/98 HCD d4; *Grassley Leaks Results of IG Audit; AHA Says No Legal Basis for DOJ Probe*, Health Care Daily Rep. (BNA), Apr. 24, 1998, at d2, *available in* WL 4/24/98 HCD d2. This statement is based on an erroneous understanding of the plausible AHA assertion that, in aggregate, hospitals file 200,000 claims per day. Taken literally, however, this statistic applied to individual hospitals would mean that the nearly 6400 hospitals that participate in Medicare submit nearly 500 billion claims a year. In fact, in total Medicare processes "only" 900 million claims annually. *Medicare: HCFA's $23 Billion Error Rate Said to Show Need for Random Audits*, Health Care Daily Rep. (BNA), July 18, 1997, at d8, *available in* WL 7/18/97 HCD d8.

117. The minimum sample size recommended by the Medicare Carrier's Manual is 320. Lester J. Perling, Esq., Address at the American Health Lawyer's Association's Institute on Medicare and Medicaid Payment Issues (Mar. 24-26, 1999) (explaining the Health Care Financing Administration's Guidelines for the use of statistical sampling in the calculation of overpayments). Carriers conducting audits, however, often use a program Med-189, which uses samples of 30 cases that are stratified into five strata of six cases each. Actual claims for overpayments, therefore, are often effectively based on samples of six cases. *See* Michael D. Intriligator, Challenging the Use of Statistical Procedures in Overpayment Determinations, Address at the American Health Lawyers Association's Institute on Medicare and Medicaid Payment Issues (Mar. 24-26, 1999).

118. *See supra* note 61 and accompanying text.

and ophthalmologists).[119]

Perhaps the greatest threat is the five year mandatory exclusion following a conviction of a felony related to the delivery of an item or service paid for by Medicare or a state health program or for fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct involving a federal, state or local government health care program.[120] Mandatory exclusion is subject to only very limited exceptions.[121] Moreover, the person or entity threatened with exclusion cannot challenge the conviction collaterally in the exclusion proceedings.[122] And if a person who is convicted (or subjected to a civil money penalty or excluded) subsequently acquires, directly or indirectly, an ownership or controlling interest of 5% or more in a Medicare provider, that entity may be excluded as well.[123]

B. Grievance #2: The Statutes and Regulations are Too Complex

Providers assert that the severity of fraud and abuse sanctions is particularly ominous because a simple misinterpretation of the intricate and enigmatic laws and regulations can subject even the most careful provider to enormous penalties.[124] Providers allege that the fraud and abuse laws are both vague in their sweeping breadth and confusing in their specificity.[125]

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119. In 1997, for example, the federal government paid for 50% of hospital care, 48% of home health care, and 42% of nursing home care. Bradley R. Braden et al., *National Health Expenditures 1997*, 20 HEALTH CARE FIN. REV. 83, 116 (1998). Over half of the work of ophthalmologists, for example, is paid for by Medicare. *Medicare Physician Referral Laws: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 106th Cong. 1 (1999) (testimony of William Rich III, M.D., Secretary for Federal Affairs of the American Academy of Opthamology).

120. 42 U.S.C. § 1320a-7(a)(1) (1994); *id.* § 1320a-7(a)(3) (Supp. III 1997). Under the 1997 BBA, moreover, providers convicted of three health care related crimes must be permanently excluded from Medicare participation. *See id.* § 1320a-7(b)(1)(B) (1994 & Supp. III 1997).

121. An exclusion may be waived in situations where a state requests a waiver because the provider is a sole community physician or sole source of essential specialized services in a community. *Id.* § 1320a-7(c)(3)(B) (1994).

122. Travers v. Shalala, 20 F.3d 993, 998 (9th Cir. 1994); JOST & DAVIES, *supra* note 39, § 5-2.

123. 42 U.S.C. § 1320a-7(b)(7).

124. *See supra* note 27 and accompanying text.

125. *See, e.g.*, SMOAK, *supra* note 25, at 1.

The FCA, for example, prohibits false and fraudulent claims generally, without specifying what constitutes a false or fraudulent claim.[126] The bribe and kickback and self-referral prohibitions, on the other hand, are subject to a labyrinth of prohibitions, explanations and exceptions that perplex even highly specialized attorneys.[127]

Beyond the complexity of the fraud and abuse provisions, however, lies the far greater intricacy of federal and state health care program billing and certification requirements. The Medicare statute, for example, spans over 400 pages in the United States Code, and the Medicare Regulations span to over 1200 dense Code of Federal Regulations pages.[128] Complexity expands exponentially as one turns to the eighteen Medicare Manuals (some of which consist of several parts) and thousands of pages of HCFA Administrator Rulings, Program Memoranda and Operational Policy Letters.[129] Medicare claims are processed by contractors known as Carriers, Intermediaries, Home Health Regional Intermediaries and Durable Medical Equipment Regional Carriers, which also each have their own medical review policies.[130] Doctors protest that errors are unavoidable when they must juggle more than 7000 Current Procedural Technology ("CPT") medical procedure codes.[131] Finally, the program is in

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126. *See infra* note 306 and accompanying text; 31 U.S.C. § 3729 (1994); 18 U.S.C. § 287 (1994); *id.* § 1003 (1994 & Supp. III 1997).

127. *See generally Medicare Physician Referral Laws: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 106th Cong. 1 (1999) (statement of Sanford V. Teplitzky, partner, Ober, Kaler, Crimes & Shriver, Baltimore, MD). This complexity, of course, not only confuses providers, but it also creates a resentment among providers that makes them more reluctant to report fraud or to condemn it in their peers. *See* Sparrow, *supra* note 64, at 6.

128. Jost, *supra* note 68, at 65, 89-96.

129. *Id.* at 92-93 nn.295, 298.

130. *Id.* at 94; *see also* David M. Frankford, *Food Allergy and the Health Care Financing Administration: A Story of Rage*, 1 WIDENER L. SYMP. J. 159, 172-77 (1996) (describing the role of Medicare contractors in policy making).

131. *See* Johnsson, *supra* note 58, at 1; *see also* Allan S. Brett, *New Guidelines for Coding Physicians' Services—A Step Backward*, 339 NEW ENG. J. MED. 1705 (1998); *A Somewhat Straighter PATH: This Troubled Medicare Audit Program Has Been Improved, But More Changes are Needed for It to Operate Fairly*, 40 AM. MED. NEWS, Aug. 11, 1997, at 17 (advising the OIG, "[i]f you are going to blame the doctor for not following the rules, you first have to make clear what the rules are"). On the other hand, the complexity of coding also makes both coding errors and coding scams difficult to detect. *See Fraud and Abuse: Lax Oversight by HCFA Enabling Hospitals to "Upcode," Overbill Medicare*, Health Care Daily Rep. (BNA), Feb. 1,

continual flux, with new payment schemes and codes continually being developed and implemented.[132] The 1997 BBA, for example, created about 240 changes affecting Medicare,[133] which represents only a fraction of the changes made at the agency or contractor level during that year.[134] Providers charge that even the government is overwhelmed by this complexity, that fraud and abuse enforcers initiate false claims investigations without understanding program rules, and that enforcers make assertions claiming provider misconduct before they really understand or have analyzed claims data on which the charges are based.[135]

Moreover, clarification of confusing requirements is often hard to obtain. The Supreme Court, for example, has held that the federal government is not estopped by the oral representations of employees of Medicare contractors in response to questions regarding program requirements.[136] Administrative review procedures under the Medicare program are multi-layered 1and time-consuming.[137] They are also not available for all payment decisions.[138] Judicial review is even less available.[139]

1999, at d4, *available in* WL 2/1/99 HCD d4.

132. *See Medicare: Congress Should Not "Undo" BBA Changes: HCFA, GAO, and Medpac Tell Senate Panel*, Heath Care Daily (BNA), Mar. 18, 1999, d7, *available in* WL 3/18/99 HCD d7.

133. *Id.*

134. *See* U.S. GEN. ACCOUNTING OFFICE, BALANCED BUDGET ACT: IMPLEMENTATION OF KEY MEDICARE MANDATES MUST EVOLVE TO FULFILL CONGRESSIONAL OBJECTIVES 4 (1998) (citing testimony of William J. Scanlon before Subcomm. on Health of the House Comm. on Ways and Means).

135. *See Operation Bad Bundle*, *supra* note 116, at d3; *Fraud and Abuse: DOJ Refutes Charges of Prosecuting "Honest Billing Errors;" Industry Continues to Cry Foul*, Health Care Daily Rep. (BNA), May 22, 1998, at d6, *available in* WL 5/22/98 HCD d6.

136. Heckler v. Community Health Servs. of Crawford Co., 467 U.S. 51, 54-57, 64-67 (1984).

137. *See generally* Eleanor Kinney, *The Medicare Appeals System for Coverage and Payment Determinations, Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1, 39-54 (1987).

138. Administrative review is not available for claims of under $100, for example. 42 U.S.C. § 1395ff(b)(2) (1994 & Supp. III. 1997); 42 C.F.R. § 405.720 (1998). For some determinations, the only remedy a disappointed provider can hope for is waiver-of-liability, under which the Medicare contractor will pay the provider while maintaining that the service claimed is not covered by Medicare. Timothy Stoltzfus Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J.

Even the fact that a Medicare policy is ultimately proven to be in error may not shield a provider who intentionally files claims in an attempt to evade the policy. A recent Ninth Circuit case, for example, stated in dicta that a provider who intentionally submitted claims that violated an administrative policy could be held liable for false claims, even if the policy was improperly promulgated under the Administrative Procedure Act ("APA").[140]

C. Grievance #3: Coerced Settlements

Finally, providers argue that even when they are innocent of submitting false claims and their interpretations of billing requirements are correct, they will often end up paying the government a penalty[141] because few fraud and abuse cases involving genuine providers are ever tried; virtually all are settled.[142] The severe sanctions threatened by the fraud and

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1, 66-67 (1989). A condition of waiver-of-liability, however, is that the provider was not on notice of the fact of non-coverage; thus, the provider can claim a waiver-of-liability only once for any particular service. *Id.; see also* 42 U.S.C. § 1395pp(a) (1994). A provider denied payment for a service is considered to be on notice thereafter of the non-coverage of the service, and any further claims for payment for the service could be seen as fraudulent. *Id.* § 1395pp(a).

139. Judicial review is available only for claims over $1000. 2 U.S.C. § 1395ff(b)(2) (1994 & Supp. III. 1997).

140. Cedars-Sinai Med. Ctr. v. Shalala, 125 F.3d 765, 765-69 (9th Cir. 1997). A subsequent decision in this case rejected the provider challenge to the Department of Health and Human Services regulation as not having been brought within the six year statute of limitations. *See* Cedars-Sinai Med. Ctr. v. Shalala, 177 F.3d 1126 (9th Cir. 1999).

141. *Fraud and Abuse: GAO Says DOJ Oversight by FCA Guidance Still Inconsistent, Superficial*, Health Care Daily Rep. (BNA), Aug. 10, 1999, at d2, *available in* WL 8/10/99 HCD d2 [hereinafter *Oversight*].

142. There are no publicly available statistics on the proportion of fraud and abuse cases that are settled and those that go to judgment. For one indication of the prevalence of settlements, see U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD REP. FISCAL YEAR 1997 (visited Sept. 29, 1999) <http://www.usdoj.gov/01whatnew/hcffraud2.htm> (describing a sampling of cases brought or settled under criminal or civil false claims authorities during FY 1997). The Report describes FCA settlements in 307 individual cases plus the settlement of 102 more hospitals in the DRG project, but it mentions only two FCA judgments. *Id.* Only a handful of FCA judgments in health care cases have been reported. *See, e.g.*, United States *ex. rel.* Trim v. McKean, 31 F. Supp. 2d 1308 (W.D. Okla. 1998); United States v. Krizek, 7 F. Supp. 2d 56 (D.D.C. 1998); United States v. Davis, [1996 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 44,907 (E.D. Mo. Oct. 10, 1996); United States v.

abuse laws place the provider charged with fraud and abuse violations in a perilous and intimidating predicament, in which settlement is often the only practical option. Whether or not a provider who innocently misconstrues a complex regulation would ever actually be found guilty in a court of law is in some ways moot if the provider cannot risk putting the issue of its culpability to a trier of fact.

Moreover, providers cannot even count on the protection of the practical constraints under which prosecutors normally operate.[143] With respect to most regulatory and criminal enforcement programs, regulators and prosecutors have limited resources and some level of political accountability.[144] We could expect, therefore, that their efforts would be focused on the most serious offenders. The FCA, however, is subject to enforcement not only by public officials, but also by private *qui tam* relators.[145] *Qui tam* relators can call into play the full panoply of false claims sanctions, and they can object to settlements reached by the government.[146] Providers, therefore, can put forth plausible claims that they are unfairly vulnerable to public and private abusive prosecutions and coerced, extortionate settlements.

V. The Backlash Critically Evaluated

Although these grievances have some force, they must be balanced against equally compelling evidence that some providers have victimized the Medicare program. Thus, the assertions of providers regarding the programs must be evaluated critically, both empirically and theoretically. We proceed in this section to do so.

Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991); United States v. Halper, 660 F. Supp. 531 (S.D.N.Y. 1987), *rev'd*, 490 U.S. 435 (1989).

143. *See Oversight*, *supra* note 141, at d2.

144. *See Fraud and Abuse: HCFA Transmittal Outlines Pilot to Encourage More Medicare Exclusions*, Health Care Daily Rep. (BNA), May 9, 1996, at d3, *available in* WL 5/9/96 HCD d3.

145. *See* 31 U.S.C. § 3730 (1994).

146. *See id.* § 3730(c)(2)(B).

A. Severity

We begin with the complaint of severity—that the civil, criminal, and administrative sanctions relied on by fraud and abuse enforcers are disproportionately severe. We approach this problem initially from the perspective of recent literature evaluating the general economic theory of the calibration of legal penalties.

Utilitarian economic theory regarding the role of penalties in deterring crime goes back to the work of Beccaria and Bentham in the eighteenth century[147] and has its modern foundations in Gary S. Becker's 1968 article, *Crime and Punishment: An Economic Approach*.[148] Much of the most recent literature in this area has examined the deterrent function of punitive damages.[149] A focal concern has been the problem of establishing the level of punitive damages necessary to achieve appropriate deterrence.[150]

In tort cases, it has been argued that damages should normally be calibrated to achieve what is referred to as "optimal deterrence," i.e., damages should be set sufficiently high to ensure that a tortfeasor fully internalizes all the costs that her conduct imposes on a victim, but penalties should not be set so high as to, on the one hand, force the tortfeasor to spend too much on loss avoidance, or on the other, compel the tortfeasor to forego gains potentially achievable through injurious conduct that exceed the losses that such conduct imposes on the victim.[151]

Therefore, the theory of optimal deterrence posits that there is a definite point at which punitive damages become inappropri-

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147. *See* CESARE BECCARIA, ON CRIMES AND PUNISHMENTS AND OTHER WRITINGS 31 (Richard Davies trans. & Richard Bellamy ed., 1995); JEREMY BENTHAM, AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION 165-66 (J.H. Burns ed., 1996).

148. 76 J. POL. ECON. 169 (1968).

149. *E.g.*, Keith N. Hylton, *Punitive Damages and the Economic Theory of Penalties*, 87 GEO. L.J. 421 (1998); A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869 (1998).

150. *See, e.g.*, Hylton, *supra* note 149, at 422; Polinsky & Shavell, *supra* note 149, at 873-75.

