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A CONCEPTUAL MODEL OF HEALTH CARE FRAUD ENFORCEMENT

*Joan H. Krause**

INTRODUCTION

The numbers are staggering: an estimated 10 percent of the federal health care budget lost to fraud.¹ More than \$12 billion improperly paid out by Medicare in fiscal year 2001—a number all the more striking in that it represents significant progress from prior years.² Corporate health care defendants settling fraud allegations for hundreds of millions of dollars in civil penalties and

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¹ See S. REP. NO. 99-345, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5268 (estimating 1 to 10 percent of the federal budget is lost to fraud). See, e.g., David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 151, 159 (2002) (arguing that “[a]lthough the figure of 10 percent was an effective political statistic, it has no empirical foundation”).

² See DEP’T OF HEALTH & HUMAN SERVICES, OFFICE OF THE INSPECTOR GEN., NO. A-17-01-02002, IMPROPER FISCAL YEAR 2001 MEDICARE FEE-FOR-SERVICE PAYMENTS 1 (2002) (acknowledging the error rate represented a significant reduction from the \$23.2 billion in improper payments identified in 1996, the first year such audits were conducted), *available at* <http://oig.hhs.gov/oas/reports/cms/a0102002.pdf>.

criminal fines.³ Federal health care fraud recoveries of more than a billion dollars a year, of which a significant percentage can be used to fund future enforcement efforts.⁴ If nothing else, it's clear there is money in health care fraud—on both sides of the law.

Federal health care fraud enforcement takes place in an atmosphere characterized by an increasing number of requirements placed on the health care providers and professionals who participate in the federal health care programs, such as Medicare and Medicaid.⁵ The federal health care programs are subject to an enormous number of legal provisions, spanning hundreds of thousands of pages.⁶ While some commentators contend that the

³ See Press Release, Dep't of Justice, TAP Pharmaceutical Products, Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001) (announcing record-setting settlement), available at <http://www.usdoj.gov/opa/pr/2001/October/513civ.htm>. See also *Kidney Dialysis Firm Will Pay \$496 Million, Plead Guilty to Defrauding Health Programs*, 9 HEALTH CARE FRAUD REP. (BNA) 127 (Jan. 27, 2000) (announcing prior record-setting settlement). In December 2002, the government announced the settlement of long-standing litigation against the former Columbia/HCA for-profit hospital chain, which ultimately will total \$1.7 billion dollars. See Press Release, Dep't of Justice, Press Statement Re: HCA (Dec. 18, 2002) (announcing settlement), available at http://www.usdoj.gov/opa/pr/2002/December/02_civ_731.htm.

⁴ See DEP'T OF HEALTH & HUMAN SERVICES & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2001 (2002), available at <http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm> [hereinafter ANNUAL REPORT 2001]; *infra* Part I (describing the allocation of anti-fraud resources).

⁵ In the federal health care programs, the term "provider" technically refers to institutional entities, such as hospitals, home health agencies, and nursing homes. 42 U.S.C. § 1395x(u) (2003) (defining "provider of services"). Because they face similar fraud liability, this article will use the term "provider" to refer more broadly to both individual health care professionals and institutional entities. See OFFICE OF THE INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: PRACTICES OF BUSINESS CONSULTANTS 1, n.1 (2001) (using term 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 Several years ago, staff at one medical center counted 132,720 pages of Medicare laws and regulations alone. See *Mayo Chronicles Medicare Regs: It's 132,720 Pages of Red Tape*, MODERN HEALTHCARE, Mar. 15, 1999, at 64.

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recent proliferation of fraud cases can be blamed on the fact “that healthcare regulations have just become too complicated to understand,”⁷ their arguments have won little sympathy in the halls of Congress and the annals of public opinion.

At the same time, the legal provisions governing health care fraud have become similarly complex. At the federal level, health care fraud is subject to a curious hybrid of *ex ante* and *ex post* enforcement mechanisms.⁸ Not surprisingly, the powerful *ex post* enforcement powers exercised by federal officials—i.e., prosecutions resulting in massive criminal and civil liability—have received the most attention. Given that both the health care industry and the government share the goal of preventing fraud before it occurs, however, the focus has shifted in recent years to informal guidance offering advice to health care providers on how to structure their activities to fit the law. Some of this advice comes in the form of opinions responding to individual queries, while other guidance takes the form of broad policy statements applicable to the entire industry.⁹ This guidance does not operate as pure *ex ante* regulation because providers are not required to demonstrate compliance with these criteria before furnishing services to program beneficiaries.¹⁰ While not required for *initial* participation in the federal health care programs, however, compliance may be required in order to *continue* participation in the programs once fraud allegations are made.¹¹ Thus, providers

⁷ Uwe E. Reinhardt, *Medicare Can Turn Anyone Into a Crook*, WALL ST. J., Jan. 21, 2000, at A28.

⁸ See Ashutosh Bhagwat, *Modes of Regulatory Enforcement and the Problem of Administrative Discretion*, 50 HASTINGS L.J. 1275, 1280-81 (1999) (setting forth the typology of regulatory enforcement schemes).

⁹ See, e.g., *infra* Parts III.B.1.a (discussing the advisory opinion process), III.B.1.b (discussing industry-wide fraud alerts) & III.B.1.c (discussing compliance guidances).

¹⁰ See Bhagwat, *supra* note 8, at 1282-85 (discussing public *ex ante* enforcement).

¹¹ See Office of the Inspector Gen., Corporate Integrity Agreements: General Information (describing the requirements of Corporate Integrity Agreements, which often are required as part of settlement), at <http://oig.hhs.gov/fraud/cias.html> (last visited Feb. 2, 2003).

may have no practical choice but to “voluntarily” comply with the agency’s position as expressed in such guidance—even if it includes requirements not found in the underlying statutes or regulations.¹²

In the health care context, this guidance currently is provided in three distinct ways: through the processes of *regulation*, *information*, and *litigation*.¹³ Despite the fact that only regulations promulgated through the notice-and-comment process are legally binding, anti-fraud efforts increasingly rely on informal expressions of agency views, as well as the use of public and private litigation to address ambiguities in substantive regulation.¹⁴ While this development offers increased guidance to the industry as to the scope of permissible activities, it simultaneously raises troubling concerns about subjecting health care providers to unofficial—and potentially inconsistent—legal interpretations.

This article analyzes the tripartite health care fraud enforcement framework. Part I offers a brief introduction to health care fraud, focusing on recent federal fraud initiatives. Part II addresses three of the key federal health care fraud laws: the Civil False Claims Act (FCA), the Medicare & Medicaid Anti-Kickback Statute, and the so-called “Stark Law” prohibiting physician self-referrals.¹⁵ Part III analyzes the impact of the tripartite regulation-information-litigation model on health care providers. Part IV addresses the implications of this model, arguing that the combination of cumbersome rulemaking procedures, the proliferation of unofficial guidance, and the growing use of litigation may create an increasingly untenable situation for the health care industry.

The article concludes by offering suggestions for how this model could be refined, focusing on regulatory *clarity* as a

¹² Bhagwat, *supra* note 8, at 1287 (identifying similar “intermediate modes of enforcement”).

¹³ “Litigation” might well have been deemed “enforcement” by this Author—except that it does not rhyme.

¹⁴ See discussion *infra* Part III.B.2.

¹⁵ See 31 U.S.C. § 3729 (2003) (Civil False Claims Act); 42 U.S.C. §§ 1320a-7b(b) (2003) (Anti-Kickback Statute); 42 U.S.C. §1395nn (2003) (Stark Law).

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necessary precondition for a legitimate fraud enforcement framework. The principle of regulatory clarity requires the development of clear rules governing the conduct of health care providers, supported by substantial penalties for clear violations. Under the current system, by contrast, fraud is addressed through a confusing combination of intricately detailed rules and vague aspirational pronouncements. While this approach offers the flexibility needed to address new developments in the ever-changing health care market, it less clearly serves the goals of clarity and efficiency—raising the troubling possibility that, in the eyes of the health care industry, we are willing to sacrifice the legitimacy of the enforcement process.

I. HEALTH CARE FRAUD AS A NATIONAL FOCUS

Health care fraud has been a top priority for federal law enforcement at least since 1994, when former Attorney General Janet Reno deemed it her “number two priority,” second only to violent crime.¹⁶ Although one might question whether the Department of Justice (DOJ) had more pressing priorities at the time, the motivation for the announcement was clear: as the authors of one treatise note, health care fraud is “where the money is.”¹⁷ The first audit of Medicare fee-for-service payments found that more than \$23 billion had been paid out improperly in fiscal year 1996 alone.¹⁸ Although the numbers have improved each year, auditors still estimate that \$12.1 billion in improper Medicare payments were made in fiscal year 2001.¹⁹

¹⁶ See 1994 ATT’Y GEN. ANN. REP., available at <http://www.usdoj.gov/ag/annualreports/ar94/finalag.txt> (last visited July 7, 2000).

¹⁷ ROBERT FABRIKANT, ET AL., HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE 1-3 (2002) (paraphrasing statements made by the infamous bank robber Willie Sutton).

¹⁸ See DEP’T OF HEALTH & HUMAN SERVICES, *supra* note 2 (reviewing 1996 data).

¹⁹ *Id.* Of course, it is not clear that all these improper payments can be attributed to “fraud” rather than to errors or good faith disagreements. See *Waste, Fraud, Abuse, and Mismanagement: Hearing Before the Task Force on Health of the House Committee on the Budget*, 106th Cong. 117 (2000)

Consistent with this focus, recent years have seen more funds appropriated to the federal agencies with jurisdiction over health care fraud, particularly the DOJ and the Department of Health & Human Services (HHS) Office of Inspector General (OIG). The key to this funding was the Health Insurance Portability and Accountability Act of 1996 (HIPAA).²⁰ Among other things, HIPAA created a “Fraud and Abuse Control Program” designed to coordinate federal, state, and local health care fraud enforcement efforts.²¹ The centerpiece of this effort is the “Health Care Fraud and Abuse Control Account,” which funds health care fraud inspections, investigations, and prosecutions undertaken by the DOJ and OIG.²² HIPAA set Control Account appropriations at \$104 million in fiscal year 1997, with an increase of up to 15 percent per year through 2003.²³ In fiscal year 2001, the Attorney General and the Secretary of HHS certified \$181 million for appropriation to the Control Account, with the Federal Bureau of Investigation (FBI) receiving a separate appropriation of \$88 million.²⁴

The DOJ and OIG benefit in both direct and indirect ways from these appropriations. Directly, this guaranteed source of funding has permitted the hiring of additional FBI and OIG agents assigned specifically to health care fraud.²⁵ Indirectly, a form of an

(statement of the OIG, explaining that the “objective is not to determine the extent of fraud in the Medicare program”), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:64510.wais.

²⁰ Pub. L. No. 104-191, 110 Stat. 1936 (1996).

²¹ *See* 42 U.S.C. § 1320a-7c (2003) (establishing the “Fraud and Abuse Control Program”).

²² 42 U.S.C. § 1395i(k)(3) (2003) (describing the appropriations to the account).

²³ *Id.* §§ 1395i(k)(3)(A)-(B) (setting out the maximum amounts available for appropriation).

²⁴ *See* ANNUAL REPORT 2001, *supra* note 4.

²⁵ *See, e.g., id.* at App. (noting that the FBI’s total allotment was used to support 445 existing agents and to hire an additional 30 agents); *Enforcement: Terrorism Focus Has Not Diverted Resources from Health Fraud Probes*, *FBI Official Says*, 6 HEALTH CARE FRAUD REP. (BNA) 155, 156 (Feb. 20, 2002) (stating the FBI expected to hire 2,000 more health care agents over the next two

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attenuated “bounty” system exists, whereby some of the money collected from health care fraud recoveries is available for appropriation back to the enforcement agencies. HIPAA directed the bulk of these recoveries to be deposited into the perennially near-insolvent Medicare Part A Trust Fund.²⁶ A significant portion of this money, however, can be appropriated back to the Health Care Fraud and Abuse Control Account to fund future law enforcement activities.²⁷ As one commentator has noted, “although this is not a pure bounty system, it is much closer than had previously been the case.”²⁸

These investments have clearly paid off. The DOJ recently announced that it recovered more than \$980 billion in civil health care fraud suits and investigations in fiscal year 2002.²⁹ This represents a slight reduction from fiscal year 2001, when the government won or negotiated more than \$1.7 billion in health care cases and collected \$1.3 billion.³⁰ Rather than signifying a downturn in enforcement activities, however, this difference is largely attributable to the fact that awards often are not collected in the same year in which they are negotiated, and to the ease with

years). In the fall of 2001, there were rumors that many of these agents had been pulled from health care investigations to staff anti-terrorism initiatives; however, the FBI later announced that health care fraud staffing remained unchanged. *Id.* (quoting FBI Health Care Unit Chief Timothy Delaney).

²⁶ 42 U.S.C. § 1395i(k)(2)(C) (authorizing the transfer of fines, penalties, and damages obtained in health care fraud cases to the Trust Fund); Sarah Lueck, *Some Premiums for Medicare to Rise 12.4%*, WALL ST. J., March 27, 2003, at B2 (reporting on Medicare’s insolvency).

²⁷ 42 U.S.C. § 1395i(k)(3) (explaining the appropriations process for the Health Care Fraud and Abuse Control Account).

²⁸ Roger Feldman, *The Regulation of Managed Care Organizations and the Doctor-Patient Relationship*, 30 J. LEGAL STUD. 569, 574 (2001) (discussing fraud and abuse in medical care and the inefficient attempts to curb it). *See also* Hyman, *supra* note 1, at 158 (“Although this structure prevents the government’s fraud control system from operating on a pure bounty system, there is still considerable suspicion in the provider community on this point.”).

²⁹ Press Release, Dep’t of 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.

³⁰ *See* ANNUAL REPORT 2001, *supra* note 4 (listing statistics).

which a particularly large settlement can skew the statistics for any given year.³¹

In addition to pursuing allegations of fraud against individual providers, the government developed proactive initiatives targeting particular sectors of the health care industry for intensive scrutiny. The prototype for such initiatives was “Operation Restore Trust,” a coordinated federal/state effort in the mid-1990s focusing on fraud by home health agencies, nursing homes, hospices, and durable medical equipment suppliers in states with large Medicare populations.³² Subsequent national and regional initiatives have included the “72-Hour Window Project” targeting hospital bills for outpatient services provided within 72 hours of a related inpatient admission,³³ the “Physicians at Teaching Hospitals” (PATH) investigations targeting academic institutions where attending physicians have billed for services actually provided by interns and residents,³⁴ and the “Lab Unbundling Project” investigating hospital laboratories that may improperly have submitted separate bills for laboratory tests performed simultaneously.³⁵ In the future, we are likely to see continued targeting of entire sectors of the health care industry, with better coordination among the relevant state and federal authorities.

Similarly, history teaches us that the anti-fraud focus tends to be cyclical. At the start of the 1990s, the focus was squarely on

³¹ *Id.* (“It should be emphasized that some of the judgments, settlements, and administrative impositions in 2001 will result in collections in future years, just as some of the collections in 2001 are attributable to actions from prior years.”).

³² See OFFICE OF INSPECTOR GEN., ORT 12-96-00020, OPERATION RESTORE TRUST ACTIVITIES (1995) (describing the initiative), available at <http://oig.hhs.gov/oei/reports/oei-12-96-00020.pdf>.

³³ See GEN. ACCOUNTING OFFICE, GAO/HEHS-98-195, MEDICARE: APPLICATION OF THE FALSE CLAIMS ACT TO HOSPITAL BILLING PRACTICES (July 1998) (reviewing the 72-Hour Window Project).

³⁴ See Pamela H. Bucy, *The PATH from Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 ST. LOUIS U. L.J. 3 (2000) (describing the PATH initiative).

³⁵ See GEN. ACCOUNTING OFFICE, *supra* note 33 (reviewing the Lab Unbundling Project).

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prescription drug sales and marketing activities.³⁶ Within a few years, the focus had shifted to fraudulent activities by laboratories,³⁷ to PATH audits of teaching physicians,³⁸ and to alleged improprieties by hospices and home health agencies.³⁹ By the late 1990s, nursing homes increasingly found themselves under scrutiny for fraud based on alleged quality-of-care deficiencies.⁴⁰ Most recently, there has been renewed interest in the activities of prescription drug companies, this time involving pricing practices in addition to sales and marketing activities.⁴¹ Thus, health care providers can take little comfort in current enforcement priorities: if one health care sector currently is not on the fraud “radar screen,” history tells us that it soon may be.

For a variety of reasons, it is not altogether clear what the Bush Administration will do with regard to health care fraud enforcement. Attorney General John Ashcroft indicated his support for some health care fraud initiatives in his confirmation hearings, albeit perhaps not as strongly as his predecessor.⁴² And after

³⁶ See OFFICE OF THE INSPECTOR GEN., OEI-01-90-00480, PROMOTION OF PRESCRIPTION DRUGS THROUGH PAYMENTS AND GIFTS (1991).

³⁷ See Leon Aussprung, *Fraud and Abuse: Federal Civil Health Care Litigation and Settlement*, 19 J. LEG. MED. 1, 8-9 (1998) (describing “Labscam” cases); Office of the Inspector Gen., Special Fraud Alert: Arrangements For the Provision of Clinical Laboratory Services (1994), reprinted in Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994) (warning of fraudulent laboratory practices).

³⁸ See generally Bucy, *supra* note 34 (describing the PATH initiative).

³⁹ See, e.g., Publication of OIG Special Fraud Alert on Physician Liability For Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 Fed. Reg. 1813 (Jan. 12, 1999), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/dme.htm>; Publication of OIG Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements With Hospices, 63 Fed. Reg. 20,415 (Apr. 24, 1998).

⁴⁰ See Publication of the OIG Compliance Program Guidance for Nursing Home Facilities, 65 Fed. Reg. 14,289, 14,295 n.49 (Mar. 16, 2000).

⁴¹ See Publication of the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 1993) (setting forth the OIG’s general views on drug manufacturer activities).

⁴² See, e.g., *Ashcroft Views Qui Tam Provisions as “Vital” in Fight Against Fraud*, HEALTH L. NEWS, Mar. 2001, at 10.

