

REGULATING, GUIDING, AND ENFORCING HEALTH CARE FRAUD

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Clearly, it is no antidote to complexity when the solution compounds the underlying problem so blatantly.¹

When the former Columbia/HCA hospital chain agreed to pay \$1.7 billion to settle civil and criminal allegations concerning the company's billing and referral practices, it not only set a record for the largest health care fraud recovery in history, but also reaffirmed the federal government's commitment to eradicating health care fraud.² Skeptics who predicted that the new Bush Administration would prove more sympathetic to the health care industry than its predecessor have seen their hopes dashed in the face of consistent fraud recoveries of close to a billion dollars a year.³ The effort that started with the enactment of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")—which created a "Fraud and Abuse Control Program" to better fund and coordinate federal, state, and local health care fraud enforcement—remains alive in

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1. James G. Sheehan, Book Review, 24 J. LEG. MED. 135, 136 (2003) (reviewing LINDA A. BAUMANN, ED., *HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES* (2002)).

2. See DOJ, *LARGEST HEALTH CARE FRAUD CASE IN U.S. HISTORY SETTLED: HCA INVESTIGATION NETS RECORD TOTAL OF \$1.7 BILLION* (June 26, 2003), *available at* http://www.usdoj.gov/opa/pr/2003/June/03_civ_386.htm.

3. See HHS & DOJ, *Health Care Fraud and Abuse Control Program Annual Report for FY 2001* (Apr. 2002), *available at* <http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm> (reporting that government won or negotiated more than \$1.7 billion and collected \$1.3 billion in health care cases in FY 2001) [hereinafter *Annual Report*]; DOJ, *Justice Department Recovers over \$1 Billion in FY 2002* (Dec. 16, 2002), *available at* http://www.usdoj.gov/opa/pr/2002/December/02_civ_720.htm (attributing \$980 million to health care fraud). As one attorney notes, "fighting fraud is not a partisan issue." Katherine E. Harris & Judith A. Thorn, *Tough Anti-Fraud Enforcement, Pro-Business Tilt Likely in 2001*, 5 *Health Care Fraud Rep.* (BNA) 48 (Jan. 10, 2001) (citing comments by Stephan Vincze).

both the rhetoric and the actions of federal officials.⁴ In short, health care fraud remains “big business.”

This attention to health care fraud comes at a time when the health care providers and professionals who participate in Medicare, Medicaid, and other federal health care programs are subject to a growing number of legal and regulatory requirements.⁵ In light of this complexity, the health care industry has sought—and federal officials willingly have provided—practical advice on how to ensure that health care business relationships comply with the law. In recent years, this advice has encompassed not only traditional efforts to *regulate* the health care activities that may give rise to fraud, but also more creative attempts to *guide* industry and to *enforce* the fraud proscriptions. Official regulations, developed through notice-and-comment rulemaking procedures, have the advantage of being legally binding; however, the regulatory process has proven to be extremely time-consuming.⁶ As a result, agency officials increasingly have turned to less formal means of expressing their views about fraud, utilizing a variety of guidance documents to communicate with the health care community.⁷ In addition, since Congress last amended the Civil False Claims Act (“FCA”) in 1986, we have seen an increase in both public and private health care fraud litigation.⁸ While these developments offer additional information about the government’s view of permissible health care activities, they also raise concerns about potentially subjecting the industry to unofficial—and at times inconsistent—interpretations from these varied sources.

4. Pub. L. No. 104-191, 110 Stat. 1936 (1996); 42 U.S.C. § 1320a-7c (2000).

5. See, e.g., *Mayo Chronicles Medicare Regs: It's 132,720 Pages of Red Tape*, MODERN HEALTHCARE, Mar. 15, 1999, at 64 (reporting that medical center staff counted 132,720 pages of Medicare laws and regulations). While the term “provider” technically refers to institutional health care entities (such as hospitals and nursing homes), this Article will use the term “health care provider” more broadly to include both individual health care professionals and institutional entities. See 42 U.S.C. § 1395x(u) (2000) (defining “[p]rovider of services”); HHS OFFICE OF THE INSPECTOR GENERAL, SPECIAL ADVISORY BULLETIN: PRACTICES OF BUSINESS CONSULTANTS (June 2001), at 1 n.1 (using “provider” to include “providers, suppliers, and practitioners that provide items or services payable in whole or in part by a Federal health care program”), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf>.

6. See *infra* Part II.A.

7. See *infra* Part II.B.

8. See False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986); Fried, Frank, Harris, Shriver & Jacobsen, *FCA Statistics*, available at <http://www.ffhsj.com/quitam/fcastats.htm> (last visited Apr. 27, 2004) (providing FCA statistics); *infra* Part II.C.

This article analyzes the current regulation-guidance-enforcement approach to health care fraud. After summarizing the major fraud laws, the article identifies both practical and theoretical problems with each conceptual prong. In short, the combination of cumbersome rulemaking procedures, the proliferation of unofficial forms of guidance, and the growing use of litigation as a regulatory strategy has created an increasingly untenable situation for the health care industry. Alleviating these problems will require us to focus on *regulatory clarity* as a necessary precondition for a legitimate enforcement framework—in other words, demanding clear rules to govern the conduct of health care providers, backed by substantial penalties for clear violations.

I.

LAWS PROHIBITING HEALTH CARE FRAUD

Health care fraud is addressed by a multitude of federal laws, which vary in significant ways. Some of these laws, such as the Medicare and Medicaid Anti-Kickback Statute⁹ and the Ethics in Patient Referrals Act (the so-called “Stark Law”),¹⁰ specifically target improper health care activities. In contrast, broad laws such as the Civil False Claims Act (“FCA”) were enacted to prohibit general fraud by government contractors, although recently these laws have been applied with renewed vigor in the health care context.¹¹ Moreover, health care fraud can be prosecuted under general fed-

9. The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving any “remuneration” to induce someone to refer patients to any facility, or to purchase, lease, or order any item or service, for which payment may be made by a federal health care program. 42 U.S.C. § 1320a-7b(b) (2000).

10. The Stark Law, nicknamed for sponsor Fortney “Pete” Stark (D-CA), is a civil statute designed to prohibit the referral of Medicare and Medicaid patients to health care providers with which the referring physician has a financial relationship. The original legislation (“Stark I”) took effect on January 1, 1992, and applied to the referral of Medicare patients for clinical laboratory services. *See* 101 Pub. L. No. 239, § 6204, 103 Stat. 2106 (1989) (codified at 42 U.S.C. § 1395nn (2000)). The Omnibus Budget Reconciliation Act of 1993 applied the prohibition to Medicaid and expanded it to include ten additional “designated health services,” effective as of December 31, 1994. Pub. L. No. 103-66, §§ 13562, 13624, 107 Stat. 31 (1993).

11. *See* 31 U.S.C. § 3729–33 (2000). The FCA was enacted in 1863 in response to reports of “rampant fraud” on the Union army during the Civil War. *See* S. Rep. No. 99-345 (1986), at 8, *reprinted in* 1986 U.S.C.C.A.N. 5273 (noting that President Lincoln signed the FCA to combat fraud in defense contracts). In general, the FCA imposes liability on a defendant who: (1) presents or causes to be presented a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the acts are undertaken “knowingly.” 31 U.S.C. § 3729(a)(1) (2000).

eral criminal statutes, such as Mail and Wire Fraud,¹² which apply to illegal conduct regardless of the business context in which it occurs.

Health care fraud laws also vary in the level of *intent* required to prove a violation. As a criminal law, the Anti-Kickback Statute requires the defendant's solicitation or receipt of prohibited remuneration to be done in a *knowing and willful* manner—a stringent *mens rea* standard, even if its precise contours remain unclear.¹³ The FCA also requires proof that the defendant's acts were undertaken "knowingly" before civil sanctions can be imposed, although the statutory definition encompasses deliberate ignorance and reckless disregard as well as actual knowledge of falsity.¹⁴ In contrast, the Stark Law contains no intent requirement, and thus functions as a strict liability prohibition: *all* patient referrals are prohibited if a financial relationship exists, subject to certain narrowly drawn exceptions.¹⁵

The penalties imposed on violators constitute another key difference among the laws. The Stark Law flatly prohibits payment for patient care furnished pursuant to a prohibited referral; moreover, any person who knowingly submits or causes a bill to be submitted for such care is subject to a civil monetary penalty ("CMP") of up to \$15,000 for *each* service.¹⁶ Under the FCA, violators are subject to a civil penalty of \$5,500 to \$11,000 per claim, plus three times the amount of damages sustained by the government.¹⁷ Because health care providers tend to generate a bill for *each* occasion of service

12. 18 U.S.C. §§ 1341, 1343, 1346 (2000); *see also* United States v. Talbott, 590 F.2d 192 (6th Cir. 1978) (affirming dentists' convictions for mail fraud and conspiracy to commit mail fraud).

13. 42 U.S.C. § 1320a-7b(b) (2000). There is an ongoing debate regarding whether the statute requires proof of specific intent. In *Hanlester Network v. Shalala*, the Ninth Circuit held that the statute could not be violated unless the defendant both *knew* the law prohibited giving or receiving remuneration in return for referrals, and acted with *specific intent* to violate the statute. 51 F.3d 1390, 1400 (9th Cir. 1995). In contrast, other circuits have held that specific intent is not required because the law is not the sort of "highly technical . . . regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct." United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998); *see also* United States v. Jain, 93 F.3d 436, 441 (8th Cir. 1996) (requiring proof that defendant "knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty'").

14. 31 U.S.C. § 3729(b) (2000).

15. 42 U.S.C. § 1395nn(b)-(e) (2003) (listing detailed exceptions).

16. *Id.* at § 1395nn(g)(3) (2003) (per-service penalty). Claims for such services will be denied, and any payments erroneously received must be refunded. *Id.* at § 1395nn(g)(1)-(2).

17. 31 U.S.C. § 3729(a) (2000) (setting \$5,000 to \$10,000 statutory penalty); 28 C.F.R. § 85.3(a)(9) (2003) (increasing penalties by 10%).

rendered to *each* patient, they submit thousands of small claims each year—and hence face significant per-claim FCA liability, even if the damage is minimal.¹⁸ In contrast, criminal violation of the Anti-Kickback Statute is a felony, punishable by up to five years in prison and a fine of up to \$25,000.¹⁹ Alternatively, the government has the authority to impose a CMP of up to \$50,000 for each Anti-Kickback violation, plus not more than three times the remuneration.²⁰ Looming over all these sanctions, moreover, is the threat of exclusion from the federal health care programs, a potentially fatal blow for entities that derive substantial revenues from treating such patients.²¹

There is also significant variation in the extent to which the fraud laws can be enforced by private parties in addition to federal prosecutors. The FCA, like the criminal provisions of the Anti-Kickback Statute, is enforced by the Department of Justice (“DOJ”). The Stark Law’s administrative penalties, as well as imposition of CMPs or exclusion under the Anti-Kickback Statute, are imposed administratively through the Department of Health and Human Services (“HHS”) Office of the Inspector General (“OIG”).²² The FCA, however, also contains a *qui tam* provision permitting private “relators” to sue on the government’s behalf in exchange for fifteen

18. See Pamela H. Bucy, *The PATH From Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 Sr. LOUIS U. L.J. 3, 39 (2000) (“Because of the billing structure for most health care services (one claim per service, per patient) even a small health care provider will submit thousands of claims each year.”). In *United States v. Krizek*, for example, a psychiatrist was accused of submitting 8002 claims, for total damages of \$245,392. 111 F.3d 934, 936 (D.C. Cir. 1997). At trial, the government requested penalties of \$10,000 per claim, for a total of \$81 million dollars. *Id.* at 936.

19. 42 U.S.C. § 1320a-7b (2000).

20. *Id.* at § 1320S-7a(a)(7) (2003) (imposing CMP). In theory, this provision has the potential to dwarf the FCA penalties, although it has not often been invoked.

21. The HHS Office of the Inspector General *must* exclude individuals and entities convicted of a felony related to health care fraud, and *may* exclude them for misdemeanor convictions. 42 U.S.C. § 1320a-7(a–b) (2000); *see also id.* at § 1395nn(g)(3)–(4) (2000) (stating that violation of Stark Law constitutes grounds for exclusion).