151. *See* Polinsky & Shavell, *supra* note 149, at 887-901.

ate.[152] Commentators commonly contrast this optimal-deterrence function of tort damages to the function of criminal penalties.[153] Criminal penalties, it is argued, must achieve "complete deterrence," i.e., completely dissuade the potential criminal from pursuing forbidden conduct, as opposed to "optimal deterrence," which implies deterrence only to the point at which society loses more in the costs of deterrence efforts than it does from the harm it seeks to deter.[154] Complete deterrence is also appropriate in civil cases, however, where the victim's loss exceeds the wrongdoer's gain from harmful conduct, since there is no benefit to society in allowing the conduct to occur under these circumstances.[155] To deter completely in either context, penalties must be high enough to deprive offenders totally of all potential gain from their wrongful conduct in order to remove any motivation for pursuing the conduct.[156]

The starting point for deterrence analysis in both the tort punitive damages and criminal law contexts is recognizing that deterrence is a function of both the level of potential penalties consequent to the wrongdoing and the likelihood that a penalty will be imposed on a wrongdoer.[157] To achieve optimal deterrence (i.e., to compel a wrongdoer to fully internalize a victim's loss), the amount of damages is derived by dividing the amount of a victim's loss by the probability of the wrongdoer being found liable for the loss.[158] Thus, if a wrongdoer causes a victim $10,000 in harm, but the likelihood of the wrongdoer being found liable is only one in ten (because, for example, the victim may not discover the cause of the injury, may not sue because the administrative costs of litigation are too high, or may not be

152. Hylton, *supra* note 149, at 422.

153. *Id.* at 421.

154. *Id.* at 421-28.

155. *Id.* at 429.

156. *See id.* at 427-30. A key distinction between tort and criminal law, it is often argued, is that the former "prices" behavior to force internalization of external costs, while the latter "prohibits" behavior in accordance with society's disdain for criminal acts. *See* John C. Coffee, *Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law*, 71 B.U. L. REV. 193, 194-98 (1991).

157. *See* Polinsky & Shavell, *supra* note 149, at 870-75.

158. Hylton, *supra* note 149, at 421-25; Polinsky & Shavell, *supra* note 149, at 887-96.

able to prove liability), total damages must be set at $10,000/0.10 or $100,000 to assure optimal deterrence.[159]

To achieve complete deterrence (as is appropriate where criminal conduct is involved), the penalty faced by the wrongdoer should equal or exceed any potential gain realizable by the wrongdoer from the wrongful conduct.[160] This level can be determined by dividing the wrongdoer's potential gain by the probability that the wrongdoer will be held liable for the conduct.[161] If, in the situation just described, the wrongdoer causes $10,000 in damages but realizes a $20,000 gain from the conduct, and the likelihood of the wrongdoer being held liable is again one in ten, the penalty necessary to achieve complete deterrence should equal or exceed $20,000/0.10, or $200,000.[162] Since any penalty greater than that necessary to deprive the wrongdoer of any gains from a course of conduct will also achieve complete deterrence, however, there is no reason not to impose upon the wrongdoer a penalty large enough to internalize the victim's losses (i.e., optimal deterrence penalties), where the victim's losses are greater than the wrongdoer's gain.[163] We have already noted that in the situation where the victim's loss exceeds the wrongdoer's gain, complete deterrence is usually appropriate.[164]

Determining whether complete or optimal deterrence is the proper objective of legal sanctions and calculating the correct penalty necessary to internalize losses (when optimal deterrence is appropriate), or to achieve elimination of gains (when complete deterrence is fitting) is a complex endeavor. We will first describe a baseline analysis of this problem with respect to various common forms of Medicare fraud, and then we will discuss a more elaborate analysis necessitated by certain situations. To begin with our conclusion, in most instances complete deterrence is the proper goal of fraud and abuse enforcement, and thus severe penalties are justifiable. In particular contexts, however,

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159. *See* Hylton, *supra* note 149, at 424; Polinsky & Shavell, *supra* note 149, at 887-96.

160. Hylton, *supra* note 149, at 426-30.

161. *Id.* at 427.

162. *See id.*

163. *See id.* at 429-30.

164. *See supra* notes 160-63 and accompanying text.

optimal deterrance might be a more appropriate goal most notably where fraud is committed by rogue corporate employees. In any event, if criminal conduct is at issue, complete deterrence is the proper goal of enforcement.[165]

B. Fraud and Abuse Baseline Deterrence Analysis

1. Claims Where No Good or Service was Provided or the Good or Service Provided Was Not Necessary.—With respect to some forms of Medicare fraud, the exercise of determining the appropriate level of deterrence is relatively straightforward. Where, for example, the wrongdoer either bills for a good or service that was simply not provided or the wrongdoer provides an unnecessary good or service just to obtain payment, the wrongdoer's gain is always less than the government's loss.[166] The loss the government suffers from health care fraud in these situations is the sum of 1) the payment the government makes to the provider, 2) the administrative costs the government incurs in making the wrongful payment (processing costs), and 3) the costs it incurs in identifying, investigating and prosecuting the false claim (policing costs).[167] To determine the provider's gain, on the other hand, we must subtract from the payment the provider receives the sum of 1) the expenses it incurs in billing the government, 2) the costs the provider incurs in concealing its activity, and 3) the money it expends in actually providing some sort of good or service. Because, by definition, the payment made by the government to the provider is exactly equal to the payment received by the provider from the government and the government's loss will always be greater than the payment amount, while the provider's gain will always be less than the

165. Hylton, *supra* note 149, at 421.

166. *See id.* at 440-41.

167. To be precise, our calculus should also consider the disutility suffered by society when the government is defrauded. This is not an insignificant consideration—one need only reflect on the state of societies where fraud against the government has come to be a widespread practice. However, social costs are very different to quantify in this context, and thus will be noted here and hereafter disregarded. *See* Hylton, *supra* note 149, at 434-39 (discussing consequential losses and secondary harms as factors to be considered in estimating social costs).

payment amount, the government's loss will exceed the provider's gain in these transactions.[168] In this situation, therefore, complete deterrence is always the proper enforcement goal.[169] Society has nothing to gain, and everything to lose, from the government paying public money to providers who do not provide anything of value to the public.

With respect to billing for unnecessary or unprovided goods or services, therefore, any penalty equal to or greater than the provider's gain, divided by the probability of the provider being found liable for the offense, will achieve complete deterrence and an efficient result.[170] If the provider knows that it faces only a 1% chance of being found liable for the fraudulent billing (because, for example, only 5% of its claims are audited, and the likelihood of the government prosecuting to settlement or judgment a false claim identified through an audit is only 1 in 5), the provider must face a penalty at least equal to the amount of its potential gain divided by 0.01 before it will be deterred from filing the false claim.[171] But any penalty in excess of this amount will also deter the provider's wrongful conduct.[172] As it is often easier for the government to measure its own losses than for it to determine a provider's gain, and as the government's loss is, again, by definition larger than the provider's gain, the government should usually be able to impose a penalty measured by its own loss, thus achieving not only complete deterrence, but also restitution of its losses.[173] But any larger penalty would also deter the provider from filing the claim and save society from the costs of the wrongful claim.[174] In sum, the objection that a penalty is excessively severe where the penalty was imposed on a provider for false claims based on the provision of unnecessary goods or services or the provider

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168. For example, if the provider bills the government $100 for a service not provided and clears $90 for the service after covering its costs of billing and concealment, while the government loses the $100 plus $5 for processing and auditing claims, the net loss to society of the transaction is $105-$90, or $15. *See supra* pp. 33-34; Hylton, *supra* note 149, at 440-41.

169. *See* Hylton, *supra* note 149, at 423, 431-33.

170. *See supra* notes 160-63 and accompanying text.

171. *See* Hylton, *supra* note 149, at 427, 429-30.

172. *See id.* at 429-30.

173. *See id.*

174. *Id.*

failed to provide anything of value is rarely supportable from an economic perspective.[175]

2. Upcoding or Unbundling Activity.—As to other types of false claims, baseline deterrence analysis is somewhat more complex, though in most instances it reaches the same result. With respect to some types of fraud, for example, an actual good or service is in fact provided to the program beneficiary (and thus to the government program), but the service provided is not the service for which the government is billed.[176] Where the provider upcodes or unbundles, for example, the beneficiary of the government program (and thus the government) actually receives a service, but the government is billed for a more valuable service than the beneficiary receives (upcoding) or for more than the government is willing to pay for the service actually provided (unbundling).[177] In these situations, the government's loss is not the sum of the total amount the government paid added to processing and policing costs,[178] as was the case where no service of value was provided, but rather, it is this amount minus the sum of the price the government would have paid for the good or service it actually received and the cost it would have incurred for processing a properly submitted claim.

The provider's gain from the fraud must also be reduced in these situations by the amount of the payment it would have received had it billed properly for the service it actually provided.[179] Thus the government's loss still exceeds the provider's

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175. There are, of course, reasons to avoid extreme penalties. Routinely invoking the death penalty for petty offenses, for example, would not only undermine marginal deterrence, but it also would insensitize us to violence. *See id.* at 426. Constitutional concerns also arise under the Eighth Amendment if penalties are too severe. *See* United States v. Bajakajian, 524 U.S. 321, 325-26 (1998) (holding that a forfeiture of $357,144 was a "grossly excessive" penalty for a willful failure to report the removal of $357,144 in currency from the United States). The Eighth Amendment's Excessive Penalty Clause mandates some proportionality between a crime and its punishment. *Bajakajian*, 524 U.S. at 325-26.

176. *See* JOST & DAVIES, *supra* note 39, §1-5.

177. *Id.*

178. Presumably, the government's losses do not include the cost of paying the claim in this case, since the government would have had to pay the claim in any event had it been billed properly, but there may be marginal extra costs involved in paying a larger claim (upcoding) or more claims (unbundling) than the government should properly have had to pay.

179. To use our example from above, if the service actually provided should have

gain (albeit by a more modest increment), and a penalty that equals the government's loss divided by the probability of establishing liability (or any greater penalty) will achieve both complete deterrence and optimal deterrence.

3. Quality of Care and Underservice Cases.—A third situation potentially addressed by the fraud and abuse laws arises when a provider fails to provide care of acceptable quality or denies the beneficiary goods or services that the provider is obligated to provide.[180] Here the government's loss is, again, the difference between the value of the service for which it contracted (i.e., a service that meets quality and service standards) and the value of the service it actually receives. The program's true loss, however, also includes policing costs, and society's total loss includes the costs of any consequential damages that program beneficiaries suffer from being improperly denied goods and services or from receiving poor quality goods and services.[181] Because wrongdoing in these cases is particularly difficult to detect and prove, policing costs will often be quite high.[182] Assigning a monetary value to the injuries suffered by program beneficiaries will also often be difficult, though no more difficult than damage measurement in other personal injury cases.

The provider's gain in deficient quality and underservice cases, on the other hand, is the money it saves by not providing the service it contracted to provide. For a nursing home, this might be the money it saves by not hiring an extra nurse or nurse's aide.[183] For a managed care organization, it might be the gains realized by underservicing enrollees or "driving out"

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been properly billed for $80, the provider's gains are now $90-$80, or $10, while the government's loss is now $20 ($100-$80), plus any additional costs of claims processing and investigation.

180. *See supra* note 74 and accompanying text.

181. These consequential damages can be quite severe in cases where essential services are denied.

182. Proof of the existence and consequences of care deficiencies, for example, will often require expert review of evidence and, if the case goes to trial, expert testimony. Davies & Jost, *supra* note 82.

183. Understaffing was recently identified as a key issue in an investigation of nursing home quality of care problems. OIG: NURSING HOMES, *supra* note 101, at 23.

high cost members.[184] Though it is more difficult to derive absolute conclusions as to the relative value of the program losses and provider gains in deficient quality and underservice cases, it is likely that in most of these cases losses to the government and its beneficiaries will exceed potential gain to providers. Again, there is no social gain to be hoped for in permitting some optimal level of fraud.[185]

4. Bribes and Kickbacks and Self-Referrals.—Applying deterrence analysis to a final type of conduct addressed by the fraud and abuse laws, bribes, kickbacks and self-referrals is somewhat more difficult. Here the provider pays a referrer (who in the self-referral situation has an ownership interest in or compensation arrangement with the provider) for the referral of a patient.[186] In these situations, one of two possibilities must occur. Either the provider is providing a good or service that would not have been provided absent the bribe or kickback (the good or service is in whole or in part unnecessary), or the provider is providing a good or service that would otherwise have been provided, but would have been provided by a competitor.[187]

If the good or service is unnecessary, the government's loss in paying for the service (the amount of the payment made plus

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184. *See Fraud and Abuse: HCFA Makes Strides to Cut "Error Rate" for FFS Medicare; Will Target Managed Care*, Health Care Daily Rep. (BNA), Mar. 29, 1999, at d4, *available in* WL 3/29/1999 HCD d4 [hereinafter *Error Rate*]; *Fraud and Abuse: Philadelphia Prosecutors Investigate Fraud in Drug Formularies, Questionable HMO Denials*, Health Care Daily Rep. (BNA), June 29, 1998, at d5, *available in* WL 6/29/1998 HCD d5.

185. It is conceivable that in some cases the level of quality or service demanded by the government is unreasonably high, and therefore neither the program nor its beneficiaries suffer any real loss from the provider's failing to provide the service or quality called for by the provider agreement. Given the tight budget constraints under which federal programs have operated for the past two decades, it is unlikely that such situations are common. In the end, however, Medicare policy is also responsive to political forces, and it is possible that certification requirements might insist on services or amenities of no real value. Even in these situations, society has nothing to gain from allowing the provider to collect from the government a payment for the service and then fail to provide it.

186. *See* 42 U.S.C. § 1320a-7b (1994 & Supp. III 1997); *id.* §§ 1395nn, 1396b(s) (1994); JOST & DAVIES, *supra* note 39, §§ 3, 4.

187. *See* James Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J. L. & MED. 205, 209-10 (1996) (discussing the literature on increased utilization due to referral fees and self-referrals).

processing and policing costs) will always exceed the potential gain to the provider (the value of *the payment received minus* the sum of the costs of providing the service, billing and escaping detection and, now additionally, the cost of the bribe or kickback). If the good or service is medically necessary and is billed at the appropriate level, but it is simply delivered by a provider who "buys" the referral rather than a competitor, the government suffers no real loss (other than the cost of detecting, investigating and prosecuting bribes and kickbacks). This is because the government would have expected to pay someone for the service, as well as the costs necessary to process that deserved payment.[188] On the other hand, society gains nothing by allowing a provider to buy business away from competitors, since some provider would have provided the service in any event.[189] Society benefits when it is not required to resolve the difficult problems of proof that accompany assessments of such referral arrangements. Society will not suffer, therefore, if penalties are set high enough to completely deter bribes and kickbacks, regardless of whether the service is necessary.[190]

There is, however, an additional consideration in some situations where a professional who is in a position to refer patients to a provider receives some form of remuneration from the provider. Some of these remuneration arrangements result in the more efficient provision of goods and services, which in turn results in gains to society or even to the government health care

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188. Of course, if the government's rate is high enough to make provision of the service profitable even when a kickback is paid, its payment rate is too high and is thus inefficient, but this is another problem. *See* JOST & DAVIES, *supra* note 39, § 1-5.

189. This point has been recognized in tax exempt organization law, where the Internal Revenue Service has recognized that physician hospital arrangements that serve no purpose other than encouraging physicians to admit patients in one hospital rather than another do not benefit the community and thus do not serve a charitable purpose. *See* Gen. Couns. Mem. 39,862 (Dec. 2, 1991). It may, however, be true in some situations that more efficient providers may be able to buy patients away from other providers and still deliver the service with lower costs.

190. Requiring the government to prove on a case-by-case basis that a good or service provided pursuant to a bribe or kickback was in fact unnecessary before a penalty was assessed would, on the other hand, significantly increase the costs of prosecution of these cases and, in all likelihood, significantly decrease the likelihood that the government would pursue any particular case. It is likely, therefore, that more providers who were, in fact, providing unnecessary services pursuant to bribes and kickbacks or self-referrals would escape liability.

programs.[191] When remuneration arrangements do this, they should be encouraged, not penalized. For example, where a provider remunerates a professional on a capitated basis, and the professional is in a position to refer patients to the provider, the provider may be able to deliver care more efficiently through the arrangement.[192] The arrangement may decrease the provision of unnecessary care and increase the provision of care in cost-effective settings.[193] If the provider contracts with Medicare to provide care on a capitated basis, Medicare and its beneficiaries might also gain from the arrangement, even though professionals within the arrangement in fact face increased incentives to refer to contracting providers rather than elsewhere.[194] It would make no sense to use the fraud and abuse laws to attempt to deter these arrangements at all, much less to deter them completely.