September 11, 2001—and the recent corporate fraud scandals—the DOJ may have more immediate enforcement priorities.⁴³ Clearly it would be a mistake, however, for health care providers to assume they can act with impunity because the government's attention lies elsewhere.

II. KEY HEALTH CARE FRAUD LAWS

Health care fraud is addressed by a variety of federal and state laws. Some of these laws, such as the Medicare and Medicaid Anti-Kickback Statute, are directed at improper activities in the health care market.⁴⁴ Others, such as the Civil False Claims Act (FCA), apply more broadly to entities that transact business with the federal government.⁴⁵ Health care fraud also is actionable under broad criminal statutes such as Mail and Wire Fraud, which are applicable to criminal conduct regardless of the business context in which it occurs.⁴⁶ Of these myriad statutes, the FCA, Anti-Kickback Statute, and “Stark Law” self-referral prohibitions are by far the most important to health care providers on a daily basis. An introduction to these laws is necessary before the tripartite enforcement model can be understood.

⁴³ The DOJ FY 2004 budget request identified anti-terrorism efforts as the Department's first goal; combating corporate fraud was listed second. *See* Press Release, Dep't of Justice, Department of Justice Requires \$23.3 Billion to Prevent and Combat Terrorism, Drug Crime, Crimes Against Children, and Corporate Fraud (Feb. 3, 2003), *available at* http://www.usdoj.gov/opa/pr/2003/February/03_ag_067.htm. The DOJ FY 2002 Performance & Accountability Report, however, identifies health care fraud as the key focus of the Department's second strategic goal, enforcing federal criminal laws. *See* DEP'T OF JUSTICE, FY 2002 PERFORMANCE AND ACCOUNTABILITY REPORT, Strategic Goal 2.4A (Reduce Fraudulent Practices in the Health Care Industry) (2003), *available at* <http://www.usdoj.gov/ag/annualreports/ar2002/sg2finalacctperftpt.htm>.

⁴⁴ 42 U.S.C. §§ 1320a-7b(b) (2003).

⁴⁵ 31 U.S.C. § 3729 (2003).

⁴⁶ 18 U.S.C. §§ 1341, 1343, 1346 (2003). *See, e.g.*, *United States v. Talbott*, 590 F.2d 192 (6th Cir. 1978) (affirming convictions for mail fraud and conspiracy to commit mail fraud based on a fraudulent scheme involving Medicaid dental benefits).

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A. Civil False Claims Act

The FCA was enacted in 1863 in response to reports of “rampant fraud” perpetrated on the Union army during the Civil War.⁴⁷ While the statute prohibits a variety of fraudulent activities, the most commonly invoked provision imposes liability on a defendant when: (1) the defendant presents (or causes to be presented⁴⁸) a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the defendant’s acts are undertaken “knowingly.”⁴⁹ This mental state includes not only actual knowledge, but also deliberate ignorance or reckless disregard of truth or falsity.⁵⁰ The types of “claims” subject to the Act include “any request or demand . . . for money or property” if any portion thereof comes from the federal government.⁵¹

⁴⁷ See S. REP. NO. 99-345, at 8 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5273 (noting that President Lincoln signed the FCA to combat rampant fraud in Civil War defense contracts); *see generally* JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 1-1 to 1-38 (Supp. 1999) (providing an historical overview of the Act).

⁴⁸ “Cause to be presented” liability generally applies where the person responsible for the falsity does not actually submit the claim, but rather directs others (who may not know of the falsity) to submit the claim on his behalf. *See, e.g.*, *United States v. Kensington Hospital*, 760 F. Supp. 1120, 1125 (E.D. Pa. 1991) (alleging that physicians who were suspended from the Medicaid program “caused” a hospital to submit improper bills on their behalf).

⁴⁹ See 31 U.S.C. § 3729(a)(1) (2003). *See also* BOESE, *supra* note 47, at 2-9 (noting that violations of § 3729(a)(1) are the most common cause of liability under the FCA). A fourth potential element, harm to the government, remains controversial. *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, 162-89 (2001) (discussing judicial approaches to fiscal harm under the FCA). Other relevant FCA provisions include § 3729(a)(2) (prohibiting the use of false records or statements to get a false or fraudulent claim allowed or paid); § 3729(a)(3) (prohibiting conspiracies “to defraud the government by getting a false or fraudulent claim allowed or paid”); and § 3729(a)(7) (prohibiting “reverse false claims,” in which false records or statements are used “to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government”).

⁵⁰ 31 U.S.C. § 3729(b) (2003).

⁵¹ *See id.* § 3729(c).

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.⁵² Due to the way health care services are billed, it does not take long for such penalties to reach significant levels. Most health care providers generate a bill for *each occasion* of services rendered to *each patient*, resulting in the submission of thousands of small claims a year.⁵³ Fraud tends to occur in small amounts, such as a few cents or a few dollars per claim.⁵⁴ While treble damages are likely to be relatively reasonable in such cases, the per-claim penalties mount quickly.⁵⁵ In *United States v. Krizek*, for example, a psychiatrist was accused of submitting 8,002 claims, each inflated by approximately \$30, for total damages of \$245,000.⁵⁶ At trial, the government requested penalties of \$10,000 per claim, for a total of \$81 million.⁵⁷ Combined with the threat of exclusion from federal health care programs, the FCA is one of the major reasons health care providers desire to settle fraud allegations.⁵⁸ Thus, this general anti-fraud law has become a key

⁵² *Id.* § 3729(a); 28 C.F.R. § 85.3(a)(9) (1999) (increasing statutory penalties by 10 percent).

⁵³ See Bucy, *supra* note 34, at 38 (“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.”). See also 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, 259 (describing “a steady stream of small claims, resulting, in the aggregate, in enormous volumes of claims”).

⁵⁴ See Bucy, *supra* note 34, at 38 (“[A]lthough the total amount of loss per fraud scheme may be large, health care fraud usually is committed in small dollar increments (\$2 per claim form, for example).”).

⁵⁵ See Jost & Davies, *supra* note 53, at 260 (“Even if individually quite small . . . astronomical sums are quickly reached.”).

⁵⁶ 111 F.3d 934, 936 (D.C. Cir. 1997).

⁵⁷ *Id.* On appeal, the D.C. Circuit upheld FCA liability on a theory of “reckless disregard,” but remanded for a variety of evidentiary issues pertaining to the calculation of damages and penalties. *Id.* at 943. The appeals in the case continued through 1999, at which time the D.C. Circuit noted, “It is time for the parties to stop refighting battles long-ago lost and for the district court to bring this prosecution to an expeditious close.” *United States v. Krizek*, 192 F.3d 1024, 1031 (D.C. Cir. 1999).

⁵⁸ See 42 U.S.C. § 1320a-7 (2003) (setting forth grounds for exclusion from

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component of the government's war against health care fraud.

One reason the FCA has been so successful is the law's *qui tam* provisions, which permit private "relators" who sue on the government's behalf to retain 15 to 30 percent of the proceeds of the suit—creating a powerful incentive for private parties to police their neighbors in the health care market.⁵⁹ 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 exponentially.⁶⁰ By 1998, nearly two-thirds of the *qui tam* suits filed concerned the federal health care programs, compared to only 12 percent in 1987.⁶¹ This powerful civil law can thus be invoked not only by federal prosecutors, but also by competitors, employees, and even patients and their families—making the FCA a significant threat to health care providers who receive payment from federal health care programs.

Traditionally, health care FCA cases have involved misrepresentation of the facts surrounding the services for which payment is requested, such as the submission of claims for services that were never rendered.⁶² Still unanswered is the question of whether the FCA can be used as a vehicle for suits alleging violations of other federal health care program requirements. Recently, prosecutors and *qui tam* relators have invoked the law in situations where health care services were in fact delivered to patients, but where the claimants may have violated underlying legal requirements (such as the federal anti-referral laws) in

federal health care programs); Krause, *supra* note 49, at 202-12 (discussing FCA settlements). See also Joan H. Krause, "Promises to Keep": Health Care Providers and the Civil False Claims Act, 23 CARDOZO L. REV. 1363 (2002) [hereinafter Krause, "Promises to Keep"].

⁵⁹ See 31 U.S.C. §§ 3730(b), (d) (2003) (noting that a private person who brings a civil action may potentially receive 15 to 30 percent of the proceeds, depending on factors such as whether the government joins in the suit).

⁶⁰ See False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986).

⁶¹ See Fried Frank Harris Shriver & Jacobson, FCA Statistics, at <http://www.ffhsj.com/quitam/fcastats.htm> (last visited Feb. 10, 2003).

⁶² See, e.g., Peterson v. Weinberger, 508 F.2d 45, 47-48 (5th Cir. 1975) (imposing liability on a physician who billed Medicare for physical therapy services that had not been performed).

furnishing the care.⁶³ Although few court opinions address the merits of such suits, these arguments have been quite successful at generating settlements.⁶⁴

B. Medicare & Medicaid Anti-Kickback Statute

The Medicare & Medicaid Anti-Kickback Statute is the major federal law affecting financial relationships within the health care market.⁶⁵ The 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.⁶⁶ Unlike the FCA, the Anti-Kickback Statute is a *criminal* law specifically targeting improper activities involving health care items and services.⁶⁷ This broadly-drawn statute governs a wide range of financial relationships, including those among health care providers, between health care providers and their patients, and between health care providers and the manufacturers/suppliers from whom they purchase health care products. At core, the statute seeks to limit the influence of financial incentives over health care decisions, demanding that such decisions be made solely on the basis of which products and services will best serve the interests of the *patient*, rather than the provider.⁶⁸

⁶³ See Krause, “Promises to Keep”, *supra* note 58, at 1391-1406 (discussing health care FCA cases).

⁶⁴ See *id.* at 1404; *infra* Part III.C.2.a.

⁶⁵ 42 U.S.C. § 1320a-7b(b) (2003).

⁶⁶ *Id.*

⁶⁷ *Id.* § 1320a-7(b) (specifying criminal penalties).

⁶⁸ See, e.g., Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies, or Cost-Effectiveness?: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 282 (1999) (“The main purpose of the antikickback law may be summarized most succinctly as preventing inappropriate financial considerations from influencing the amount, type, cost, or selection of the provider of medical care received by a federal health care program beneficiary.”); Medicare and Medicare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 54 Fed. Reg. 3,088, 3,089 (proposed Jan. 23,

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More specifically, the statute prohibits: (1) the knowing and willful; (2) offer or payment (or solicitation or receipt); (3) of any form of remuneration; (4) to induce someone to refer patients or to purchase, order, or recommend; (5) any item or service that may be paid for under a federal health care program.⁶⁹ Several aspects of this definition require elaboration. First, because the statute prohibits both the offer/payment and the solicitation/receipt of remuneration, *both* parties to an improper transaction are subject to prosecution (provided, of course, they have the requisite intent). Second, the definition of “remuneration” is quite broad, incorporating payment made “directly or indirectly, overtly or covertly, in cash or in kind.”⁷⁰ As such, the prohibition extends beyond simple kickbacks and bribes to reach not only the exchange of money, but anything of value or any type of benefit offered to the referring party, including relieving that party of a financial burden she would otherwise have to bear.⁷¹

Third, the concept of *intent* is key to understanding the statute. Unfortunately, intent has been used to refer to two similar yet distinct concepts in Anti-Kickback jurisprudence. The first is the general motivation behind the questionable financial relationship—whether it was designed *to induce* the referral of patients or the purchase of items or services. In this respect, the law has been interpreted quite broadly to encompass situations in which even *one purpose* of the remuneration—rather than the sole or primary purpose—is to induce prohibited referrals.⁷² Recognizing that few

1989) (to be codified at 42 C.F.R. pt. 1001) (“[I]t is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance to this market.”).

⁶⁹ 42 U.S.C. § 1320a-7b(b).

⁷⁰ *Id.* §§ 1320a-7b(b)(1) & (2).

⁷¹ *See, e.g.*, Medicare and Medicare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 54 Fed. Reg. at 3,090 (describing abusive rental schemes).

⁷² *See, e.g.*, *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) (“[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.”); *United States v. Greber*, 760 F.3d 68, 72 (3d Cir. 1985) (“If the payments were intended to induce the physician to use [defendant’s] services, the statute was violated, even if the payments were also

transactions are entered into without at least *some* contemplation of business advantage, however, the Tenth Circuit recently acknowledged that “a hospital or individual may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from the doctor, as long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals.”⁷³ Whether it will be feasible to parse the parties’ motivations in such a detailed manner remains to be seen.

The second meaning of intent tracks the traditional criminal law definition of *mens rea*: did the parties make or receive the improper payments with the requisite “knowing and willful” state of mind?⁷⁴ In *Hanlester Network v. Shalala*, the Ninth Circuit held that a violation of the statute could not be found unless the defendant both *knew* that the law prohibited giving or receiving remuneration in return for referrals and acted with the *specific intent* to violate the statute.⁷⁵ Although this narrow interpretation was heartening to the health care industry, it remains confined to those parties falling within the Ninth Circuit’s jurisdiction. Courts in other circuits have declined to adopt such a stringent intent standard, finding that the Anti-Kickback Statute is not the sort of “highly technical . . . regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct,” for which

intended to compensate for professional services.”).

⁷³ *McClatchey*, 217 F.3d at 834. The court, however, gave no indication of how to separate the parties’ collateral hopes and expectations from their “purpose” in such situations. *See also* *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989) (approving a jury instruction that prohibited conviction if the improper purpose was “incidental” or “minor”).

⁷⁴ *Mens rea* is defined as “[t]he state of mind that the prosecution, to secure a conviction, must prove that a defendant had when committing a crime; criminal intent or recklessness.” BLACK’S LAW DICTIONARY 1999 (7th ed. 1999).

⁷⁵ 51 F.3d 1390, 1400 (9th Cir. 1995) (relying on *Ratzlaf v. United States*, 510 U.S. 135 (1994), in which the Supreme Court addressed willfulness in the context of the prohibition against structuring financial transactions to avoid currency reporting requirements, 31 U.S.C. § 5322).

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specific intent is appropriate.⁷⁶ At present, then, the applicable *mens rea* standard will vary depending on the jurisdiction in which the action is brought.

Finally, it is important to remember that the statute applies to referrals made in connection with beneficiaries of *any* of the federal health care programs.⁷⁷ For many years the prohibition applied only to Medicare and Medicaid patients, leaving an apparent loophole for improper behavior in other federally-funded programs.⁷⁸ As of January 1, 1997, however, the prohibition is applicable to all federal health care programs other than the Federal Employees Health Benefits Program (FEHBP).⁷⁹ While a case involving significant monetary damage to the federal health care programs may present a particularly attractive target for federal prosecutors, no actual payment by the government is required; the mere *potential* for increased costs will suffice.⁸⁰

Penalties for violating the statute are severe, consisting of both criminal and civil/administrative sanctions: violation of the statute is a felony, punishable by up to five years in prison and/or a fine of

⁷⁶ *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (paraphrasing *Bryan v. United States*, 118 S. Ct. 1939, 1946 (1998)). *See also* *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996) (requiring proof that the defendant “knew that his conduct was wrongful, rather than proof that he knew it violated a known legal duty”). For a general discussion of these issues, see Timothy J. Aspinwall, *The Anti-Kickback Statute Standard(s) of Intent: The Case for a Rule of Reason Analysis*, 9 *ANNALS HEALTH L.* 155 (2000); Sharon L. Davies, *The Jurisprudence of Willfulness: An Evolving Theory of Excusable Ignorance*, 48 *DUKE L.J.* 341 (1998).

⁷⁷ 42 U.S.C. § 1320a-7-b(b) (2003).

⁷⁸ *See* Health Insurance Portability & Accountability Act, Pub. L. No. 104-191, § 204, 110 Stat. 1936, 1999 (amending 42 U.S.C. § 1320a-7b (2003)).

⁷⁹ *Id.* The FEHBP, the health insurance program for federal employees, is likely excluded for two reasons: (1) it is an employment benefit program, rather than a social welfare or entitlement program; and (2) it is administered by the Office of Personnel Management, rather than by HHS. *See* 5 C.F.R. § 890 (2003).

⁸⁰ *See, e.g., United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980) (“The potential for increased costs if such . . . agreements become an established and accepted method of business is clearly an evil with which the court was concerned and one Congress sought to avoid in enacting [the statute].”).

up to \$25,000.⁸¹ Upon conviction, the defendant is subject to exclusion from all federal health care programs, a potentially fatal blow for entities that derive substantial revenues from such business.⁸² In lieu of a criminal prosecution, the OIG may also seek “permissive” exclusion of the provider.⁸³ Prior to being excluded, the provider will receive notice and an opportunity to request a hearing before an administrative law judge (ALJ).⁸⁴ Although the provider has the right to an attorney, to discovery, and to present evidence on its behalf, the administrative hearing is not identical to a trial and the ALJ is not bound by the Federal Rules of Evidence.⁸⁵ Thus, one of the most severe penalties available for violating the statute—exclusion from all federal health care programs—can be imposed without a full-fledged civil or criminal proceeding.

Prior to the late 1990s, the OIG had indicated that it would not seek to exclude entities who were not paid directly by the federal health care programs, such as drug manufacturers who sell their products to physicians and pharmacists (who may in turn submit claims for reimbursement).⁸⁶ In 1998, however, the OIG reversed course and issued regulations permitting the exclusion of entities that “indirectly furnish” items and services to federal health care program beneficiaries.⁸⁷ Because of the potential for exclusion—as

⁸¹ 42 U.S.C. § 1320a-7b.

⁸² The OIG must exclude individuals and entities convicted of a felony related to health care fraud, and may exclude them for misdemeanor convictions. *See* 42 U.S.C. § 1320a-7(a).

⁸³ 42 U.S.C. § 1320a-7(b)(7) (permitting the exclusion of “[a]ny individual or entity that the Secretary determines has committed an act which is described in section . . . 1128B . . .”); 42 C.F.R. § 1001.951 (2003) (permitting exclusion in limited circumstances).

⁸⁴ 42 C.F.R. § 1001 (2003).

⁸⁵ *See* 42 C.F.R. §§ 1005.3 (2003) (rights of parties), 1005.17 (evidence), & 1005.21 (appeals).