22. *See, e.g.*, 42 C.F.R. pts. 1001, 1003 (2002) (governing OIG exclusion process and assessment of civil monetary penalties); 31 U.S.C. § 3730 (2003) (permitting FCA civil actions by Attorney General); Robert N. Rabecs, *Kickbacks as False Claims: The Use of the Civil False Claims Act to Prosecute Violations of the Federal Health Care Program’s Anti-Kickback Statute*, 2001 L. REV. M.S.U.-D.C.L. 1, 5–6 (2001) (setting forth DOJ responsibility for enforcing Anti-Kickback Statute).

to thirty percent of the proceeds of the suit.²³ While neither the Anti-Kickback Statute nor the Stark Law contains a private right of action, some courts nonetheless have permitted relators to base *qui tam* actions on alleged violations of these provisions.²⁴ Although not all jurisdictions have accepted this proposition, health care providers are understandably troubled by the prospect of private anti-referral suits brought by employees, competitors, and even patients.²⁵

Recent years have also brought significant changes in the funding—and hence the incentives—for investigating health care fraud. HIPAA created a “Fraud and Abuse Control Account” to fund inspections, investigations, and prosecutions.²⁶ This guaranteed source of funding has permitted the hiring of additional FBI and OIG agents who focus exclusively on health care fraud.²⁷ Under HIPAA, recoveries in most health care fraud cases are deposited into the perennially near-insolvent Medicare Part A Trust Fund. However, a significant portion of this money can be appropriated—at the discretion of the Attorney General and Secretary of HHS—back to the Control Account to fund future enforcement.²⁸ This

23. 31 U.S.C. §§ 3730(b), (d) (2000) (noting that a private person who brings a civil action may potentially receive fifteen to thirty percent of the proceeds, depending on factors such as whether the government joins in the suit). Since amendments in 1986 modernized the Act and made it more lucrative to pursue *qui tam* actions, the number of health care-related FCA suits has grown dramatically. See 1986 FCA Amendments, Pub. L. No. 99-562, 100 Stat. 3153 (2000); Fried Frank, *supra* note 8 (estimating that nearly two-thirds of *qui tam* suits targeted the federal health care programs in 1998, compared to only twelve percent in 1987).

24. See, e.g., *United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507, 1507, 1511 (M.D. Tenn. 1996) (holding that because compliance with the anti-referral laws was a prerequisite for participation in Medicare and Medicaid, claims submitted in violation of the laws were by definition false and fraudulent).

25. See, e.g., *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (limiting FCA’s application to situations in which the claimant falsely *certifies* compliance with a condition that is a *prerequisite* for payment); John T. Boese, *When Angry Patients Become Angry Prosecutors: Medical Necessity Determinations, Quality of Care and the Qui Tam Law*, 43 ST. LOUIS U. L.J. 53 (1999) (concluding that the costs imposed by private enforcement outweigh the benefits conferred).

26. 42 U.S.C. § 1395i(k)(3) (2000) (describing appropriations). Initial appropriations were set at \$104 million, with an increase of up to 15% per year through FY 2003. *Id.*

27. See Annual Report 2001, *supra* note 3, at app. (noting that FBI’s 2001 funding supported 445 existing and 30 new agents).

28. 42 U.S.C. § 1395i(k)(2)(C) (2000) (authorizing the transfer of fines, penalties, forfeitures and damages obtained in health care fraud cases to the Trust Fund); *id.* at § 1395i(k)(3) (explaining appropriations process for Control Ac-

creates a form of an attenuated “bounty” system, whereby some of the money collected in health care fraud cases is available for appropriation back to the prosecuting agencies. The prospect of “a self-perpetuating enforcement machine” is of concern to many providers, who worry that “[r]ewarding those who enforce Medicare fraud and abuse regulations with more program funds creates strong institutional incentives for those enforcers to pursue as many . . . prosecutions as possible, thus increasing the risk that the innocent as well as the guilty will suffer punishment.”²⁹ Assuaging these concerns will require, above all, clear advice from government officials as to how these laws apply to common health care business activities.

II. A THREE-PRONGED APPROACH TO HEALTH CARE FRAUD

Although at times it may seem that the health care fraud laws are all-encompassing, the meaning of their proscriptions is not self-evident. Given the complexity of the provisions and the significant sanctions that apply to violations, it is crucial that the health care community understand how the government intends to apply them. The abstract contours of fraud and abuse principles must be translated into practical requirements to which health care providers can adhere—and against which their compliance can be measured.

There are three general pathways through which such information has been conveyed to health care providers. First, and most basically, HHS conveys information by *regulating* health care fraud, using the traditional rulemaking process to interpret existing law and to adapt current rules to the changing health care environment. Second, HHS offers informal *guidance* to health care providers on how these laws will be applied. Finally, both government prosecutors and *qui tam* relators convey information about fraud through the types of *enforcement actions* they pursue. Due to the extremely cumbersome nature of the regulatory process, as explained below, health care fraud enforcement increasingly has taken the

count). In FY 2001, the Secretary of HHS and the Attorney General certified \$181 million for appropriation to the Control Account, with the FBI receiving a separate appropriation of \$88 million. See Annual Report 2001, *supra* note 3.

29. Jonathan W. Emord, *Murder by Medicare*, REG., Summer 1998, at 31–32 (1998); see also Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 580–87 (2001) (arguing that this funding “taints” prosecutorial incentives for pursuing fraud).

latter two forms. While these developments offer some practical guidance, they also may mean that providers will be subjected to *more*—yet not necessarily *clearer*—legal interpretations.

A. *Regulating Health Care Fraud*

As used in this Article, *regulation* refers to the development of official, binding guidance pursuant to the Administrative Procedure Act (“APA”), which requires an administrative agency such as HHS to provide notice and an opportunity for public comment regarding most proposed rulemaking.³⁰ The Medicare statute elaborates on this requirement, stating that no “rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits [or] the payment for services shall take effect unless” properly promulgated by HHS.³¹ Notice-and-comment rulemaking has long been used in the health care fraud context. In 1987, for example, Congress directed HHS to develop “safe harbor” regulations exempting certain practices from the scope of the Anti-Kickback Statute, in addition to the few exceptions contained in the law.³² Notice-and-comment rulemaking similarly has played a key role in revising these provisions to reflect evolving industry practice.³³ Indeed, the significance of this process in interpreting the Anti-Kickback Statute was acknowledged by HIPAA, which required HHS to engage in a nego-

30. 5 U.S.C. §§ 551, 553 (2000). For a more conceptual definition of regulation, see Troyen A. Brennan, *The Role of Regulation in Quality Improvement*, 76 MILBANK Q. 709, 710–11 (1998) (defining medical “regulation as any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behavior”).

31. 42 U.S.C. § 1395hh(a)(2) (2000).

32. *See* 42 U.S.C. § 1320a-7b(b)(3) (2000) (exempting practices such as discounts, employment compensation, and group purchasing organizations from the scope of the prohibition); Medicare & Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 697–98 (1987) (requiring development of safe harbors); 42 C.F.R. § 1001.952 (2002) (listing current safe harbors).

33. The initial safe harbors were developed in the early 1990s, with significant revisions in the late 1990s. *See* Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63,504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 57 Fed. Reg. 52,723 (Nov. 5, 1992); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991).

tiated rulemaking to develop a new safe harbor for managed care risk-sharing arrangements.³⁴

For many years, rulemakings provided virtually the only guidance available as to the government's interpretation of the fraud laws. As a result, health care attorneys painstakingly read the preamble to each Federal Register notice, trying to glean a few nuggets of regulatory intent. Agency personnel were fully aware of these efforts, and used the notices to convey information that was not explicitly contained in the regulations themselves—such as the factors OIG would take into account in determining whether to pursue a potential Anti-Kickback violation.³⁵

According to OIG, “Congress intended the safe harbor regulations to be evolving rules to reflect changing business practices and technologies in the health care industry.”³⁶ Yet traditional regulation, burdened by cumbersome notice-and-comment procedures, is unlikely to perform this function in a timely manner. Indeed, administrative law scholars have long complained about the “ossification” of the formal rulemaking process.³⁷ Rulemaking is particularly ill-suited to an industry in constant flux. The health care market is a dynamic one, with providers adjusting to changing market conditions by continually developing new business arrangements (and often new forms of fraud). Fraud regulation, in contrast, is primarily *reactive* by nature, a response to improper

34. See Pub. L. No. 104-191, § 216, 110 Stat. 1936, 2007–08 (1996) (requiring negotiated rulemaking); Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63,504 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952(t), (u) (2002)) (finalizing risk-sharing safe harbors). HIPAA also required HHS to publish an annual notice soliciting proposals for new and revised safe harbors, with amendments to be made through notice-and-comment procedures. See Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000–01 (1996).

35. See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,954 (July 29, 1991) (listing factors considered by OIG).

36. Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor Under the Anti-Kickback Statute for Waiver of Beneficiary Coinsurance and Deductible Amounts, 67 Fed. Reg. 60,202, 60,203 (Sept. 25, 2002).

37. See, e.g., Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385 (1992) (describing how rulemaking “has become increasingly rigid and burdensome”); Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483 (1997) (defining ossification as “the inefficiencies that plague regulatory programs because of analytic hurdles that agencies must clear in order to adopt new rules”).

practices that *currently* take place.³⁸ As Professor Dayna Matthews notes, the “process is not an a priori exercise, but rather an ex post response to innovations in the market as providers seek new financial arrangements to allow them to compete successfully.”³⁹ This phenomenon suggests that fraud regulations may be doomed to failure, as they always remain one step behind real-life market innovations.⁴⁰ In the words of Professor James Blumstein, the result resembles a “speakeasy,” where “conduct that is illegal is rampant and countenanced by law enforcement officials because the law is so out of sync with the conventional norms and realities of the marketplace.”⁴¹

Few topics illustrate the pitfalls of the regulatory process as much as the Stark Law. The initial Stark I prohibition on physician “self-referrals” of Medicare patients for clinical laboratory services, which took effect on January 1, 1992, was expanded by OBRA '93 to encompass additional categories of designated health services as of December 31, 1994.⁴² Regulations implementing the original laboratory prohibitions were proposed soon after the law went into effect, in the Spring of 1992.⁴³ Due to the volume of comments generated by the proposal, however, publication of the Final Rule was delayed until August 1995—not only three years after Stark I

38. See, e.g., Sheehan, *supra* note 1, at 136 (“Complex rules lead to complex schemes to avoid, evade, or manipulate the rules . . .”). For a discussion of the ways in which the Anti-Kickback Statute has failed to keep pace with developments in the health care market, see James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J. L. & MED. 205 (1996).

39. Matthew, *supra* note 29, at 551.

40. As an OIG official recently noted, “Fraud, waste and abuse are becoming increasingly complex, national in scope, and constantly changing in response to the latest oversight efforts.” *Hearing on Fraud, Waste and Abuse in the Medicare and Medicaid Programs Before the House Budget Comm.*, 108th Cong, 1 (2003) (statement of Dara Corrigan, Acting Principal Deputy Inspector General, HHS), available at <http://oig.hhs.gov/testimony/docs/2003/070903fin.pdf> (hereinafter Corrigan Testimony).

41. Blumstein, *supra* note 38, at 218. Moreover, if fraud regulations are *successful* in changing provider behavior, there is a possibility that they may freeze the industry at a less-than-optimal point in time. See, e.g., James Sheehan, *Bio-Tech Fraud: Reality or Fantasy?* 2 HOUS. J. HEALTH L. & POL'Y 11, 12 (2002) (noting “risk that the rule people destroy the energy and creativity of the industry”).

42. See *supra* note 10.

43. See Medicare Program; Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services, 57 Fed. Reg. 8,588 (Mar. 11, 1992).

went into effect, but also eight months after the expanded Stark II provisions became effective.⁴⁴

Two and a half years later, the Health Care Financing Administration (“HCFA”) finally proposed Stark II regulations.⁴⁵ The proposal was exceedingly controversial, adding several new exceptions to the self-referral ban, significantly revising key exceptions, and potentially exceeding the scope of the statute.⁴⁶ Once again, voluminous comments delayed publication of the Final Rule, this time until January 2001—a full *six years* after the revised law had gone into effect.⁴⁷ Despite filling 110 pages in the Federal Register, however, the saga was by no means over. Instead, the Rule was designated as “Phase I” of the regulations, incorporating the basic Stark II prohibition, definitions, and general exceptions; a subsequent rule (“Phase II”) would address the remaining provisions, including additional exceptions, reporting requirements, and sanctions.⁴⁸ Moreover, HCFA delayed the effective date of the Rule for a year to allow providers to comment on and comply with the new requirements.⁴⁹

The one-year delay was soon marked by additional problems. After taking office in January 2001, President George W. Bush postponed for sixty days the operative date of new federal regulations that had not yet gone into effect, generating short-lived confusion about the future of the rules.⁵⁰ In November 2001, HCFA’s succes-

44. Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41,914 (Aug. 14, 1995) (codified at 42 C.F.R. § 411.350–.389). The Health Care Financing Administration (“HCFA”) instructed, “Until we publish a rule covering the designated health services, we intend to rely on our language and interpretations in this final rule when reviewing referrals [under Stark II].” *Id.* at 41,916.