In fact, the bribe and kickback laws accommodate this reality. The bribe and kickback prohibitions are subject to a host of statutory and administrative provisions that exempt from their reach numerous remuneration arrangements under which linkages between referrals and remuneration are considered to be efficient rather than harmful.[195] MCOs are thus permitted to enter into certain otherwise outlawed remuneration arrangements,[196] as are group purchasing organizations ("GPO"s).[197] Bona fide employment relationships are also statutorily exempt.[198] In addition, safe harbor regulations have been promulgated to exempt certain discount agreements,[199] investment in-

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191. *See* Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace*, *supra* note 187, at 213-19; James Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 HEALTH AFF., Winter 1996, at 118.

192. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace*, *supra* note 187, at 210-11, 213-19.

193. *See Id.*

194. *Id.*

195. *See* 42 U.S.C. § 1320a-7b(b)(3) (1994 & Supp. III 1997); *id.* § 1395nn(b)-(e) (1994); 42 C.F.R. § 1001.952 (1998); JOST & DAVIES, *supra* note 39, §§ 3-10, -11, 4-4 to -7.

196. 42 U.S.C. § 1320a-7b(b)(3)(F) (Supp. III 1997).

197. *Id.* § 1320a-7b(b)(3)(C); 42 C.F.R. § 1001.952(j).

198. 42 U.S.C. § 1320a-7b(b)(3)(B).

199. 42 C.F.R. § 1001.952(h).

terests,[200] space and equipment rental agreements,[201] personal services and management contracts,[202] sales of practices,[203] warranties,[204] and offers or agreements to waive coinsurance and deductibles.[205] These express exemptions plainly reflect the judgment of Congress and the HCFA that some remuneration agreements are socially beneficial and thus are to be encouraged. The challenge to providers is to determine correctly when their own arrangements satisfy or defy the limitations set by the exemptions.

Another measure of protection for providers is furnished by the rigorous scienter requirements of the anti-kickback provisions. A provider may not be penalized for a bribe and kickback violation absent a showing of wrongful intent.[206] At a minimum, this requires proof that at least one of the provider's purposes in entering into the arrangement was to *induce* a referral,[207] and at least one federal circuit court has suggested that the government must also prove that a provider had knowledge that the arrangement in fact violated the law.[208] Although this holding remains a minority view,[209] even the more generally accepted view that the government must prove that a provider had a "bad purpose" or "evil meaning mind"[210] poses formidable challenges to successful criminal prosecution. We pursue these

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200. *Id.* § 1001.952(a).
201. *Id.* §§ 1001.952(b), (c).
202. *Id.* § 1001.952(d).
203. *Id.* § 1001.952(e).
204. 42 C.F.R. § 1001.952(g).
205. *Id.* § 1001.952(k).
206. 42 U.S.C. § 1320a-7b (1994 & Supp. III 1997); *id.* § 1395nn(b)(2) (1994).
207. United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985). The bribe and kickback statute prohibits the "knowing and willful" exchange of remuneration "in return" for an item or service reimbursable under one of the federal health programs. 42 U.S.C. § 1320a-7b(b)(1), (2) (1994 & Supp. III 1997). If money or another item of value is exchanged for some other purpose, the provisions simply do not apply. *See id.*
208. Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (holding that the statute's "know[ing] and willful" language required proof that the provider intentionally entered into an arrangement that he knew violated the law).
209. *Compare* United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); *with* United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996); *and* United States v. Neufeld, 908 F. Supp. 491, 495 (S.D. Ohio 1995).
210. United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (quoting Bryan v. United States, 524 U.S. 184 (1998)).

issues more fully below when discussing the providers' complaint of complexity.[211] But the bottom line here is that the federal bribe and kickback laws appropriately call for total deterrence of bribes and kickbacks without redeeming social value, and they exempt from the prohibition remuneration arrangements that offer social gain.

5. Conclusion: Although Severe, Complete Deterrence is the Proper Goal for the Fraud and Abuse Laws.—To conclude our baseline analysis, the gains providers receive through most conduct addressed by the fraud and abuse laws rarely exceed, and in most instances are less than, the losses that the government suffers because of the challenged conduct. There is, therefore, rarely a social benefit in permitting most forms of fraud and abuse to continue at any level. Consequently, any penalty equal to or in excess of:

- the provider's gain or (if easier to determine) the government's losses in any particular transaction,
- divided in either case by the likelihood of liability being imposed in the transaction, will be efficient.[212]
- Further, because a penalty can never be too high to achieve complete deterrence, it is not necessary to compute too closely the actual losses incurred by the government in any particular instance of fraud and abuse as a prerequisite to setting penalties.[213]

The ramifications of these conclusions for fraud and abuse enforcement are straightforward as we turn from theory to practice. The level of serious auditing in federal health care pro-

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211. Although the self-referral prohibition applies without regard to intent, the sanction imposed for unintentional self-referrals is simply restitution of the amount received for the service—no additional penalty is assessed. *See* 42 U.S.C. § 1395nn (1994) (forbidding physicians with financial relationships to various entities from making referrals and preventing claims that spring from such referrals). It is also not surprising that there has been considerable debate as to whether these prohibitions should be further limited. *See, e.g.*, Christian D. Humphreys, Comment, *Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?*, 30 SAN DIEGO L. REV. 161 (1993) (arguing that the federal self-referral laws are overly broad and hastily developed). This debate will not be pursued further here.

212. *See generally* Hylton, *supra* note 149, at 426-30.

213. *See generally id.* at 427-30.

grams is very low. Historically, Medicare has audited or investigated only an exceedingly small number of claims and rarely has prosecuted providers who were caught filing improper claims.[214] In 1995, Medicare paid more claims with less scrutiny that at any other time in the previous five years.[215] Between 1989 and 1994, the percentage of claims required to be reviewed dropped from 20% to 5%.[216] Indeed, until FY 1998 when funding for program oversight was significantly increased by the HIPAA, Medicare was spending less on claims processing and auditing fewer claims than it had a decade earlier.[217] Between 1988 and 1996, the number of Medicare claims climbed 70%, but resources committed to claims review grew only 11% without adjusting for inflation, causing the amount contractors spent for auditing to shrink from $0.74 to $0.48 per claim.[218] Between 1991 and 1996, the likelihood that the cost report of an institutional provider would be subject to detailed review fell from one in six, to one in thirteen.[219] Even after the infusion of HIPAA Medicare Fraud Program money, which will increase funding for program safeguard activities by 80%, inflation-adjusted spending per claim for audits and investigations will still be at only half of the 1989 levels.[220]

Further, even when audits or investigations uncover improper claims or payments, they rarely result in false claims prosecutions.[221] Day-to-day claims processing under the Medi-

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214. *Sparrow*, *supra* note 64, at 29-30, 35-38, 86-95; U.S. GEN. ACCOUNTING OFFICE, MEDICARE SPENDING: MODERN MANAGEMENT STRATEGIES NEEDED TO CURB BILLIONS IN UNNECESSARY PAYMENTS 11-14 (1995) [hereinafter MEDICARE SPENDING].

215. U.S. GEN. ACCOUNTING OFFICE, HIGH RISK SERIES: MEDICARE CLAIMS 7 (1995) [hereinafter MEDICARE CLAIMS].

216. *See* MEDICARE CLAIMS, *supra* note 215, at 7.

217. U.S. GEN. ACCOUNTING OFFICE, MEDICARE: HCFA'S USE OF ANTI-FRAUD-AND-ABUSE FUNDING AND AUTHORITIES (1998). For a description of HCFA Medicare safeguard activities, see *id.* at 4.

218. U.S. GEN. ACCOUNTING OFFICE, HIGH RISK SERIES: MEDICARE 16 (1996) [hereinafter MEDICARE].

219. MEDICARE, *supra* note 218, at 22.

220. *Id.* at 29-31. One of the reasons that the administrative costs of the Medicare program are lower than those of private insurers is because, even after the HIPAA, Medicare does not audit utilization of services at a level approximating that applied by private insurers. *See* INSTITUTE OF MEDICINE, CONTROLLING COSTS AND CHANGING PATIENT CARE? THE ROLE OF UTILIZATION MANAGEMENT 38-51 (1989).

221. *See Fraud and Abuse: DOJ Refutes Charges of Prosecuting "Honest Billing Errors," Industry Continues to Cry Foul*, Health Care Daily Rep. (BNA), May 22,

care program is handled by private insurance companies known as intermediaries in Part A (the hospital/home health/nursing home side of Medicare) and carriers in Part B (the professional services side of Medicare).[222] As a practical matter, in the vast majority of cases in which carriers or intermediaries discover improper claims or payments in the auditing process, they simply ask for the money back.[223] Similarly, providers who discover that they have been overpaid customarily simply write a check to the carrier or intermediary, which is usually the end of the matter.[224] Where providers adopt compliance plans to audit their own performance, the DHHS-OIG and DOJ are particularly likely to treat billing errors as good faith mistakes.[225] Thus, in practice, only a tiny number of egregious cases are referred on for fraud and abuse investigation.[226]

Because the level of auditing and enforcement in federal health care programs is very low, deterrence theory would seem to dictate that penalties imposed on providers who are found liable for fraud and abuse must be set very high before even optimal deterrence is achieved.[227] As noted above, the basic provider complaint regarding severity is that civil FCA treble

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1999, at d6 [hereinafter *Honest Billing Errors*].

222. BARRY R. FURROW ET AL., HEALTH LAW § 13-3 (1995).

223. *Honest Billing Errors*, *supra* note 221, at d6.

224. This is in fact what they are advised to do by the OIG when simple overpayments and errors, not suggesting a violation of the law, are involved. *See* Publication of the OIG's Provider Self Disclosure Protocol, 63 Fed. Reg. 58,399, 58,400 (1998).

225. *See* APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES, *supra* note 115, at 16-17.

226. *See id. See also Fraud and Abuse: Pneumonia Upcoding, Hospital Discharges Chief Targets of Government Enforcement*, Health Care Daily Rep. (BNA), Feb. 2, 1999, at d4, *available in* WL 2/2/99 HCD d4 (quoting June Gibbs Brown, Inspector General, stating, "[i]nnocent billing errors are not the target of our criminal or civil enforcement actions. We do not devote our limited investigative resources to pursuing cases unless we strongly suspect a pattern of abuse or a particularly egregious . . . situation").

227. *See supra* notes 154-64 and accompanying text. An important caveat to this analysis is that when the OIG and DOJ are pursuing national initiatives, which focus on particular billing practices, the likelihood that institutional providers will be audited is much higher. It should be noted, however, that in these initiatives, the government commonly settles for amounts far below those permitted under the FCA, recognizing implicitly that as the likelihood of being found liable increases, the penalty necessary to achieve deterrence decreases. *See* APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES, note 115, at 9-10.

damages plus $5,000 to $10,000 per claim penalties result in wildly disproportionate penalties, given the large number of small claims submitted by health care providers.[228] Ironically, if only a small fraction of fraudulent claims are discovered or pursued, and only a fraction of these result in liability, civil FCA sanctions may, in some cases, be too mild rather than too severe.[229] Moreover, since the proper goal of fraud and abuse enforcement is not optimal, but rather complete deterrence, objections to the severity of fraud and abuse sanctions seem largely groundless. If civil FCA sanctions are so severe that no reasonable provider would ever attempt to file a false claim, the civil FCA has achieved its purpose. But fraud and abuse sanctions are harsh not simply because they are intended to assure that providers do not gain from their fraudulent conduct; they are also severe because they address criminal conduct.

6. Severity and the Criminal Offender.—At the outset, we suggested that complete deterrence might be appropriate in two circumstances: 1) where the victims' losses exceed the wrongdoer's gains and 2) where the wrongdoer's conduct is sufficiently reprehensible that the law should prohibit it even though it is efficient, i.e., where the conduct is "criminal."[230] Thus, even in cases where optimal rather than complete deterrence might otherwise seem to be dictated by a utilitarian analysis of the situation (because society's losses are less than the entity's gains, for example), complete deterrence might nonetheless be warranted because the entity's conduct at issue is appropriately considered "criminal." If conduct is criminal, even when a straightforward utilitarian analysis would support the imposition of optimal penalties, criminal penalties effective to achieve complete deterrence should be imposed instead. This inevitably leads us to consider the murky line between civil and criminal

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228. *See supra* notes 151-53 and accompanying text.

229. Assume, for example, that 3% of 100 false $200 claims are audited, and an FCA penalty of three times damages plus $5000 per claim is assessed. The total FCA damages and penalty will amount to $16,800. The government's true loss from the 100 false claims, however, is $20,000. In this instance, therefore, the FCA's "severe" penalties are inadequate to achieve optimal deterrence.

230. *See* Hylton, *supra* note 149, at 421-29; *see also supra* text accompanying notes 153-55.

misconduct.

Under traditional common law concepts of tort, contract and property law, civil and criminal sanctions were widely believed to serve importantly different goals.[231] Civil sanctions were sought (usually by private parties) to *compensate* private injuries, while criminal sanctions were reserved for *punishing* public wrongs, generally at the initiation of the state.[232] Under this traditional view, the goal of civil justice was not to shape future behavior, but merely to remedy past harms.[233] As we discussed above, consequentialist thinkers reconceptualized the civil sanction as both an instrument that affects future behavior and an instrument that could be used to enforce a scheme of public regulation, supplementing its traditional role as a device to remedy private harms.[234] For utilitarians, this meant that civil sanctions should be fashioned to achieve optimal results—compliance with the law, provided the actor's gain did not exceed the social cost of violation.[235]

For many, this reconceptualization placed the civil sanction uncomfortably close to the criminal sanction, also long thought of as a deterrent instrument, though one exclusively used to enforce public rather than private law.[236] With growing recognition that the criminal and civil sanction share common deterrent functions[237] and the concern that some nominally civil

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231. *See* Carol S. Steiker, *Punishment and Procedure: Punishment Theory and the Criminal-Civil Procedural Divide*, 85 GEO. L.J. 775, 784-85 (1997).

232. *Id.*

233. *Id.* at 784; Cass Sunstein, *The Limits of Compensatory Justice*, *in* COMPENSATORY JUSTICE: NOMOS XXXIII 281, 282 (John W. Chapman ed., 1991).

234. *See* Steiker, *supra* note 231, at 785; Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 YALE L.J. 1795, 1846 (1992).

235. *See* Steiker, *supra* note 231, at 785.

236. The fading difference between criminal and civil law can be seen in many places within the criminal and civil justice systems, including in the alleged rapid growth of punitive damage awards in civil suits, the increase in suits brought by citizens acting as private attorneys general, the authority granted to administrative agencies to impose penalties upon transgressors of regulations, the explosion in civil commitment proceedings to "incarcerate" the dangerous in mental health facilities, and the increased use of "remedial" procedures such as the forfeiture authority. *See, e.g.*, Steiker, *supra* note 231, at 776-80. In the health care fraud and abuse context, the same blurring can be observed. Sanctions nominally civil are trebled to increase their deterrent punch and thus look more like prohibitory penalties than compensation. *See* Mann, *supra* note 234, at 1814-31.

237. *See* Gerard Lynch, *The Role of Criminal Law in Policing Corporate Miscon-*

penalties can be so punitive that they are effectively criminal,[238] courts and legal commentators have looked for other ways to distinguish one from the other. One recent tendency among some scholars has been to assert that civil sanctions "price,"[239] while criminal sanctions "prohibit" violations.[240] Under this view, the aim of a civil regulatory and penalty scheme is to deter certain harmful conduct by pricing it in such a way as to make it economically undesirable, while countenancing that violations will occur when economic efficiencies make them desirable.[241] By contrast, the aim of the criminal law, these scholars urge, is (or at least should be) to ban proscribed conduct outright.[242] Thus, the civil law contemplates harms for a fee, but the criminal law tolerates no violation, for society has a right to be unburdened by conduct deemed criminal, regardless of the price an actor might be willing to pay to engage in

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duct, 60 LAW & CONTEMP. PROBS. 23, 44 (1997) ("[A]lthough criminal sanctions tend to be more severe, and thus to provide a more significant deterrent than civil sanctions, this is not always the case, and there are many situations in which various civil or administrative remedies may provide a more significant deterrent than criminal punishments.").