⁸⁶ *See* Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from Public Law 100-93, 57 Fed. Reg. 3298, 3300 (Jan. 29, 1992) (declining to invoke the exclusion authority against manufacturers).

⁸⁷ *See* Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. 46,676 (Sept. 2,

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well as civil and criminal sanctions—it is fair to say that the Anti-Kickback Statute now poses a significantly stronger threat to drug manufacturers than in the past.

Violations of the statute are also punishable by civil and administrative monetary sanctions.⁸⁸ The government has the authority to impose a civil monetary penalty (CMP) for violation of the statute in the amount of \$50,000 for each violation, plus not more than three times the remuneration involved.⁸⁹ In theory, this provision has the potential to dwarf even the FCA provisions, under which penalties presently are limited to \$11,000 per violation.⁹⁰ In reality, however, this relatively new CMP has not often been invoked.

As noted above, some courts have now permitted *qui tam* actions under the FCA based on allegations that the defendant violated the Anti-Kickback Statute.⁹¹ In *United States ex rel. Pogue v. American Healthcorp. Inc.*, for example, a relator alleged that the defendant hospitals and physicians had submitted claims for services furnished pursuant to referrals that violated the Medicare & Medicaid Anti-Kickback Statute and the Stark Law.⁹² The relator argued that because compliance with the anti-referral laws was a prerequisite for participation in Medicare and Medicaid, any claims submitted in violation of these provisions were, by definition, false and fraudulent.⁹³ In other words, the relator posited that the defendants were liable because the government *would not have paid* them for their services had it

1998) (codified at 42 C.F.R. § 1001.10 (2003)). The OIG characterized its about-face as a “clarification,” rather than a change in policy. *Id.*

⁸⁸ 42 U.S.C. § 1128A(a)(7) (2003) (imposing civil penalty on a person who “commits an act described in paragraph (1) or (2) of section 1128B(b)”).

⁸⁹ *Id.*

⁹⁰ 28 C.F.R. § 85.3(a)(9) (2003).

⁹¹ *See supra* notes 63-64 and accompanying text.

⁹² 914 F. Supp. 1507, 1508 (M.D. Tenn. 1996) (denying defendants’ motion to dismiss).

⁹³ *See id.* at 1509. The district court initially rejected the relator’s theory, *see United States ex. rel. Pogue v. American Healthcorp, Inc.*, No. 3-94-0515, 1995 WL 626514 (M.D. Tenn. Sept. 14, 1995), but later reconsidered. *See Pogue*, 914 F. Supp. at 1507 (granting motion to reconsider).

known of the referrals.⁹⁴ While this proposition has not been accepted by all jurisdictions,⁹⁵ such cases raise troubling concerns for providers—especially to the extent they essentially create a private right of action for kickbacks.

The language of the Anti-Kickback Statute is very broad, as have been judicial interpretations of the law. As commentators have noted, “[t]he statute has been held applicable to a wide variety of financial relationships that are quite different from an obvious kickback for a patient referral or a bribe to recommend the purchase of specific products or services.”⁹⁶ Read literally, the statute prohibits the transfer of *any* amount of remuneration to a potential referral source—including a hospital or drug company offering physicians free pens, paper, or coffee and donuts. Intuitively, it may appear that such minor gifts are unlikely to influence physician referral practices, and are not worth the time and energy required for a successful prosecution.⁹⁷ The statute contains no dollar threshold, though, and the few cases to

⁹⁴ 914 F. Supp. at 1509.

⁹⁵ *See, e.g.*, United States ex. rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997) (rejecting per se approach and limiting FCA’s application to situations in which the claimant falsely certifies compliance with a condition that is a prerequisite for payment).

⁹⁶ Bulleit & Krause, *supra* note 68, at 283.

⁹⁷ *But see* Mary-Margaret Chren et al., *Doctors, Drug Companies, and Gifts*, 262 J. AM. MED. ASS’N 3448, 3449 (1989) (“Even mundane things . . . can have significance when they are gifts—a book is not simply a book if it is used to engender a response.”); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASS’N 373, 376 (2000) (concluding that there is “an independent association between benefiting from sponsored meals and formulary additional requests” for drugs). Although prosecutors might appear to be unlikely to pursue such small cases, the OIG repeatedly has warned the industry about offering even minimal gifts to referral sources. *Cf.* Notice, Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55,855 (Aug. 30, 2002), *available at* <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf> (permitting providers to offer beneficiaries “inexpensive gifts” under 42 U.S.C. § 1320a-7a(a)(5), defined as gifts having no more than \$10 individual retail value and no more than \$50 annually per patient).

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recognize a *de minimis* exception have set the bar extremely low.⁹⁸ Thus, while the statute is very good at prohibiting all financial ties that *might* impermissibly influence referral decisions, it is not very good at distinguishing truly problematic activities from ones that are neutral—or perhaps even beneficial for the industry.⁹⁹

Fortunately, Congress has “recognized that the Anti-Kickback Statute’s broad language ha[s] the potential for creating confusion in the health care industry regarding the legality of many commonplace business arrangements.”¹⁰⁰ The statute contains explicit exceptions for a few categories of activities, including discounts and payment to employees.¹⁰¹ Moreover, Congress directed the Secretary of HHS to issue regulations exempting additional practices from the scope of the law.¹⁰² These regulations—known as the “safe harbors”—identify “transactions that are deemed to pose little or no threat of abuse or to be otherwise desirable or legitimate arrangements,” and hence do not violate the statute.¹⁰³ The initial safe harbors were published in 1991; a second set of exceptions followed in 1992, with significant

⁹⁸ See, e.g., Inspector General v. Hanlester Network, Dec. No. 1275 (HHS Dept. App. Bd., App. Div., 1991), *reprinted in* Medicare & Medicaid Guide (CCH), 1992-1 Transfer Binder, ¶ 39,566 at 27,763 n.34 (noting that “*de minimis* or very remote forms of remuneration, such as drug samples or recruitment lunches, may not be subject to prosecution . . . If the remuneration offered is unlikely to affect physician referral decisions, it is probably not intended to induce referrals” under the statute).

⁹⁹ See Aspinwall, *supra* note 76, at 182-84 (discussing the need for a rule of reason” analysis to prevent the Anti-Kickback Statute from restricting the development of innovative cost-effective health care arrangements).

¹⁰⁰ 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. MICH. ST. U. DETROIT. C.L. 1, 7 (2001).

¹⁰¹ See 42 U.S.C. § 1320a-7b(b)(3) (2003) (exempting practices such as discounts, employment compensation, and group purchasing organizations from the scope of the prohibition).

¹⁰² See Medicare & Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697-98 (1998).

¹⁰³ John T. Boese & Beth C. McClain, *Why Thompson is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 ALA. L. REV. 1, 26 (1999); see generally 42 C.F.R. § 1001.952 (2003) (safe harbor regulations).

amendments finalized in 1999.¹⁰⁴ Pursuant to HIPAA, the OIG is required to solicit recommendations from the public for adding or revising the safe harbors on an annual basis.¹⁰⁵

The safe harbors address a variety of common business transactions, such as personal services contracts and the lease of office space and equipment, as well as such health-care-specific activities as the sale of a medical practice and subsidization of malpractice insurance.¹⁰⁶ As the name suggests, “parties who structure their business arrangements to satisfy all the criteria of an applicable safe harbor are sheltered from liability under the Anti-Kickback Statute.”¹⁰⁷ In general, the safe harbor requirements are very narrow and do not provide protection for many real-life business arrangements.¹⁰⁸ Because a statutory violation can be proven only if there is sufficient evidence of *intent*, however, arrangements that do not fall within a safe harbor are *not* necessarily illegal.¹⁰⁹

In determining whether to prosecute under the statute, the OIG has said that it will look to a variety of factors, including: (a) the

¹⁰⁴ 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 & State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991).

¹⁰⁵ See 42 U.S.C. § 1320a-7d(a).

¹⁰⁶ See generally 42 C.F.R. § 1001.952 (2003) (listing the safe harbor provisions).

¹⁰⁷ Rabecs, *supra* note 100, at 7.

¹⁰⁸ 42 C.F.R. § 1001.952. While each safe harbor has specific criteria, common requirements include: (1) a signed written agreement; (2) a minimum one-year term; (3) payment consistent with “fair market value”; and (4) compensation set in advance and not dependent on the volume/value of referrals or other business between the parties. See, e.g., 42 C.F.R. § 1001.952(d) (describing the criteria for personal services and management contracts).

¹⁰⁹ See Medicare and State Health Care Programs, 56 Fed. Reg. at 35,954 (stating that the legality of an arrangement will depend upon a fact-specific analysis).

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potential for increased charges or costs to payers, especially the government; (b) the potential encouragement of overutilization (*i.e.*, the ordering or performance of health care services beyond those which are medically necessary); (c) the potential for adverse effects on competition; and (d) the intent of the parties.¹¹⁰ As discussed below, recent years have seen a proliferation of Anti-Kickback guidance in addition to the safe harbors, including Advisory Opinions, Special Fraud Alerts, and Special Advisory Bulletins.¹¹¹

C. Limitations on Physician Self-Referrals (“Stark Law”)

Originally introduced by Representative Fortney “Pete” Stark as the “Ethics in Patient Referrals Act of 1989,” the so-called “Stark Law” was enacted as part of the Omnibus Budget Reconciliation Act of 1989.¹¹² The Stark Law is a civil statute designed to prohibit the referral of Medicare and Medicaid patients to health care providers with whom the referring physician has a financial relationship.¹¹³ The statute was enacted in response to studies suggesting an unexplained increase in the utilization of Medicare laboratory services when the referring physician had a financial interest in the laboratory to which the patients were referred.¹¹⁴

The original legislation, which has come to be known as “Stark I,” took effect on January 1, 1992, and applied to the referral of Medicare patients for clinical laboratory services.¹¹⁵ Several years later, as part of the Omnibus Budget Reconciliation Act of 1993

¹¹⁰ *See id.* at 35,954, 35,956.

¹¹¹ *See infra* Part III.B.

¹¹² 101 Pub. L. No. 239, § 6204, 103 Stat. 2106 (1989), codified at 42 U.S.C. § 1395nn (2003).

¹¹³ 42 U.S.C. § 1395nn (2003).

¹¹⁴ *See* Medicare Program: Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services, 57 Fed. Reg. 8,588, 8,589 (proposed May 11, 1992) (to be codified at 42 C.F.R. pt. 411) (describing studies).

¹¹⁵ *See* Pub. L. No. 239, § 6204, 103 Stat. 2106 (specifying the original prohibition).

(OBRA '93), Congress extended the prohibition to Medicaid patients and expanded it to include a list of ten additional “designated health services”—including inpatient and outpatient hospital services, outpatient prescription drugs, physical and occupational therapy, and home health services—as of December 31, 1994.¹¹⁶

The Stark Law takes a different approach than the Anti-Kickback Statute, which looks for abuses on a case-by-case basis.¹¹⁷ Instead, Stark prohibits *all* patient referrals if a relevant financial relationship exists, subject to numerous narrowly drawn exceptions.¹¹⁸ In its most basic form, the law prohibits referrals of patients for designated health services if the referring physician (or an immediate family member) has a “financial relationship” with the entity providing the services—a category that includes both ownership/investment and compensation relationships.¹¹⁹ An entity that provides such designated health services may not bill *anyone* for services furnished as a result of a prohibited referral.¹²⁰ To the extent it contains no intent requirement, the law is in essence a strict liability prohibition.

The relevant definitions under the statute are correspondingly broad.¹²¹ Most notably, the compensation arrangements that trigger the prohibition include *any* arrangement involving *any* remuneration—directly or indirectly, overtly or covertly, in cash and in kind—between the physician (or an immediate family member) and the health care entity.¹²² Ownership and investment interests include those held in equity, debt, or by any other means.¹²³ Prohibited referrals include (a) the request or

¹¹⁶ See Pub. L. No. 103-66, §§ 13562 & 13624, 107 Stat. 31 (1993). The other designated health services are radiology, radiation therapy, durable medical equipment, parenteral and enteral nutrients, and prosthetics/orthotics. 42 U.S.C. § 1395nn(h)(6).

¹¹⁷ 42 U.S.C. § 1320a-7b(b) (2003).

¹¹⁸ 42 U.S.C. §§ 1395nn(a)-(e).

¹¹⁹ *Id.* § 1395nn(a) (general prohibition).

¹²⁰ *Id.*

¹²¹ *Id.* § 1395nn(h).

¹²² *Id.* § 1395nn(h)(1).

¹²³ *Id.* § 1395nn(a)(1). To further complicate things, HHS interprets these

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establishment by a physician of a plan of care that includes the provision of designated health services, and (b) the request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for consultation with another physician as well as any test or procedure ordered by, or performed by or under the supervision of, the consulting physician.¹²⁴

Unlike the Anti-Kickback Statute, the Stark Law is not a criminal statute and is not punishable by imprisonment. From the perspective of health care providers, however, the consequences may be nearly as dire. The statute prohibits payment for a designated health service furnished pursuant to a prohibited referral: claims for such services will be denied, and any payments erroneously received must be refunded.¹²⁵ Moreover, any person who knowingly submits or causes a bill to be submitted for prohibited services is subject to a civil monetary penalty of up to \$15,000 for *each* such service.¹²⁶ If those provisions are not onerous enough, violation of Stark also constitutes grounds for exclusion from the federal health care programs—the equivalent of a financial “death penalty” for many health care providers.¹²⁷

The harshness of the Stark prohibition is mitigated, to a certain extent, by numerous statutory exceptions.¹²⁸ Yet here, too, the law is stricter than the Anti-Kickback Statute: because there is no intent requirement, the law is violated unless *all* the criteria for an

definitions to apply to “indirect” as well as “direct” financial relationships. *See* 42 C.F.R. § 411.354 (2003).

¹²⁴ 42 U.S.C. § 1395nn(h)(5).

¹²⁵ *Id.* § 1395nn(g)(1)-(2).

¹²⁶ *Id.* §§ 1395nn(g)(3) (per-service penalty) & (g)(4) (imposing a penalty of up to \$100,000 for an “arrangement or scheme” designed to circumvent the prohibition).

¹²⁷ *Id.* § 1395nn(g)(3)-(4) (referencing exclusion provisions in 42 U.S.C. § 1320a-7). For a discussion of the ways in which such civil actions can be considered to have a “punitive” effect, see generally, Kenneth Mann, *Punitive Civil Sanctions: The Middleground between Criminal and Civil Law*, 101 *YALE L.J.* 1795 (1992).

¹²⁸ 42 U.S.C. § 1395nn(b)-(e).

exception are met.¹²⁹ The exceptions are divided into three categories: (1) general exceptions, which apply to both ownership and compensation arrangements; (2) exceptions relating only to ownership or investment interests; and (3) exceptions relating to compensation arrangements.¹³⁰ General exceptions include such things as ancillary services provided in a physician's office (such as an in-office laboratory) or services provided by another physician in the referring physician's group practice.¹³¹ Exceptions applicable to ownership/investment interests include the types of investments that might be made by a layperson, such as the purchase of publicly traded securities or mutual funds.¹³² Not surprisingly, the exceptions applicable to compensation arrangements include a number of common business practices, many of which have corresponding Anti-Kickback safe harbors (such as the rental of office space or equipment, *bona fide* employment, and personal services arrangements).¹³³

As described below, a great deal of uncertainty continues to surround the status of the Stark II regulations, which have yet to be completed.¹³⁴ Moreover, issues similar to those under the Anti-Kickback Statute have arisen regarding the propriety of using alleged Stark Law violations as the basis for suits under the FCA.¹³⁵ In fact, the majority of alleged Stark Law violations thus

¹²⁹ *Id.*

¹³⁰ *Id.* Additional exceptions were added by the regulations. *See* 42 C.F.R. §§ 411.355, 411.357 (2003).

¹³¹ *Id.* § 1395nn(b)(1)-(2); 42 C.F.R. § 411.355. For both exceptions, the physician group must meet the complicated definition of a "group practice." *Id.* § 1395nn(h)(4); 42 C.F.R. § 411.352.

¹³² 42 U.S.C. § 1395nn(c); 42 C.F.R. § 411.356.

¹³³ 42 U.S.C. § 1395nn(e); 42 C.F.R. § 411.357 (adding new exceptions).

¹³⁴ "Phase I" of the regulations was published in January 2001 and took effect (with minor exceptions) in January 2002. As of December 2003, however, CMS had yet to publish "Phase II" of the regulations, which will address additional exceptions, sanctions, and reporting requirements. *See* Medicare Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (codified at 42 C.F.R. pts. 411 & 424 (2003)). *See also infra* Part II.A.

¹³⁵ *See supra* notes 63-64 and accompanying text; *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 900-01 (5th Cir.

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far have been brought via *qui tam* suits, rather than as direct enforcement of the statute by HHS.¹³⁶

III. CURRENT THEMES IN FRAUD AND ABUSE

With that brief overview, this article now turns to a discussion of current federal efforts to eliminate health care fraud and abuse. Recent scholarship provides a variety of perspectives on these efforts. Some commentators decry the expanded use of the fraud laws, arguing that recent initiatives are unfair and ultimately will work to the detriment of both providers and patients.¹³⁷ While acknowledging that minor adjustments may be necessary, other commentators stress that “fraud and abuse is morally wrong and fiscally harmful,” and praise recent enforcement innovations.¹³⁸ The debate—in part practical, in part theoretical—shows few signs of abating.¹³⁹

1997) (addressing an FCA suit based on alleged Stark and Anti-Kickback violations).

¹³⁶ 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*, 13 No. 5 HEALTH LAW, Aug. 2001, at 1 (describing cases); Press Release, Dep’t of Justice, Justice Department Announces Settlements with South Dakota Hospital and Doctors for \$6,525,000, at http://www.usdoj.gov/opa/pr/2002/December002_civ_739.htm (Dec. 20, 2002) (announcing settlement of Stark-based *qui tam* suit against South Dakota hospital).