45. *See* Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1,659 (Jan. 9, 1998).

46. As one group of attorneys concluded, the proposal “raise[s] as many questions as it answers.” *Self-Referral: HCFA Issues Proposed Rule Governing Physician Stark II Self-Referrals*, 2 HEALTH CARE FRAUD REP. (BNA) 7 (Jan. 1, 1998) (quoting a statement by the law firm of Winston & Strawn).

47. *See* Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001).

48. *See id.* at 856, 859–60 (describing phases).

49. *Id.* at 859.

50. *See* Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships: Delay of Effective Date of Final Rule and Technical Amendment, 66 Fed. Reg. 8,771 (Feb. 2, 2001) (explaining that the Administration’s action only delayed a discrete subsection of

sor, the Centers for Medicare & Medicaid Services (“CMS”), delayed the effective date of another Stark II provision in order to reconsider the government’s approach.⁵¹ When Phase I finally went into effect in January 2002, the provisions inadvertently contained errors that CMS had intended to repeal—a mistake that would require further revisions to the regulations.⁵² To make matters worse, a federal district court held that the agency’s inclusion of one particular medical procedure in the list of “designated health services” was contrary to congressional intent, and enjoined implementation of the definition.⁵³ An interim final Phase II rule—permitting additional public comment—was not published until three years later, in March 2004.⁵⁴

Thus, more than a decade after the enactment of the original Stark legislation, health care providers do not yet have access to final regulations interpreting the law’s complicated prohibitions. As one commentator quipped, “[a]lthough the intent was to provide comprehensive bright-line rules, regulators have had great difficulty in figuring out where the lines are.”⁵⁵ While most fraud regulations do not have quite as tortured a history as the Stark provisions, this saga illustrates that the advantages of binding regula-

the regulations concerning home health agencies, which had been scheduled to take effect in February 2001).

51. Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Partial Delay of Effective Date, 66 Fed. Reg. 60,154–56 (Dec. 3, 2001) (delaying definition of “set in advance” as applied to percentage compensation arrangements). In November 2002 and April 2003, CMS delayed the effective date for additional six month periods. *See* Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Extension of Partial Delay of Effective Date, 68 Fed. Reg. 20,347–48 (Apr. 25, 2003); Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Extension of Partial Delay of Effective Date, 67 Fed. Reg. 70,322–23 (Nov. 22, 2002).

52. *See Self-Referral: CMS Fails to Remove Portion of Rule Effective Jan. 4, Despite Earlier Statement*, 6 HEALTH CARE FRAUD REP. (BNA) 9 (Jan. 9, 2002) (quoting letter from CMS representative acknowledging the error).

53. *Am. Lithotripsy Soc’y v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002) (addressing lithotripsy, which uses a shock wave generator to break urinary tract stones into small pieces, enabling them to pass through the body without the need for surgery). The court found clear evidence in the legislative history of congressional intent to exclude lithotripsy from the Stark prohibition. *Id.* at 35–36.

54. *See* Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004).

55. David A. Hyman, *Health Care Fraud and Abuse: Market Changes, Social Norms, and the Trust “Reposed in the Workmen,”* 30 J. LEG. STUD. 531, 551 (2001).

tions may well be outweighed by the necessity of generating more timely forms of guidance.

B. Guiding Health Care Fraud

The disadvantages of notice-and-comment rulemaking led to the proliferation of informal sources of health care fraud *guidance* outside the traditional regulatory process. Such guidance is used to convey the agency's current interpretation of the fraud laws to the public on a more timely—albeit less concrete—basis. The proliferation of informal interpretive materials, however, may have significant repercussions for health care providers.

1. Forms of Health Care Fraud Guidance

Various forms of health care fraud guidance are now available; some are mandated by statute, while others have been developed within HHS. For example, HIPAA requires the Secretary of HHS, in consultation with the Attorney General, to provide written Advisory Opinions addressing whether proposed health care transactions would violate the Anti-Kickback Statute or subject the requestor to CMPs or exclusion.⁵⁶ Mindful of resource constraints and the potential for interagency conflicts, Congress specified that Advisory Opinions could not address questions of fair market value or whether an individual qualifies as a *bona fide* employee under the Internal Revenue Code.⁵⁷ While Advisory Opinions are binding only on HHS and the requestors, they are available to the public in redacted form on the agency's website.⁵⁸ Not surprisingly, the opinions have become valuable sources of information as to the agency's likely views concerning analogous transactions.

While an improvement over notice-and-comment rulemaking, the Advisory Opinion process remains cumbersome. OIG is required to issue an Opinion within sixty days of a request, although that period is tolled by requests for additional information, payment, or consultation with outside experts.⁵⁹ Moreover, requestors

56. 42 U.S.C. § 1320a-7d(b) (2000); 42 C.F.R. § 1008.1, 1008.3 (2002). The original mandate expired in August 2000, but was permanently reinstated in the Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, § 543, 114 Stat. 2763. A similar advisory process is required under the Stark Law, although it appears moribund. See 42 U.S.C. § 1395nn(g)(6) (2001); 42 C.F.R. §§ 411.370–.389 (2002).

57. 42 U.S.C. § 1320a-7d(b)(3) (2004).

58. See *id.* § 1320a-7d(b)(4) (2004); 42 C.F.R. § 1008.53 (2002) (identifying affected parties). A complete list of Advisory Opinions is available at <http://oig.hhs.gov/fraud/advisoryopinions/opinions.html> (last visited Apr. 27, 2004).

59. 42 C.F.R. § 1008.43(c) (2002).

must submit detailed information about the transaction, including all operating documents for existing arrangements, and drafts, models, or proposed terms for contemplated arrangements. As one critic argues:

In other words, regulatory advice—which may kill the deal entirely—is not available until the parties have gone through the time and expense of drafting and negotiating each of the contracts and agreements necessary to finalize the deal. . . . In terms of business planning and compliance, a decision to withhold regulatory advice until the deal is all but executed is a decision to make the advice largely meaningless.⁶⁰

Thus, the Advisory Opinion process is by no means as expedient as it might first appear.

Broader guidance is provided through Special Fraud Alerts, through which OIG identifies “suspect practices” that the agency believes are taking place (particularly involving the Anti-Kickback Statute).⁶¹ Providers engaged in these practices are *not* necessarily violating the law, although the Alert puts them on notice that the practice may attract scrutiny. OIG began to issue public alerts in 1989 after years of issuing internal agency alerts.⁶² The agency appears to be partial to this form of informal guidance; in fact, OIG offered the Fraud Alert mechanism as an alternative to adopting an earlier iteration of the Advisory Opinion process.⁶³ Although Fraud Alerts are not specifically authorized by law, HIPAA established a mechanism for private parties to request that OIG issue an

60. Scott D. Godshall, *Death By Regulation: HHS's Advisory Opinion Guidelines*, ANDREWS HEALTH CARE FRAUD LITIG. REP., May, 1997, at 3. Moreover, OIG has the right to rescind, terminate, or modify a previous Advisory Opinion upon reconsideration of the issues, although the requestor will be given an opportunity to respond and to discontinue or modify its actions. 42 C.F.R. § 1008.45(a) (2002).

61. *See, e.g.*, Special Fraud Alert: Hospital Incentives to Physicians, 59 Fed. Reg. 65,372, 65,375–76 (Dec. 19, 1994) (issued May, 1992) (listing suspect hospital incentives, such as the provision of free or significantly discounted items, space, or services); Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services, 59 Fed. Reg. 65,377–78 (Dec. 19, 1994) (issued Oct. 1994) (identifying suspect inducements offered by clinical laboratories, such as providing free services to physicians who generate business).

62. Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,373 (Dec. 19, 1994).

63. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,959 (July 29, 1991) (declining to create an advisory opinion process for Anti-Kickback queries, and indicating “that OIG fraud alerts are the best mechanism for imparting practical and continuing guidance to individuals and entities seeking to avoid violations of the statute”).

Alert.⁶⁴ Recent Alerts have addressed such topics as nursing home arrangements with hospice programs, home health fraud, and rental of physician office space by entities to which the physician refers patients.⁶⁵

One of the most significant developments in health care fraud has been the growing emphasis on corporate compliance, as illustrated by OIG's issuance of a series of Compliance Program Guidelines. Since the mid-1990s, it has become standard practice for the government to require health care providers to enter into corporate integrity agreements ("CIAs") as a condition of settlement; the provider agrees to onerous compliance measures in return for OIG's agreement not to seek exclusion.⁶⁶ Once compliance was established as a *remedy* for fraud, however, it did not take long for both the government and the health care industry to realize that compliance could also function proactively to *prevent* fraud.

The basis for both CIAs and voluntary compliance efforts can be found in the Federal Sentencing Guidelines for Organizations, which went into effect in 1991.⁶⁷ Under the Guidelines, a court may reduce an organization's culpability score "[i]f the offense occurred despite an effective program to prevent and detect violations of law."⁶⁸ To develop an "effective" program, the organization must: establish, communicate, monitor, and enforce compliance standards and procedures for its employees and contractors; assign responsibility for compliance to high-level personnel; not delegate authority to individuals with a history of illegal behavior; and take appropriate steps when an offense is detected.⁶⁹ While the Guide-

64. 42 U.S.C. § 1320a-7d(c) (2000) (permitting requests).

65. A complete list of alerts can be found at HHS-OIG Fraud Prevention & Detection—Fraud Alerts, Bulletins and Other Guidance, at <http://oig.hhs.gov/fraud/fraudalerts.html> (last visited Apr. 27, 2004).

66. See HHS-OIG Fraud Prevention & Detection—Corporate Integrity Agreements, at <http://oig.hhs.gov/fraud/cias.html> (last visited Apr. 27, 2004) ("A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs."). A link to current CIAs can be found on OIG's web site. *Id.* Although each CIA is tailored to the defendant's conduct, common elements include a five year term, appointment of a compliance officer or committee, development of compliance training procedures, development of a confidential disclosure program, and submission of reports to the OIG. *Id.*

67. See U.S. SENTENCING GUIDELINES MANUAL ch. 8 (1998) (sentencing of organizations).

68. *Id.* at § 8C2.5(f).

69. *Id.* at § 8A1.2, cmt. n.3(k). These provisions also form the basis for the common CIA elements noted above. See *supra* note 66. In December 2003, the

lines apply only to criminal sentences, OIG has made clear that a compliance program similarly may benefit defendants accused of violating civil and administrative provisions—both by decreasing the likelihood of improper activities occurring, and by minimizing exposure if wrongdoing is detected and reported on a timely basis.⁷⁰

While compliance programs must be tailored to the unique needs of each entity, OIG's Compliance Program Guidances provide general advice to particular sectors of the health care industry. The documents provide valuable information as to what OIG believes to be the key compliance issues for each group, although adherence remains voluntary.

The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse and waste in these health care plans while at the same time further the fundamental mission of [the providers]. . . . [R]egardless of a [provider's] size and structure, the OIG believes that every [provider] can and should strive to accomplish the objectives and principles underlying all of the compliance policies and procedures recommended within this guidance.⁷¹

By July 2003, OIG had issued Guidances for hospitals, clinical laboratories, home health agencies, third-party medical billing companies, durable medical equipment suppliers, hospices, Medicare+Choice organizations, nursing facilities, individual and small group physician practices, pharmaceutical manufacturers, and ambulance companies.⁷²

OIG also has offered guidance in the form of Special Advisory Bulletins, which address a wide range of potentially fraudulent activities. Recent Bulletins have targeted the activities of business consultants, the patient anti-dumping statute, the effect of exclusion, and the offering of gifts and other inducements to program

Sentencing Commission proposed changes that would "provide greater guidance to organizations and courts regarding the criteria for an effective" compliance program. Notice of proposed amendments to sentencing guidelines, policy statements, and commentary. Request for public comment, including public comment regarding retroactive application of any of the proposed amendments, 68 Fed. Reg. 75,340, 75,354 (Dec. 30, 2003).

70. *See, e.g.*, Publication of the OIG Compliance Program, Guidance for Hospices, 64 Fed. Reg. 54,031, 54,032–33 (Oct. 5, 1999) (describing the benefits of a compliance program).

71. *Id.* at 54,032.