238. *See, e.g.*, Kansas v. Hendricks, 521 U.S. 346, 361-71 (1997) (considering whether law permitting the indefinite involuntary civil commitment of sexually violent predators, although putatively civil, was in fact criminal and thus subject to double jeopardy and ex post facto principles); United States v. Ursery, 518 U.S. 267, 273-92 (1996) (considering whether double jeopardy prevented federal government from bringing parallel criminal and civil forfeiture proceeding based on the same underlying events).

239. *See, e.g.*, Robert Cooter, *Prices and Sanctions*, 84 COLUM. L. REV. 1523, 1538-51 (1987). Under this view, the purpose of a civil sanction was to remedy the harm, i.e., to set a "price" for the actor's harmful behavior. Thus, such conduct was taxed but permitted to occur. Therefore, under a purely civil regulatory scheme, an actor is free to choose whether or not to engage in harmful behavior and, as we argue above, the actor's choice, assuming rationality, is likely to be made with due regard for the maximum potential penalty and the probability of detection. *Id.*

240. *See, e.g., id.* at 1538-51; John C. Coffee, Jr., *Paradigms Lost: The Blurring of the Criminal and Civil Law Models—And What Can Be Done About It*, 101 YALE L.J. 1875, 1876-77 (1992); Stephen L. Pepper, *Counseling at the Limits of the Law: An Exercise in the Jurisprudence and Ethics of Lawyering*, 104 YALE L.J. 1545, 1558-59 (1995). The Supreme Court has adopted a similar taxonomy when deciding whether constitutional procedural protections normally reserved for criminal cases should be applied in civil cases where the civil sanction in question seems to do more than compensate harm. United States v. Salerno, 481 U.S. 739, 747 (1987) (comparing "punishment" with "regulation").

241. *See* Coffee, *supra* note 240, at 1882-83.

242. *See id.* at 1884.

it.[243] Viewed in this way, and returning to our earlier optimal/complete deterrence distinction, civil sanctions would appear to seek "optimal deterrence" and criminal sanctions "complete deterrence."

Other scholars have persuasively argued that the more fundamental difference between the two forms of sanctions can be completely explained neither by consequential notions of deterrence[244] nor by semantical differences between "price" and "prohibit."[245] Rather, the more fundamental difference between the civil and the criminal sanction is the absence or presence of the community's moral condemnation surrounding a particular violation.[246] As put by Professor Gerard Lynch:

> "Prohibition" is a moral term, which refers more to the moral stance we take with respect to the activity than to the degree to which we penalize it or the practical importance of encouraging compliance. . . . The question, rather, is what we think of the person who deliberately chooses to arrogate to himself the benefits of the violation while being willing to pay the price. In the case of the true "price," we do not condemn the person who chooses to pay it and proceed, any more than we condemn the person who elects to avoid the price and forgo the conduct. In the case of the true "prohibition," we disapprove of the person who violates the rule, even if he is prepared to pay . . . [and] we regard such a person as preeminently a proper subject of criminal punishment.[247]

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243. *See* Cooter, *supra* note 239, at 1538-51; Coffee, *supra* note 240, at 1882-87; Pepper, *supra* note 240, at 1558-59.

244. *See* Steiker, *supra* note 231, at 787 (stating that economic analysis is unable "to account fully for the existence of the criminal sanction"); Alvin K. Klevorick, *On the Economic Theory of Crime*, *in* CRIMINAL JUSTICE: NOMOS XXVII 289, 301-03 (J. Roland Penrock & John W. Chapman eds., 1985).

245. *See* Lynch, *supra* note 237, at 41-42.

246. *See id.* at 43.

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> What society wants from its members . . . is not an intelligent calculation of the costs and benefits of abiding by its basic norms, but more or less unthinking obedience to them. To the extent people are specifically comparing the costs and benefits of breaking criminal laws, the battle is already lost. . . . For society to function, most people have to obey the law for reasons of conscience and conviction, and not out of fear of punishment.

Lynch, *supra* note 237, at 46.

Viewed in this way, the criminal sanction seeks to do more than to deter undesirable conduct; it seeks to publicize and promote the community's moral norms and to stigmatize those who break them.[248] To take this view is not to eschew the notion that criminal law also serves a utilitarian function, but only to emphasize that deterrence is neither its only nor perhaps even its chief purpose. For example, the moral stigma that adheres to a fraud and abuse conviction may figure into the cost/benefit calculation of a would-be offender and, in some instances, deter crime. But the real force of the criminal sanction, we believe, is its unparalleled power to communicate a code of moral conduct, the composition of which demarcates the outer boundary of acceptable human behavior.[249] This is quite unlike the civil sanction, which, as explained above, anticipates and exacts a price for violations of the fraud and abuse laws, does so but without either stigmatizing violators who breach those laws or clearly expressing society's condemnation of the conduct.[250]

This argument has several implications for fraud and abuse violators. Most fundamentally, the criminal fraud and abuse prohibitions and the criminal sanctions made available for their enforcement reflect a congressional judgment that some conduct by providers and professionals is so morally corrupt that the conduct should be condemned by society, and those who commit it should be stigmatized as criminal offenders.[251] Although this judgment has its detractors, in most cases the acts of health care white collar offenders fit easily within traditional criminal law categories.[252] The criminal law has long extended to intentional injurious acts to people and property. The bulk of the fraud and abuse provisions reviewed above fall comfortably within this classification. The fact that white collar offenders

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248. *See id.*; *see also* Dan M. Kahan, *What Do Alternative Sanctions Mean?*, 63 U. CHI. L. REV. 591, 620-24 (1996).

249. *See* Steiker, *supra* note 231, at 788; Lynch, *supra* note 237, at 47. As put by Professor Cynthia Williams, "law implies obligation, even when the 'price' of violations is affordable." Cynthia Williams, *Corporate Compliance with the Law in the Era of Efficiency*, 76 N.C. L. REV. 1265, 1385 (1998).

250. "Fines . . . are politically unacceptable not because the public perceives that they are insufficiently severe, but because it believes that fines are insufficiently expressive of condemnation." Kahan, *supra* note 248, at 620.

251. *See* Bucy, *Crimes by Health Care Providers*, *supra* note 40, at 590-91.

252. *See id.* at 590.

here are physicians or health care facilities neither magically dispels the moral depravity of acts of intentional deception for personal profit, nor does it by itself justify civil over criminal penalties if the offender has intentionally inflated claims for payment.[253] For such actors, the criminal law has a special moral role to play that is separate from the compensatory and deterrent functions of the co-existing civil and administrative fraud and abuse provisions.

Nevertheless, a vexing question is raised by a statutory and regulatory scheme that authorizes civil, administrative *and* criminal penalties to be imposed for the same underlying event but which makes little effort to identify when one, two or all three should be imposed. What criteria should counsel the law enforcer's pursuit of civil and/or administrative remedies over criminal penalties for particular transgressions of the fraud and abuse laws? It is one thing to say that criminal punishment *may* justifiably be imposed upon health care providers whose conduct falls within traditional criminal law categories, and it is quite another to say that it *must* be imposed in every such case.

With the increased availability of civil penalties for legal transgressions and in particular, civil penalties that look decidedly "punitive," resort to the criminal process to penalize such transgressions may often be unnecessary.[254] Thus, in less egregious cases (such as where the offender's conduct is intentional, but aberrational, or where the financial harm caused by the conduct is minimal), the government might choose to seek to remedy fraud and abuse violations through the civil process only.[255] A policy favoring civil and administrative sanctions might also be advisable in cases where the offender is the sole provider for a particular community which would suffer special harm by the provider's exclusion.[256] Finally, where a corporate

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253. *See* Paul Jesilow et al., *Fraud by Physicians Against Medicaid*, 266 JAMA 3318, 3320 (1991) (reporting reticence of physicians convicted of Medicaid fraud to see themselves as wrongdoers).

254. *See* H. PACKER, THE LIMITS OF THE CRIMINAL SANCTION 355 (1968).

255. Mann, *supra* note 237, at 1802 (proposing that punitive civil monetary sanctions be used more often, which would, in turn, justify "shrinking" the use of criminal law, confining it to areas of the most egregious misconduct for which civil sanction, even civil punitive sanction, is insufficient).

256. There are other sound reasons to prefer civil over criminal sanctions to punish health care fraud and abuse in many cases. Criminal sanctions are costly to

entity faces vicarious criminal liability for the conduct of a rogue employee, and the entity was unaware of the employee's wrongdoing and had an operational good faith compliance program (a situation explored more fully shortly), civil rather than criminal sanctions seem appropriate. Again, it is perhaps unsurprising that law enforcers have for the most part exercised their discretion in accordance with these recommendations. It is not uncommon for a United States Attorney's Office to consider all of these things—aberrational conduct, minimum harm, lack of knowledge of the conduct of a rogue employee and the adoption of a compliance program implemented in good faith—when deciding whether to prosecute.[257]

We could conceive of further restrictions on the exercise of prosecutorial discretion, of course, but we are unwilling to advocate these, though we recognize that others do not share our hesitancy. Some scholars have developed punishment theories that would cabin criminal fraud and abuse prosecutions to cases involving misconduct by non-corporate providers.[258] Still others suggest that criminal liability should not be an option for redressing violations (corporate or otherwise) of a regulatory scheme as voluminous, inconsistent and complex as the fraud and abuse regulations.[259] We reject the corporate liability exception, however, and believe that the second problem is ade-

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society in a way that civil penalties are not. For example, the costs of a criminal trial borne by taxpayers may be higher due to the constitutional right to counsel that adheres to criminal cases. In addition, if a conviction is secured and a term of imprisonment imposed, taxpayers bear the sizable costs of the prisoner's incarceration. Further, throughout the period of incarceration, society is deprived of the prisoner's potential lawful production, and after his release, his productive ability may be significantly diminished due to the stigma that accompanies criminal conviction. RICHARD POSNER, ECONOMIC ANALYSIS OF LAW 227 (4th ed. 1992).

257. *See* Jerome T. Levy, *Use of Compliance Programs Offers Benefits to Providers*, N.Y. L.J., Aug. 3, 1999, at 7.

258. *See* Daniel R. Fischel & Alan O. Sykes, *Corporate Crime*, 25 J. LEGAL STUD. 319, 320-21 (1996) (arguing that the civil liability system is better suited to penalize organizational defendants); *see also* Frank Easterbrook & Daniel R. Fischel, *Antitrust Suits by Targets of Tender Offers*, 80 MICH. L. REV. 1155, 1168 n.36, 1177 n.57 (1982). Others appear to support the use of the criminal process against corporate defendants in very limited circumstances. *See, e.g.*, V.S. Khanna, *Corporate Criminal Liability: What Purpose Does it Serve?*, 109 HARV. L. REV. 1477, 1533-34 (1996) (arguing that corporate criminal liability is appropriate only in "the rarest of circumstances").

259. *See supra* note 256 and accompanying text.

quately addressed by the intent requirements of the fraud and abuse laws. To these issues we now turn.

7. Severity and Organizational Offenders–the Problem of the Rogue Agent.—Providers of health care in government programs are often organizations that act through agents.[260] If an institutional health care provider intentionally and as a matter of corporate policy defrauds the government or violates billing or program participation requirements, the baseline deterrence analysis developed above can appropriately be applied: complete deterrence is the correct enforcement goal. Any penalty equal to or greater than that necessary to fully compensate the government for its losses in a particular transaction is permissible.[261] Criminal liability might also be appropriate.

Often, however, an institutional provider charged with fraud and abuse claims that it did nothing wrong, that its official policy was to bill correctly, but that this policy was subverted by a "rogue" agent (usually an employee, but in some cases an independent billing agent) who submitted fraudulent claims to the government without the knowledge or acquiescence of the organizational employer.[262]

An institutional provider, of course, is not helpless in the face of the nefarious schemes of its employees. The provider can often eliminate much of the risk of employee fraud by implementing an effective compliance program, which guarantees proper billing through the careful hiring, training and monitoring of employees.[263] Compliance programs are not costless,

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260. IAIN HAY, MONEY, MEDICINE, AND MALPRACTICE IN AMERICAN SOCIETY 169 (1992).

261. *See* Hylton, *supra* note 149, at 423; SUSAN WOLF, THE LEGAL AND MORAL RESPONSIBILITY OF ORGANIZATIONS IN CRIMINAL JUSTICE 267, 285 (J. Roland Rennock & John W. Chapman eds., 1985).

262. Sometimes this defense is offered not just by large institutions, but also by individual professionals, who claim that fraudulent bills were in fact submitted by their billing assistants. Because, however, Medicare requires professionals to certify the correctness of and take responsibility for all billing forms they submit (Form 1500), this defense rings somewhat hollow.

263. The DHHS has published several model compliance plans to encourage the initiation of such compliance efforts, including a model compliance plan for clinical laboratories, for hospitals, and for managed care organizations. For excellent summaries of the plans, see *Dep't of Health and Human Services, Inspector General Releases Model Plan for Clinical Laboratories Industry*, 1 Health Care Fraud Rep. (BNA)

however, and rational organizations must consider carefully how much of their resources to devote to overseeing compliance.

At an earlier stage of our analysis, we weighed the gain that health care providers receive from various types of fraudulent or abusive transactions against the loss the government suffers from these transactions. We concluded that only rarely might the individual provider's gain equal or exceed the program's loss.[264] Where a fraud is committed by a rogue agent of an organizational provider, however, the loss/gain calculus changes. The true gain an organizational provider receives from a fraud committed by a rogue agent is not simply the direct gain that results from the fraud itself,[265] but also the cost that the provider avoids by not having in place a compliance program that would have prevented the fraud in the first place.[266] If, for example, an employee's fraud enriches the provider by $10,000, but a compliance program that would have prevented the particular fraud would have cost $20,000, the true gain to the provider of not preventing the fraud is $30,000.[267] If the government's full loss from the fraud (the payment improperly made plus processing and policing payments) is less than the provider's true gain (the government's loss will often be something in excess of the amount by which the provider is enriched by the employee's fraud), complete deterrence ceases to be the appropriate enforcement strategy.

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117 (1997) (clinical laboratories plan); *Compliance Audits, Programs Represent Latest Growth in Industry*, 1 Health Care Fraud Rep. (BNA) 256 (1997); *Providers that Outsource Functions Need to be Wary of Fraud, Abuse Risks*, 1 Health Care Fraud Rep. (BNA) 257 (1997). *See also* Greg Radinsky, *Making Sense of the Federal Sentencing Guidelines: How Health Care Corporations Can Manage Risk by Adopting Corporate Compliance Guidelines*, 30 J. HEALTH & HOSP. L. 113 (1997); Charles J. Walsh & Alissa Pyrich, *Corporate Compliance Programs as a Defense to Corporate Liability: Can a Corporation Save its Soul?*, 47 RUTGERS L. REV. 605, 646-49 (1995).

264. *See supra* notes 168-69 and accompanying text.

265. In instances where the agent is not simply defrauding the government but is also defrauding the organization, this gain may be minimal, even negative. If the gain the organization enjoys from the fraud of the rogue employee is substantial, one must wonder whether the rogue employee is truly a rogue, though it is always possible that the employee hopes for indirect gain (through promotions, raises, prestige within the organization) rather than direct personal gain from the fraud.

266. *See* Fischel & Sykes, *supra* note 258, at 341; Coffee, *supra* note 240, at 245.

267. Of course, if the compliance program would not only prevent this fraud, but several others as well, the costs of the program must be allocated in such a way that only the costs of preventing this particular fraud will be considered.