¹³⁷ See, e.g., Boese & McLain, *supra* note 103, at 55 (arguing that the *Thompson* decision “perpetuated a regime in which health care providers are subjected to a degree of uncertainty that undermines the bedrock principles of the rule of law”); Krause, *supra* note 49, at 212 (arguing that widespread provider perception that the laws are being used unfairly may jeopardize the legitimacy of the anti-fraud agenda); Dayna Bowen Matthew, *An Economic Model to Analyze the Impact of False Claims Act Cases on Access to Healthcare for the Elderly, Disabled, Rural and Inner-City Poor*, 27 AM. J. L. & MED. 439, 467 (2001) (arguing that false certification cases are “flawed tools . . . likely to have a disproportionately negative impact on the availability of healthcare to the poor”).

¹³⁸ Jost & Davies, *supra* note 53, at 318 (arguing that only “targeted corrections” are needed).

¹³⁹ See Hyman, *supra* note 1, at 174 (noting that assessment of whether

Rather than adopting one of these viewpoints, the tripartite conceptual model addressed here focuses instead on the *mechanisms* by which government officials communicate with the provider community about permissible behaviors. Currently, such communications take the form of *regulation*, *information*, and *litigation*. Despite the fact that only properly promulgated regulations are legally binding, health care fraud efforts increasingly have followed the latter two approaches. On the positive side, this development offers increased guidance to health care providers as to the scope of their permissible business activities. At the same time, however, it raises the possibility that providers may be subjected not only to additional—but perhaps also to *inconsistent*—legal interpretations from these varied sources.

A. Regulation

By *regulation*, I mean the development of official, binding guidance through traditional notice-and-comment procedures in accordance with the Administrative Procedure Act (APA).¹⁴⁰ The APA requires an agency such as HHS to provide notice and an opportunity for public comment regarding all proposed “rule makings.”¹⁴¹ The Social Security Act reiterates this requirement for the Medicare program, providing that “[n]o 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 the Secretary of HHS.¹⁴²

Notice-and-comment rulemaking has a long history in the health care context, particularly under the Anti-Kickback Statute. The Statute itself contains several exceptions, and Congress

current efforts “mark[] a step in the right direction” depends on a number of “preexisting assumptions regarding the frequency and severity of the problem”).

¹⁴⁰ 5 U.S.C. § 551 (2003).

¹⁴¹ *Id.* § 553. A “rule” is defined as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” *Id.* § 551(4).

¹⁴² 42 U.S.C. § 1395hh(a)(2) (2003).

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directed the Secretary of HHS to develop additional “safe harbor” regulations exempting additional practices from the scope of the law.¹⁴³ Although the basic contours of the safe harbors were established by the early 1990s, notice-and-comment rulemaking continues to play a key role in their development. As the OIG recently stated, “Congress intended the safe harbor regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.”¹⁴⁴

For example, HIPAA explicitly required HHS to engage in a negotiated rulemaking process to develop a new exception for risk-sharing arrangements, such as those commonly found in managed care.¹⁴⁵ HIPAA similarly invoked the traditional APA process by requiring the Secretary of HHS to publish an annual notice soliciting proposals for new and revised safe harbors, with the resulting amendments to be made through notice-and-comment procedures.¹⁴⁶ Most recently, this procedure was used to develop a new safe harbor exempting health care facilities from liability for restocking certain ambulance supplies used in transporting

¹⁴³ See 42 U.S.C. 1320a-7b(b)(3) (2003) (exempting practices such as discounts, employment compensation, and group purchasing organizations from the scope of the prohibition); Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 697-98 (requiring development of safe harbors); 42 C.F.R. § 1001.952 (listing current safe harbor provisions).

¹⁴⁴ 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 (proposed Sept. 25, 2002) (to be codified 42 C.F.R. pt. 1001).

¹⁴⁵ See Pub. L. No. 104-191, § 216, 110 Stat. 1936, 2007-8 (1996). The resulting safe harbors were published in November 1999, along with revisions to a number of the existing regulations. See Medicare and State 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. § 100.952(t) & (u) (2003)) (finalizing risk sharing safe harbors); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518 (Nov. 19, 1999) (codified at 42 C.F.R. pt. 1001 (2003)) (amending safe harbors).

¹⁴⁶ See Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000-01 (1996).

patients.¹⁴⁷

For a long time, the traditional notice-and-comment process was virtually the only way for health care providers to obtain guidance from the government on how to interpret the fraud laws. As a result, attorneys pored over the lengthy preamble to each *Federal Register* notice, trying to glean some nugget of regulatory intent to help decipher the complicated language of the law and regulations. The government was not blind to this phenomenon, and the agencies artfully used the notices to convey information that was not explicitly contained in the regulations themselves—such as the factors that would be taken into account in determining whether to pursue a particular Anti-Kickback allegation.¹⁴⁸

Over time, however, it became abundantly clear that the traditional regulatory process was too cumbersome to respond to the practical realities of the complex health care market. This observation is by no means limited to health care; the administrative law literature is replete with examples of the “ossification” of the formal rulemaking process.¹⁴⁹ In the health care fraud context, however, this phenomenon denies providers the immediate guidance they need to determine the legality of many

¹⁴⁷ Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 Fed. Reg. 62,979 (Dec. 4, 2001), codified at 42 C.F.R. § 1001.952(v) (2003).

¹⁴⁸ See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991) (codified at 42 C.F.R. pt. 1001 (2003)) (listing factors); Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 352 (1999) (reiterating the aspects of an Anti-Kickback inquiry).

¹⁴⁹ See, e.g., Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 11-14 (1997) (describing the disadvantages of the traditional agency rulemaking process); 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”).

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commonplace business transactions. In particular, the time lag between a Notice of Proposed Rulemaking and the issuance of a Final Rule raises the possibility that industry practice—and the law itself—may change significantly in the interim. As but one example, the OIG proposed several new Anti-Kickback safe harbors in 1993, and proposed to amend a number of the existing safe harbors in 1994.¹⁵⁰ The amendments were not finalized, however, until after the Clinton Health Plan debates had resulted in the enactment of HIPAA—which created a new statutory exception and required the development of additional safe harbors concerning risk sharing arrangements.¹⁵¹

Similarly, the dynamic nature of the health care market and the innovative ways in which health care providers seek to adjust to changing market conditions create a situation in which the official regulations always seem to be one step behind industry practice. Due to the pace of health care innovation—as well as the existence of a few entrepreneurial providers who seek to “game” the increasingly complex system—the financial arrangements regarding health care (and the attendant forms of fraud) essentially are moving targets.¹⁵² The OIG has acknowledged this, noting,

¹⁵⁰ See Health Care Programs: Fraud and Abuse; Additional Safe Harbor Provisions Under the OIG Anti-Kickback Statute, 58 Fed. Reg. 49,008 (proposed Sept. 21, 1993) (to be codified at 42 C.F.R. § 1001.952) (proposing seven additional safe harbors); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the OIG Safe Harbor Anti-Kickback Provisions, 59 Fed. Reg. 37,202 (proposed July 21, 1994) (to be codified at 42 C.F.R. § 1001.952) (proposing revisions to safe harbors).

¹⁵¹ Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 204, 110 Stat. 1936. Final revisions were not published until November 1999. 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) (codified at 42 C.F.R. § 1001.952 (2003)); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952 (2003)).

¹⁵² “Gaming the system” refers to “an artificial restructuring of employment or social relationships to maximize individual benefits.” Edward G. Grossman, *Comparing the Options for Universal Coverage*, HEALTH AFF.,

“Congress intended the safe harbor regulations to be evolving rules to reflect changing business practices and technologies in the health care industry.”¹⁵³ Although health care fraud regulations are designed to provide flexibility, by necessity they are based on a loose snapshot of industry practice at a single point in time. Enshrining such practices in law not only risks the creation of regulations that are outdated from the moment of creation, but also raises the possibility of freezing the industry at a sub-optimal point in time. As a result, according to Professor James Blumstein, current health care fraud enforcement is analogous to 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.”¹⁵⁴

Perhaps no topic illustrates the perils of health care fraud regulation as much as the ongoing saga of the Stark Law. As described above, the current law is derived from two different pieces of legislation: (1) an initial prohibition on physician self-referrals of Medicare patients for clinical laboratory services, which took effect on January 1, 1992; and (2) the OBRA ‘93 expansion covering additional categories of designated health services, which took effect as of December 31, 1994.¹⁵⁵ By December 2003, however, the Stark II regulations had yet to be completed.

The initial regulations implementing the Stark I prohibitions

Spring (II) 1994, at 86. In the health care context, for example, “physicians may attempt to game the system so as to evade cost control measures” that might reduce their revenue. Arti K. Rai, *Health Care Fraud and Abuse: A Tale of Behavior Induced by Payment Structure*, 30 J. LEG. STUD. 579 (2001).

¹⁵³ 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 (proposed Sept. 25, 2002) (to be codified at 42 C.F.R. § 1001.952).

¹⁵⁴ 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, 218 (1996).

¹⁵⁵ See *supra* Part II.C.

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were proposed in the spring of 1992.¹⁵⁶ The proposal resulted in the submission of almost three hundred comments to the Health Care Financing Administration (HCFA, now renamed the Centers for Medicare and Medicaid Services (CMS)).¹⁵⁷ As a result, the final rule was not published until August of 1995—three years after the original law went into effect, and eight months after the expanded Stark II provisions had become effective.¹⁵⁸ While indicating its intention to publish a separate notice of proposed rulemaking for Stark II, HCFA stated:

[W]e believe that a majority of our interpretations in this final rule with comment will apply to the other designated health services. Until we publish a rule covering the designated health services, we intend to rely on our language and interpretation in this final rule when reviewing referrals for the designated health services in appropriate cases.¹⁵⁹

In the interim, health care lawyers were forced to improvise, offering their best guesses as to the meaning of the Stark II provisions based on the broad statutory language and extrapolating from analogous, but not identical, Stark I regulations.

And a long interim it turned out to be. After two and a half years of uncertainty, proposed Stark II regulations were published in January of 1998.¹⁶⁰ Far from clarifying the prohibitions,

¹⁵⁶ See Medicare Program: Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services, 57 Fed. Reg. 8,588 (proposed Mar. 11, 1992) (to be codified at 42 C.F.R. pt. 411). An interim final rule concerning only Stark I reporting requirements was published in December of 1991. Medicare Program; Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities that Furnish Selected Items and Services, 56 Fed. Reg. 61,374 (Dec. 3, 1991) (codified at 42 C.F.R. § 411.361 (2003)).

¹⁵⁷ Medicare Program: Physician Ownership of, 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 (2003)).

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 41,916.

¹⁶⁰ Medicare and Medicaid Programs: Physicians' Referrals to Health Care

however, the proposal proved to be exceedingly controversial, in large part because some of the provisions went beyond what the statute required (or perhaps allowed).¹⁶¹ The rule included a number of new exceptions to the self-referral ban and proposed significant revisions to components of the key group practice definition, leading one group of attorneys to conclude that the proposal “raise[s] as many questions as it answers.”¹⁶²

Once again, any hope of a speedy resolution to these questions was dashed. A “final” Stark II rule was published in January of 2001, three years after the proposed rule and a full *six* years after the revised law went into effect.¹⁶³ Despite filling 110 pages of the *Federal Register*, however, the Stark saga was by no means over.¹⁶⁴ Instead, HCFA indicated that the regulations merely comprised *Phase I* of the final regulations, addressing the basic Stark II prohibition, definitions, and general exceptions; a subsequent “Phase II” rule would be needed to address the remaining provisions of the statute, including additional exceptions, reporting requirements, and sanctions.¹⁶⁵ Moreover, HCFA delayed the effective date of the regulations for a year to allow time for providers to comment and comply with the new requirements.¹⁶⁶

Health care providers were not amused. A prominent group of

Entities with Which They Have Financial Relationships, 63 Fed. Reg. 1,659 (proposed Jan. 9, 1998) (to be codified at 42 C.F.R. pts. 411, 424, 435 & 455).

¹⁶¹ See, e.g., *Id.* at 1,682 (refusing to exclude lithotripsy from the definition of “inpatient hospital services” despite requests to do so). This decision was later held to be erroneous. *Am. Lithotripsy Soc’y v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002) (holding that inclusion was contrary to congressional intent).

¹⁶² *Self-Referral: HCFA Issues Proposed Rule Governing Physician Stark II Referrals*, 2 HEALTH CARE FRAUD REP. (BNA) 7 (Jan. 1, 1998) (quoting a statement by the law firm of Winston & Strawn). See, e.g., Medicare and Medicaid Programs, 63 Fed. Reg. at 1,687-91 (discussing group practices), 1,699 (discussing the new exception for “de minimis” compensation).

¹⁶³ Medicare and Medicaid Programs: Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (codified at 42 C.F.R. pts. 411 & 424 (2003)).

¹⁶⁴ *Id.* at 856-965.

¹⁶⁵ *Id.* at 856, 859-60 (describing phases).

¹⁶⁶ *Id.* at 859.

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health care attorneys criticized the one-year delay, “call[ing] the rule a ‘virtual’ regulatory event” and deriding HCFA’s “post-publication schizophrenia.”¹⁶⁷ Nevertheless, providers and their attorneys set to work to bring practices into compliance before the rule took effect in January 2002. Unfortunately, even the one-year delay was marked by problems. Soon after taking office in January 2001, President Bush postponed for sixty days the effective date of any regulations that had not yet gone into effect, generating short-lived confusion about the future of the Stark II rule under the new Administration.¹⁶⁸ In November of 2001, CMS delayed the effective date of one provision (the definition of the phrase “set in advance” as applied to percentage compensation arrangements) yet again, in order to give the agency time to reconsider its approach.¹⁶⁹ When the rule finally went into effect in January 2002, it inadvertently contained minor errors that CMS had intended to repeal, which will require further revisions to the Phase

¹⁶⁷ *Self-Referral: Stark II “Virtual” Final Regulations Reflect HCFA “Schizophrenia,” Attorneys Say*, 5 HEALTH CARE FRAUD REP. (BNA) 257 (Mar. 21, 2001) (describing comments contained in a briefing by the American Health Lawyers Association).

¹⁶⁸ 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. 8771 (Feb. 2, 2001) (codified at 42 C.F.R. pts. 411 & 424 (2003)). Despite the initial confusion, CMS took the position that the Administration’s action only delayed a discrete subsection of the regulations concerning home health agencies, which had been scheduled to take effect in February 2001. *Id.*

¹⁶⁹ 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 (Dec. 3, 2001). In November 2002 and April 2003, CMS delayed the effective date of this provision for additional six month periods “in order to avoid unnecessarily disrupting existing contractual arrangements for physician services.” 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 (Nov. 22, 2002). *See also* 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 (April 25, 2003).

I regulations.¹⁷⁰ 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 prohibition. As one commentator wryly noted, "[a]lthough the intent was to provide comprehensive bright line rules, regulators have had great difficulty in figuring out where the lines are."¹⁷¹

While most health care fraud regulations do not have quite as tortured a history as the Stark Law, this saga illustrates that traditional regulation can be an extraordinarily cumbersome process. In the complicated and constantly evolving arena of health care financial relationships, the advantages offered by binding regulations, developed after extensive public input, may well be outweighed by the necessity of generating more timely forms of guidance.

B. Information

Growing concern about the disadvantages of traditional notice-and-comment rulemaking led to the development of what I call *information*: the proliferation of sources of health care fraud guidance *outside* the traditional regulatory process. These informal forms of guidance are used to convey the agency's current interpretation of the law to the health care community. As former HHS Inspector General June Gibbs Brown noted in an Open Letter to Health Care Providers, "[t]hrough public awareness efforts . . . we alert the provider community of our concerns and hope to encourage self-correcting behavior."¹⁷² As described below,

¹⁷⁰ 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 a letter written by a CMS representative acknowledging the error). Moreover, a federal district court enjoined implementation of one aspect of the definition of "designated health services," holding that the inclusion of lithotripsy in the definition was contrary to congressional intent. *Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002).

¹⁷¹ 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) [hereinafter, Hyman, *Health Care Fraud and Abuse*].

¹⁷² Letter from June Gibbs Brown, Office of Inspector General, An Open

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however, the necessity of relying on informal interpretive materials can have significant repercussions for health care providers, both under administrative law principles and in terms of day-to-day practice.

1. Forms of Health Care Fraud Information

Various forms of health care fraud information are now available to health care providers, including both statutorily mandated advisory processes and informal guidance mechanisms developed solely within HHS. While some types of guidance are binding on the entities who request the advice, they may not be binding on the general public—although judges may nonetheless find the agency’s views to be persuasive.¹⁷³ Among the most common forms of fraud guidance are Advisory Opinions, Special Fraud Alerts, Compliance Program Guidances, and Special Advisory Bulletins.

a. Advisory Opinions

HIPAA required the Secretary of HHS, in consultation with the Attorney General, to provide written Advisory Opinions as to whether a proposed transaction would, *inter alia*, violate the Anti-Kickback Statute or subject the requestor to civil monetary penalties or exclusion.¹⁷⁴ Advisory Opinions are thus an example

Letter to Health Care Providers (Mar. 9, 2000), *available at* <http://oig.hhs.gov/fraud/docs/openletters/openletter.htm>.

¹⁷³ See *infra* notes 208-12 and accompanying text.

¹⁷⁴ See 42 U.S.C. § 1320a-7d(b) (2003); 42 C.F.R. pt. 1008 (2003). The original Advisory Opinion mandate expired in August 2000, but was permanently reinstated as part of the 2001 appropriations process. See Consolidated Appropriations Act, Pub. L. No. 106-554, § 543, 114 Stat. 2763 (2001). A similar process is required under the Stark Law, although few opinions have been issued. See 42 U.S.C. § 1395nn(g)(6) (2003); 42 C.F.R. §§ 411.370 (2003) et seq. Despite initial concern that Advisory Opinions could only be requested for activities already underway, the regulations made clear that requests may pertain to activities “which the requestor in good faith plans to undertake.” 42 C.F.R. § 1008.15(a) (2003); see also 42 U.S.C. § 1128D(b)(2) (2003) (opinions are available concerning arrangement/activity or proposed

of “voluntary preclearance,” a form of intermediate ex ante regulatory enforcement.¹⁷⁵ Mindful of resource constraints and inter-agency conflicts, Congress specified that Advisory Opinions could not address whether a transaction involves fair market value or whether an individual qualifies as a *bona fide* employee under the Internal Revenue Code.¹⁷⁶ While Advisory Opinions are binding only as to the Secretary of HHS and the requestor(s), they are made available to the public (in redacted form) on the agency’s web site.¹⁷⁷ Even if third parties are not entitled to rely on the conclusions, however, Advisory Opinions nonetheless function as valuable sources of information as to the agency’s likely views regarding analogous transactions.