72. *See* HHS-OIG Fraud Prevention & Detection—Corporate Integrity Agreements, at <http://oig.hhs.gov/fraud/complianceguidance.html> (last visited Apr. 27, 2004).

beneficiaries.⁷³ Although Bulletins are not explicitly authorized by statute, OIG grounds its authority in HIPAA's broad mandate that the agency provide "guidance to the health care industry to prevent fraud and abuse, and to promote the highest level of ethical and lawful conduct."⁷⁴

The decision to utilize a Special Advisory Bulletin, rather than another form of guidance, can be controversial. A good example is the July 1999 Special Advisory Bulletin on gainsharing arrangements, which addressed arrangements "in which a hospital gives physicians a percentage share of any reduction in the hospital's cost for patient care attributable in part to the physicians' efforts."⁷⁵ In prior months, OIG had received several requests for Advisory Opinions concerning the legality of such arrangements in light of a CMP prohibiting hospitals from knowingly making payments to a physician as an inducement to reduce or limit services to beneficiaries under her care.⁷⁶ Concluding that such arrangements posed a high risk of abuse, and required comprehensive regulation rather than case-by-case analysis, OIG found the issue unsuitable for Advisory Opinions; instead, the agency issued an industry-wide Bulletin interpreting the CMP to prohibit such relationships.⁷⁷ Thus, Bulletins offer a viable (if at times controversial) way to disseminate information outside the Advisory Opinion, Fraud Alert, and Compliance Program Guidance contexts.

73. See Fraud Alerts, *supra* note 65.

74. See Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

75. See *id.*

76. See *id.*; 42 U.S.C. § 1320a-7a(b)(1) (2000) (setting CMP).

77. See Gainsharing Arrangements, *supra* note 74. While acknowledging that hospitals have a legitimate interest in persuading physicians to engage in cost-containment efforts, OIG nonetheless interpreted the CMP as prohibiting a hospital from compensating a physician directly or indirectly based on cost savings derived from the treatment of the physician's own patients. The Bulletin was controversial in light of the Internal Revenue Service's approval of the tax consequences of similar arrangements. See, e.g., Gregory M. Luce & Jesse A. Witten, *HHS IG's Gainsharing Prohibition Lacks Legal Support*, 3 HEALTH CARE FRAUD REP. (BNA) 753 (Aug. 11, 1999) (characterizing OIG's reasoning as "dubious," and arguing that "OIG rely[d] upon a selective account of the legislative history"); *IRS Approves Gainsharing Programs in Two Unreleased Private Letter Rulings*, 8 HEALTH LAW REP. (BNA) 295 (Feb. 25, 1999) (describing two private letter rulings approving gainsharing arrangements between tax-exempt hospitals and physician groups). For a general discussion of gainsharing activities, see Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U.L. REV. 145 (2003).

2. Reliance on Informal Fraud Guidance

While offering additional insight as to the government's current interpretation of the fraud laws, informal guidance may have significant disadvantages for the industry. At the very least, the proliferation of guidance means that there are now many more sources to research than in the past. In addition to consulting the statute, regulations, and relevant Federal Register notices, health care attorneys must now scrutinize all relevant Advisory Opinions, Fraud Alerts, Compliance Program Guidances, Special Advisory Bulletins, and other HHS documents. While much of this information is available on the OIG web site, the chronological organization within each form of guidance does not facilitate research regarding individual statutes.⁷⁸ Moreover, this guidance does not necessarily clarify the practical issues faced by health care providers on a daily basis. Especially with Advisory Opinions, attorneys must not only extrapolate general principles from the government's response to fact-specific inquiries, but they must then combine those principles with the language of the statutes and regulations. Thus, it is possible that the proliferation of unofficial sources of guidance results simply in *more* information—rather than *clearer* information—regarding health care fraud.

Moreover, the ability of providers to challenge such informal agency interpretations is unclear. Pursuant to the APA, the Social Security Act requires notice-and-comment rulemaking for any “rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits [or] the payment for services” under the Medicare program.⁷⁹ However, this requirement does not apply “to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.”⁸⁰ In determining whether notice-and-comment rulemaking applies, courts inquire whether the rule is fundamentally “interpretive” or “legislative” in nature.

An interpretive rule simply states what the administrative agency thinks the [underlying] statute means, and only reminds affected parties of existing duties. On the other hand, if

78. See <http://oig.hhs.gov/index.html> (indexing OIG documents) (last visited Apr. 27, 2004).

79. 42 U.S.C. § 1395hh(a)(2) (2003); 5 U.S.C. § 553 (2003).

80. 5 U.S.C. § 553(b)(A) (2003).

by its action the agency intends to create new law, rights, or duties, the rule is properly considered to be a legislative rule.⁸¹ Informal fraud guidance—in which OIG merely reiterates the prohibitions and opines that certain activities may be problematic—would most likely be considered “interpretive” under this test. The majority of federal courts have held that Medicare manuals, letters, and directives are interpretive in nature.⁸² Such guidance is not subject to challenge unless it sets forth a new position inconsistent with prior law or regulations.⁸³ Although the majority of such provisions are upheld,⁸⁴ on rare occasions such interpretations have been deemed contrary to law. As the Seventh Circuit explained, “[a]lthough the Secretary’s interpretation of his own regulations is usually accorded substantial deference . . . such deference is appropriate only if the Secretary’s interpretation of the regulation is consistent with the language of the regulations them-

81. *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992) (citations omitted; alteration in original); *see also* *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) (setting forth test).

82. Indeed, the Supreme Court described one of the Medicare manuals as “a prototypical example of an interpretive rule.” *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995) (construing Provider Reimbursement Manual provision).

83. *See id.* at 100. The timing of judicial review of Medicare cases is complex and has been extensively litigated. Prior to 1986, the Social Security Act did not permit judicial review of the amount of Medicare Part B benefits. *See, e.g.*, *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982). Judicial review of Medicare Part A claims became available only after the Secretary rendered a “final decision.” *See Heckler v. Ringer*, 466 U.S. 602, 605–06 (1984). However, in *Bowen v. Michigan Academy of Family Physicians*, the Supreme Court permitted an immediate judicial challenge to a Medicare Part B regulation, noting that the law “simply does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves.” 476 U.S. 667, 675 (1986) (emphasis in original). A 1986 amendment subsequently permitted judicial review of the “amount of benefits” under both Medicare Part A and Part B, potentially mooted the amount-or-methodology distinction and requiring exhaustion of remedies for *all* disputes. *See Omnibus Budget Reconciliation Act of 1986*, Pub. L. No. 99-509, § 9341(a)(1), 100 Stat. 1874 (1986) (clarifying that “any individual dissatisfied with any determination . . . as to the amount of benefits under part A or part B” may ultimately seek judicial review) (codified as amended at 42 U.S.C. § 1395ff(b) (2001)); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 14, 20 (2000) (interpreting *Bowen* to permit review in cases where plaintiff “can obtain no review at all unless it can obtain judicial review in a § 1331 [federal question] action”).

84. *See, e.g.*, *Guernsey*, 514 U.S. at 94–95 (finding that Manual provision authorizing departure from generally accepted accounting principles “is a reasonable regulatory interpretation, and we must defer to it”) (citations omitted); *see also Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (deferring to agency’s interpretation of its own statutory mandate).

selves.”⁸⁵ Unless such a showing could be made regarding a particular fraud guidance document, a challenge likely would be unavailing.

Judicial deference to agency interpretation is not limited to challenges to the rulemaking process. The agency’s views similarly play a pivotal role in private litigation between health care entities. For example, in *Zimmer, Inc. v. Nu Tech Medical, Inc.*, an orthopedic products manufacturer sought to extricate itself from a consignment agreement by arguing that the contract violated the Anti-Kick-back Statute.⁸⁶ In support of its position, the manufacturer obtained an Advisory Opinion characterizing the agreement as “problematic” and “potentially abusive.”⁸⁷ While acknowledging that the Opinion did not bind any agency other than HHS, the district court reiterated the principle that “courts give great deference to agency regulations and agency interpretations of those regulations,” and permitted the plaintiff to introduce the Advisory Opinion into evidence.⁸⁸ The court went on to agree with OIG’s analysis, holding that because the agreement violated the Anti-Kick-back Statute, it was void and unenforceable under Indiana law.⁸⁹ Such cases raise the possibility that plaintiffs may be able to use informal fraud guidance to help them set aside undesirable contracts as void and against public policy—an odd result for laws designed primarily to protect *patients*, rather than to immunize health care providers from the consequences of unsatisfactory business deals.

85. *Loyola U. of Chi. v. Bowen*, 905 F.2d 1061, 1071–72 (7th Cir. 1990) (rejecting Secretary’s contention that educational activities must occur in a facility that is “part of the provider” in order to be reimbursed because the Manual provision contained an additional requirement not found in the law or regulations); *see also* *Am. Lithotripsy Soc’y v. Thompson*, 215 F. Supp.2d 23, 37 (D.D.C. 2002) (holding that inclusion of lithotripsy as a Stark II “designated health service” was contrary to congressional intent, and enjoining its implementation).

86. 54 F. Supp.2d 850, 853 (N.D. Ind. 1999).

87. *Id.* at 854–56 (quoting Advisory Opinion No. 98-1 (1998)).

88. *Id.* at 856.

89. *Id.* at 863. Similarly, in *Polk County v. Peters*, a hospital unsuccessfully sued a physician for money that had been advanced pursuant to a recruitment agreement. 800 F. Supp. 1451 (E.D. Tex. 1992). The court relied on a Fraud Alert detailing suspect hospital incentives to physicians—many of which were present in the arrangement—to find that the agreement violated the anti-referral statutes and was void and unenforceable under Texas law. *Id.* at 1455–56; *cf.* *Feldstein v. Nash Cmty. Health Servs., Inc.*, 51 F. Supp.2d 673, 682–85 (E.D.N.C. 1999) (citing Fraud Alert but finding that agreement’s language precluded summary judgment with respect to whether patient referrals were required in return for hospital’s payment).

Similarly, the extent to which health care providers are entitled to *rely* on such informal guidance to defend their actions is unclear. As the Supreme Court has noted, “[i]nterpretive rules do not require notice and comment, although . . . they also do not have the force and effect of law and are not accorded that weight in the adjudicatory process.”⁹⁰ It is well-accepted that the government cannot be estopped by misleading representations made by its employees and agents, particularly regarding questions of benefit entitlements.⁹¹ This principle applies to written as well as oral forms of advice—a troubling proposition in light of recent government studies concluding that the advice available from Medicare contractors is not always accurate.⁹² It is not inconceivable, then, that a provider might have difficulty defending itself based on informal fraud guidance alone, particularly if the government’s views have changed in the interim.

Even if not a defense as a matter of law, however, such reliance should be relevant to the *intent* requirements found in all health care fraud laws (except, of course, the Stark Law).⁹³ The fact that the defendant sought in good faith to comply with OIG’s guidance suggests that she lacked the nefarious intent needed to violate the laws. As the Ninth Circuit has noted, “[a] contractor relying on a

90. *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995).

91. *See* *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 415–16 (1990) (holding that erroneous oral and written advice regarding a claimant’s eligibility did not entitle the claimant to disability benefits that were not authorized by law). In such cases, courts often focus on the provider’s duty to be familiar with program requirements. *See, e.g., Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 64 (1984) (refusing to bind government to oral advice given by fiscal intermediary regarding whether salary payments were reimbursable as reasonable costs under Medicare, and noting that “[a]s a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement”).

92. *See Richmond*, 496 U.S. at 417–18 (addressing both oral misinformation and an outdated government form containing erroneous information); *Medicare Regulatory and Contracting Reform Act of 2001: Hearing on H.R. 2768 Before the House Comm. on Ways and Means, Subcommittee on Health*, 107th Cong. 107-45 (2001) (statement of Leslie G. Aronovitz, Director, Health Care Program Administration and Integrity Issues, U.S. General Accounting Office (“GAO”)) (noting “that carrier bulletins and Web sites did not contain clear or timely enough information,” and “responses to phone inquiries . . . were often inaccurate, inconsistent with other information . . . received, or not sufficiently instructive to properly bill the program”).

93. *See, e.g.,* 42 U.S.C. § 1320a-7b(b)(1)–(2) (2001) (prohibiting defendants from “knowingly and willfully” engaging in acts that violate the Anti-Kickback Statute); 42 U.S.C. § 1395n(a)(1) (2001) (outlining Stark prohibition); 31 U.S.C. § 3729(a)(1) (2001) (barring defendants from “knowingly” submitting false claims under the FCA).

good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or ‘reasonable,’ but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.”⁹⁴ Moreover, if the government desires to use the guidance process to strengthen its relationship with industry—as recent OIG commentary indicates⁹⁵—it would be counterproductive to reverse agency policy without giving providers time to adjust their practices. For example, mindful that the Special Advisory Bulletin on gainsharing arrangements might come as a genuine surprise to providers, OIG agreed to “take into consideration in exercising its enforcement discretion whether [such an] arrangement was terminated expeditiously following” the announcement.⁹⁶ Thus, health care providers are unlikely to be penalized for following informal agency guidance, as long as they revise their practices in a timely fashion. Nonetheless, even the bare potential for liability may be unsettling, particularly when combined with other practical difficulties raised by such guidance.