Returning to our initial analysis, deterrence theory as applied in civil tort disputes suggests that where the wrongdoer's gain from certain conduct exceeds the loss suffered by the victim, optimal rather than complete deterrence is appropriate, calculated by dividing the victim's actual losses by the probability of liability.[268] If sanctions are imposed that are appropriate to achieving complete deterrence, there is a risk that society will lose the benefit of the excess of the wrongdoer's gain over the victim's loss.[269]

The efficient enforcement goal in the situation of the rogue agent would appear normally to be optimal enforcement.[270] Under this regime, the organization that does not prevent a rogue agent from presenting fraudulent claims to the government would have to pay penalties equal to the government's losses (including processing and policing costs) divided by the probability of liability if the fraud is detected and punished. For reasons discussed above, the probability of the provider being found liable is usually very low; thus even the optimal deterrence penalty would be substantial. If this penalty is less than the cost of a fail-safe compliance program, however, the organization normally should be permitted to choose to make the government whole for its losses rather than to expend an inappropriately large amount on monitoring the compliance of its agents. Moreover, if optimal compliance is our goal, criminal penalties and exclusion—remedies appropriate to complete deterrence—would

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268. *See supra* notes 160-63 and accompanying text.

269. The rogue employee situation is not the only instance where enforcement based on complete deterrence might reach inefficient results. There are some situations where, as a theoretical matter, complete deterrence, achieved perhaps by criminal prosecution leading to incarceration or exclusion, may be appropriate (billing for services not provided, for example). Imposition of these penalties may also, however, deprive a community of its sole provider of a particular set of health care services. In these situations, the loss to the community must be considered as well as the loss to the program. It may be necessary, therefore, to calibrate the sanction more carefully, so as to create incentives for the provider not to commit the fraud, while at the same time not imposing such substantial penalties on a provider who is caught as to drive the provider out of business. One practical recognition of this factor in the fraud and abuse laws is the provision that a state may request that exclusion be waived where the provider "is the sole community physician or sole source of essential specialized services in a community." 42 U.S.C. § 1320a-7(b)(14) (1994).

270. Hylton, *supra* note 149, at 443-44.

not be appropriate, as the provider facing criminal sanctions may implement a compliance plan, the cost of which far exceeds the losses that rogue billing could impose upon the government, in order to avoid exclusion or criminal penalties.

The fact that optimal rather than complete deterrence is appropriate with respect to some corporate conduct means that severity is not a trivial concern—there are some situations where the full force of fraud and abuse sanctions might result in excessive penalties.[271] This possibility is recognized by fraud and abuse case law. In *Hanlester Network v. Shalala*,[272] for example, the court refused to uphold the harshest fraud and abuse

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271. One issue that might be implicated here, for example, is the appropriateness of statistical extrapolation in FCA cases. One of the justifications offered above for the imposition of FCA penalties is that even when our goal is only optimal deterrence, the amount of government losses that is identified in a particular incident of fraud must be divided by the likelihood that the defendant will be found liable for that fraud to assure that all government losses are internalized by the offender. (If, of course, complete deterrence were our goal, penalties would not need to be limited to the government's losses, but would rather need to equal the offender's gains divided by the likelihood of liability.) Because provider fraud is so rarely detected and prosecuted, even if optimal deterrence is our goal, FCA sanctions still might not be excessive. If, however, statistical extrapolation is applied to false claims that are identified through an audit to project the true number of false claims submitted, and then multiple damages and penalties are claimed for the total universe of extrapolated claims, it is likely that penalties would be imposed at levels well above that necessary to result in optimal deterrence.

Assume, for example, that a provider is identified in an audit that looks at 5% of the provider's claims to have submitted 20 $100 claims for services not provided. To assure optimal deterrence, the provider should pay penalties of 20 X $100 X 1/0.05, or $400,000, plus processing and policing costs. Application of the FCA to the claims actually identified as false would yield a recovery of (20 X $100 X 3) (20 X $5000 to $10,000), or $106,000 to $206,000. A claim for restitution based on statistical extrapolation calculated by projecting the 20 claims to a total universe of 20 times as many claims would result, on the other hand, in a recovery of $400,000. Both recoveries would result in suboptimal deterrence, but both are of the same order of magnitude as the appropriate penalty. Application of first statistical extrapolation and then FCA multipliers and penalties, however, would result in a penalty of (20 X 20 X $100 X 3) (20 X 20 X $5000 to $10,000), or from $2,120,000 to $4,120,000, approximately five to ten times the optimal penalty. The combined application of statistical extrapolation and FCA penalties would, therefore, rarely be appropriate if the goal is optimal deterrence. The difficulty of combining FCA penalties and statistical extrapolation has been recognized by some courts. For example, even thought the Court of Appeals approved of the use of statistical sampling in United States v. Krizek, 111 F.3d 934, 939-40 (D.C. Cir. 1997), on remand the district court limited the government to recovery of a penalty on only three claims. United States v. Krizek, 7 F. Supp. 2d 56, 59 (D.D.C. 1998).

272. 51 F.3d 1390 (9th Cir. 1995).

sanction, exclusion, against a corporate defendant, finding that the statutory violations were the fault of a single corporate employee who had already been excluded from program participation.[273] In other cases, courts have rejected civil FCA liabilities where the person who was being sued could not properly be held vicariously liable for the actions of the person who submitted false claims.[274]

One might, of course, question whether criminal punishment is ever an appropriate tool for controlling corporate conduct when corporate entities cannot be imprisoned. Put slightly differently, since corporations cannot be jailed and are primarily subject to monetary penalties, why is a civil sanction not a sufficient enforcement response to corporate wrongdoing?

The answer lies, we think, in the argument that we have advanced above respecting the fundamental distinction between civil and criminal law. If, as some believe, the civil/criminal law distinction revolves around notions of deterrence (that is, the civil law deters "optimally" by "pricing" harmful conduct, while the criminal law deters "completely" by "prohibiting" wrongful conduct), then there would appear to be little reason to subject corporations to criminal liability. As discussed above, civil penalties, if steep enough, can also achieve (or at least strive for) complete deterrence. Indeed, corporations seem particularly well suited for financial penalties, and in fraud and abuse cases, trebled civil penalties are likely to be much higher than available criminal fines for the same conduct in many cases. Further, since corporations cannot be jailed, no additional deterrent value is gained by the threat of imprisonment.[275] It has also been argued that an inanimate entity does not suffer the same stigma from being found a "criminal" as does an individual defendant.[276] Finally, although exclusion accompanies a fraud and

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273. *Hanlester Network*, 51 F.3d at 1402.

274. United States v. Nazon, No. 93-C-5456, 1993 WL 459966, at *2 (N.D. Ill. Nov. 3, 1993); United States *ex rel.* Piacentile v. Wolk, No. 93-5773, 1995 WL 20833, at *4 (E.D. Pa. Jan. 17, 1995).

275. PACKER, *supra* note 254, at 361.

276. We are less convinced of this point. A corporation convicted of a crime may not suffer from the stigma of that conviction in the same way as an individual would, but it may still suffer from the stigma. Consumers may not wish to purchase the products or services of a corporation that has been convicted of a crime, particularly if the goods and services of a competitor are available for consumption, and

abuse conviction and thus might be thought of as a deterrent imposed by the criminal process separate from the civil process, criminal conviction is not a condition precedent for exclusion. Exclusion may accompany civil sanction as well.[277]

What, then, is the justification for applying the criminal sanction to corporate breaches of the law? Again, we contend that the criminal law seeks more than to deter—it also expresses the moral standards of the community, stigmatizes those who violate those standards, and delimits the boundaries of acceptable conduct. These functions are as applicable to the corporate as to the individual offender,[278] and we can think of no valid reason to except business actors from them. Provided the moral limits of the law are capable of being made known to the public, conduct which violates those limits is appropriate for criminal punishment, whether the actor is corporate or otherwise.[279]

Nevertheless, imposing criminal liability upon a corporation for the unlawful acts of a rogue employee presents special problems. As we have asserted above, through the exercise of prosecutorial discretion, such cases might best be reserved for civil rather than criminal penalties and for civil penalties appropriate to achieve optimal rather than complete deterrence. It must be said, however, that claims of "unknown rogue conduct" are easy

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the corporation's profits would suffer. *But see* PACKER, *supra* note 254, at 361-62; Sanford H. Kadish, *Some Observations on the Use of Criminal Sanctions in Enforcing Economic Regulations*, 30 U. CHI. L. REV. 423, 434-35 (1963).

277. 42 U.S.C. § 1320a-7a(a) (1994 & Supp. III 1997).

278. A similar argument might be made by those who believe that retribution is the primary justification for the imposition of criminal punishment. A retributivist is likely to balk at the notion that a corporate defendant who breaks the law should receive less onerous punishment than the individual defendant who violates the same law. JAMES W. COLEMAN, THE CRIMINAL ELITE: THE SOCIOLOGY OF WHITE COLLAR CRIME 168-88 (1989); BARRY KRISBERG, CRIME AND PRIVILEGE: TOWARD A NEW CRIMINOLOGY 34-41 (1975).

279. For the same reasons, we disagree with the argument that only insolvent defendants should be subject to criminal liability for conduct that can be penalized by "punitive" civil sanctions. Some legal commentators have suggested that criminal sanctions should be imposed only when civil sanctions fail adequately to account for wrongdoing, such as where civil damages would be meaningless because the defendant is insolvent. Aside from the obvious criticism that this would make criminals of only the "have-nots," the proposition also fails to acknowledge the importance of policing the boundaries of acceptable conduct consistently and in an even-handed way.

to make and hard to disprove.[280] For this reason, it strikes us as preferable to leave the determination of whether a particular case should be excluded from prosecution because it involves the action of a rogue employee (as opposed to corporate acquiescence in conduct from which it stands to profit) to the sound exercise of prosecutorial discretion. The courts stand as a final shield against the wrongful exercise of such discretion, and case law reflects the judiciary's acceptance of this gate-keeping function.[281] It should not be forgotten that providers possess a clear economic incentive to intentionally violate the fraud and abuse laws if punishment for doing so is not swift, severe and certain and if decisions to intentionally violate these laws are not met with the same moral condemnation meted out to individual actors.[282] Where, however, the provider proves that the misconduct was that of a rogue employee, any consequent corporate penalty for the employee's misconduct should be oriented toward achieving optimal rather than complete deterrence.

C. Complexity and Uncertainty

Though our analysis to this point suggests that the severity of fraud and abuse sanctions is on the whole appropriate, the complaint regarding severity must be considered in tandem with provider concerns about complexity and uncertainty. Deterrence is possible and moral condemnation appropriate only if the law communicates intelligibly what conduct is prohibited. We may decide retrospectively for various reasons that A, who causes a loss to B, should compensate B for the loss, even though it was not possible to know beforehand that A's conduct could possibly result in loss.[283] But this intervention can only be justified by deterrence theory to the extent that it might communicate intelligible information to future actors about wrongful or harmful

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280. PACKER, *supra* note 254, at 360.

281. *See, e.g., Hanlester Network*, 51 F.3d at 1400-01; United States v. Krizek, 7 F. Supp. 2d 56, 59-60 (D.D.C. 1998).

282. Bucy, *Health Care Reform and Fraud by Health Care Providers*, *supra* note 74, at 1009.

283. Any strict liability scheme would have this effect. The self-referral provisions, which have no mens rea requirements, are an example. JOST & DAVIES, *supra* note 39, § 4-1.

conduct. By definition, we cannot punish A in this situation for injuring B because A "should have known better" unless the law penalizes negligent conduct.

It should not be surprising, therefore, that provider arguments about the severity of civil FCA penalties are so inextricably entwined with provider complaints about program complexity. Providers should not, it is argued, be put at risk of enormous civil penalties and of criminal punishment when the law itself has not made it clear that the conduct is unlawful.[284] The requirements and limitations of Medicare participation and billing are, it is claimed, too numerous, too uncertain, and at times too conflicting to make sense of, much less to support criminal liability.[285] In sum, the severity argument has much more weight when combined with the argument of complexity, where severe sanctions are imposed for truly unwitting conduct.

In truth, there are many uncertainties about the billing requirements imposed on providers,[286] and doubtless, there are instances when well-meaning individuals with billing responsibilities are simply unable to parse these complexities. Nevertheless, the intent requirements of the fraud and abuse laws, discussed shortly, are designed to address this concern. The scienter proof requirements demarcate the line between non-offenders and offenders by distinguishing between those who mistakenly transgress billing requirements or other restrictions and those who know that they are, or are reckless as to the chance that they may be, violating the law but act anyway.

We might be more troubled by the complexity argument if the fraud and abuse laws permitted civil or criminal liability based on unintentional conduct. It could be more persuasively argued that penalties that achieve complete deterrence are not appropriate if liability is imposed without fault or even for negligent conduct. Instead, in these situations, optimal deterrence is appropriate. It is appropriate because imposing a harsh penalty upon actors who accidentally commit acts, even acts that are criminal, may lead people to forgo activities that are socially

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284. *See* Julie Johnsson, *Are You Guilty Until Proven Innocent?: Tougher Rules on Fraud Enforcement Put Providers on the Defensive*, AM. MED. NEWS, June 9, 1997, at 1.

285. *See supra* notes 124-27 and accompanying text.

286. *See infra* notes 325-29 and accompanying text.

desirable, though at the margins of legality. The penalty for the negligent actor may be less severe not only because the negligent actor is less deterrable, but also because society may be better off if such actors feel free to walk close to, if not on, the line of liability.[287]

Where, however, the law imposes criminal sanctions or civil penalties on intentional conduct (whether willful, purposeful, knowing or reckless), as is the case with health care fraud violations, complete deterrence is a proper goal. An intentional actor, by definition, acts with more deliberation and therefore should be more deterrable than a negligent actor. If the cost of the prohibited intentional conduct is sufficiently high, deterrence theory posits that the intentional actor will choose lawful over unlawful conduct.[288] This is not to suggest that such actors will in fact be completely deterred, but only that complete deterrence is an appropriate goal and that the means to that end is to eliminate any gain that might motivate the intentional actor to choose to defraud or abuse Medicare. It is also, of course, appropriate to use the criminal law to express moral condemnation of such conduct.

In the civil context, the outer limits of this reasoning would capture the reckless provider as well, of course, and this strikes us as entirely appropriate. Although the reckless provider proceeds with less deliberation than the provider who acts with knowledge of his wrongdoing, proof of the reckless provider's awareness of wrongdoing is still required for civil liability. Put slightly differently, the reckless provider must have been aware of the fact that he or she was taking some risk (e.g., that his or her bill for services provided *might* be inflated) and have been willing to disregard that risk.[289] It is fair to burden a provider with the obligation to choose correctly, once it can be proved that the provider realized that he or she was at hazard of ob-

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287. *See* POSNER, *supra* note 256, at 239 ("[S]ince criminal sanctions are severe, to attach them to accidental conduct (and *a fortiori* to unavoidable conduct) is to create incentives to steer clear of what may be a very broad zone of perfectly lawful activity in order to avoid the risk of criminal punishment.").

288. JEREMY BENTHAM, AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION 166 (J.H. Burns ed., 1996).

289. *See* Alan C. Michaels, *Acceptance: The Missing Mental State*, 71 S. CAL. L. REV. 953, 959 (1998).

taining a benefit to which he or she was not entitled. For criminal liability, even more is required, and this too is appropriate. Proof of a knowing violation or an effort to consciously avoid obtaining knowledge is necessary.[290]

Although there are surely cases in which individuals and entities submit bills with undisputable actual knowledge of their falsity—as where a provider bills for goods and services when none have been provided—in the majority of cases, some service will have been provided, and the provider's intent in submitting the bill will be more ambiguous. This ambiguity will be heightened if the law fails to define clearly the goods and services for which bills may be submitted and the amount that may be sought. How, in such cases, is it to be determined that a provider has acted intentionally in violation of the fraud and abuse laws? At bottom, this is a proof problem more likely to haunt prosecutors than providers. If the fraud and abuse laws set unclear limits, it will be more difficult to prove that providers intentionally failed to satisfy those limits.

Both the civil and criminal false claims acts require a showing of intent. To impose penalties under terms of the civil FCA, the government must prove that a provider "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval" or "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."[291]

The civil FCA specifically defines "[k]nowingly" to mean "that a person, with respect to information—1) has actual knowledge of the information; 2) acts in deliberate ignorance of the truth or falsity of the information; or 3) acts in reckless disregard of the truth or falsity of the information."[292] It further stipulates that "no proof of specific intent to defraud is re-

290. *See* 31 U.S.C. § 3729(b) (1994) (requiring that the provider acted with "deliberate ignorance").