Despite offering a relatively informal mechanism for obtaining guidance from the OIG, the Advisory Opinion process remains cumbersome.¹⁷⁸ Although the OIG is required to issue an Opinion within sixty days after accepting a request, that time period is tolled by requests for additional information, requests for payment, and decisions to seek external expert consultation.¹⁷⁹ Moreover, in order to obtain an Opinion the requestor must submit “[a] complete and specific description of all relevant information bearing on the arrangement . . . and on the circumstances of the conduct,” including copies of all operative documents for existing arrangements, and copies of drafts, model documents, or

arrangement/activity). However, hypothetical requests are not acceptable. 42 C.F.R. § 1008.15(b).

¹⁷⁵ Bhagwat, *supra* note 8, at 1289. For a description of similar processes in other agencies, *see, e.g., id.* at 1289-91 (describing various agency practices); Spencer Weber Waller, *Prosecution by Regulation: The Changing Nature Antitrust Enforcement*, 77 OR. L. REV. 1383, 1395 (1998) (describing business review letters issued by the DOJ Antitrust Division).

¹⁷⁶ 42 U.S.C. § 1320a-7d(b)(3).

¹⁷⁷ *See id.* § 1320a-7d(b)(4); 42 C.F.R. § 1008.53 (identifying affected parties). A complete list of advisory opinions is available at <http://oig.hhs.gov/fraud/advisoryopinions.html> (last visited Feb. 28, 2004).

¹⁷⁸ *See* Phyllis A. Avery & Andrew B. Wachler, *Advisory Opinion Regulations Will Discourage Many Potential Requestors*, HEALTH LAW., Vol. 9, No. 6, at 24 (1997).

¹⁷⁹ 42 C.F.R. § 1008.43(c).

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descriptions of proposed terms for contemplated arrangements.¹⁸⁰ Significant resources thus must be expended to develop the information needed to support the request—a request that may well result in the abandonment of the transaction.¹⁸¹ In addition, the OIG retains the right to rescind, terminate or modify a previous Opinion upon reconsideration of the issues involved, although the requestor will be given an opportunity to discontinue or modify its actions.¹⁸² Thus, the advice available through the Advisory Opinion process is by no means as timely, easily obtained, or reliable as it might first appear.

b. Special Fraud Alerts

The OIG periodically issues Special Fraud Alerts in areas in which the agency believes there may be abuse, particularly those involving improper referrals under the Anti-Kickback Statute.¹⁸³ Rather than setting out discrete tests for liability, Special Fraud Alerts merely identify “suspect practices” that may attract scrutiny.¹⁸⁴ While a health care provider who engages in one of

¹⁸⁰ *Id.* § 1008.36(b)(4).

¹⁸¹ See Scott D. Godshall, *Death By Regulation: HHS's Advisory Opinion Guidelines*, ANDREWS HEALTH CARE FRAUD LITIG. REP., May 1997, at 3. “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.” *Id.*

¹⁸² 42 C.F.R. § 1008.45 (explaining procedures for rescission, termination, or modification).

¹⁸³ See, e.g., Special Fraud Alert: Hospital Incentives to Physicians (May 1992), *reprinted in* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994) (describing Alerts).

¹⁸⁴ See, e.g., *id.* at 65,375-76 (listing suspect hospital incentives, such as the provision of free or significantly discounted items, spaces, or services); Special Fraud Alert: Prescription Drug Market Schemes (Aug. 1994), *reprinted in id.* at 65,376 (identifying possible improper payments and gifts from drug manufacturers, including those offered to physicians in exchange for prescribing a manufacturer’s products); Special Fraud Alert: Arrangements for the Provision

these suspect practices is *not* automatically in violation of the law, the Fraud Alert serves to put the provider on notice that the practice may attract attention.

Special Fraud Alerts occupy a unique position on the spectrum of health care fraud guidance. Unlike the safe harbors or Advisory Opinions, there is no explicit legislative authority for the issuance of Fraud Alerts; instead, they are an exercise of the agency's general administrative interpretive authority.¹⁸⁵ For many years, the OIG issued internal fraud alerts "to identify fraudulent and abusive practices within the health care industry."¹⁸⁶ In 1989, the agency began to issue periodic alerts intended for wider publication distribution, explaining:

[T]he OIG Special Fraud Alerts have served to provide general guidance to the health care industry on violations of Federal law (including various aspects of the anti-kickback statute), as well as to provide additional insight to the Medicare carrier fraud units in identifying health care fraud schemes.¹⁸⁷

Despite their unofficial status and highly fact-specific nature, the OIG has viewed such Alerts quite favorably; indeed, the agency offered the Special Fraud Alert mechanism as an alternative to adopting an earlier iteration of the Advisory Opinion process.¹⁸⁸

Congress officially recognized the existence of Special Fraud Alerts in HIPAA, which created a mechanism for private parties to

of Clinical Lab Services (Oct. 1994), *reprinted in id.*, at 65,377-78 (identifying problematic inducements by clinical laboratories, including providing free services to physicians who generate business for the laboratory).

¹⁸⁵ See *infra* notes 227-30 and accompanying text (discussing interpretive authority).

¹⁸⁶ See Notice, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. at 65,373 (describing the history of fraud alerts).

¹⁸⁷ *Id.*

¹⁸⁸ See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,959 (July 29, 1991) (codified at 42 C.F.R. pt. 1001 (2003)) (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").

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request that the OIG issue an Alert to “inform the public of practices which the [OIG] considers to be suspect or of particular concern” under the federal health care programs.¹⁸⁹ In recent years, Special Fraud Alerts have addressed such topics as nursing home arrangements with hospice programs, home health fraud, rental of physician office space by entities to which the physician refers patients, and physician liability for fraudulent medical equipment and home health certifications.¹⁹⁰

c. Compliance Program Guidances

One of the most significant recent developments in health care fraud and abuse has been the increasing emphasis on corporate compliance. Since the mid-1990s, it has become standard practice for the OIG and DOJ to require health care providers to enter into corporate integrity agreements (CIAs) as a condition of settling health care fraud allegations, most often in return for the OIG’s agreement not to seek the provider’s exclusion from the federal health care programs.¹⁹¹ Although each CIA is tailored to the specific conduct at issue, common elements include the appointment of a compliance officer, the development of compliance training procedures in key areas (such as billing rules), the development of confidential mechanisms by which employees can report potential violations, and the submission of reports to the government documenting the provider’s compliance efforts.¹⁹² The

¹⁸⁹ 42 U.S.C. § 1320a-7d(c) (2003) (permitting such requests).

¹⁹⁰ A complete list of Special Fraud Alerts can be found at <http://oig.hhs.gov/fraud/fraudalerts.html#1> (last visited July 15, 2002).

¹⁹¹ See Office of Inspector Gen., Corporate Integrity Agreements: General Information, <http://oig.hhs.gov/fraud/cias.html#1> (last visited Feb. 14, 2003). As the OIG explains, “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.” *Id.* See also Thomas E. Bartrum & L. Edward Bryant, Jr., *The Brave New World of Health Care Compliance Programs*, 6 ANNALS HEALTH L. 51, 55 (1997) (explaining CIA requirements).

¹⁹² A list of common elements, as well as a list of current CIAs, can be found on the OIG’s web site. See <http://oig.hhs.gov/fraud/cias.html#1> (last

reporting and oversight provisions are onerous and typically last for at least five years.¹⁹³

Not surprisingly, the emphasis has moved from compliance as a *remedy* to compliance as a *preventive* mechanism. The genesis of voluntary compliance efforts, resulting in so-called “corporate compliance programs,” can be traced to the Federal Sentencing Guidelines for Organizations, which went into effect in 1991.¹⁹⁴ The Guidelines permit the court to reduce an organization’s culpability score “[i]f the offense occurred despite an effective program to prevent and detect violations of the law.”¹⁹⁵ An effective program requires, at a minimum, that the organization: establish, communicate, monitor, and enforce compliance standards and procedures for its employees and contractors; assign responsibility for compliance to specific high-level personnel; refrain from delegating authority to individuals with a history of illegal behavior; and take appropriate steps when an offense is detected.¹⁹⁶ Although the Guidelines only apply to organizations convicted of *criminal* activities, the OIG has indicated that a compliance program may also benefit organizations accused of violating *civil* laws—both by preventing some improper activities from occurring in the first place and by minimizing the organization’s exposure if wrongdoing is detected and reported on a timely basis.¹⁹⁷

Rather than requiring each health care provider to create a

visited Feb. 14, 2003).

¹⁹³ *Id.*

¹⁹⁴ See U.S. SENTENCING GUIDELINES MANUAL ch. 8 (sentencing of organizations) (2001); Bartrum & Bryant, *supra* note 191, at 55 (tracing the emphasis on corporate compliance to the Guidelines).

¹⁹⁵ U.S. SENTENCING GUIDELINES MANUAL § 8C2.5(f).

¹⁹⁶ *Id.* at § 8A1.1, Commentary 3(k). These provisions also form the basis for the common CIA elements noted above. See *supra* note 192 and accompanying text.

¹⁹⁷ See, e.g., Publication of the OIG Compliance Program Guidance for Hospices, 64 Fed. Reg. 54,031, 54,033 (Oct. 5, 1999) (describing the benefits of a compliance program). For details as to when such leniency may be applicable, see *id.* at 54,033 n.5 (referencing sources); 31 U.S.C. § 3729(a) (2003) (providing that a person who voluntarily discloses a violation of the FCA may be subject to double, rather than treble, damages).

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program anew, the OIG has published a series of “Compliance Program Guidances” designed to guide members of a particular sector of the health care industry in establishing their own voluntary compliance programs.¹⁹⁸ While adherence to these Guidances are not mandatory (and may not be feasible for smaller entities), the documents provide valuable advice as to what the OIG believes are the key compliance issues for such providers. As the OIG has stated:

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.¹⁹⁹

The OIG issued a Model Compliance Plan for Clinical Laboratories in 1997, following several highly publicized fraud settlements involving national laboratory companies.²⁰⁰ By June 2003, the OIG had issued Compliance 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,

¹⁹⁸ See HHS Office of Inspector General, Fraud Prevention and Protection, Compliance Guidance, at <http://oig.hhs.gov/fraud/complianceguidance.html> (last visited Jan. 3, 2004) (listing guidelines).

¹⁹⁹ Publication of the OIG Compliance Program Guidance for Hospices, 64 Fed. Reg. at 54,032.

²⁰⁰ See Notice, Publication of the OIG Model Compliance Plan for Clinical Laboratories, 62 Fed. Reg. 9,435 (Mar. 3, 1997); *United States ex rel. Wagner v. Allied Clin. Labs.*, No. C-1-94-092, 1995 WL 254405 (S.D. Ohio 1995) (settling allegations that a laboratory billed for tests not supported by patient diagnoses). The model plan was revised in 1998 to better track the format of subsequent Guidances. See Notice, Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076 (Aug. 24, 1998) (revising Guidance “to refine and build on” the original document).

and ambulance companies.²⁰¹ Thus, a wide range of health care providers can consult Guidances directly targeting their practices, while many others can argue by analogy from Guidances designed for similar entities.²⁰²

d. Special Advisory Bulletins

The OIG has also issued several Special Advisory Bulletins, which offer additional guidance as to whether health care activities will violate federal law.²⁰³ Bulletins are similar to Special Fraud Alerts in that they address a range of impermissible activities, rather than answering specific queries from health care providers.²⁰⁴ In other respects, however, the issues addressed in Bulletins do not fit the Special Fraud Alert model, in part because they concern a wider range of fraud laws. Recent Bulletins have addressed the practices of billing consultants, the patient anti-dumping statute, the effect of exclusion from the federal health care programs, and the offering of gifts and other inducements to beneficiaries.²⁰⁵ Although Bulletins are not explicitly authorized by law, the OIG typically grounds its authority in HIPAA's broad mandate that the agency provide "guidance" to the health care

²⁰¹ For a complete list, see HHS, Office of Inspector General, Fraud Prevention & Detection, Compliance Guidance, at <http://oig.hhs.gov/fraud/complianceguidance.html> (last visited June 16, 2003).

²⁰² It is unclear whether the compliance effort ultimately will prove successful. See Hyman, *Health Care Fraud and Abuse*, *supra* note 171, at 566 (arguing "there is a big difference between a compliance program and a compliance norm, and provider norms have proved extremely resistant to change").

²⁰³ See HHS Office of Inspector General, Fraud Alerts, Bulletins and Other Guidance, <http://oig.hhs.gov/fraud/fraudalerts.html#2> (last visited Feb. 14, 2003).

²⁰⁴ *Id.*

²⁰⁵ *Id.* The issuance of an informal Bulletin does not preclude the subsequent development of binding regulations on the topic. See, e.g., Solicitation of Public Comments on Exceptions Under Section 1128A(a)(5) of the Social Security Act, 67 Fed. Reg. 72,892 (Dec. 9, 2002) (following up on the August 2002 Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries).

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industry regarding fraudulent conduct.²⁰⁶

Perhaps the most controversial Special Advisory Bulletin to date was the July 1999 Bulletin concerning “Gainsharing Arrangements.”²⁰⁷ In that Bulletin, the OIG construed a civil monetary penalty (CMP) provision prohibiting hospitals from knowingly making payments to a physician as an inducement to reduce or limit services to Medicare/Medicaid beneficiaries under the physician’s care.²⁰⁸ The OIG interpreted this provision to prohibit “gainsharing,” which it defined as “an arrangement 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.”²⁰⁹ While acknowledging that hospitals have legitimate reasons for desiring that physicians support cost-containment efforts, the OIG nonetheless stated that the CMP prohibited a hospital from compensating a physician directly or indirectly based on cost savings derived from the treatment of the physician’s own patients.²¹⁰ The Bulletin has proven to be quite controversial, particularly in light of the Internal Revenue Service’s earlier approval of the tax consequences of similar arrangements.²¹¹

²⁰⁶ See Notice, Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985 (July 14, 1999), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm> [hereinafter Special Advisory Bulletin on Gainsharing Arrangements] (stating that “[t]he Fraud and Abuse Control Program, established by [HIPAA], authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote the highest level of ethical and lawful conduct”).

²⁰⁷ See *id.*

²⁰⁸ See *id.*; 42 U.S.C. § 1320a-7a(b)(1) (2003).

²⁰⁹ See Special Advisory Bulletin on Gainsharing Arrangements, *supra* note 206.

²¹⁰ *Id.*

²¹¹ 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 the OIG’s reasoning as “dubious,” and arguing that “the OIG relie[d] upon a selective account of the legislative history”); *IRA Approves Gainsharing Programs in Two Unreleased Private Letter Rulings*, 8

Similar to Special Fraud Alerts, the issuance of such Bulletins is purely within the agency's discretion.²¹² In fact, the Gainsharing Bulletin itself arose out of several requests for Advisory Opinions concerning gainsharing arrangements.²¹³ Finding that a variety of concerns made the issue unsuitable for individual Opinions, including the high risk of abuse, the need for ongoing oversight, and the need for comprehensive regulations rather than case-by-case analysis, the OIG chose instead to issue the industry-wide Bulletin.²¹⁴ It is likely this mechanism will be used in the future to disseminate information outside the Special Fraud Alert context, especially when the government's concerns encompass laws beyond the Anti-Kickback Statute.

e. Other Forms of Guidance

In addition to these categories, the OIG from time to time offers other types of guidance to the health care industry. For example, the HHS Inspector General periodically posts "Open Letters" to the health care community on the agency's web site, designed to explain the agency's goals and priorities.²¹⁵ In addition, the OIG periodically releases redacted versions of Anti-Kickback-related correspondence. For example, in April 2000, the OIG posted copies of two letters addressing providers who impermissibly charge the federal health care programs amounts that are "substantially in excess" of the provider's usual charge for the services provided.²¹⁶ While these postings have the virtue of

HEALTH LAW REP. (BNA) 295 (Feb. 25, 1999) (describing two private letter rulings approving gainsharing arrangements between tax-exempt hospitals and physician groups).

²¹² See Special Advisory Bulletin on Gainsharing Arrangements, *supra* note 206.

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ For a list of such documents, see HHS, Office of Inspector General, Fraud Prevention & Detection, Open Letters, at <http://oig.hhs.gov/fraud/openletters.html> (last visited July 15, 2002).

²¹⁶ The correspondence is available at HHS Office of Inspector General, Fraud Prevention & Detection, Fraud Alerts, Bulletins, and Guidance,

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making the OIG's current interpretations accessible to anyone with an Internet connection, their legal effects remain unclear.

2. Reliance on Informal Guidance

The government's evolving views of these informal sources of fraud guidance is instructive, particularly with regard to Advisory Opinions. Despite numerous requests from health care providers, historically the OIG was vehemently opposed to instituting an Advisory Opinion process under the Anti-Kickback Statute.²¹⁷ During the notice-and-comment period for the proposed safe harbor regulations, the agency received numerous comments requesting the development of an advisory mechanism.²¹⁸ Citing the statute's criminal provisions, which are enforced by the DOJ, the OIG concluded that it lacked "authority to make judgments that are within the exclusive domain of another agency."²¹⁹ Noting the practical problems caused by the "knowing and willful" intent requirement, as well as the resources that such a process would require, the OIG argued that the safe harbor regulations were the most appropriate mechanism for addressing provider concerns:

[W]e do not believe that an advisory opinion process is a necessary or appropriate mechanism for keeping the Department aware of new developments in industry practice and ensuring that the regulation remains current We believe that periodic updating of this regulation, with the opportunity for public input, is the best way to ensure that these regulations remain practical and relevant in the face of changes in health care delivery and payment arrangements.²²⁰

<http://oig.hhs.gov/fraud/fraudalerts.html#3b> (last visited July 15, 2002).

²¹⁷ See, e.g., Godshall, *supra* note 181, at 3 (describing the convoluted Advisory Opinion regulations as "demonstrat[ing] the agency's continuing opposition" to the process); *supra* note 188 and accompanying text.