C Enforcing Health Care Fraud Prohibitions

The disadvantages of both traditional regulation and informal guidance have led to anti-fraud efforts focusing instead on *enforcement*. The majority of these cases have been brought under the FCA, either via direct DOJ prosecutions or as private *qui tam* actions. Such litigation is an example of *ex post* enforcement, under which the government prosecutes entities who have violated the legal prohibitions against health care fraud.⁹⁷

Ex post enforcement is most appropriate when there are clear rules to apply, and efficient methods of identifying violators. In contrast, health care fraud enforcement must contend with significant ambiguities in the voluminous program reimbursement rules, the difficulty of detecting fraud during routine claims processing, and the fairly low risk of an individual fraudulent provider being

94. *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir. 1999).

95. *See, e.g.*, Corrigan Testimony, *supra* note 40, at 9 (describing OIG “Industry Outreach and Education” efforts).

96. Gainsharing Arrangements, *supra* note 74 *see also* 42 C.F.R. § 1008.45(b)(2)–(3) (2002) (explaining conditions for terminating or modifying a previously issued Advisory Opinion).

97. *See* Ashutosh Bhagwat, *Modes of Regulatory Enforcement and the Problem of Administrative Discretion*, 50 HASTINGS L.J. 1275, 1281–83 (1998–99) (describing public *ex post* enforcement).

caught.⁹⁸ Moreover, to the extent such litigation is resolved by settlements in which the defendant agrees to abide by novel program conditions not found in law or regulation, *ex post* enforcement effectively becomes an *ex ante* means of imposing compliance as the “price” of continued participation in the federal health care programs.⁹⁹ As health economist Uwe Reinhardt has noted, “[r]ather than engaging in a long, protracted fight to set the record straight, throughout which share prices suffer and business slumps, a health company’s best bet may simply be to hand over the fines and get on with business.”¹⁰⁰ While enforcement has had practical success, it raises a variety of troubling concerns—particularly when the enforcement process is used to shape *substantive* legal determinations outside the legislative and regulatory arenas.

1. Enforcement as a Substitute for Regulation

When a defendant chooses to settle fraud allegations, the factual and legal issues underlying those allegations are removed from judicial scrutiny.¹⁰¹ Disposing of purely factual issues in this manner, such as the truth or falsity of claims, is a well-accepted litigation strategy. By settling accusations that she billed for services that were not rendered, for example, a physician obviously sacrifices her ability to prove that the services were in fact provided as claimed. Although many settlement agreements state that the defendant “does not admit to any liability or wrongdoing,”¹⁰² it is equally clear that settlement waives the defendant’s right to contest the truth of the government’s accusations. The decision to settle factual disputes is a strategic one, based on whether the parties are willing to incur the time and expense of a trial.¹⁰³ As such, these settlements

98. See Hyman, *supra* note 55, at 538–39 (describing low likelihood of detection and punishment for providers who submit fraudulent bills).

99. See Bhagwat, *supra* note 97, at 1287–94 (describing similar “intermediate” forms of enforcement).

100. Uwe E. Reinhardt, *Medicare Can Turn Anyone Into a Crook*, WALL ST. J., Jan. 21, 2000, at A18; see also William M. Sage, *Fraud and Abuse Law*, 282 JAMA 1179, 1180 (1999) (noting that “large organizations have such a large stake in avoiding exclusion from Medicare that they readily settle pending charges, making much of fraud control resemble a rebate program more than a law enforcement exercise”).

101. As one commentator has argued, “many aspects of the law are never litigated and never face the winnowing effects of judicial scrutiny.” Sarah A. Klein, *Protection or Persecution?*, AM. MED. NEWS, Feb. 15, 1999, at 5.

102. United States v. Mississippi Baptist Med. Ctr., Settlement Agreement, Oct. 10, 1999, reprinted in HEALTHCARE COMPLIANCE REP. (CCH), ¶ 130,318.

103. See, e.g., *id.* at ¶ 130,318 (“The United States and the Hospital disagree on whether any of the Claims described . . . might qualify as ‘false claims’”).

should have little effect on defendants facing different factual allegations in subsequent cases.

In contrast, a decision to settle *legal* issues—such as when, if ever, claims for legitimately rendered services may be deemed to be legally “fraudulent”—has broader implications. Such a settlement may preclude the judiciary from addressing issues that are crucial not only to the development of the fraud laws, but also to general health care policy. For example, health care facilities must satisfy a series of detailed conditions in order to participate in the federal health care programs.¹⁰⁴ Failure to satisfy these conditions will subject the provider to a variety of sanctions, including CMPs and possible program exclusion.¹⁰⁵ In recent years, federal prosecutors and *qui tam* relators have argued that a request for payment submitted when the provider is out of compliance with these standards should be considered “false or fraudulent” under the FCA, regardless of whether program administrators have imposed—or likely would impose—sanctions under the circumstances.¹⁰⁶ Federal prosecutors have invoked this theory broadly against nursing homes that allegedly billed the government for “inadequate” care, negotiating a number of high-profile settlements since the mid-1990s.¹⁰⁷ When the FCA is used to negotiate settlements based on such “regulatory” violations, the litigation process, in essence, circumvents

However, to avoid the time, expense, and uncertainty of litigation, the parties have agreed to settle the matter.”).

104. See, e.g., 42 C.F.R. § 482 (2003) (describing “conditions of participation” for hospitals).

105. See, e.g., 42 C.F.R. § 488.406 (2003) (identifying remedies that may be imposed when long-term care facility fails to comply with conditions of participation).

106. See, e.g., *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs.*, 945 F. Supp. 1485, 1487 (W.D. Okla. 1996) (describing the government’s accusation that psychiatric hospital submitted claims for services rendered while the hospital was out of compliance with the Medicaid requirement that patients be provided a “reasonably safe environment”); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000) (repeating the government’s allegation that nursing home “was so severely understaffed that it could not possibly have administered all of the care it was obligated to perform” for federal health care program patients).

107. See, e.g., David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Care Facilities*, 6 ANNALS HEALTH L. 147, 148 (1997) (prosecuting attorney’s discussion of *United States v. GMS Management-Tucker, Inc.*, No. 96-1271 (E.D. Pa., settled Feb. 21, 1996)). Although the targeted nursing facilities have not admitted any wrongdoing, common elements of these settlements include the payment of civil penalties, development of training and oversight procedures, third-party quality monitoring, and adoption of a corporate compliance program. See *id.* at 154–55.

the normal adjudicative processes for determining whether a program violation has occurred and what sanctions are appropriate.¹⁰⁸

At trial, a defendant would have the opportunity to persuade the court that her activities were legal, or at least a good faith interpretation of ambiguous program requirements. By settling, the defendant sacrifices the opportunity to make this argument, regardless of whether she believes the government's theory to be a legitimate interpretation of current law. Thus, the settlement acquiesces in the government's broad *legal* interpretation—a more significant result than failing to challenge the government's *factual* allegations in an individual case. This effect is compounded by the sheer numbers of FCA health care settlements.¹⁰⁹ When fraud settlements happen *en masse*, they create a body of unofficial, legally untested theories of falsity and fraud.¹¹⁰ While these interpretations have no binding precedential value—*i.e.*, they do not indicate judicial acceptance of the government's legal theories—prosecutors nonetheless will rely on them in future negotiations.

Moreover, these settlements may be used to achieve substantive results that neither Congress nor HHS has been willing to embrace. A recent example from the pharmaceutical industry is illustrative. Pharmaceutical manufacturers have long been the target of fraud investigations. Much of the scrutiny has focused on pharmaceutical sales and marketing, which may implicate the Anti-Kickback Statute if remuneration flows to potential referral sources.¹¹¹ More recently, the focus has broadened to include the ways in which manu-

108. See, e.g., Timothy P. Blanchard, *Medicare Medical Necessity Determinations Revisited: Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse*, 43 ST. LOUIS U. L.J. 91, 94 (1999) (noting that “in routine claims processing, the reversal rate on appeal is extraordinarily high”; therefore, when medical necessity disputes are handled through administrative appeals rather than the FCA, health care providers often prevail); Matthew, *supra* note 29, at 575 (arguing that underlying regulatory issues should be disposed of before a court entertains such FCA cases).

109. See Leon Aussprung, *Fraud and Abuse: Federal Civil Health Care Litigation and Settlement*, 19 J. LEG. MED. 1, 3 (1998) (noting that “only a small minority of health care fraud and abuse cases go to trial”).

110. See *id.* at 1 (describing settlements as “a *de facto* body of health care fraud and abuse law”).

111. See, e.g., Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994) (issued Aug. 1994) (identifying suspect sales and marketing practices). Because drug manufacturers do not directly bill the federal health care programs, but instead sell their products to physicians, pharmacists, and patients (who may later file claims for reimbursement), it has been difficult to prosecute these companies for false billing. However, OIG recently revised the exclusion regulations to encompass entities that *indirectly* furnish items and services to program beneficiaries, thereby strengthening the govern-

facturers influence the *prices* at which their products are reimbursed by the federal health care programs (particularly Medicare).¹¹² Prior to January 2004, physicians generally were reimbursed on the lower of (1) their actual charges or (2) 95% of the “Average Wholesale Price” (“AWP”) for drugs administered in their offices.¹¹³ Historically, AWP “has generally been understood . . . to be the manufacturer’s suggested list price for wholesalers to charge retail pharmacies for drugs.”¹¹⁴

Notwithstanding this general understanding, the Medicare statute and regulations historically did not define AWP. Instead, the Medicare contractors performed their own AWP calculations, based on pharmaceutical pricing publications and databases such as the National Drug Data File—which in turn receive their information directly from the manufacturers.¹¹⁵ Despite the continued existence of this methodology, there has been widespread agreement that these publications do *not* reflect the actual prices that customers pay for the drugs: many physicians, for example, are able to purchase directly from manufacturers or through non-wholesaler intermediaries (such as group purchasing organizations), taking advantage of volume discounts and other purchasing incentives.¹¹⁶ In short, Medicare’s historical reliance on the published “wholesale” price has often resulted in reimbursements that were higher than what physicians paid for the drug, allowing the physician to retain a nice profit—or perhaps a “kickback.”¹¹⁷

As a practical matter, this disconnect between drug cost and Medicare reimbursement raises significant concerns. The magnitude of Medicare funds at stake is substantial: while the program does not cover the vast majority of self-administered outpatient

ment’s position in such cases. See 42 C.F.R. § 1000.10 (2002) (revising exclusion authority).

112. See Paul E. Kalb et al., *The Average Wholesale Price: It “Ain’t What the Government Wants to Pay,”* 5 HEALTH CARE FRAUD REP. (BNA) 182 (2001).

113. 42 U.S.C. §§ 1395u(o)(1), 1395l(a)(1)(S) (2000); 42 C.F.R. § 405.517(b) (2002); see also Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2233 (2003) (revising payment methodology as of 2004). The Medicare program pays 80% of the cost for Medicare Part B services, with the remaining 20% paid as a copayment by beneficiaries. 42 U.S.C. § 1395l(a)(1)(s) (2000).

114. See ROBERT FABRIKANT ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE 10-3 (2002).

115. See John K. Iglehart, *Medicare and Drug Pricing*, 348 NEW ENG. J. MED. 1590, 1591 (2003).

116. See, e.g., *id.* at 1591; H.R. REP. No. 108-391, at 584 (2003) (describing availability of discounts to physicians).

117. See Kalb, *supra* note 112.

medications (such as pills), preliminary estimates indicate that the program nonetheless paid out \$8.4 billion for drugs in 2002.¹¹⁸ Even more troubling, these practices have the potential to cause direct financial harm to *patients*, who pay a portion of the inflated price through their 20% copayments.¹¹⁹

The potential for “AWP manipulation” became evident in October 2001, when TAP Pharmaceutical Products agreed to pay \$875 million to settle civil and criminal fraud allegations related to the sale of its cancer drug, Lupron.¹²⁰ The government alleged that TAP knowingly reported AWP information that was significantly higher than the product’s average sales price, thus ensuring a large “spread” between the actual price and Medicare reimbursement. Because the company does not sell its products directly to the Medicare program, this strategy did not automatically translate into higher revenues. However, the government further contended that TAP “marketed the spread” to physicians, offering its customers a financial inducement to prescribe Lupron in violation of the Anti-Kickback Statute (and possibly the FCA). In addition, by concealing the true price from Medicare and fraudulently advising its customers to report AWP rather than the actual price, TAP allegedly caused its customers to submit false claims for the drug.¹²¹ The FCA allegations, which included two separate *qui tam* complaints, comprised approximately \$560 million of the total TAP settlement.¹²²

Although the TAP settlement (and similar investigations against other drug manufacturers¹²³) focused attention on the is-

118. See 42 U.S.C. § 1395x(s)(2)(A) (2000) (explaining coverage of drugs); Medicare Program: Payment Reform for Part B Drugs, 68 Fed. Reg. 50,428, 50,429 (Aug. 20, 2003) (proposing new payment methodologies).