291. 31 U.S.C. § 3729(a)(1)-(2) (1986). The civil FCA covers several other types of conduct (such as obtaining property from the government by false pretenses), but other than § 3 covering conspiracy to defraud, the other sections are seldom at issue in health care cases.

292. *Id.* § 3729(b).

quired."[293]

This definition of "knowingly" was added by the 1986 False Claims Amendments Act.[294] The 1986 amendments explicitly reject both a specific intent and an actual knowledge requirement, required by some of the earlier cases interpreting the pre-1986 FCA, but they also reject a simple negligence standard.[295] The House Report accompanying the 1986 amendments states:

> A major problem that has been encountered in the prosecution of fraud by the Government under the current law concerns the appropriate standard of knowledge necessary for a violation of the Act. [The Report then sets out the language of the Amendment quoted above.] By adopting this definition of knowledge, the committee intends not only to cover those individuals who file a claim with actual knowledge that the information is false, but also to confer liability upon those individuals who deliberately ignore or act in reckless disregard of the falsity of the information contained in the claim. It is intended that persons who ignore "red flags" that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim should be held liable under

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293. *Id.*

294. Pub. L. No. 99-562, 100 Stat. 3153 (1986).

295. Prior to 1986, the circuits had been split as FCA to the mental state needed to establish a civil FCA violation. Michael S. McGarry, *Winning the War on Procurement Fraud: Victory at What Price?*, 26 COLUM. J.L. & SOC. PROBS. 249, 259-61 (1993). The Fifth, Ninth, and Eleventh Circuits had held that the civil FCA required proof that the defendant had acted with specific intent to deceive the government. *See* United States v. TDC Management Corp., 24 F.3d 292, 296-97 (D.C. Cir. 1994) (citing United States v. Davis, 809 F.2d 1509, 1512 (11th Cir. 1987)); United States v. Aerodex, Inc., 469 F.2d 1003, 1007 (5th Cir. 1972); United States v. Mead, 426 F.2d 118, 121 (9th Cir. 1970). The Seventh, Eighth and Tenth Circuits, and the Court of Claims had held that the pre-1986 civil FCA did not require proof of intent to deceive. *TDC Management Corp.*, 24 F.3d at 297 (citing United States v. Hughes, 585 F.2d 284, 287-88 (7th Cir. 1978)); Miller v. United States, 550 F.2d 17, 23 (1977); United States v. Cooperative Grain & Supply Co., 476 F.2d 47, 56-58 (8th Cir. 1973); Fleming v. United States, 336 F.2d 475, 479 (10th Cir. 1964). The First, Sixth and Tenth Circuits had, however, required proof that the defendant had submitted claims with "actual knowledge" of the falsity of the claims, while the Eighth Circuit and Court of Claims held that "knowingly" encompassed deliberate ignorance or reckless disregard for the truth. *TDC Management Corp.*, 24 F.3d at 297 (citing United States v. Data Translation, Inc., 984 F.2d 1256, 1266 (1st Cir. 1992)); United States v. Murphy, 937 F.2d 1032, 1038 (6th Cir. 1991); *Miller*, 550 F.2d at 23; *Cooperative Grain & Supply Co.*, 476 F.2d at 60; *Fleming*, 336 F.2d at 480.

> the Act. This definition, therefore, enables the Government not only to effectively prosecute those persons who have actual knowledge, but also those who play "ostrich."[296]

Since the 1986 amendments, a considerable body of judicial opinion has considered the mental state requirement of the civil FCA. These decisions have uniformly recognized that Congress intended to cast a broad net by the 1986 amendments, specifically capturing those who act in reckless disregard of the truth or in deliberate ignorance.[297] Some cases suggest further that gross negligence in billing may be sufficiently reckless to support liability.[298] Others have refused to countenance conscious attempts to take advantage of billing requirements by shifting blame to confusion surrounding the use of codes.[299] Finally, courts have uniformly recognized that the "ostrich" type of neglect of responsibility for the improper claims of subordinates can support liability.[300]

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296. H.R. REP. NO. 99-660, at 20-21 (1986) (to accompany the FCA of 1986). The House language for the bill was chosen over the Senate Language, which would have defined "knowingly" as meaning that the defendant had actual knowledge or had acted "in gross negligence of the duty to make such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim." S. REP. NO. 99-345, at 20 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5285. The Reports, however, do not indicate that the two chambers found the language of the two versions to be inconsistent. H.R. REP. NO. 99-660, at 20-21.

297. Covington v. Sisters of the Third Order of Saint Dominick, 61 F.3d 909, No. 93-15194, 1995 WL 418311, at *4 (9th Cir. 1995) (holding that deliberate ignorance or reckless disregard of the truth is covered); United States v. Lorenzo, 768 F. Supp. 1127, 1131-32 (E.D. Pa. 1991) (holding that reckless billing is enough). Older cases, in fact, have had to deal with the question of whether this lesser mens rea standard should be applied retroactively to claims presented or statements made before 1986. *See, e.g.*, United States v. TDC Management Corp., 24 F.3d 292, 297-98 (D.C. Cir. 1994); United States *ex rel* Newsham v. Lockheed Missiles & Space Co., 907 F. Supp. 1349, 1358 (N.D. Cal. 1995), *vacated by* No. C-88-20009-JW, 1997 WL 858547 (N.D. Cal. Nov. 8, 1995), and *aff'd in part and rev'd in part sub nom* United States v. Lockheed Missiles & Space Co., 171 F.3d 1208 (9th Cir. 1999).

298. United States v. Krizek, 111 F.3d 934, 941 (D.C. Cir. 1997) (holding that "reckless disregard is 'simply a linear extension of gross negligence'").

299. United States *ex rel.* Trim v. McKean, 31 F. Supp. 2d 1308, 1315-16 (W.D. Okla. 1998).

300. *E.g.*, Lamers v. City of Green Bay, 998 F. Supp. 971, 987 (E.D. Wis. 1998); United States *ex rel.* Garibaldi v. Orleans Parish Sch. Bd., 21 F. Supp. 2d 607, 619 (E.D. La. 1998). It is also not a defense to a false claim action that the claim was based on erroneous information provided by another. United States v. Jointer, 910 F. Supp. 279, 281 (S.D. Miss. 1995).

By contrast, innocent mistakes and mere negligence in billing is not enough to support liability under the civil FCA.[301] A claim must be "a lie"[302] to fall within the proscription of the civil FCA. If a defendant genuinely believes that it is billing correctly and the defendant's interpretation of a billing requirement is "superficially plausible," the defendant has not "knowingly" filed a false claim.[303] Further, though prior government knowledge of the defendant's conduct no longer automatically bars a *qui tam* action as it did before the 1986 amendments, cooperation between the government and the defendant, including sharing of information, supports a conclusion that the defendant did not "knowingly" submit a false claim.[304]

The problem of intention is often entangled with the issue of whether the claim was in fact "false." The amended FCA does not specifically define what is meant by a "false or fraudulent" claim or a "false" statement.[305] It is clear that the terms "false" and "fraudulent" are not intended to be redundant, that false claims violate the statute regardless of whether they would be considered fraudulent under preexisting law.[306] But the courts

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301. *See* United States *ex rel.* Hochman v. Nackman, 145 F.3d 1069, 1073 (9th Cir. 1998); Hindo v. University of Health Sciences/The Chicago Med. Sch., 65 F.3d 608, 613, 614 (7th Cir. 1996); United States *ex rel.* Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991); Wang v. FMC Corp., 975 F.2d 1412, 1420-21 (9th Cir. 1992).

302. *See Hindo*, 65 F.3d at 613; *Wang*, 975 F.2d at 1420.

303. *See Hochman*, 145 F.3d at 1073-76.

304. *Compare* United States *ex rel.* Butler v. Hughes Helicopter, 71 F.3d 321, 326 (9th Cir. 1995) (resulting in summary judgment for defendant where government knew of defendant's alleged noncompliance with contract requirements), *and* United States *ex rel.* Lamers v. City of Green Bay, 998 F. Supp. 971, 988 (E.D. Wis. 1998) (stating, "[s]ince the crux of an FCA violation is intentionally deceiving the government, no violation exists where the government has not been deceived"), *with* United States *ex rel.* Kreindler & Kreindler v. United Tech. Corp., 985 F.2d 1148, 1156-57 (2d Cir. 1992), *and* United States *ex rel.* Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) (holding that alleged government knowledge is not automatic defense to *qui tam* action).

305. *See* 31 U.S.C. § 3729 (1994).

306. This distinction is indicated by the use of the disjunctive. But this interpretation is also supported by the legislative history of the statute. As originally written, the section covered "false, fictitious, or fraudulent" claims. In 1982, the word "fictitious" was dropped "to eliminate unnecessary words." By implication, false is not surplusage and has a meaning other than "fraudulent." *See* United States v. TDC Management Corp., 24 F.3d 292, 297 (D.C. Cir. 1994); *see also* H.R. REP. NO. 97-651, at 12 (1982), *reprinted in* 1982 U.S.C.C.A.N. 1895, 1895.

are also clear in recognizing that "false" claims or statements are more than simply "wrong" claims or statements.[307] Good faith scientific, engineering and mathematical errors, for example, are not false statements.[308] In addition, good faith errors based on misunderstanding a complex coding scheme[309] and statements that, though literally inaccurate, are rational responses to a government requirement and not intended to deceive do not qualify as false statements.[310]

Indeed, civil FCA opinions often evidence judicial sympathy for providers grappling with the complexity of government programs. As federal judges struggle to understand the complex coding schemes of the Medicare program, they become increasingly tolerant of defendants who are caught miscoding.[311] Courts are particularly sympathetic when multiple small claims filed by health care providers could lead to penalties in the millions of dollars after civil FCA multipliers and penalties are applied.[312] In sum, courts do not generally impose FCA penalties for simple mistakes, and they are often willing to go some distance in viewing suspicious billing as mistaken.

A similar forgiving attitude is detectable in criminal cases involving false claims charges brought under 18 U.S.C. § 287. The mens rea requirements of the criminal false claims statute are intended to ensure that providers who mistakenly file claims in contravention of program requirements will not be prosecuted.[313] Section 287 makes clear that only a provider who makes

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307. *See Lamers*, 998 F. Supp. at 986.

308. *See* United States *ex rel* Anderson v. Northern Telecom., Inc., 52 F.3d 810, 815 (9th Cir. 1995); Wang v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992); Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1047 (N.D. Ill. 1998); United States *ex rel.* Milam v. University of Cal., 912 F. Supp. 868, 885 (D. Md. 1995). "The phrase 'known to be false' [of the pre-1986 FCA] . . . does not mean 'scientifically untrue'; it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors." *Wang*, 975 F.2d at 1421.

309. *See* United States v. Krizek, 859 F. Supp. 5, 10-11 (D.D.C. 1994).

310. *See* United States v. Data Translation, Inc., 984 F.2d 1256, 1266 (1st Cir. 1992).

311. *See Krizek*, 859 F. Supp. at 8-11; *see also Baxter Healthcare Corp.*, 2 F. Supp. 2d at 1049 (stating that the court will not "hold a defendant to the government's strict interpretation [of a statutory requirement], so long as defendant's interpretation was reasonable").

312. *See, e.g., Krizek*, 859 F. Supp. at 10, 14, *on remand*, 7 F. Supp. 2d 56, 59-60 (D.D.C. 1998); United States *ex rel.* Trim v. McKean, 31 F. Supp. 2d 1308, 1315-16 (W.D. Okla. 1998).

313. *See* United States v. Cooperative Grain & Supply Co., 476 F.2d 47, 56 (8th

a claim upon an agency of the United States *"knowing* such claim to be false, fictitious, or fraudulent" shall be criminally liable.[314] Thus, juries are specifically instructed that they may convict under § 287 only if they find that the defendant provider knew that its claims were false or acted with "deliberate disregard" for their truth or falsity.[315] If the jury finds the provider acted "through ignorance, mistake, or accident," it must acquit.[316] Because a provider's mistakes will not support a false claims conviction,[317] the exacting mens rea requirement of § 287 prompts auditors and investigators to issue warnings to providers suspected of abusing billing practices before bringing criminal charges.[318]

The intent requirement may be even more formidable when a criminal statute requires proof of "willful" conduct,[319] as does the anti-kickback statute,[320] the general false statement prohibition in 18 U.S.C. § 1001, and the more specific false statement law relating to health care matters in 18 U.S.C. § 1035.[321] The meaning of the term "willfully" has been the subject of considerable controversy and has played out most fully in the context of the anti-kickback law. The anti-kickback statute prohibits the "knowing and willful" solicitation, receipt, offer or payment of

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Cir. 1973).

314. 18 U.S.C. § 287 (1994) (emphasis added).

315. *See* United States v. Nazon, 940 F.2d 255, 258-59 (7th Cir. 1991); United States v. Precision Med. Lab., Inc., 593 F.2d 434, 443-44 (2d Cir. 1978).

316. *Nazon*, 940 F.2d at 258.

317. *Id.*

318. For example, in *Nazon*, two separate audits conducted years apart revealed the defendant's seriously defective billing practices. As a result of the first audit, the defendant was issued a demand-for-refund letter, and a meeting was scheduled to discuss the erroneous charges. *Id.* at 256. The defendant failed to attend. Six years later, a second audit revealed similar substantially defective billing practices. *Id.* at 257. Medicaid personnel again advised the defendant that the practices were impermissible and must be discontinued. *Id.* The defendant failed once again to heed the government's warnings. *Nazon*, 940 F.2d at 257. It was only after three more years of unabated deviant billing that the defendant was finally charged and convicted of filing false claims. *Id.*

319. The heightened mens rea requirements imposed by the scienter term "willfully" have not been confined to the health care fraud and abuse prosecutions. For an article discussing the judicial trend to interpret the term to require proof of knowledge of the law, see Sharon L. Davies, *The Jurisprudence of Willfulness: An Evolving Theory of Excusable Ignorance*, 48 DUKE L.J. 341, 343-47, 361-96 (1998).

320. *See* 42 U.S.C. § 1320a-7b(b)(1)-(2) (1994).

321. 18 U.S.C. § 1001 (1994 & Supp. III 1997).

remuneration for referrals of goods or services reimbursable under a federal health care program.[322] Providers have argued that this special mens rea term requires prosecutors to prove that a provider knew its financial arrangements violated the law before the government may secure a kickback conviction. In the celebrated *Hanlester* decision,[323] the Ninth Circuit agreed that such proof was necessary. The court held that prosecutors must show that a provider was aware of the anti-kickback prohibitions and acted with knowledge that its transactions violated those provisions.[324]

Although the *Hanlester* view is as yet a minority one,[325] there can be no doubt that the willfulness requirement erects a formidable hurdle for prosecutors. At minimum, to prove willful conduct in a criminal case, a prosecutor must establish that the targeted provider acted "with a 'bad purpose,'"[326] i.e., that the provider "acted with an evil-meaning mind" and "with knowledge that his conduct was unlawful."[327] Whether this will require in future kickback cases proof that the provider was aware that its conduct violated the specific anti-kickback provisions is not yet firmly resolved.[328] Even if the courts eventually agree

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322. 42 U.S.C. § 1320a-7b(b)(1)-(2).

323. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995).

324. *Hanlester*, 51 F.3d at 1400.

325. Perhaps in recognition of the grueling proof problems that would be presented under this interpretation, other courts have declined to adopt the *Hanlester* standard. *See* United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. Jain, 93 F.3d 436, 440-41 (8th Cir. 1996) (holding that the "mens rea standard should only require proof that [the defendant] knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty'"); United States v. Neufeld, 908 F. Supp. 491, 495-96 (S.D. Ohio 1995); Medical Dev. Network, Inc. v. Professional Respiratory Care/Home Med. Equip. Serv., Inc., 673 So. 2d 565, 567 (Fla. Dist. Ct. App. 1996).

326. *See* Bryan v. United States, 524 U.S. 184, 191 (1998). The issue before the Court in *Bryan* was whether the term "willfully" in a federal firearms statute required proof that the defendant had known that his conduct was unlawful generally, or whether it imposed the more stringent requirement of proof that he had known about the specific federal licensing requirement violated by his conduct. *Bryan*, 524 U.S. at 184-85.