²¹⁸ See Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,959 (July 29, 1991) (describing comments).

²¹⁹ *Id.*

²²⁰ *Id.*

The OIG's comments thus reflected serious concerns about agency authority and resources, as well as a clear preference for the traditional regulatory process.

With the passage of HIPAA, however, many of these concerns disappeared. The explicit grant of advisory authority to HHS, combined with a mandate for interagency coordination, assuaged concerns about potential interference with DOJ investigations. Resource concerns were addressed by the HIPAA funding provisions, including the creation of the Fraud and Abuse Control Program.²²¹ Over time, OIG personnel apparently realized that the advisory process could be a very good way of making the agency's views known in a timely and informal manner. By the summer of 2001, agency personnel appeared to have done an about-face, and strongly supported permanent extension of the Advisory Opinion authority.²²²

In addition to this curious pedigree, the proliferation of these quasi-official forms of guidance has important practical implications for health care providers. For one thing, there are many more places to look for guidance on specific fraud issues than in the past. In addition to consulting the statute and safe harbors, and poring over the relevant *Federal Register* preambles, health care attorneys now must scrutinize all relevant Advisory Opinions, Special Fraud Alerts, Compliance Program Guidances, Special Advisory Bulletins, and other forms of guidance. Although most of this information is available on the OIG's web site, it tends to be organized in loose topical and chronological fashion (rather than, for example, keyed to the relevant statutory provisions).²²³

²²¹ See 42 U.S.C. § 1395i(k)(3) (2003) (describing appropriations to the Health Care Fraud and Abuse Control Account); *supra* Part I.

²²² See Testimony of Lewis Morris, Assistant Inspector General for Legal Affairs, Before the Senate Special Committee on Aging, at <http://oig.hhs.gov/reading/testimony/2001/072601lm.pdf> (July 26, 2001) ("In addition to assisting the health care industry [to] comply with the law, the advisory opinion and safe harbor mechanisms enhance the OIG's understanding of new and emerging health care business arrangements and guide the development of new safe harbor regulations, fraud alerts, and advisory bulletins.").

²²³ See HHS, Office of Inspector General, available at <http://oig.hhs.gov/index.html> (indexing documents) (last visited June 19, 2003).

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Moreover, this additional guidance does not necessarily clarify the ambiguities faced by providers on a daily basis. Especially with Advisory Opinions and correspondence, attorneys must try to extrapolate general principles from the government's response to a specific set of facts, and then combine that information with the binding guidance found in the law and safe harbor provisions. Thus, there is a distinct risk that the proliferation of unofficial sources of guidance results simply in *more*—rather than *better*—information regarding health care fraud.

In addition, because such unofficial guidance generally is not binding, such advice is not always *consistent*. For example, in its July 1999 Special Advisory Bulletin, the OIG stated that gainsharing arrangements were not an appropriate topic for Advisory Opinions.²²⁴ But in January 2001, with little fanfare (and even less attention to the previous Bulletin), the OIG issued an Advisory Opinion *approving* a transaction that was in essence a gainsharing arrangement.²²⁵ Perhaps, as the OIG argued, the new proposal departed so significantly from previous gainsharing proposals that different treatment was warranted,²²⁶ or perhaps the Opinion signaled the OIG's retreat from its previous hard-line prohibition. Of course, no one would argue that agency interpretations should not evolve over time; indeed, the ability to be responsive to changes in industry practice is one of the greatest advantages of informal guidance. Nonetheless, the lack of any formal mechanism to warn of policy shifts can make it difficult for health care providers to plan future transactions that may implicate these concerns.

Moreover, administrative law principles have significant repercussions for health care providers who seek to challenge—or

²²⁴ See Special Advisory Bulletin on Gainsharing Arrangements, *supra* note 206 (stating that requests “contain common elements that preclude our issuance of any favorable opinion,” including high risk of abuse, need for ongoing oversight, and need for comprehensive regulation in the area).

²²⁵ OIG Advisory Opinion No. 01-1 (Jan. 18, 2001), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-01.pdf> (declining to impose sanctions for a proposal involving a hospital sharing a percentage of cost savings with cardiac surgeons who implement certain cost reduction measures).

²²⁶ *Id.*

even to rely on—such quasi-official agency interpretations. As noted above, 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.²²⁷ However, the APA requirement does not apply “to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.”²²⁸ In determining whether rulemaking is required, courts have focused on whether the rule is “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 by its action the agency intends to create new law, rights, or duties, the rule is properly considered to be a legislative rule.²²⁹

It is likely that most of OIG fraud guidance would qualify as interpretive rules under this test, and hence would not be subject to challenge unless they adopted a new position that was inconsistent with prior law or regulations.²³⁰

Disputes over the nature of agency policy usually arise when a health care provider seeks to challenge the agency’s informal interpretation as contrary to established law, and thus subject to the APA rulemaking requirements.²³¹ In the majority of cases, federal

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

²²⁸ 5 U.S.C. § 553(b)(A).

²²⁹ *Metropolitan Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992); *see also* *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (providing the test for determining whether a rule is interpretive or legislative).

²³⁰ *See Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 100 (1995) (stating “that APA rulemaking would . . . be required if [the rule] adopted a new position inconsistent with any of the Secretary’s existing regulations”).

²³¹ Many such cases arise when a provider asks a court to enjoin the enforcement of the challenged provision. The timing of judicial review of Medicare cases is complex and has been extensively litigated, generally in the context of whether a provider has “exhausted” the relevant administrative

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courts have held that Medicare manuals, letters, and directives are interpretive in nature. Indeed, the Supreme Court described one of the Medicare program manuals as “a prototypical example of an interpretive rule.”²³² On rare occasion, however, courts have found a specific policy to be contrary to law. For example, in *Loyola University of Chicago v. Bowen*, the Seventh Circuit refused to defer to the Secretary’s interpretation of regulations governing hospital reimbursement for education expenses, on the grounds that the Medicare Carriers Manual provision on which the Secretary relied contained a requirement not found in the law or regulations.²³³ As the court noted, “[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

review processes prior to going to court. Briefly, prior to 1986, the Social Security Act did not permit judicial review of the amount of Medicare Part B benefits. *See United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982). Moreover, the Supreme Court had held that judicial review of claims “arising under” Medicare Part A was available only after the claimant pursued all levels of available HHS review and the Secretary rendered a “final decision.” *See Heckler v. Ringer*, 466 U.S. 602, 605-06 (1984). However, in the 1986 case of *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, 675-76 (1986) (emphasis added). The situation was further complicated by a 1986 amendment permitting judicial review of the “amount of benefits” under both Medicare Part A and Part B, which may have mooted the amount/methodology distinction and required exhaustion of remedies for *all* disputes. *See Omnibus Budget Reconciliation Act of 1986*, Pub. L. No. 99-509, 100 Stat. 1874 (codified at 42 U.S.C. § 1395ff(a) (2003)); *Shalala v. Illinois 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 [federal question] action”).

²³² *Guernsey Mem’l Hosp.*, 514 U.S. at 99 (construing a Provider Reimbursement Manual provision authorizing the Secretary to depart from generally accepted accounting principles when making certain reimbursement decisions).

²³³ 905 F.2d 1061, 1071-72 (7th Cir. 1990) (rejecting the Secretary’s contention that education activities must occur in a facility that is “part of the provider” in order to be reimbursed by Medicare).

the regulations themselves.”²³⁴ Unless such a showing could be made regarding one of the OIG’s informal fraud guidance documents, however, a challenge likely would be unavailing.²³⁵

Unlike HHS’ interpretation of the Medicare billing requirements, however, the focus of fraud guidance is not primarily on reimbursement methodology. Of course, the Medicare carriers and intermediaries strive to identify fraud (and to deny payment) at the time bills are submitted.²³⁶ But the primary manner in which the fraud laws are enforced is through the administrative, civil, and criminal adjudication processes outlined above.²³⁷ While a carrier or intermediary may “flag” a particular set of claims as raising concerns under the FCA or the Anti-Kickback Statute, the contractor has no authority to adjudicate the claimant’s guilt; instead, the case must be referred to the OIG (and possibly on to the DOJ) for investigation and prosecution.²³⁸ In any resulting litigation against the claimant, the agency’s guidance will likely play a pivotal role in determining whether the law was violated,

²³⁴ *Id.* at 1071; *see also* *Am. Lithotripsy Soc’y v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002) (holding that regulation defining lithotripsy as a Stark II “designated health service” was contrary to Congressional intent).

²³⁵ *See, e.g., Guernsey Mem’l Hosp.*, 514 U.S. at 94-95 (finding that the Manual provision authorizing departure from generally accepted accounting principles “is a reasonable regulatory interpretation, and we must defer to it”); *Downtown Med. Ctr./Comprehensive Health Care Clinic v. Bowen*, 944 F.2d 756, 768-69 (10th Cir. 1991) (finding that a Medicare Carrier’s Manual provision construing billing requirements was “reasonable and not inconsistent with the statute and regulations”).

²³⁶ *See, e.g.,* 42 U.S.C. §§ 1395nn(g)(1) (providing that no payment may be made for designated health services furnished pursuant to a prohibited referral under the Stark Law) & 1893 (creating the Medicare Integrity Program, under which HHS is authorized to enter into contracts with entities—including existing carriers and intermediaries—to carry out a variety of fraud detection and prevention activities).

²³⁷ *See, e.g.,* 42 C.F.R. pts. 1001, subch. B (2003) (setting out procedures for imposing exclusion), 1003 (setting out procedures for imposing civil monetary penalties, assessments, and exclusions) & 1005 (describing the appeals process for exclusions, civil monetary penalties, and assessments).

²³⁸ *See, e.g., United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (finding sufficient evidence from which the jury could have convicted the defendant of violating the Anti-Kickback Statute).

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even in situations where the agency's interpretation is not directly binding.

For example, Advisory Opinions are binding only on the parties who request them.²³⁹ In *Zimmer, Inc. v. Nu Tech Med., Inc.*, a manufacturer of orthopedic products sought to extricate itself from a consignment agreement with a supplier by arguing that the contract violated the Anti-Kickback Statute.²⁴⁰ In support of its contention, the manufacturer sought and received an Advisory Opinion from the OIG characterizing the agreement as “problematic” and “potentially abusive,” and refusing to immunize the relationship from prosecution.²⁴¹ While noting that the Opinion did not bind any agency other than HHS, the court acknowledged that “[n]onetheless, courts give great deference to agency regulations and agency interpretations of those regulations,” and found it proper for the plaintiff to introduce the Opinion into evidence.²⁴² The court ultimately agreed with the OIG's analysis of the facts and held that because the agreement violated the Anti-Kickback Statute, it was void and unenforceable under Indiana law.²⁴³

As this example suggests, courts will look to the agency's interpretation of the fraud and abuse statutes not only in enforcement actions *against* a defendant health care provider, but also in civil actions *between* the parties to an agreement. For example, in *Polk County v. Peters*, a hospital unsuccessfully sued a physician for money the hospital had advanced pursuant to a recruitment agreement.²⁴⁴ Noting that the OIG had issued a Special Fraud Alert detailing suspect hospital incentives to physicians—many of which were present in the case—the court found the

²³⁹ See 42 U.S.C. §1320a-7d(b)(4) (2003) (describing the effect of opinions).

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

²⁴¹ *Id.* at 854-56 (quoting Advisory Opinion No. 98-1, Mar. 19, 1998, available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_19.pdf).

²⁴² 54 F. Supp. 2d at 856. See also *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (deferring to the agency's interpretation of its own statutory mandate).

²⁴³ 54 F. Supp. 2d at 863.

²⁴⁴ 800 F. Supp. 1451 (E. D. Tex. 1992).

agreement to be in violation of the anti-referral statutes, and thus void and unenforceable under Texas law.²⁴⁵ Such cases raise the possibility that plaintiffs may be able to use this guidance as a tool to help them avoid onerous health care contracts as against public policy—something of an odd result for guidance designed primarily to protect *patients*, rather than to assist providers who are dissatisfied with their business deals.

Just as health care providers have a limited ability to *challenge* such informal sources of agency guidance, it similarly is unclear how far they are entitled to *rely* on them to defend their actions. As the Supreme Court has noted, “[i]nterpretive rules do not require notice and comments, although . . . they also do not have the force and effect of law and are not accorded that weight in the adjudicatory process.”²⁴⁶ It is well-accepted that the government cannot be estopped by erroneous representations made by its employees and agents, particularly regarding questions of benefit entitlements.²⁴⁷ In the health care context, courts have held that providers are not entitled to rely on erroneous *oral* advice from carriers and intermediaries with regard to Medicare rules and regulations.²⁴⁸ The fact that the relevant forms of OIG guidance are

²⁴⁵ *Id.* at 1455-56. Another district court cited the same Special Fraud Alert in a similar physician recruitment case, but found that unlike in *Polk*, the agreement’s language was ambiguous enough to preclude summary judgment with respect to whether patient referrals were required in return for the hospital’s payment. *See Feldstein v. Nash Community Health Servs., Inc.*, 51 F. Supp 673 (E.D.N.C. 1999).

²⁴⁶ *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995).

²⁴⁷ *See Office of Personal Mgmt. v. Richmond*, 496 U.S. 414, 414 (1990) (holding that erroneous oral and written advice regarding a claimant’s eligibility for disability benefits did not entitle the claimant to benefits that were not authorized by law).

²⁴⁸ In so holding, courts often focus on the provider’s duty to be familiar with relevant program requirements. *See, e.g., Heckler v. Community Health Servs. of Crawford County*, 647 U.S. 51, 64 (1984) (refusing to bind the government to oral advice given by a fiscal intermediary regarding whether certain 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”); *Downtown Med. Ctr./Comprehensive Health Care Clinic v. Bowen*, 944 F.2d

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written, however, is unlikely to provide protection; indeed, the challenged advice in one such case included not only oral statements, but also an outdated government form containing the erroneous information.²⁴⁹ It is not inconceivable, then, that a provider might have difficulty relying on informal guidance in its defense, at least if the government's views have since changed.

Nonetheless, a provider's reliance on fraud guidance should be strengthened by the fact that the majority of health care fraud laws require evidence of the defendant's fraudulent *intent* before a violation can be established.²⁵⁰ Although reliance on erroneous agency statements will not establish a defense as a matter of law, the fact that the defendant sought in good faith to comply with such advice may establish that the defendant lacked the requisite intent needed to violate the law.²⁵¹ Moreover, to the extent the government desires that informal guidance strengthen its relationship with the industry, it would be counterproductive to revise agency policy without giving providers enough time to comply with new interpretations.²⁵² For example, mindful that the Special Advisory Bulletin on Gainsharing Arrangements would

756, 760, 771 (10th Cir. 1991) (refusing to estop the government from denying reimbursement for physical therapy and psychological services on the ground that the Medicare carrier erroneously had advised the provider that it could bill for the services under a single provider number).

²⁴⁹ See *Office of Personal Mgmt.*, 496 U.S. at 417.

²⁵⁰ See, e.g., 42 U.S.C. § 1320a-7b(b)(1)-(2) (2003) (prohibiting defendants from "knowingly and willfully" engaging in acts that violate the Anti-Kickback Statute); 31 U.S.C. § 3729(a)(1) (2003) (barring defendants from "knowingly" submitting false claims under the FCA). The major exception is the Stark Law, which has no intent requirement. See 42 U.S.C. § 1395nn(a)(1) (2003) (outlining the prohibition).

²⁵¹ See, e.g., *United States ex. rel. Oliver v. Parsons Company*, 195 F.3d 457, 464 (9th Cir. 1999) ("A contractor relying on a good faith interpretation of a regulation is not subject to liability . . . because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.").

²⁵² Cf. William E. Kovacic, *The Civil False Claims Act as a Deterrent to Participation in Government Procurement Markets*, 6 SUP. CT. ECON. REV. 201, 203 (1998) (arguing that "[r]educing idiosyncratic risks of doing business with federal purchasing agencies is a key step toward establishing effective public/private partnerships . . .").

come as a surprise to many providers, the OIG agreed to “take into consideration in exercising its enforcement discretion whether [such an] arrangement was terminated expeditiously following publication of the Bulletin.”²⁵³ Thus, providers are unlikely to be penalized for following agency advice as long as they seek to revise their practices in a timely fashion. Nonetheless, providers may find the potential for liability due to their reliance on outdated advice to be unsettling, particularly when combined with other practical difficulties raised by the proliferation of informal guidance sources.

C. Litigation

The problems with both traditional forms of regulation and the proliferation of informal guidance mechanisms have generated attempts to address legal and regulatory ambiguity through litigation based on novel interpretations of the underlying provisions. The majority of these cases have been brought under the FCA, either as direct government prosecutions or as private actions under the law’s broad *qui tam* provisions. Such litigation is traditionally viewed as an example of *ex post* enforcement, under which the government investigates and prosecutes conduct by entities who have violated the rules against health care fraud.²⁵⁴ The situation is complicated, however, by the existence of an inordinate number of “gray areas” in federal health care program reimbursement, the difficulty of detecting fraud during claims processing, and the concomitantly low risk of an individual provider being caught and disciplined for any misbehavior.²⁵⁵ As

²⁵³ Special Advisory Bulletin on Gainsharing Arrangements, *supra* note 206. See also 42 C.F.R. §§ 1008.45(b)(2)-(3) (2003) (providing that if the OIG terminates or modifies a previously issued Advisory Opinion, it “will not proceed against the requestor . . . if such action was promptly, diligently, and in good faith” discontinued or modified within a reasonable period of time).

²⁵⁴ See Bhagwat, *supra* note 8, at 1282-88 (describing public *ex post* enforcement).

²⁵⁵ See Hyman, *Health Care Fraud and Abuse*, *supra* note 171, at 538-39 (describing the low likelihood of fraud being detected and punished); *supra* note 6 and accompanying text (explaining the complexity of federal health care

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Professor David Hyman has noted, “program administrators can compensate for a low risk of detection/conviction (that is, ex ante underinvestment in claims review) by imposing substantial ex post sanctions for misconduct,” an approach that may be “relatively unproblematic from an economic perspective . . . [but] questionable on psychological grounds.”²⁵⁶ Moreover, when the threat of such litigation can only be reduced by the defendant’s agreement to abide by novel program conditions not otherwise imposed by law or regulation, the settlement process may have the effect of transforming an ex post enforcement mechanism into an ex ante means of imposing compliance as the “price” of continued participation in the programs.²⁵⁷ Thus, while these cases have met with a certain degree of practical success, they raise a variety of troubling procedural and jurisprudential concerns.