119. See, e.g., H.R. REP. NO. 108-391, at 583 (2003) (noting that “inflated AWP’s cause Medicare beneficiaries to pay hundreds of millions of extra dollars in inflated co-payments every year”); *In re Lupron Mktg. & Sales Pracs. Litig.*, 245 F. Supp.2d 280 (D. Mass. 2003) (suit by consortium of patients and health plans against drug manufacturer for damages based on alleged inflation of AWP).

120. See DOJ, TAP PHARMACEUTICAL PRODUCTS, INC. AND SEVEN OTHERS CHARGED WITH HEALTH CARE CRIMES; COMPANY AGREES TO PAY \$875 MILLION TO SETTLE CHARGES (Oct. 3, 2001), available at <http://www.usdoj.gov/opa/pr/2001/October/513civ.htm> [hereinafter DOJ, TAP].

121. See 31 U.S.C. § 3729(a)(1) (2004) (prohibiting persons from presenting, or causing to be presented, a false claim).

122. TAP also pleaded guilty to a conspiracy to violate the Prescription Drug Marketing Act by selling drug samples, 21 U.S.C. §§ 331, 353, and paid a \$290 million criminal fine. See DOJ, TAP, *supra* note 120.

123. See, e.g., TAP Pharmaceuticals, *Bristol-Myers Squibb Targets of Federal Marketing, Pricing Probe*, 4 HEALTH CARE FRAUD REP. (BNA) 207 (2001) (describing investi-

sue, the pitfalls of using AWP as a pricing benchmark have long been known. As early as 1974, the government sought to limit the prices paid to pharmacists under the Medicaid program, noting that “the published prices overstate[] the actual prices paid by pharmacists by an average of 15 to 18%.”¹²⁴ Similarly, in revising the Medicare physician payment methodology in 1991, HHS noted that “the Red Book and other wholesale price guides substantially overstate the true cost of drugs.”¹²⁵ In fact, the General Accounting Office (“GAO”) recently estimated that physicians are able to purchase Medicare-covered drugs at an average of 13% to 34% below AWP.¹²⁶

Prior to the fall of 2003, recognition of the problem had led to several failed attempts to revise the Medicare reimbursement methodology. Although both the first Bush Administration and the Clinton Administration attempted to convince Congress to reduce drug reimbursement rates during the 1990s, the compromise reached in 1997 only reduced payment to 95% of AWP—an amount clearly insufficient to offset the 13–34% discounts actually received.¹²⁷ In addition to complaints from the pharmaceutical industry, a significant reason for this failure has been opposition from oncologists,

gations against other large pharmaceutical companies); *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp.2d 172 (D. Mass. 2003) (allowing in part and denying in part motions to dismiss class action suit against numerous drug companies).

124. HEW Fact Sheet: Proposed Regulations Limiting Drug Costs, 39 Fed. Reg. 40,302 (Nov. 15, 1974), *reprinted in* [1974 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,141.

125. Medicare Program; Fee Schedule for Physicians’ Services, 56 Fed. Reg. 25,792, 25,800 (June 5, 1991).

126. See GAO, MEDICARE: PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS’ COSTS 4 (Sept. 2001) hereinafter GAO, MEDICARE].

127. See Pub. L. No. 105-33, § 4556(a), 111 Stat. 251 (1997) (amending 42 U.S.C. § 1395u(o)(1) (2000)); Iglehart, *supra* note 115, at 1591 (describing lack of consensus for revising methodology). Similar defeats were suffered at the regulatory level. In 2000, HCFA notified Medicare contractors of an “alternative” source of AWP information developed by DOJ and the National Association of Medicaid Fraud Control Units. See Health Care Fin. Admin. Program Mem. AB-00-86, at http://www.cms.gov/manuals/pm_trans/AB0086.pdf (Sept. 8, 2000). But later that year, Congress imposed a moratorium on administrative decreases in drug reimbursement rates until the Comptroller General prepared a comprehensive study of the current payment methodology. Consolidated Appropriations Act, Pub. L. No. 106-554, app. F, § 429, 114 Stat. 2763, 2763A-522-27763A-524 (2000). The GAO report was completed in September 2001. GAO, MEDICARE, *supra* note 126. CMS revisited the issue in 2002, establishing a “single drug pricer” for Medicare-covered drugs in an effort to reduce geographic price variations. See Centers for Medicare & Medicaid Services Program Memorandum AB-02-174 (Dec. 3, 2002), available at http://www.cms.gov/manuals/pm_trans/AB02174.pdf.

who argue that the “spread” subsidizes the special costs of storing and administering oncology drugs.¹²⁸ Recent GAO reports suggest that oncologists may well be correct that Medicare does not accurately take account of their practice expenses.¹²⁹ Under Medicare’s budget-neutral approach to physician practice expenses, however, increasing reimbursement for oncologists would have required an equal reduction in expenses for other specialists.¹³⁰ Thus, Congress and HHS faced the wrath of the oncology lobby if drug reimbursement was reduced, and the wrath of other powerful physicians’ groups if oncologists received favorable treatment. In light of these pressures, the failure of the legislative and regulatory processes was understandable, if not exactly laudable—and the stage was set for health care fraud litigation to be used as a way to break the stalemate.

Admittedly, it is somewhat disingenuous to accuse a company of committing fraud when it takes advantage of a well-known loophole in current law—a loophole there has not yet been the political will to close. Notwithstanding that point, fraud enforcement was used successfully as a way to *close* that loophole, at least with regard to TAP’s products. This end was achieved through TAP’s CIA, which required the company to report the “Average Sales Price” (“ASP”) of each of its products on a quarterly basis.¹³¹ ASP was defined in the CIA as the average of all final sales prices charged to all purchasers (except direct sales to hospitals and sales not included in calculating the Medicaid best price).¹³² Because ASP must be net of all volume discounts, prompt pay discounts, cash discounts, chargebacks, short-dated products, free goods, rebates, and all other price concessions (with the exception of bona fide

128. Certain chemotherapy drugs account for much of the program’s expenditures. See Iglehart, *supra* note 115, at 1590, 1595–96 (describing controversy over calculating practice expenses for oncologists); Kalb, *supra* note 112, at 182 (describing oncology community’s opposition).

129. GAO, MEDICARE PHYSICIAN FEE SCHEDULE: PRACTICE EXPENSE PAYMENTS TO ONCOLOGISTS INDICATE NEED FOR OVERALL REFINEMENTS (Oct. 2001) (agreeing that the reimbursement methodology for oncologists should be reexamined).

130. See 42 U.S.C. § 1395w-4(c)(2)(F) (2000) (setting forth budget neutrality requirements); Iglehart, *supra* note 115, at 1595 (citing remarks by William J. Scanlon, director of health care issues for GAO).

131. See Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and TAP Pharmaceutical Products, Inc., at § III.D (Sept. 28, 2001), at http://oig.hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf [hereinafter Corporate Integrity Agreement].

132. *Id.* at § III.D.2.a.

charity care or grants), it clearly is a more accurate assessment of a drug's *actual* market price than the company-reported AWP.

The apparent goal of TAP's ASP reporting was not only to *track* actual drug prices, but also to use them to *revise* reimbursement for the products. The CIA permitted CMS to rely on ASP information in establishing reimbursement rates for TAP's products, although the rates could not be changed without conducting "meaningful review for all government reimbursed therapeutically similar products."¹³³ Of course, at the time there may not have been any authority for CMS to obtain this information from TAP's competitors other than on a voluntary basis (or pursuant to CIAs negotiated by the other companies under investigation).¹³⁴ Moreover, to the extent the then-current statute based reimbursement on the lower of actual charge or 95% of AWP, it was not clear that ASP would suffice: while ASP may be an average of *all* sales, it is not necessarily an indication of the price paid by an *individual* physician, nor is it clearly the drug's overall wholesale price.¹³⁵ Nonetheless, it is clear that, in the face of legislative and regulatory failure, the TAP CIA was designed to generate a more accurate source of drug pricing information.

And it was clear that the government's concerns were not limited to TAP. In the May 2003 *Compliance Guidance for Pharmaceutical Manufacturers*, OIG identified the "Integrity of Data Used to Establish or Determine Government Reimbursement" as one of the key risk areas for pharmaceutical manufacturers in general:

A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement . . . for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly . . . failed to generate or report such information completely and accurately.¹³⁶

Given ongoing investigations against other large pharmaceutical companies, it appeared possible that the government would be able

133. *Id.* at § III.D.2. The information may also be used by state Medicaid programs, subject to the provisions of their own settlements with the company. *Id.* at § III.D.2.d.

134. In fact, TAP's primary competitor pled guilty to similar allegations in June 2003, and entered into a similar CIA. See DOJ, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay \$355 Million to settle charges, at http://www.usdoj.gov/opa/pr/2003/June/03_civ_371.htm (June 20, 2003).

135. See *supra* note 113.

136. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,733 (May 5, 2003) (identifying specific risk areas).

to use the CIA process to obtain similar information for many of the products reimbursed by the Medicare program—the exact result that had eluded the legislative and regulatory processes thus far.¹³⁷

The import of the government's strategy became clear in the latter half of 2003, which finally brought about regulatory and legislative action. In August 2003, CMS published a notice in the Federal Register proposing to revise the drug payment methodology by one of four approaches: (1) enforcing "comparability" between drug prices paid by contractors for their Medicare and private policyholders; (2) applying a greater AWP discount; (3) setting prices based on market surveys; and (4) establishing a competitive acquisition program.¹³⁸ Soon afterwards, Congress began to debate the expansion of Medicare to include a broader prescription drug benefit, which resulted in the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹³⁹ Under the new legislation, reimbursement for outpatient prescription drugs in 2004 generally is set at 85% of AWP, subject to adjustments based on market surveys.¹⁴⁰ Beginning in 2005, payment for single-source drugs will be based on the lesser of: (1) the manufacturer's "average sales price," which is defined broadly to include sales to all purchasers except certain nominal sales and those exempted from the Medicaid best price determination; or (2) the "wholesale acquisition cost" ("WAC"), which is defined as the manufacturer's list price to wholesalers and direct purchasers.¹⁴¹ OIG will be required to conduct surveys to monitor the market prices of drugs, and reimbursement may be adjusted accordingly.¹⁴² Manufacturers who misrepresent a drug's average sales price will be subject to civil monetary penalties as well as potential FCA liability.¹⁴³ Beginning

137. As one observer has argued, prosecutors "are trying to use litigation to force companies to change their practices, not just to win damages." Reed Abelson & Jonathan D. Glater, *New York Will Sue 2 Big Drug Makers on Doctor Discount*, N.Y. TIMES, Feb. 13, 2003, at A1 (quoting law professor Jennifer Arlen).

138. Medicare Program: Payment Reform for Part B Drugs, 68 Fed. Reg. 50,428 (Aug. 20, 2003) (proposing new payment methodologies).

139. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

140. *Id.* at § 303(b)(2) (to be codified at 42 U.S.C. § 1395u(o)(4)).

141. *Id.* at § 303(c) (to be codified at 42 U.S.C. § 1395w-3a(b)(4), (c)). The definition of average sales price is similar to that used in the TAP CIA. See Corporate Integrity Agreement, *supra* note 131, at § III.D.2.a.

142. See Medicare Prescription Drug, Improvement, and Modernization Act, § 303(c) (to be codified at 42 U.S.C. § 1395w-3A(d)(3)).

143. *Id.* (to be codified at 42 U.S.C. § 1395w-3A(d)(4)); H.R. CONF. REP. NO. 108-391, at 592 ("The Conferees intend that if a manufacturer knowingly . . . sub-

in 2006, physicians will also have the option to obtain outpatient drugs through a competitive acquisition system.¹⁴⁴ In order to address the oncology issues mentioned above, the pricing revisions are explicitly linked to an increase in reimbursement for drug administration, with such revisions exempted from the budget neutrality requirement.¹⁴⁵

While these changes are encouraging, many issues remain to be resolved. Despite the law's revisions to practice expenses, oncologists have already complained that the post-2005 reimbursement methodology will disadvantage them economically.¹⁴⁶ Moreover, because the law adopts several different pricing mechanisms—steeper AWP discounts in 2004, broad-based market monitoring in 2005, and a competitive acquisition option in 2006—the new pricing methodologies will be extremely complicated to administer. The complexity of both the pricing and the practice expense provisions is likely to require extensive rulemaking by CMS, which—similar to other regulatory initiatives described in this Article—may result in unanticipated implementation delays. From the perspective of fraud enforcement, however, it is significant that the most recent round of legislative and regulatory activity occurred only *after* the widely publicized AWP investigations and settlements drew public attention to the issue and forced officials to devise alternative reimbursement methodologies. In this way, the litigation process not only foreshadowed, but in many ways provided the model for, the necessary legal changes.