327. *Id.* at 184-85.

328. When "willfully" appears in a "highly technical" statute, proof of precise knowledge of the law may be required. *Id.* at 194. This higher mens rea may be required in cases involving alleged violations of complex tax laws or federal anti-structuring laws. *See* Cheek v. United States, 498 U.S. 192, 200-01 (1991) (construing "willfully" to require proof that the defendant had known about the specific tax-

that the anti-kickback provisions are not so "highly technical" that they require such proof, at minimum prosecutors will have to show that the provider was *generally aware* of the unlawfulness of its conduct.[329] In many cases, this evidentiary obstacle will be insurmountable.

In sum, complaints that the complex false claims and anti-kickback laws will lead to unwarranted convictions of "innocent" providers who mistakenly transgress the statutes' intricate requirements ring hollow in light of the rigorous intent obligations imposed by the laws. Any persuasive evidence that a provider was mistaken about its obligations under these laws will effectively derail the prosecutor's case, leading either to an acquittal or, more likely, to a decision not to prosecute in the first place.

The problems of complexity and uncertainty in Medicare billing requirements, though real, are also overstated. No one person, of course, could master all Medicare certification and billing requirements for all covered goods and services. But no one is required to do so. Physicians, for example, generally have specialized practices and submit the vast majority of their bills under a limited number of codes with which they or their billing assistants are quite familiar.[330] Hospital billing is done by bill-

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related duty he was accused of violating); *see also* Ratzlaf v. United States, 510 U.S. 135, 146 (1994) (construing "willfully" to require proof that the defendant had known about the specific anti-structuring law that forbade his conduct). But where the term appears in a statute that is not "highly technical," proof of knowledge of *general* illegality is required, but the government need not offer proof of the defendant's knowledge of the specific provision that prohibited his conduct. *See Bryan*, 524 U.S. at 196. This bifurcated standard raises the obvious, critical question: is the anti-kickback statute "highly technical"? If so, a provider must be shown to have known that its conduct constituted unlawful anti-kickback activity at the time the provider engaged in the conduct. To date, the only federal court to apply *Bryan* to the anti-kickback statute has answered that question negatively, holding that the statute is not highly technical. *See* United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (holding that the anti-kickback statute is not highly technical). It remains to be seen whether other courts will follow suit.

329. *Bryan*, 524 U.S. at 196.

330. The Current Procedural Terminology ("CPT") Code system, under which most Medicare physician billing takes place, was developed and is regularly updated by the American Medical Association. *See* C.G. KIRSCHNER ET AL., CPT 1998, PHYSICIANS' CURRENT PROCEDURAL TERMINOLOGY (1998). The CPT is logically organized by body system and by type of procedure. The most difficult decision in applying the code is usually identifying the correct level of procedural complexity at which to bill, but the CPT manual offers guidance on this issue as well. P. John Steward, *Foreward* to KIRSCHNER ET AL., CPT 1998: PHYSICIANS' CURRENT PROCE-

ing experts assisted by a computer program specially designed to code correctly.[331] A recent GAO study applying up-to-date commercial technology to review claims found that 92% of the providers in its sample billed correctly and that only 4% of the claims it reviewed had to be adjusted.[332] The most recent financial audit of Medicare by the HCFA's Chief Fiscal Officer found that Medicare had a 7.1% erroneous payment rate in 1998.[333] While a 7.1% error rate is unacceptably high, it does mean that at least 93% of providers billed correctly. The HCFA continues to work with providers to assist them in correct billing, including a major new initiative to educate hospital billing agents in correct coding and documentation.[334] Finally, recent legislation permits providers to seek a written advisory opinion from the HCFA where there is genuine uncertainty as to whether a claim is appropriate.[335]

Just as the severity concern breaks down under critical analysis, so does that of complexity. The fraud and abuse laws only sanction conduct that is culpable, characterized by willfulness, knowingness or, with respect to civil penalties, recklessness or deliberate indifference—not innocent mistakes.[336] The more severe the sanction, moreover, the higher the level of culpability that is required.[337] While Medicare coding and claiming requirements are certainly complex, the fraud and abuse laws do not impose liability on those who misconstrue, misunderstand or simply miss a coding or claiming requirement.[338] One can hardly complain that a billing requirement is too difficult to understand if one understands it and nonetheless pro-

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DURAL TERMINOLOGY iii (1998).

331. *See* FURROW ET AL, *supra* note 222, § 13-11 (1995); 42 C.F.R. § 412.60 (1998).

332. *See* U.S. GEN. ACCOUNTING OFFICE, MEDICARE CLAIMS: COMMERCIAL TECHNOLOGY COULD SAVE BILLIONS LOST TO BILLING ABUSE 8-10 (1998).

333. *Fraud and Abuse: Medicare's Rate of Improperly Paid Claims Drops to Lowest in Three Years, IG Reports*, Health Care Daily Rep. (BNA), Feb. 10, 1999, at d2, *available in* WL 2/10/99 HCD d2.

334. *See Error Rate*, *supra* note 184, at d4; MEDICARE ONLINE TRAINING (Sept. 23, 1999) <http://www.medicaretraining.com>.

335. *See* Health Insurance Portability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000 (to be codified at 42 U.S.C. § 1320a-7d).

336. *See* discussion *supra* pp. 8-9.

337. *See supra* note 295 and accompanying text.

338. *See* discussion *supra* pp. 8-9.

ceeds to violate it or if one is reckless or deliberately indifferent as to correct coding.

In the end, however, rejection of provider complaints of severity and complexity is based on a fundamental assumption—that there is a fair procedure for determining who is culpable and for exonerating those who innocently misconstrue complex billing requirements. Thus, the most important provider grievance turns out to be that of vulnerability to unfair, coerced settlements.

D. Vulnerability

The complaint of vulnerability to coercive settlements is certainly plausible. In the most common situation, a fraud and abuse case begins when a government audit or coordinated national investigation identifies a number of allegedly improper claims filed by a provider.[339] The OIG or FBI, at the direction of the DOJ or some other law enforcement entity, investigates further, often surreptitiously, to identify the scope and nature of the problem.[340] Following investigation, the government may contact the provider, demanding a very large settlement sum, often calculated by extrapolating the number of improper claims identified to the total number of projected improper claims and then applying the civil FCA damage and penalty formula (treble damages plus $5,000 to $10,000 per claim).[341] The government may also threaten criminal prosecution and subsequent exclusion.[342]

Alternatively, a case may be initiated by a *qui tam* relator, usually an insider and often an employee or former employ-

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339. *See supra* notes 202-08 (discussing the upward trend in frequency of prophylactic audits by health care providers).

340. *See* JOST & DAVIES, *supra* note 39, §§ 1-3, 7-4 to -6.

341. *See supra* note 24 and accompanying text (discussing the provider complaint that health care fraud enforcement agencies initiate their prosecutions of health care fraud by using "demand letters" that threaten providers with huge monetary fines).

342. If the government identifies a case as involving criminal misconduct, on the other hand, it often proceeds directly from investigation to indictment, skipping the settlement negotiation stage. *See supra* notes 41-49, 58-63 (discussing the various criminal and administrative sanctions available to force compliance with health care fraud and abuse laws).

ee.[343] The case, filed under seal, usually triggers a government investigation, which leads in about one fifth of the cases to government intervention.[344] The civil FCA gives the government a substantial role in *qui tam* cases, permitting it to intervene,[345] to direct and control the litigation if it chooses to intervene,[346] to intervene at a later time if it chooses to decline intervention initially,[347] to reach settlement agreements,[348] and even to dismiss *qui tam* cases without the consent of the relator (though only with court permission).[349] The relator, on the other hand, initiates the litigation and can object to a settlement.[350] The course of the proceedings is affected by the government, the relator and the defendant.

Whether a case is initiated based on government audit and investigation or by *qui tam* filing, it generally moves quickly toward settlement. Civil FCA cases rarely go to judgment, and many are settled before filing in court.[351] Once serious settlement discussions are underway, the government commonly offers to forego exclusion and to settle the case for a figure in excess of simple repayment of the amount billed, but also far short of the total potential claim.[352] In the lab unbundling national initiative, for example, only two thirds of the hospitals were required to repay overpayments plus interest; the hospitals that the DOJ considered most culpable paid only double damages; and, none of the hospitals that settled paid a penalty.[353]

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343. *See* JOST & DAVIES, *supra* note 39, § 6-3.

344. Since the 1986 amendments, the DOJ has intervened in 1549 of the 1961 *qui tam* cases that have been filed. Telephone Interview with Shelly Slade, Senior Counsel for Health Care Fraud, Department of Justice (May 26, 1999).

345. 31 U.S.C. § 3730(b)(2) (1994).

346. *Id.* § 3730(c)(1).

347. *Id.* § 3730(c)(3).

348. *Id.* § 3730(c)(2)(B).

349. *Id.* § 3730(c)(2)(A).

350. *See* 31 U.S.C. § 3730(c)(2)(B).

351. *See* discussion, *supra* note 142.

352. *See* APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES, *supra* note 115, at 9-10.

353. *See supra* note 225-29 and accompanying text. A report of another recent settlement quoted a U.S. Attorney as stating that the case was settled by applying a multiplier of 2.1 to 2.5 times actual damages to reach the settlement, suggesting that at least some U.S. Attorneys have devised approaches to settling FCA cases for amounts far below the penalties legally available under the FCA. *See Fraud and Abuse: Baltimore Hospital to Pay $827,000 to Settle Medicare Fraud Allegations,*

A provider may well believe that its legal position in a case is defensible—that if it would refuse to settle and insist on going to trial, it could win on the issue of culpability, perhaps even on its interpretation of the underlying program requirement. But there is always a possibility that it will lose. Given the high level of deference that the federal courts afford the DHHS in its interpretation of the Medicare regulations, it is in fact quite likely that the provider will lose if its case involves a regulatory interpretation. Given the fact that the government need only prove knowledge, recklessness or deliberate ignorance by the preponderance of the evidence in civil cases,[354] the risk that a provider will be found culpable for its billing error is also significant. Further, given the crowded dockets of the federal courts, the ultimate resolution of the case if the provider goes to trial will come only after a period of prolonged uncertainty and after the provider has incurred substantial litigation expenses.

To a provider who faces the risk of penalties often running into the millions of dollars, the finality of swift settlement will often look quite attractive compared to the risk of a much larger judgment and possibly criminal penalties or exclusion if the case goes to trial. By settling early, the provider avoids future litigation costs, which might well be substantial. If the provider is a publicly traded corporation, a quick resolution of the case that avoids criminal culpability or exclusion and simply subjects the provider to a modest penalty might also increase investor confidence.[355] It is not surprising, therefore, that providers settle virtually all false claims cases.

A more interesting question is why the government settles these cases, usually by agreeing to accept damages far smaller than those authorized by law.[356] Assuming that the primary goal of the government in policing the billing system through the fraud and abuse laws is to deter improper billing and that only a

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Health Care Daily Rep. (BNA), June 15, 1998, at d7, *available in* WL 6/15/98 HCD d7.

354. *See* 31 U.S.C. § 3729(b) (1994); *supra* notes 272-92 and accompanying text.

355. Aggressive health care fraud enforcement has been identified as a factor in the dramatic decline in the value of health care stocks at the end of the 1990s. *See* Robert Kuttner, *The American Health Care System, Wall Street and Health Care*, 340 NEW ENG. J. MED. 664-68 (1999).

356. *See supra* notes 224-27 and accompanying text.

small fraction of improper bills will be detected, the government should, in theory, insist on large penalties whenever it catches a provider submitting improper claims.[357] To settle false claims cases routinely for significantly less "than the legally authorized penalties" is to undermine even optimal deterrence and to risk encouraging improper billing.

There are obvious partial explanations for the government's willingness to settle these cases. The cost of litigating fraud and abuse cases is substantial, particularly if expert testimony will be required, as when the necessity or nature of the treatment provided is at issue. Like defendants, the government must also consider the possibility that it will lose in court and that the loss might establish a bad precedent for other cases. Moreover, it is not clear that settlement will actually undermine deterrence. A highly publicized settlement or series of settlements for sums well below the amount dictated by deterrence theory may largely achieve the goal of deterrence, as long as the full deterrent penalty remains potentially available.[358] Assume, for example, that Medicare requires that a particular service be billed using a particular code (which pays, let us assume, $100 per service) but that providers have in the past routinely billed using a more remunerative code (which pays $200 per service) and have not been challenged. An audit of 5% of claims identifies a provider who has billed 200 claims in this fashion. To achieve optimal deterrence (and in this case, assuming the provider's gain is less than the government's loss, also complete deterrence), the provider should be assessed a penalty of at least $400,000 ($100 x

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357. As noted earlier, this calculus might change where a national enforcement initiative, involving much more widespread audits, is involved. *See supra* notes 227-29 and accompanying text.

358. Health care fraud settlements are, in fact, commonly reported in the reporting services and trade periodicals followed by health care providers and their attorneys. *See, e.g.*, Jane Erikson, *Medicare Paperwork is Labeled Big Burden*, ARIZ. DAILY STAR, Sept. 19, 1999, at 1B (reporting that the University of California at San Diego was forced to pay a $4.7 million settlement after being accused of improperly billing Medicare for experimental procedures); Ihen Blichenstaff, *Strong Medicine Needed for Fighting Health Care Fraud*, CHI. DAILY L. BULL., July 13, 1999, at 6 (reporting a $111.4 million settlement by National Health Laboratories, Inc.); Mark Taylor, *On the Ropes: Beefed-Up Anti-Kickback Laws, Growing Cohort of Whistleblowers Pound Away at Health Care Fraud*, MOD. HEALTH CARE, June 28, 1999, at 30 (reporting health care fraud settlement between the Simi Valley Community Hospital and the Department of Health and Human Services).

200 cases/0.05).[359] The civil FCA would yield a penalty of $1,060,000 to $2,060,000.

Even if the government agrees to settle its claim, however, for a sum much less than $400,000 (combined with the establishment of a corporate compliance program), several goals could be achieved. First, the settlement would achieve specific deterrence by rendering it very unlikely that the particular provider would again bill Medicare improperly for the particular service. Second, the settlement, when publicized through the usual trade publications and fraud and abuse reporting services, would achieve general deterrence by putting the provider community on notice that in the future similar claims must be submitted for the proper amount with the use of the proper code. Any provider who continued to bill for the higher rate would risk prosecution for the full statutory penalty (plus, perhaps, criminal sanctions and exclusion) and would be hard pressed to argue that the billing was an innocent mistake.[360] Third, the particular provider's corporate compliance program, customarily instituted at the government's insistence, could address a range of billing issues going well beyond the narrow issues of the particular case, thus achieving compliance more broadly.

The settlement calculus of *qui tam* relators is much easier to understand. The relator is interested in maximizing the amount of the civil FCA recovery and his or her share of the recovery.[361] Although the civil FCA permits a prevailing relator to recover "reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs,"[362] the relator only recovers fees and expenses if he or she settles or prevails at trial.[363] By refusing to settle, the *qui tam* relator risks losing the case and being left with the costs of litigation.[364] If the government declines intervention and the

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359. The amount should, of course, be adjusted upward for processing and policing costs before the multiplier is applied. *See supra* note 116 and accompanying text.

360. Note that providers are much more likely to change their practices to comply with the law if the sanctions necessary to achieve complete deterrence remain in place, even if they are not imposed in the particular settlement. *See supra* notes 216-17 and accompanying text; *see also* discussion *supra* pp. 45-46.

361. *See* 31 U.S.C. § 3730 (1994) (allowing relators in successful *qui tam* actions to be awarded a portion of the total recovery under the FCA).

362. *See id.* § 3730(d)(1)-(2).

363. *Id.* § 3730(d)(1)-(2).