1. Procedural Concerns

The procedural issues involved in the litigation process primarily concern the role of the *qui tam* relator, particularly the question of whether the relator has standing to maintain the suit if the government declines to intervene.²⁵⁸ In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, a company was accused of billing the government for more hours than its employees actually spent on federally funded projects; the United States declined to intervene in the suit.²⁵⁹ The Supreme Court held that in such circumstances, the relator has standing to sue as a

program requirements).

²⁵⁶ Hyman, *Health Care Fraud and Abuse*, *supra* note 171, at 540. *See also id.* 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”).

²⁵⁷ Bhagwat, *supra* note 8, at 1287 (describing immediate forms of enforcement).

²⁵⁸ *See* Krause, *supra* note 49, at 158-61 (presenting a detailed analysis of standing and fiscal harm). *See id.* at 136 n. 60 (discussing other procedural issues raised by *qui tam* suits).

²⁵⁹ 529 U.S. 765, 843-44 (2000).

partial assignee of the government's own damages claim.²⁶⁰ By holding that the relator has standing only in a derivative capacity, however, *Stevens* left open the issue of whether the government would have standing in the absence of its own financial injury.

The *Stevens* Court did offer a modicum of guidance:

It is beyond doubt that the complaint asserts an injury to the United States—both the injury to its sovereignty arising from violation of its laws (which suffices to support a criminal lawsuit by the Government) and the proprietary injury resulting from the alleged fraud.²⁶¹

In recognizing that the requisite harm can arise both from a “proprietary” injury and from an injury to the government’s “sovereignty,” the Court suggested that the government can be harmed under the FCA in ways that are *not* primarily financial, such as by violation of underlying program requirements or interference with government functions.²⁶² Because the allegations in the case concerned both sovereign and proprietary injury, however, the Court had no occasion to address whether non-proprietary injury, standing alone, would suffice.²⁶³ While *Stevens* suggests that government standing is unlikely to be at issue in most FCA cases, the question may remain open in the rare case where it can be shown that the government suffered no conceivable harm from the defendant’s acts.

Moreover, while *Stevens* resolved the Article III standing question, it did not address whether *qui tam* suits violate the Article II Appointments or Take Care Clauses of the United States Constitution.²⁶⁴ The Article II issues have been developed most fully in *Riley v. St. Luke’s Episcopal Hospital*, where a former

²⁶⁰ *Id.* at 846 (holding “that the United States’ injury in fact suffices to confer standing on respondent Stevens”).

²⁶¹ *Id.* at 844.

²⁶² See Krause, *supra* note 49, at 167-84 (discussing non-financial ways in which government can be harmed by false claims).

²⁶³ 529 U.S. 765.

²⁶⁴ U.S. CONST. art. II, §§ 2, 3; see *Stevens*, 529 U.S. at 848 n.8. *But see Stevens*, 529 U.S. at 878 (Stevens, J., dissenting) (arguing that the evidence was “sufficient to resolve the Article II questions” as well).

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nurse sued a hospital under the *qui tam* provisions.²⁶⁵ Despite the plaintiff's allegations that the defendants had conspired to defraud the United States Treasury, the government declined to intervene in the suit.²⁶⁶ In 1997, before the *Stevens* case reached the Supreme Court, a district court dismissed the suit for lack of standing.²⁶⁷ On appeal, a fifth circuit panel held that Riley had standing to sue, but that the suit violated the separation of powers doctrine and the Take Care Clause.²⁶⁸ The court subsequently agreed to rehear the case *en banc*, but delayed its decision pending the Supreme Court's opinion in *Stevens*.²⁶⁹ Finally, in May 2001, the Fifth Circuit issued an *en banc* opinion holding that the alleged delegation of prosecutorial power to the relator does not violate the Take Care or Appointments Clauses.²⁷⁰ Nonetheless, in the absence of guidance from the Supreme Court, the issue remains controversial.

2. *Jurisprudential Concerns*

While the constitutional contours of FCA enforcement remain confusing, judicial precedent offers a framework under which these issues eventually may be clarified. More troubling, however, are the fundamental fairness issues raised by permitting the litigation process to be used to make *substantive* legal

²⁶⁵ *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001) (*en banc*) (reversing the panel's decision that the *qui tam* provisions violated the Take Care Clause and separation of powers principles).

²⁶⁶ *Id.* at 751 (relating procedural history).

²⁶⁷ *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 982 F. Supp. 1261, 1268-69 (S.D. Tex. 1997).

²⁶⁸ *Riley v. St. Luke's Episcopal Hosp.*, 196 F.3d 514 (5th Cir. 1999).

²⁶⁹ *Id.*

²⁷⁰ *Riley*, 252 F. 3d at 749. The district court subsequently dismissed the *qui tam* claims, *see United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 200 F. Supp. 2d 673 (S.D. Tex. 2002), but they were reinstated by the Fifth Circuit. *See United States ex. rel Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370 (5th Cir. 2004). *See also* Richard A. Bales, *A Constitutional Defense of Qui Tam*, 2001 WISC. L. REV. 381, 437 (arguing that "dispersal of power among the citizens," unlike the aggrandizement of one branch at the expense of another, is consistent with the separation of powers doctrine).

determinations in the absence of traditional legislative and regulatory rulemaking procedures. In the health care fraud context, these concerns center on one particular phenomenon: the fact that the vast majority of such cases settle, rather than proceeding to trial.²⁷¹

The enormous potential liability under the Act, which includes not only tremendous civil penalties but also the specter of exclusion from federal health care programs, convinces many health care providers to settle FCA allegations for more reasonable sums plus the government's agreement not to pursue exclusion.²⁷² 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."²⁷³

While settlements may be preferable from the perspective of the parties involved in the litigation, they may not benefit the industry as a whole. To the extent settlement removes many factual and legal issues from judicial scrutiny, it may preclude a health care provider from arguing a range of issues that are crucial to the development of health care regulatory policy.²⁷⁴ The result of such

²⁷¹ See Aussprung, *supra* note 37, at 3.

²⁷² See Krause, "Promises to Keep", *supra* note 58, at 1413 (arguing that settlements permit unchecked prosecutorial discretion); Aussprung, *supra* note 37, at 3 (noting "only a small minority of health care fraud and abuse cases go to trial"); *supra* notes 53-57 and accompanying text (explaining the astronomical penalties that may be imposed under the FCA). This appears to be part of a broader trend in civil litigation. See Hope Viner Samborn, *The Vanishing Trial*, A.B.A.J., Oct. 2002, at 24 (discussing the decline in number of federal trials and the increase in settlements and alternative dispute mechanisms).

²⁷³ Reinhardt, *supra* note 7. See also William M. Sage, *Fraud and Abuse Law*, 282 J. AM. MED. ASS'N 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"); Hyman, *Health Care Fraud and Abuse*, *supra* note 171, at 552 (arguing that "the FCA makes it possible for the government and *qui tam* relators to extract the equivalent of greenmail as a discount off list price").

²⁷⁴ As one commentator has argued, "many aspects of the law are never

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settlements is an unofficial body of law comprised of legally untested theories of falsity and fraud—an amorphous body of quasi-legal guidance with no precedential value, but on which the government will nevertheless rely in future enforcement efforts.²⁷⁵

Admittedly, not all such settlements are equally troublesome. Many settlements dispose of purely factual issues, such as the truth or falsity of the claims submitted. For example, if a physician settles accusations that she “upcoded” bills by charging for a more expensive category of services than was rendered, the physician clearly will sacrifice her ability to prove that some of the challenged codes were in fact accurate.²⁷⁶ Although many settlement agreements make clear that the defendant is not admitting liability, it is equally clear that by settling, the defendant has waived the right to contest the truth of the government’s allegations.²⁷⁷ While the result might strike us as unfair if the government’s accusations lacked any evidentiary basis, the decision to settle these factual disputes is a strategic one based on whether the defendant wants to incur the time and expense of a trial.²⁷⁸

litigated and never face the winnowing effects of judicial scrutiny.” Sarah A. Klein, *False Claims Act: Protection or Persecution?* AM. MED. NEWS, Feb. 15, 1999, at 6. Cf. Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WISC. L. REV. 873, 926-27 (urging increased judicial oversight of agency consent decrees); Waller, *supra* note 175, at 1413 (decrying the “long-standing trend in which the courts appear to focus more on the enforcement of the private bargain reached by the parties rather than engage in a meaningful review of the public interest aspects of the private bargain itself” in the antitrust context).

²⁷⁵ See Aussprung, *supra* note 37, at 1 (describing settlements as “a *de facto* body of health care fraud and abuse law”).

²⁷⁶ Cf. Bucy, *supra* note 34, at 6 (describing a University of Pennsylvania PATH settlement based, in part, on allegations of upcoding for services rendered by physicians on the medical school faculty).

²⁷⁷ See, e.g., *United States v. Mississippi Baptist Med. Ctr., Settlement Agreement*, Oct. 10, 1999, reprinted in HEALTHCARE COMPLIANCE REP. (CCH) ¶ 130,318 (noting that “the Hospital by executing this Agreement does not admit to any liability or wrongdoing”).

²⁷⁸ See *id.* at ¶ 130,318 (“The United States and the Hospital disagree on whether any of the Claims described . . . might qualify as ‘false claims’ However, to avoid the time, expense, and uncertainty of litigation, the parties

What is more troubling, at least to this author, are situations in which the settlement process is used to circumvent judicial review of legal theories of falsity, fraud, or other elements of the law. For example, defining the requisite elements of falsity and intent under the FCA has proven to be a complicated task for the judiciary, at times resulting in inconsistent opinions.²⁷⁹ At trial, this ambiguity offers the defendant an opportunity to try to persuade the judge that its interpretation of the rules was correct, or at least constituted a good faith error. As commentators have noted, however, “[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 the trier of fact.”²⁸⁰ Recent enforcement efforts offer many examples of this phenomenon, but two will suffice: (a) the “bootstrapping” of regulatory violations into a basis for FCA liability; and (b) the recent debate over the prices the Medicare program pays for prescription drugs.

a. FCA Liability Based on Regulatory Violations

As noted above, a major FCA dispute concerns whether the law can be used as a vehicle for allegations that the defendant has violated other legal provisions pertaining to the federal health care programs—provisions that do not themselves provide private rights of action.²⁸¹ For several years, federal prosecutors and *qui tam* relators have invoked the FCA in situations where health care services were delivered to patients as claimed, but where the provider may have violated underlying legal requirements (such as the anti-referral laws) in furnishing the care.²⁸² Although there are few reported opinions on the merits of these allegations, several courts appear sympathetic to the proposition that a violation of the

have agreed to settle the matter.”).

²⁷⁹ See Krause, *supra* note 49, at 151-58 (discussing the judiciary’s tendency to confuse the elements of the FCA cause of action).

²⁸⁰ Jost & Davies, *supra* note 53, at 265.

²⁸¹ See *supra* notes 63-64 and accompanying text.

²⁸² See Krause, “Promises to Keep”, *supra* note 58, at 1391-1406 (discussing FCA cases).

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Anti-Kickback or Stark provisions may render subsequent claims for legitimate health care services per se false.²⁸³

Not all courts have accepted this argument. In *United States ex rel. Thompson v. Columbia/HCA Healthcare*, the Fifth Circuit rejected such per se allegations, limiting FCA suits to situations involving the false *certification* of compliance with relevant laws.²⁸⁴ As the court noted, “where the government has conditioned payment of a claim upon certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.”²⁸⁵ Under this approach, liability will hinge on whether certification of compliance with the relevant legal provisions truly is a condition of payment—often a difficult proposition to prove with regard to the federal health care programs.²⁸⁶

²⁸³ See *id.* (describing cases); *United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504, 1506 (S.D. Ohio 1994) (holding the relator “could produce evidence that would show that the kickbacks allegedly paid to the defendant physicians somehow tainted the claims for Medicare”); *United States ex rel. Pogue v. American Healthcorp., Inc.*, 914 F. Supp. 1507, 1509 (M.D. Tenn. 1996) (noting that “[a] recent trend of cases appear to support [the] proposition that a violation of Medicare anti-kickback and self-referral laws also constitutes a violation of the False Claims Act”). In a later proceeding after the *Pogue* allegations were transferred as part of multidistrict litigation, the district court affirmed the validity of these basic allegations. See *United States ex. rel. Pogue v. Diabetes Treatment Ctrs. Of America, Inc.*, 238 F. Supp. 2d 258, 263-66 (D.D.C. 2002) (upholding validity of theory).

²⁸⁴ 125 F.3d 899, 902 (5th Cir. 1997) (noting that “claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA”). See also *United States ex. rel. Barmak v. Sutter Corp.*, No. 95 CIV.7637 KTD RLE, 2002 WL 987109 (S.D.N.Y. May 14, 2002), at *5-6 (rejecting the argument “that a violation of the anti-kickback statute is *ipso facto* a violation of the FCA,” and noting the lack of causal relation between the alleged violations and the submission of claims); Krause, *supra* note 49, at 175-81 (discussing the certification approach).

²⁸⁵ 125 F.3d at 902 (emphasis added).

²⁸⁶ Krause, “*Promises to Keep*”, *supra* note 58. As the author previously has argued, claims submitted in violation of the Anti-Kickback Statute are *not* automatically “statutorily ineligible for payment,” as some commentators posit. *Id.* at 1394 (disagreeing with the district court’s conclusion on remand in *United*

A few years later, the Fifth Circuit appeared to retreat from its focus on express certification. In *United States v. Southland Mgt. Corp.*, the owners of a low-income housing project were accused of misrepresenting the condition of apartments subsidized by the Department of Housing and Urban Development (HUD).²⁸⁷ The government argued that the defendants' payment vouchers falsely certified that the units were in "decent, safe, and sanitary condition," despite the fact that repeated inspections had documented numerous deficiencies.²⁸⁸ HUD, however, continued to pay the vouchers while negotiating a corrective action plan.²⁸⁹ Given HUD's knowledge of the true conditions of the premises, the district court held that the misrepresentations obviously were not material to the agency's decision to disburse funds to the defendants.²⁹⁰

While acknowledging that the FCA contains a materiality requirement, a panel of the Fifth Circuit disagreed with the district court's reliance on how HUD *factually* handled the claims.²⁹¹ Instead, the court cited *Thompson* for the proposition that materiality is to be judged by the *legal* requirements of the statute, noting that the "disposition of this claim clearly indicates that if a certification of compliance with a statute or regulation is a

States ex. rel. *Thompson v. Columbia/HCA Health Care Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998)). Failure to comply with the Anti-Kickback Statute does *not* necessarily lead to either non-payment or expulsion from federal health care programs. *Id.*

²⁸⁷ 288 F.3d 665 (5th Cir. 2002).

²⁸⁸ *Id.* at 673.

²⁸⁹ *Id.*

²⁹⁰ 95 F. Supp. 2d 629 (S.D. Miss. 2000). Moreover, the district court suggested the government's prior knowledge of the defendants' activities could preclude a finding of falsity and/or intent. *Id.* at 643.

[B]ecause the defendants were fully apprised of HUD's awareness of the problems at the apartments which now form the basis of the Government's suit, and in fact, corresponded with HUD with respect to those very same problems, there can simply be no reasonable finding that defendants "knowingly" made a false statement or claim to HUD regarding the condition of the property.

Id.

²⁹¹ *Southland Mgt. Corp.*, 288 F.3d at 695.

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prerequisite to the defendant's *legal* entitlement to funds, the certification is a material misrepresentation and renders the claim false as a matter of law.²⁹² To the extent the court focused on the language of the statute and regulations in the abstract, rather than the government's actual payment procedures, litigants feared one avenue of FCA defense had been foreclosed.²⁹³

In April 2003, however, after rehearing the case *en banc*, the Fifth Circuit issued a new opinion upholding the district court's judgment for the defendant property owners.²⁹⁴ This time, the court's inquiry focused on the language of the agreement in question.²⁹⁵ Noting that the contract permitted HUD to undertake a variety of remedial actions against owners who failed to comply with program regulations, the court held that "[d]uring the corrective action period . . . claims for housing assistance payments are not false claims because they are claims for money to which the Owners are entitled (and which provide the wherewithal both to operate the property and to take the necessary corrective actions)."²⁹⁶ In essence, the *en banc* opinion returned the focus to the government's *actual* payment decision rather than an abstract reading of the program requirements, suggesting that defendants should have an opportunity to prove their alleged misrepresentations were not truly material to the government's payment decision and hence not actionable under the FCA.

Although much of the controversy thus far has centered on

²⁹² *Id.* at 679 (emphasis added). According to the dissent, the majority's interpretation of this novel "claim materiality" requirement was "ingenious but wrong." See *id.* at 693 (Jones, J., dissenting). See also Krause, *supra* note 49, at 188-201 (discussing FCA materiality requirement).

²⁹³ *Southland Mgt. Corp.*, 288 F.3d 665.

²⁹⁴ *United States v. Southland Mgt. Corp.*, 326 F.3d 669 (5th Cir. 2003).

²⁹⁵ *Id.*

²⁹⁶ *Id.* at 676. In a separate concurrence, Judge Jones objected to the majority's reliance on the contract terms, arguing that the case should have been affirmed because: (1) the defendants' certifications were not material to HUD's payment decision; and (2) the defendants could not "knowingly" have submitted false claims because the government was fully aware of the condition of the property. *Id.* at 678 (Jones, J., concurring). In her words, "[t]he government got exactly what it was willing to pay for." *Id.*

attempts to base FCA suits on violations of the anti-referral provisions, the more significant long-term impact of this approach may result from its application in the quality-of-care context. Health care providers, particularly institutions, must satisfy a wide range of highly technical conditions for participation in the federal health care programs.²⁹⁷ Failure to satisfy these conditions will subject the provider to a variety of sanctions, including civil penalties and possible program exclusion.²⁹⁸ Recently, the government and *qui tam* relators have argued that a request for payment submitted when the provider is out of compliance with any of these standards should be considered “false or fraudulent” under the FCA, even if the underlying noncompliance likely would not lead to any significant sanctions by program administrators.²⁹⁹

One of the first uses of this approach occurred in *United States ex. rel. Aranda v. Community Psychiatric Centers*, in which a psychiatric hospital was accused of failing to provide Medicaid patients with the “reasonably safe environment” required by federal law.³⁰⁰ The government argued that by billing Medicaid for patient care services, the hospital had implicitly and untruthfully certified that it was in compliance with all program-related quality requirements.³⁰¹ The district court agreed this could be a viable

²⁹⁷ See, e.g., 42 C.F.R. pt. 482 (2003) (describing the “conditions of participation” for hospitals).