2. Assessing Enforcement

The phenomenon of “regulation by litigation” has been recognized as a growing—and at times problematic—trend in American law.¹⁴⁷ A recent analysis attributes this increase to “‘unfinished bus-

mits false information, that such information be considered a ‘false record or statement’ made or used ‘to get a false or fraudulent claim paid or approved by the government’ for purposes of the FCA.”).

144. See Medicare Prescription Drug, Improvement, and Modernization Act, § 303(d) (to be codified at 42 U.S.C. § 1395w-3B).

145. *Id.* at § 303(a) (providing for practice expense adjustments), (f) (prohibiting Secretary of HHS from revising drug payment amounts in 2004 unless concurrent practice expense adjustments are made).

146. See, e.g., Darrin Schlegel, *US Oncology Says Medicare Changes Threat to Profits*, HOUS. CHRON., Dec. 3, 2003, at Business 1.

147. See, e.g., William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387 (2003); Michael I. Krauss, *Regulation Masquerading as Judgment: Chaos Masquerading as Tort Law*, 71 MISS. L.J. 631 (2001) (arguing against use of government tort suits to accomplish regulation).

iness'—historical, structural, and conceptual incompleteness in health care system design that channels major issues in health policy into second-best solutions played out in the courts.”¹⁴⁸ In other areas of law, such as hazardous products, litigation has been driven by private attorneys seeking recompense for injured individuals (and profits for themselves).¹⁴⁹ Health care fraud litigation has evolved somewhat differently, in part due to the dual private-public enforcement mechanism embodied in the FCA.

Regardless of whether it is initiated by federal prosecutors or *qui tam* relators, health care fraud enforcement offers significant advantages to the government. As discussed above, enforcement may achieve a quicker “fix” to a problem than would be possible in the legislative or regulatory arenas. If those processes have failed to resolve the issue—as with Medicare drug reimbursement, for example—prosecutors may regard enforcement as the only practical method of achieving the “right” result.¹⁵⁰ When politics and inertia stymie the development of necessary regulations, litigation provides an alternative. Moreover, by taking on the costs of filing suit, private relators may supplement scarce governmental resources.¹⁵¹

However, enforcement is not a panacea for fraud concerns; if left unchecked, it may work to the detriment of overall health care regulatory policy. Private litigation, in particular, can interfere with necessary regulation by diverting limited government resources, generating unfavorable legal precedent, and damaging regulators’ relationships with the industry.¹⁵² Moreover, an emphasis on enforcement—at the expense of substantive regulation—may lull policymakers into a sense of complacency, where difficult decisions are delayed in the hopes that the desired result will be achieved through the litigation process. As one judge recently observed in the nursing home context, “[a]lthough extensive regulatory authority exists for punishing unscrupulous facilities, the Government has increasingly opted for the expedited results of lawsuits under the

148. Sage, *supra* note 138, at 389.

149. *See id.* at 389–90 (describing example of tobacco litigation).

150. *Id.* at 411 (noting that litigation may “reflect the government’s desire to recapture ‘overpayments’ that, because of the political bargains that underlie Medicare and Medicaid, are not avoidable through *ex ante* regulation”).

151. *Id.* at 394 (characterizing private fraud enforcement as “off budget”).

152. *See, e.g.,* Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1, 65–66 (2002) (positing that private justice may hinder efforts to promote industry self-regulation, and discussing harmful precedent generated by private plaintiffs); Marsha J. Ferziger & Daniel G. Currell, *Snitching for Dollars: The Economics and Public Policy of Federal Civil Bounty Programs*, 99 U. ILL. L. REV. 1141, 1171, 1185 (1999) (noting that false “tips” can be costly because they consume scarce agency resources).

FCA's powerful threats of significant fines, treble damages, and costly litigation fees."¹⁵³

Once again, these concerns are illustrated by the Stark Law. As noted above, interim final regulations were not announced until more than eight years after enactment of the expanded Stark II prohibitions.¹⁵⁴ In the interim, enforcement of the self-referral ban through the administrative channels specified in the statute was almost non-existent. On the other hand, numerous *qui tam* actions were filed based on alleged Stark violations, a number of which DOJ has joined.¹⁵⁵ In other words, while HHS has struggled to figure out just what the prohibition meant, the administrative enforcement scheme was virtually supplanted by traditional civil enforcement mechanisms. This raises the disturbing possibility that the long-term regulatory delay generated, in essence, a form of *regulatory irrelevance*, sending the message that the regulations simply aren't necessary to achieve the underlying goals of the Stark legislation. Under the structure designed by Congress, however, the task of parsing these detailed prohibitions was given to the *regulators* in HHS, not the *prosecutors* in DOJ—the exact opposite of what has occurred. Clearly, a problem exists when enforcement is given a higher priority than developing the implementing Stark II regulations. As long as providers feel compelled to settle these allegations, however, there will be little incentive for policymakers to make such controversial decisions.¹⁵⁶

153. *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1152 (W.D. Mo. 2000); see also Patric Hooper, *Health Care Fraud Frenzy: An Exercise in Overzealous Law Enforcement*, 1 HEALTH CARE FRAUD REP. (BNA) 799 (1997) (arguing that "Congress and federal and state agency policymakers are delegating by default substantial policy-making authority to enforcement agencies and prosecutors").

154. See Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 69 Fed. Reg. 16,054 (Mar. 26, 2004); *supra* notes 42–55.

155. See, e.g., Robert Salcido, *The Government Unleashes the Stark Law to Enforce the False Claims Act: The Implications of the Government's Theory for the Future of False Claims Act Enforcement*, HEALTH LAW., Aug. 2001, at 1, 3–5 (describing cases); DOJ, Justice Department Announces Settlements with South Dakota Hospital and Doctors for \$6,525,000, at http://www.usdoj.gov/opa/pr/2002/December/02_civ_739.htm (Dec. 20, 2002) (announcing settlement of Stark-based *qui tam* suit).

156. See, e.g., Arti K. Rai, *Health Care Fraud and Abuse: A Tale of Behavior Induced by Payment Structure*, 30 J. LEG. STUD. 579 (2001) (arguing "that federal regulators have used politically appealing health care fraud strategies to attempt cost and quality control simply because the government lacks effective mechanisms for addressing these problems directly"); Matthew, *supra* note 29, at 573–79 (arguing that the doctrine of primary jurisdiction dictates that courts should not entertain

III. THE CONSEQUENCES OF THE CURRENT APPROACH TO FRAUD

The ultimate effect of this three-pronged approach to health care fraud—the cumbersome regulatory process, the proliferation of informal guidance, and the use of enforcement as a substitute for substantive regulation—is an increasingly complex environment for health care providers. As one federal prosecutor acknowledged, “[t]he passage of time seldom brings a simplification or reduction of law, regulation, guidance, and informal advice; rather, accretion and increasing complexity are the characteristics of any mature bureaucratic system. Complexity in regulation feeds on itself.”¹⁵⁷

From the perspective of many health care providers, such a regime lacks not only clarity, but also basic *legitimacy*.¹⁵⁸ When the potential for astronomical liability under the FCA is combined with the threat of exclusion from federal health care programs, providers may have little choice but to settle, even if they believe they might well prevail at trial. As commentators have argued, “[w]hether 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.”¹⁵⁹ Some provider organizations have characterized recent enforcement as “border[ing] on extortion.”¹⁶⁰ These fears are not groundless: the courts have acknowledged that the government’s posture has been “rather

FCA cases until DOJ and OIG have addressed the underlying regulatory allegations).

157. Sheehan, *supra* note 1, at 137.

158. See Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 212 (2001) (arguing that widespread provider perception that the laws are being used unfairly may jeopardize the legitimacy of the anti-fraud agenda); John C. Danforth, *When Enforcement Becomes Harassment*, N.Y. TIMES, May 6, 2003, at A31 (“[W]hen government overreaches its authority, it undermines its legitimacy.”).

159. Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 265 (1999); see also David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 151, 155 (2002) (“Providers who believe they are blameless are under tremendous pressure to settle, because of the legal expenses associated with mounting a defense and the high probability of bankruptcy and professional disgrace if the jury does not see things the same way the provider does.”).

160. GAO, [Untitled Report], B-279893 (July 22, 1998), at 15 n.30 (describing comments made by the Louisiana Hospital Association).

draconian.”¹⁶¹ Even providers who are vindicated may incur substantial legal fees in responding to the allegations.¹⁶²

Given the balance of power, it should come as no surprise that prosecutors have the power to “encourage” settlements, even where abstract legal analysis might favor the defendant. As one commentator has argued, such administrative “[a]rm-twisting succeeds, and evades judicial or other scrutiny, in part because companies in pervasively regulated industries believe that they cannot afford to resist agency demands.”¹⁶³ These agencies may demand, as a condition of settlement, that the provider comply with requirements that are not otherwise imposed by law—such as TAP’s agreement to report ASP (rather than AWP) information. The danger is that “the agency possesses the ability to impose its will on the firm in ways which may not be authorized by the governing statute, may not have been envisioned by the creators of the agency, and indeed may exceed the agency’s formal powers.”¹⁶⁴ This danger is heightened when conditions are imposed outside the established procedures for judicial review of agency action, as is true of many health care fraud settlements.¹⁶⁵

Such concerns may be an inevitable consequence of the prosecutorial discretion granted by the fraud laws. Congress drafted these laws broadly, leaving the details to be developed through case law.¹⁶⁶ Where a statute leaves room for interpretation

161. *Assn. of Am. Med. Coll. v. United States*, 217 F.3d 770, 781 (9th Cir. 2000) (noting that “OIG could still modify its rather draconian view of the [Medicare] Act’s requirements for Part B billing”); *see also* GAO, *MEDICARE FRAUD AND ABUSE: DOJ’S IMPLEMENTATION OF FALSE CLAIMS ACT GUIDANCE IN NATIONAL INITIATIVES VARIES* 4 (Aug. 1999) (concluding that U.S. Attorneys who participated in “Operation Bad Bundle” laboratory initiative had no evidentiary basis for targeting the selected hospitals).

162. *See, e.g.*, Bucy, *supra* note 152, at 63 (discussing academic medical center that spent \$1.7 million and delayed planned expansion to undertake an audit that resulted in vindication); Hyman, *supra* note 55, at 564 (characterizing the current process as “the haphazard extraction of ex post discounts from some providers and the ritual sacrifice (either through conviction/program exclusion or the imposition of staggering defense costs) of other providers.”).

163. Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 Wis. L. Rev. 873, 922 (1997).

164. Bhagwat, *supra* note 97, at 1299–1300.

165. *See id.* at 1304–05 (noting that traditional rulemaking and adjudication occur in the context of judicial review, whereas “coerc[ed] or negotiat[ed] . . . compliance [occurs] in a context where outside supervision is lacking”); Noah, *supra* note 163, at 936–37 (arguing that “[t]he opportunity to challenge agency action in court provides a critical deterrent to arbitrary action.”).

166. As one commentator notes, “[t]o be sure, Congress must *speak* before a person can be convicted of a federal crime, but it needn’t *say* much of anything

as to the prohibited conduct, as with the fraud laws, prosecutors will be motivated to “bring previously undefined conduct to trial in the hope that the court will criminalize it.”¹⁶⁷ In exercising this discretion, however, prosecutors must take care not to usurp the basic legislative task of *defining* prohibited public behavior.¹⁶⁸ This concern is heightened in disputes over the proper scope “of statutes that mark the boundary line between socially desirable and socially undesirable behavior.”¹⁶⁹ The laws addressing health care fraud tread this fine line, protecting against improper financial activities while at the same time encouraging the delivery of cost-effective, high-quality medical innovations.¹⁷⁰

This enforcement scheme is further complicated by the role of private prosecutors. Under the FCA, *qui tam* relators are free to maintain their suits even when the government declines to intervene.¹⁷¹ To many observers, the motivations of such private plaintiffs are suspect. Barely a decade after the 1986 FCA Amendments took effect, the Supreme Court acknowledged that “*qui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good.”¹⁷² Indeed, *qui tam* statutes fell out of favor in early 17th century England, in part, because of “abuses by the informers, such as fraudulent prosecutions and extortion.”¹⁷³ There is thus a long-standing perception that it is improper for substantial government enforcement authority to be delegated to private entities.¹⁷⁴ While prosecutorial discretion may be an imperfect

when it does.” Dan M. Kahan, *Is Chevron Relevant to Federal Criminal Law*, 110 HARV. L. REV. 469, 471 (1996).