364. *Qui tam* cases may be brought on a contingent fee basis, *see* JOST &

relator proceeds, then there is also always some risk that the relator may end up responsible for the defendant's costs and attorneys' fees, if the court determines that the relator's position was "clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment."[365] Most importantly, the relator who refuses an early settlement offer risks the possibility that a court may determine that the relator is not qualified to proceed under the complex standing rules of the civil FCA, disqualifying the relator from sharing in the judgment.[366] Reported cases document vigorous litigation of these standing issues by health care providers in *qui tam* cases, particularly where the government declines intervention.[367] A rational relator, therefore, would be expected to accept a prompt settlement of civil FCA case well below the statutory maximum, as long as the relator can count on a substantial share of this settlement.[368]

Because settlement of health care fraud and abuse cases (or at least civil FCA cases) seems usually to be in the interest of all parties, it is not surprising that most civil FCA health care cases seem to settle rather than to proceed to judgment, usually for payments well below the levels of damages and penalties set by the civil FCA. The provider who consents to the settlement, however, may nonetheless feel deeply wronged if the provider truly believes that the interpretation of program requirements urged by the government or relator is wrong (or that, in any event, the billing was not culpable) and that the settlement was

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DAVIES, *supra* note 39, § 6-3, but this simply means that the relator's lawyer rather than the relator is at risk. The lawyer will presumably encourage the relator to accept a reasonable settlement offer, realizing the risk of proceeding to trial and losing.

365. *See* 31 U.S.C. § 3730(d)(4).

366. *See id.* § 3730.

367. *See* BOESE, *supra* note 10, §§ 4-187 to -195.

368. The problem of vulnerability to abuse by *qui tam* relators has been overemphasized by providers. If the government intervenes in a *qui tam* case, as it does about one fifth of the time, the government controls the litigation and the provider is only slightly more vulnerable than it is in government-initiated litigation. If the government declines intervention, that case is often dismissed, but even where it is not dismissed, the provider rarely loses. Of the $2.249 billion recovered through *qui tam* cases between the 1986 amendments and 1998, all but $60 million was recovered in suits in which the government intervened. *See Fraud and Abuse: Some $2.2 Billion Recovered Since 1986 Under False Claims Act, Justice Announces*, Health Care Daily Rep. (BNA), Oct. 26, 1998, at d5, *available in* WL 10/26/98 HCD d5.

extorted from it because of the threat of massive penalties under the civil FCA and criminal penalties or exclusion.[369]

In response to this concern, the DOJ and the OIG have recently taken steps to cabin the vulnerability of providers to coerced settlements. On June 3, 1998, the DOJ released a *False Claims Act Guidance*,[370] which announced procedures for handling "national initiatives" involving common wrongful actions committed by multiple health care providers.[371] The *Guidance* stipulates that before alleging violations of the civil FCA (whether in the context of national initiatives or not), a DOJ attorney must first determine separately that the provider 1) submitted false claims to the government and 2) that it did so knowing of their falsity.[372] To determine whether a claim was false, the *Guidance* directs DOJ attorneys to 1) examine relevant statutory and regulatory provisions and interpretive guidance to establish the legal requirements for billing; 2) verify data or other evidence on which claims were based; and 3) conduct investigative steps necessary to establish liability.[373] Once the DOJ attorney concludes that the provider has submitted false claims, he or she must determine whether a provider "knowingly" submitted a false claim.[374] To this end, the DOJ attorney should consider: 1) whether the provider had actual or constructive notice of the policy on which the case was based; 2) the clarity of the rule or policy; 3) the pervasiveness and magnitude of the false claims; 4) the presence or absence of compliance plans or other steps to comply with billing rules; 5) efforts to remedy wrongful conduct

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369. *See* discussion *supra* notes 141-46; *see also supra* notes 334-51 and accompanying text.

370. U.S. DEP'T OF JUSTICE, FALSE CLAIMS ACT GUIDANCE, *reprinted in* 2 Health Care Fraud Rep. (BNA) 459 (1998) [hereinafter GUIDANCE].

371. The DOJ defines "national initiatives" to include only multidistrict projects that rely on national claims data. Only four such initiatives existed in early 1999: the laboratory unbundling projects, the 72 hour window projects, the prospective payment system ("PPS") transfer project, and the pneumonia upcoding projects. These four initiatives, however, accounted for 2101 of the 4722 health care claims cases that the DOJ had open at that time. *Fraud and Abuse: GAO Says Too Early to Tell How Well DOJ Complying With FCA Enforcement Guidelines*, Health Care Daily Rep. (BNA), Feb. 4, 1999, at d5, *available in* WL 2/4/99 HCD d5 [hereinafter *Too Early to Tell*].

372. GUIDANCE, *supra* note 370, at 459.

373. *Id.*

374. *Id.* at 459-60.

and to cooperate with the agency; 6) sincere efforts by the provider to obtain guidance from the agency on billing and reasonable reliance on guidance obtained; and 7) the presence or absence of prior audits or other notice to the provider of the problem.[375] Only once this process concludes with a decision that further action is necessary should the case proceed.

The *Guidance* further directs the establishment of working groups to supervise national initiatives to assure that such initiatives are warranted and to establish policy for their pursuit.[376] It counsels DOJ attorneys to consider alternative remedies before initiating civil FCA actions and to consider the provider's ability to pay in establishing fair and feasible settlements.[377] It requires DOJ attorneys to consider the impact of an action on the availability of services from rural and community providers, to be particularly careful in dealing with providers not represented by counsel, and to minimize the burdens placed on providers during investigations.[378] Perhaps most important symbolically, the *Guidance* replaces settlement "demand" letters, previously issued by the DOJ to providers suspected of violating the civil FCA, with "contact" letters, inviting the provider to discuss its potential liability before a specific amount is demanded.[379]

On the same day the *Guidance* was issued, June Gibbs Brown, Inspector General, issued a National Project Protocol governing OIG investigations.[380] The Protocol attempts to memorialize recommendations for "best practices" for OIG investigations "developing and participating in national enforcement projects."[381] The Protocol first directs the OIG to establish minimum monetary thresholds and/or percentage error rates to de-

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375. *Id.* at 460.

376. Id.

377. GUIDANCE, *supra* note 370, at 460.

378. *Id.* at 460-61.

379. *Id.*

380. *See* DEPARTMENT OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., NATIONAL PROJECT PROTOCOLS (1998), *reprinted in* 2 Health Care Fraud Rep. (BNA) 464 (1998) [hereinafter PROTOCOLS].

381. A year earlier, in the summer of 1997, the OIG scaled back and tightened up its Physicians at Teaching Hospitals audits in response to provider demands. Sean Martin, *Protests Prompt HHS to Retool PATH Audits of Teaching Hospitals*, 40 AM. MED. NEWS, July 28, 1997, at 1.

termine whether a health care provider should be referred to a carrier or intermediary for an overpayment recoupment or, alternatively, to the DOJ for civil FCA investigation.[382] This goes beyond the DOJ *Guidelines*, which do not recognize such a threshold.[383] Obviously, the thresholds are flexible, depending on the project, the size of the provider and its dependence on federal health care revenues, prior audits and notice to the provider community, the number of erroneous claims, and the size of the overpayment.[384] The Protocol further includes provisions to encourage the equitable treatment of providers and, where appropriate, communications with the provider community and provider representatives, thorough assessment of the legal basis of enforcement actions before their initiation, and centralized coordination of national projects.[385]

Congress, responding to provider complaints of unfairness in civil FCA enforcement, included provisions in the 1998 Budget Bill instructing the GAO to monitor the continuing implementation of DOJ policy and to report by February 1, 1999 and August 2, 1999 on progress with implementation.[386] The first GAO report found that the DOJ was taking steps to comply with the law but that it was still too early to evaluate DOJ compliance.[387] It found, moreover, that seven times as many national initiative matters had been closed as opened since the initiative, with about half of the closed cases involving settlements.[388]

In sum, provider complaints about enforcement vulnerability, though not frivolous, also seem to be oversold. The question remains, however, whether more needs to be done to level the fraud and abuse playing field. To this question we now turn in concluding this Article.

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382. PROTOCOLS, *supra* note 380, at 464.

383. *See DOJ, DHHS IG Issue New Guidelines for Health Care Enforcement Efforts*, 2 Health Care Fraud Rep. (BNA) 437 (1998).

384. *See id.*

385. *See* PROTOCOLS, *supra* note 380, at 464-65.

386. Omnibus Consolidated and Emergency Appropriations Act, Pub. L. No. 105-277, § 118, 112 Stat. 2681 (1998).

387. *Too Early to Tell*, *supra* note 371, at d5.

388. *Id.*

VI. FURTHER STEPS

Our analysis suggests that the fundamentals of fraud and abuse enforcement are sound. Fraud and abuse penalties should, in most instances, be sufficiently large to achieve complete deterrence and in fact are. Though Medicare billing requirements are complex, providers who violate them innocently are not liable. Vulnerability to coerced settlements is an issue, but it is being addressed by changes in enforcement procedure.

Legislative changes that would significantly change the balance in fraud and abuse cases might well dramatically undermine fraud and abuse enforcement. For example, the 1998 proposed legislation would have raised the burden of proof under the civil FCA from the ordinary civil standard of "preponderance of the evidence" to "clear and convincing" evidence in cases involving federally funded health care programs.[389] Imposing this heightened burden of proof on federal enforcers would have, in all probability, significantly changed the settlement calculus of providers and led to far fewer settlements of false claims cases. This, in turn, would have dramatically diminished the willingness of enforcers to bring false claims cases and, thus, the utility of fraud and abuse enforcement for policing provider compliance with program requirements.

The 1998 legislation would have also amended the civil FCA to provide that "no action may be brought . . . based on a claim that is submitted under a federally funded health care program unless the amount of damages alleged to have been sustained by the United States Government . . . is a material amount."[390] "Material" would have been defined as the term is used by the American Institute of Certified Public Accountants, which the government claimed in its response to the legislation would have permitted providers to bill fraudulently up to 10% of their Medicare billings.[391]

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389. S. 2007, 105th Cong. § 32(a) (1998); H.R. 3523, 105th Cong. § 2(a) (1998).

390. S. 2007 § 2(a); H.R. 3523 § 2(a).

391. S. 2007 § 2(a); H.R. 3523 § 2(a). In determining whether the amount of damages suffered by the government as a result of claims submitted by a health care provider was material, the bill also prohibited the aggregation of claims unless the "acts or omissions resulting in such damages were part of a pattern of related acts or omissions by such person." S. 2007 § 2(a); H.R. 3523 § 2(a).

This proposal is very troubling. As long as federal programs audit only a tiny fraction of health care claims, the amounts involved in identified false claims will rarely amount to "material" damages to the federal government, as that term was defined in the bill. Only if Congress were willing to fund a much higher level of claims auditing would this change begin to make sense. Even then, one would have to question the wisdom of a policy that allows providers to cheat the government, provided they do not go too far.

Our analysis, however, suggests that more narrowly targeted changes in fraud and abuse law, or enforcement strategies may be appropriate. First, organizational providers in false claims actions, civil or criminal, should be allowed to raise an affirmative defense that the false claim or statement was submitted by a rogue employee. This defense could only be raised if 1) the entity had in place a viable compliance program operated in good faith and 2) the entity offered affirmative proof that it lacked knowledge of the agent's action. If the organization could prove this defense by the preponderance of the evidence and the government did not rebut the defense, the entity would be subject only to treble damages (a sanction more or less appropriate to achieve optimal deterrence) and not to the $5,000 to $10,000 civil FCA penalties, criminal penalties or exclusion, which are complete deterrence penalties.

Second, providers should be entitled to an affirmative defense in false claims cases in which they can establish their good faith reliance on the written advice of the HCFA or of a Medicare contractor in submitting a bill. The 1998 proposed legislation would have created a safe harbor from civil FCA liability for false claims in federal health care programs if the claims were based on "erroneous information supplied by a Federal agency (or an agent thereof) . . . or . . . in reliance on . . . written statements of Federal policy" affecting the claims.[392] This proposal is perhaps too permissive, in that it might allow providers to claim reliance where their action was not taken in good faith. If it assumes, moreover, that the provider action was reasonable and taken in good faith, it is largely redundant, as it is unlikely that the government could prove the requisite degree of culpabil-

392. S. 2007 § 2(c); H.R. 3523 § 2(c).

ity in such a case. But further clarification of the point that providers cannot be held liable for innocent billing mistakes is probably harmless and perhaps helpful.

Third, an informal means of expedited appeal should be permitted within the DOJ in situations in which a provider believes that it is being unfairly subjected to an abusive settlement demand or to the threat of unwarranted prosecution. There is precedent for requiring special authorizations from the DOJ in cases involving criminal charges that present a danger of "ensnaring" moral innocents.[393] For example, United States Attorneys are required to obtain DOJ approval simply to initiate grand jury proceedings relating to suspected tax violations.[394] Separate written authorization is required from the Tax Division of the DOJ after a grand jury has completed its tax investigation in order to pursue the prosecution of any Title 26 tax charges.[395] Finally, targets of tax investigations are generally granted an opportunity to meet with Tax Division personnel before the DOJ decides whether to permit formal tax charges to go forward.[396] At such meetings, counsel has the opportunity to alert the DOJ to facts and circumstances relevant to his or her client's case which warrant declination of prosecution.[397] Similar prophylactic procedural protections could be instituted in health care fraud investigations to reduce criticism that providers are being railroaded into multi-million dollar settlements without due process.

Finally, it may be appropriate for the government to exercise somewhat tighter control over *qui tam* cases. The civil FCA provides that "[t]he Government may dismiss the [*qui tam*] action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."[398] Cases interpreting this section have permitted the government to dismiss *qui tam* cases when it did not initially intervene in the action[399]

393. Bryan v. United States, 524 U.S. 184, 194 (1998).
394. U.S. ATTORNEYS' MANUAL § 6-4.120 (1996).
395. *Id.* § 6-4.242.
396. *Id.* § 6-4.214.
397. *Id.*
398. 31 U.S.C. § 3730(c)(2)(A) (1994).
399. United States *ex rel.* Sequoia Orange Co. v. Baird-Neece Packing Corp., 151

and even when it did not intervene at all.[400]

The government cannot unilaterally dismiss *qui tam* actions—it must have leave of the court. But the standard of dismissal is not the 12(b)(6) motion to dismiss standard; the court can dismiss a *qui tam* case even though the case itself has merit.[401] Indeed, the court is not even required to consider prejudice to the *qui tam* relator, a standard suggested by Federal Rule of Civil Procedure 41(a)(2).[402] Rather the standard is whether the government's dismissal is "reasonable," i.e., does it bear a rational relationship to a legitimate government purpose?[403] Thus, in *Sequoia Orange*, the leading case interpreting this standard, the court held that the government's interest in achieving peace within an industry and avoiding further litigation costs were good reasons for dismissing a *qui tam* action over the relator's objection.[404] It also held that there was nothing improper with the defendants and sympathetic members of Congress having pressured the government to secure a dismissal, as long as there was no evidence of bribery, fraud, coercion or illegal conspiracy.[405]

If a provider defending a *qui tam* action in which the government has declined intervention believes the claim to be frivolous, it should request that the government move to dismiss the case. In marginal cases, the government should take such requests seriously. Without any change in the law, such actions could go a long way toward protecting providers from unreasonable *qui tam* litigation.

F.3d 1139, 1144 (9th Cir. 1998).

400. Juliano v. Federal Asset Disposition Ass'n, 736 F. Supp. 348, 351 (D.D.C. 1990).

401. *Sequoia Orange Co.*, 151 F.3d at 1144.

402. *Id.* at 1144-45.

403. *Id.* at 1145.

404. *Id.* at 1145-46.

405. *Id.* at 1146; United States *ex rel.* Sequoia Orange Co. v. Sunland Packing House, 912 F. Supp. 1325, 1348-51 (E.D. Cal. 1995).

VII. CONCLUSION

Though fraud and abuse enforcement receives nearly unanimous support in principle, it has proved increasingly controversial in practice. In particular, providers have complained about the severity of fraud and abuse sanctions, the complexity of Medicare program requirements, and the unfairly coercive nature of false claims settlement practices. Closer analysis reveals that these complaints, though not wholly without merit, are not wholly correct either. A nuanced consideration of fraud and abuse enforcement suggests that targeted corrections, not wholesale transformation, are advisable.