167. Geraldine Szott Moohr, *Mail Fraud and the Intangible Rights Doctrine: Someone to Watch Over Us*, 31 HARV. J. ON LEGIS. 153, 179 (1994).

168. See Kahan, *supra* note 166, at 479 (explaining why “prosecutors . . . end up with a significant share of delegated lawmaking authority”); notes 154–56, *supra* (describing how enforcement of Stark Law has proceeded through FCA in the absence of implementing regulations).

169. Kahan, *supra* note 166, at 485.

170. See Matthew, *supra* note 29, at 566 (noting that anti-referral laws “both constrain the behavior of market participants . . . [and] seek to allow providers the freedom to compete in a market that demands efficiency and innovativeness to survive”).

171. 31 U.S.C. § 3730(b)(4), (c)(3) (2000); Vermont Agency of Nat. Resources v. United States *ex rel.* Stevens, 529 U.S. 765, 769 (2000) (upholding relator’s standing to maintain FCA suit after government’s decision not to intervene).

172. Hughes Aircraft Co. v. United States *ex rel.* Schumer, 520 U.S. 939, 949 (1997).

173. Richard A. Bales, *A Constitutional Defense of Qui Tam*, 2001 WIS. L. REV. 381, 386 (2001).

174. As one commentator explains, “[p]rivate actors exacerbate all of the concerns that make the exercise of agency discretion so problematic. They are

means of preventing overreaching in health care fraud cases, it seems preferable to a bounty system enforced by private individuals who have no obligation to further the government's health care agenda.¹⁷⁵

Even if relators do not mirror prosecutors' priorities, however, this view is far too simplistic. Private parties are given a role in enforcement for two primary reasons: (1) because they can provide information about improper activities that the government otherwise would not discover; and (2) because experience has shown that agencies, left to their own devices, are apt to be "captured" by the interests they purport to regulate."¹⁷⁶ The former concern was clearly on the minds of the drafters of the 1986 FCA Amendments, who observed that "[d]etecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity."¹⁷⁷ The more complex the crime, the more critical such "private justice":

No matter how talented or dedicated our public law enforcement personnel may be nor how many resources our society commits to regulatory efforts, a public regulatory system will always lack the one resource that is indispensable to effective detection and deterrence of complex economic wrongdoing: inside information Private justice is not simply a helpful adjunct to public regulation. Done correctly, it is an essential ingredient. Without the key resource of inside information that is available through private justice actions, public regula-

one step further removed from direct accountability to the electorate. . . . [They] may pursue different goals and respond to different incentives than do public agencies, interfering with their capacity to be as public-regarding as we expect agencies to be." Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 574 (2000).

175. See, e.g., Ferziger & Currell, *supra* note 152, at 1185 (noting that "private enforcers have no incentive to engage in discretionary nonenforcement"); William E. Kovacic, *Whistleblower Bounty Lawsuits As Monitoring Devices in Government Contracting*, 29 LOY. L.A. L. REV. 1799, 1825 (1996) (noting that "it is likely that the aims of qui tam relators and taxpayers . . . are not invariably coincident"). Cf. Matthew, *supra* note 29, at 581-87 (arguing that the Control Account funding mechanism similarly taints the motivations of government prosecutors).

176. Spencer Weber Waller, *Prosecution by Regulation: The Changing Nature of Antitrust Enforcement*, 77 OR. L. REV. 1383, 1428 (1998).

177. See S. REP. NO. 99-345, at 4, 23 (1986), *reprinted in* 1986 U.S.C.C.A.N. (100 Stat.) 5269.

tors cannot effectively detect, prove, or deter complex economic crime or public corruption.¹⁷⁸

In short, without the help of relators, we fear much health care fraud will go undetected.

Similarly, private relators counteract the phenomenon of agency capture. As one commentator notes, “[p]ublic choice theory suggests that . . . regulation[] is rarely, if ever, practiced to maximize an abstract form of the public interest, but rather represents a battleground for warring private interests.”¹⁷⁹ The drafters of the 1986 FCA Amendments were keenly aware of the need for input from entities outside the established administrative and prosecutorial systems.¹⁸⁰ By providing an additional source of information to support government investigations—and an alternate enforcement mechanism to counter government inertia—the *qui tam* provisions establish a form of independent oversight of health care enforcement priorities.

One recent example illustrates the dangers of restricting the private role in enforcement. In the 1990s, an increase in private securities fraud litigation led Congress to prohibit civil Racketeer Influenced and Corrupt Organizations Act (“RICO”) suits based on fraud in the purchase or sale of securities, the primary vehicle through which such challenges had been brought.¹⁸¹ The amendment had the immediate effect of preventing frivolous lawsuits, as desired. The long-term consequences, however, may only recently have become clear: some commentators attribute the recent Enron debacle, in part, to the fact that the amendment significantly reduced the legal risks faced by auditors, thereby allowing fraud to

178. Bucy, *supra* note 152, at 4–5, 8. For a general discussion of private enforcement, see John C. Coffee, *Rescuing the Private Attorney General: Why the Model of the Lawyer as Bounty Hunter is Not Working*, 42 MD. L. REV. 215 (1983).

179. Waller, *supra* note 176, at 1428.

180. Bales, *supra* note 173, at 388 (noting that “Congress believed that many public officials were active participants in the corruption and therefore were unlikely to enforce the law diligently”); see also Coffee, *supra* note 178, at 227 (noting that “private enforcement also performs an important failsafe function by ensuring that legal norms are not wholly dependent on the current attitudes of public enforcers or the vagaries of the budgetary process and that the legal system emits clear and consistent signals to those who might be tempted to offend”).

181. See Private Securities Litigation Reform Act of 1995 (“PSLRA”), Pub. L. No. 104-67, 109 Stat. 758, Tit. I, § 107 (1995) (codified at 18 U.S.C. § 1964(c)) (stating that “no person may rely upon any conduct that would have been actionable as fraud in the purchase or sale of securities to establish a violation” of RICO).

flourish undetected.¹⁸² Thus, recent history teaches us to beware of short-term “fixes” to appease health care providers, to the possible long-term detriment of the nation’s health.

IV. CONCLUSION

The current federal approach to health care fraud fits a three-pronged model, which combines regulatory inertia with the proliferation of informal, non-binding guidance and an increasing amount of public and private enforcement. While the latter two mechanisms help fill the informational void left by the cumbersome notice-and-comment rulemaking process, they pose significant disadvantages in terms of providing reliable information to the industry. In short, this model is unsatisfactory because it fails to generate a key commodity for health care providers: clear directions from those who are charged with interpreting and enforcing the fraud laws. As Professor Troyen Brennan has argued, “regulation should be linked explicitly with shared aims. Regulators should define specific goals and then give [providers] the opportunity to meet them.”¹⁸³

Given the potential severity of the sanctions, the need for clarity is acute.

The law deters a particular form of wrongdoing most effectively when it prohibits it in clear terms. If a statute prohibits a particular form of wrongdoing only ambiguously, some individuals will engage in it either out of ignorance of the law or in the hope that courts will resolve the ambiguity in their favor. Ultimately, then, the best way to prevent the exploitation of a potential loophole is to close it.¹⁸⁴

In the Medicare context, it is indeed possible to close such loopholes in a way that comports with program goals. For example, the Medicare statute has been interpreted as excluding coverage of drugs and devices that are “experimental or investigational” in nature.¹⁸⁵ In the 1990s, OIG investigated hospitals for billing for newer generations of existing devices, such as pacemakers, that had

182. See, e.g., John C. Coffee, *Understanding Enron: “It’s About the Gatekeepers, Stupid,”* 57 Bus. Law. 1403, 1409 (2002) (identifying the PSLRA as one reason the legal risks for auditors decreased during the 1990s).

183. Brennan, *supra* note 30, at 727.

184. Kahan, *supra* note 166, at 493–94.

185. See *Medicare Part A Intermediary Letter*, No. 77-4 (Jan. 1977), reprinted in [1976–1977 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,152 (excluding coverage of experimental or investigational items and services); Cedars-

not yet been approved by the Food and Drug Administration (“FDA”). Although a challenge to the validity of the coverage rule was unsuccessful, a simultaneous industry lobbying effort convinced HHS to develop a mechanism for covering a limited group of low-risk non-approved devices that FDA designated as “non-experimental/investigational” in nature.¹⁸⁶ Similar clarifications in key areas—such as pharmaceutical pricing—could help allay industry concerns.

In addition, it may be time to rethink the *qui tam* incentive structure in health care cases. The number of *qui tam* cases filed since the 1986 FCA Amendments suggests that Congress’ strategy of generating inside information is working, perhaps better than anyone anticipated. When it comes to a private bounty system, however, success should not be measured by volume alone; instead, a successful system must generate primarily *meritorious* suits, and weed out frivolous ones.¹⁸⁷ To achieve this goal, the incentives must be generous enough to induce participation by insiders, yet not so tempting as to engender meritless suits.¹⁸⁸ The FCA *qui tam* structure has much to recommend it, including the government’s role in the suit, the fact that the relator’s recovery is tailored to the level of help provided, and the existence of a “jurisdictional bar” precluding *qui tam* suits based on information already in the government’s possession.¹⁸⁹ On the other hand, given the minimal chances of success if the government fails to intervene, the system provides extraordinarily high recoveries for a few successful relators but leaves the majority with nothing.¹⁹⁰ It is worth exploring

Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457, 1462 (C.D. Cal. 1996) (addressing challenge to denial of claims, and quoting Medicare Hospital Manual § 260.1).

186. See *Cedars-Sinai*, 939 F. Supp. at 1457; 42 C.F.R. § 405, subpt. B (2003) (setting forth rules for coverage of such devices).

187. See Coffee, *supra* note 178, at 271 (arguing that “from an ex ante perspective, the focus should be on how to discourage the filing of frivolous law suits”); Kovacic, *supra* note 175, at 1831 (noting that “[t]he net benefits of *qui tam* monitoring shrink as the number of ‘false positives’—challenges to benign or beneficial conduct—increase”).

188. Commentators suggest that the ideal bounty system is one that combines a relatively small bounty (such as 3% of the recovery) with a relatively high degree of certainty that the bounty will be paid. Ferziger & Currell, *supra* note 152, at 1197–98.

189. See Bucy, *supra* note 152, at 61 (praising FCA *qui tam* model); 31 U.S.C. § 3730(d) (2000) (describing range of awards for *qui tam* plaintiffs); 31 U.S.C. § 3730(e)(4) (2000) (jurisdictional bar).

190. See Bucy, *supra* note 152, at 51 (noting historical lack of success when DOJ declines to intervene); DOJ, TAP, *supra* note 120 (describing TAP relators’ recovery of approximately \$95 million); see also Kovacic, *supra* note 175, at

whether a revised bounty system could decrease the numbers of frivolous FCA cases without sacrificing meritorious ones—perhaps along the lines of the Medicare Beneficiary Incentive Program, under which beneficiaries are eligible for 10% or up to \$1,000 of funds recovered as a result of their “tips” about fraud.¹⁹¹

What is clear is that the federal government now characterizes health care fraud enforcement as protecting both *patients* and the *federal Treasury*—as in the pharmaceutical context, where price inflation causes harm not only to federal programs, but also to the patients who are forced to pay artificially high copayments. This rhetoric has proven to be very powerful, and suggests that health care fraud enforcement will remain a priority for the foreseeable future. The model analyzed here suggests that we will continue to see three concurrent strategies for reducing health care fraud: traditional notice-and-comment regulation, an ever-expanding variety of informal guidance, and a combination of private and public enforcement that increasingly reaches beyond simple cases of “raw fraud.”¹⁹² If we truly want to reduce fraud, however, *clear* guidance—rather than simply *more* guidance—is the key.

1845–46, 1849 (calling for a change in the “formula for calculating the relator’s bounty” and for enhanced screening by DOJ to weed out inappropriate *qui tam* suits).

191. See 42 U.S.C. § 1395b-5 (2000) (explaining incentives); Mary DuBois Krohn, Comment, *The False Claims Act and Managed Care: Blowing the Whistle on Underutilization*, 28 CUMB. L. REV. 443, 469–71 (1997–98) (comparing Beneficiary Incentive Program to FCA incentives).

192. James F. Blumstein, Editorial, *What Precisely is “Fraud” in the Health Care Industry?*, WALL ST. J., Dec. 8, 1997, at A25.