²⁹⁸ 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).

²⁹⁹ See Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 123 (1999).

[T]hese conditions are not conditions of payment. To the contrary, the relevant Medicare regulations make clear that if a condition of participation is not satisfied, the provider is not excluded from the program, and payment is not stopped unless the HCFA determines that an immediate threat to the health or safety of patients exists.

Id.

³⁰⁰ 945 F. Supp. 1485 (W.D. Okla. 1996) (alleging that the environment was not “reasonably safe” because patients suffered physical injury and sexual abuse).

³⁰¹ *Id.* at 1487.

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theory of falsity and denied the hospital's motion to dismiss, noting that the Medicaid law and regulations mandated compliance with certain quality standards.³⁰²

Similar allegations were made in *United States v. NHC Healthcare Corp.*, in which the government argued that the defendant 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.³⁰³ The district court held that this approach required the government to prove "that the patients were not provided the quality of care which promotes the maintenance and the enhancement of the quality of life," as required by the Medicare and Medicaid programs.³⁰⁴ Citing *Aranda*, the court found that the FCA applied to the submission of claims for services not actually performed, and denied the defendant's motion to dismiss.³⁰⁵

Federal prosecutors have invoked this theory more broadly against nursing homes that allegedly bill the government for "inadequate" care. Since 1996, the United States Attorneys Office for the Eastern District of Pennsylvania has taken the lead in these cases, negotiating a number of high-profile settlements.³⁰⁶ Although the facilities generally have not admitted any wrongdoing, common elements of these settlements include the payment of civil penalties, development of training and oversight procedures for specific problem areas, third-party monitoring of

³⁰² *Id.* at 1488. Because the opinion concerned a motion to dismiss, the court did not have occasion to address whether the plaintiff ultimately would have prevailed on the merits. For a detailed discussion of the implied certification approach, as contrasted with the explicit certification and per se approaches, see Krause, "*Promises to Keep*", *supra* note 58, at 1392-1406.

³⁰³ 115 F. Supp. 2d 1149 (W.D. Mo. 2000).

³⁰⁴ *Id.*

³⁰⁵ *Id.*

³⁰⁶ 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 (1997) (prosecuting attorney's discussion of *United States v. GMS Management-Tucker, Inc.* No. 96-1271 (E.D. Pa., settled Feb. 21, 1996)); *Northern Health Facilities, Inc. v. United States*, 39 F. Supp. 2d 563 (D. Md. 1998).

quality conditions, and adoption of a corporate compliance program.³⁰⁷ While critics have argued that the inherently subjective issue of health care “quality” is better addressed through the health care licensing and disciplinary systems than through fraud prosecutions, quality of care clearly has become one of the government’s top fraud enforcement priorities.³⁰⁸ As the OIG warned in its *Compliance Program Guidance for Nursing Facilities*, “knowingly billing for nonexistent or substandard care, items, or services” may be actionable under the FCA.³⁰⁹ Thus, despite the lack of case law on the merits of these disputes, the FCA successfully has been used to negotiate settlements based on regulatory violations.

The consequences of using the litigation approach in this context are significant. In both the anti-referral and quality-of-care contexts, plaintiffs have successfully utilized FCA litigation to circumvent the normal adjudicative processes for determining whether an underlying violation has occurred and what sanctions may be appropriate.³¹⁰ When the suits are brought by the government, this strategy allows prosecutors to negotiate a favorable resolution of the allegations without proving that a violation actually occurred. Of course, to the extent a settlement primarily benefits patients, it is difficult to argue that the result is anything but a success. But when the suit is brought by a private party under the FCA *qui tam* provision, the result is somewhat different: the circumvention of the standard regulatory appeals process results in the diversion of some part of the proceeds into the pockets of private individuals, rather than into the Medicare

³⁰⁷ See, e.g., Hoffman, *supra* note 306, at 154-55.

³⁰⁸ See Fabrikant & Solomon, *supra* note 299, at 160-61 (arguing that a more appropriate remedy is to strengthen federal and state regulatory agency oversight of such institutions).

³⁰⁹ Publication of the OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14289, 14295 n.49 (March 16, 2000).

³¹⁰ See 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 when medical necessity disputes are handled through the administrative appeals process, rather than the FCA, health care providers often prevail).

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Trust Fund or the Health Care Fraud and Abuse Control Account. In such circumstances, the benefit to patients is reduced significantly.

b. Drug Pricing Issues

Another example of the use of FCA litigation to address regulatory ambiguity concerns the prescription drug industry, which has been under considerable scrutiny in recent years. In the past, the majority of this attention focused on drug sales and marketing practices, which potentially implicate the Anti-Kickback Statute.³¹¹ As the OIG noted in a 1994 *Special Fraud Alert on Prescription Drug Marketing Schemes*:

Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is compensated for promoting the selection of a specific product.³¹²

Because drug manufacturers do not submit bills directly to the federal health care programs, but rather sell their products to physicians, pharmacists, and patients, it has been difficult to reach these companies under traditional false billing theories. However, the recent extension of the exclusion sanction to include entities that indirectly furnish items and services to federal health care program beneficiaries has markedly strengthened the government's negotiating position relative to drug manufactures.³¹³

In addition to their sales and marketing practices, prescription drug companies have come under scrutiny for allegedly inflating the prices paid for their products by the federal health care

³¹¹ See generally Bulleit & Krause, *supra* note 68.

³¹² Office of the Inspector Gen., *Special Fraud Alert: Prescription Drug Marketing Schemes* (Aug. 1994), *reprinted in* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

³¹³ See 42 C.F.R. § 1000.10 (2003); *supra* notes 86-87 and accompanying text.

programs, particularly Medicare.³¹⁴ As of December 2003, Medicare generally reimbursed physicians on the basis of (i) their actual charges or (ii) 95 percent of the “Average Wholesale Price” (AWP) for drugs they administer in the office setting.³¹⁵ Unfortunately, the Medicare statute and regulations did not define this “average” price. Instead, the Medicare contractors based their calculations on information contained in pharmaceutical pricing publications and databases, which in turn received information directly from the manufacturers.³¹⁶ There is widespread agreement that the published prices do not reflect the actual price at which many physicians are able to purchase these products, due to volume discounts and other purchasing incentives.³¹⁷ Thus, reliance on published AWP may result in payments that are significantly *higher* than what many physicians actually pay for the drug, resulting in a nice profit—or “kickback”—when the physician is reimbursed.³¹⁸

³¹⁴ 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).

³¹⁵ 42 U.S.C. §§ 1395u(o)(1) & 13951(a)(1)(s) (2003). Medicare generally does not cover self-administered outpatient prescription drugs, such as pills. *Id.* § 1395x(s)(2)(A) (excluding coverage). Despite this significant limitation, preliminary estimates are that the program spent \$8.4 billion on prescription drugs in 2002. See Medicare Program; Payment Reform for Part B Drugs, 68 Fed. Reg. 50428, 50429 (Aug. 20, 2003) (citing statistics).

³¹⁶ John K. Iglehart, *Medicare and Drug Pricing*, 348 NEW ENG. J. MED. 1590, 1591 (2003).

³¹⁷ *Id.*

³¹⁸ See Kalb, *supra* note 314. Similarly, the Medicaid pricing provisions are notoriously complex. In brief, payment for single-source drugs may not exceed the lower of the estimated acquisition cost plus a reasonable dispensing fee, or the usual or customary charge. 42 C.F.R. § 447.331(b) (2003). Within these limits, states may develop their own reimbursement methodologies, which often are based on discounted AWP. See STATE MEDICAID MANUAL § 6305.1.B (stating that AWP, without a “significant” discount, is no longer an acceptable price estimate). In addition, the state Medicaid programs receive rebates from drug manufacturers, based on the greater of: (a) a statutory minimum percentage; or (b) the difference between the average price paid by wholesalers for products distributed for retail trade (“average manufacturer price”) and the “best price” paid for the product (i.e., the lowest price actually paid by any

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The most famous example of “AWP fraud” to date involved TAP Pharmaceutical Products, which in October 2001 agreed to pay a record \$875 million dollars to settle a variety of civil and criminal fraud allegations stemming from the sale of its cancer drug Lupron.³¹⁹ The government alleged that TAP knowingly reported AWP information that was significantly higher than Lupron’s true average sales price, thus assuring Medicare reimbursement would remain artificially high.³²⁰ Of course, this strategy did not directly translate into higher revenues for TAP: because the company does not sell its products directly to the Medicare program, it could not directly reap the benefits of the inflated price.³²¹ So the government further alleged that TAP “marketed the spread” between the discounted prices paid by its physician customers and the artificially high Medicare reimbursement—thus offering its customers a financial inducement to prescribe Lupron in violation of the Anti-Kickback Statute, and potentially implicating the FCA.³²² Moreover, by concealing the true pricing structure from Medicare and falsely advising its customers to report AWP rather than the actual price of the drug, TAP allegedly caused its customers to submit false claims.³²³ Settlement of the FCA allegations accounted for approximately \$560 million of TAP’s total payment, and disposed of two separate *qui tam* cases against the company.³²⁴

purchaser for the product, with the exception of certain government purchases). 42 U.S.C. § 1396r-8(c)(1) (2003).

³¹⁹ See Press Release, Dep’t of Justice, *supra* note 3. A consortium of patients and health plans are also pursuing civil actions for damages based on the company’s pricing activities. See *In re: Lupron(R) Marketing & Sales Practices Litig.*, 245 F. Supp. 2d 280 (D. Mass. 2003) (denying in part and allowing in part the parent company’s motion to dismiss for want of personal jurisdiction).

³²⁰ See Press Release, Dep’t of Justice, *supra* note 3.

³²¹ *Id.*

³²² *Id.*

³²³ *Id.*

³²⁴ See Press Release, Dep’t of Justice, *supra* note 3. TAP also pleaded guilty to a conspiracy to violate sections 331 and 353 of the Prescription Drug Marketing Act of 1987 by selling drug samples, and paid a \$290 million criminal fine. *Id.* The *qui tam* suits included a suit filed by TAP’s former Vice

Perhaps the greatest surprise surrounding the TAP case—aside from the magnitude of the settlement—was the fact that AWP problems had long been a matter of common knowledge. For the past thirty years, the federal government has been aware that published AWP does not reflect the actual price paid for many prescription drugs. 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 [percent].”³²⁵ 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.”³²⁶ A series of reports by the OIG and GAO in the 1990s further illustrated the problem, concluding that physicians were able to purchase these products at significant discounts from AWP.³²⁷

Prior to late 2003, longstanding recognition of the problem had led to several failed legislative and regulatory attempts to revise the Medicare drug reimbursement methodology.³²⁸ In 2000, for example, HCFA sent a memorandum to the Medicare contractors announcing an “alternative” source of AWP information developed by the DOJ and the National Association of Medicaid Fraud

President of Sales, who claimed to have quit because of his concerns about the company’s sales and marketing practices, and a suit filed by a urologist employed by one of TAP’s HMO customers, who reported that he had been offered an “educational grant” if he agreed to reverse the HMO’s decision to cover one of Lupron’s less-expensive competitors. *Id.* The whistleblowers received approximately \$95 million of the proceeds. *Id.*

³²⁵ Proposed Regulations Limiting Drug Costs, 39 Fed. Reg. 40,302 (Nov. 15, 1974).

³²⁶ Dep’t Health & Human Services, Medicare Program: Fee Schedule for Physicians’ Services, 56 Fed. Reg. 25,792, 25,800 (proposed June 5, 1991).

³²⁷ *See, e.g.*, GEN. ACCOUNTING OFFICE, MEDICARE: PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS’ COSTS, GAO-01-1118 (Sept. 2001), at 4 (estimating that physicians are able to purchase most Medicare-covered drugs at average discounts of 13 to 34 percent off of AWP, with some discounts running as high as 65 to 86 percent).

³²⁸ *See* CMS, Medicare Program; Payment Reform for Part B Drugs, 68 Fed. Reg. 50428, 50429 (proposed Aug. 20, 2003) (describing the history of payment methodology).

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Control Units.³²⁹ Two months later, HCFA instructed the contractors not to use the new data, noting that “congressional action may preclude the use of this alternative source.”³³⁰ Similarly, when Congress revisited the payment methodology in 1997, consensus could only be achieved to reduce payment to 95 percent of AWP—an amount clearly insufficient to offset the 13 to 34 percent actual discounts discussed above.³³¹

The reasons for these failures have been mostly political. Most significantly, efforts to revise drug payments have encountered strong opposition from the powerful oncology lobby, which has argued that the higher reimbursement reflected in the “spread” is needed to subsidize the special costs of storing and administering oncology drugs.³³² Recent reports have suggested that there is

³²⁹ See Program Memorandum AB-00-86 from Department of Health and Human Services, Health Care Financing Administration (Sept. 8, 2000), available at http://www.cms.gov/manuals/pm_trans/AB0086.pdf. See also, e.g., Grant Bagley et al., *The Bayer CIA: A Glimpse Into the Future of Pharmaceutical Reimbursements?*, 5 HEALTH CARE FRAUD REP. (BNA) 330, 332-33 (Apr. 18, 2001) (describing unsuccessful attempts to use revised, government-generated AWP data for certain drugs).

³³⁰ Program Memorandum AB-00-115 from Department of Health and Human Services, Health Care Financing Administration (Nov. 17, 2000), available at http://www.cms.gov/manuals/pm_trans/AB00115.pdf; Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, 114 Stat. 2763, § 429 (imposing moratorium on administrative decreases in drug reimbursement rates until completion of GAO study of current payment methodology). In August 2003, CMS reopened the issue by publishing a notice in the Federal Register proposing to revise the drug payment methodology by one of four approaches: (a) enforcing “comparability” between prices paid by contractors for drugs for their Medicare and private policyholders; (b) applying a greater AWP discount; (c) setting prices based on increased market monitoring; and (d) establishing a competitive acquisition program for drugs. Centers for Medicare & Medicaid Services, Medicare Program; Payment Reform for Part B Drugs, 68 Fed. Reg. 50428 (proposed Aug. 20, 2003) (to be codified at 42 C.F.R. pt. 405). Due to subsequent legislative activity, however, the future of the CMS provisions is unclear. See *infra* notes 345-51 and accompanying text.

³³¹ See Pub. L. No. 105-33, § 4556(a), 111 Stat. 251 (1997) (amending 42 U.S.C. § 1395u(o)(1)); *supra* note 327.

³³² See Iglehart, *supra* note 316, at 182 (describing the oncology community’s opposition to reform efforts).

indeed a problem with the current oncology practice expense methodology.³³³ Under Medicare's general budget-neutral approach to practice expenses, however, increasing oncologists' reimbursement would have required an equivalent reduction in payments for other types of specialists.³³⁴ Faced with the wrath of the oncology lobby if drug reimbursement were reduced—and the wrath of other powerful physicians' groups if oncologists' reimbursements were increased at their own expense—turning a blind eye to the AWP loophole may have been the most palatable alternative.

Given this historical context, two aspects of the TAP case stand out. First, 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. Second, and more important, the DOJ and HHS essentially used the fraud settlement process as a means of *closing* that loophole, at least with respect to TAP's products. The government did this through TAP's Corporate Integrity Agreement, which required the company to report the "Average Sales Price" (ASP) of each of its products on a quarterly basis.³³⁵ The ASP is defined as the average of all final sales prices charged by TAP for each product to all purchasers except (1) direct sales to hospitals and (2) sales not included in calculating the Medicaid

³³³ The GAO has agreed that the reimbursement methodology for oncologists should be revisited. See GEN. ACCOUNTING OFFICE, MEDICARE PHYSICIAN FEE SCHEDULE: PRACTICE EXPENSE PAYMENTS TO ONCOLOGISTS INDICATE NEED FOR OVERALL REFINEMENTS, GAO-02-53 (Oct. 2001).

³³⁴ See Iglehart, *supra* note 316, at 1595 (citing remarks by William J. Scanlon, director of health care issues for GAO). In the August 2003 Proposed Rule, CMS indicated its intent to resolve this issue by increasing the practice expense allocation for drug administration. 68 Fed. Reg. at 50,436-39. To the extent the payment increases were not offset by the savings from the revised drug reimbursement methodology, CMS stated that an exception to the budget neutrality requirement would apply. *Id.* at 50,439.

³³⁵ See Corporate Integrity Agreement Between The Office Of Inspector General Of The Department Of Health And Human Services And TAP Pharmaceutical Products Inc., § III.D (Sept. 28, 2001) [hereinafter Corporate Integrity Agreement], available at http://oig.hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf.

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rebate “best price.”³³⁶ The 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 charity care or grants.³³⁷ Thus, the ASP is a far more accurate assessment of the drug’s average market price than the company-reported AWP.

Clearly, the ASP reporting requirement was intended not only to track the price of the drugs, but also to permit CMS to *alter* their reimbursement. The CIA stated that the pricing information could be relied upon by CMS in establishing reimbursement rates for TAP’s products, although CMS could not change the rates without conducting “meaningful review for all government reimbursed therapeutically similar products.”³³⁸ Prior to late 2003, however, there appeared to be no authority for CMS to obtain ASP information from other manufacturers in the Medicare context, except on a voluntary basis (or pursuant to CIAs negotiated by other companies facing similar litigation).³³⁹ Moreover, to the extent the Medicare statute at the time mandated reimbursement on the basis of either actual charges or 95 percent of AWP, it is not clear that CMS had the authority to change reimbursement on the basis of ASP information: while ASP may be an average of *all* sales, it is not necessarily an estimate of the price paid by an individual physician, nor is it equivalent to the wholesale price.³⁴⁰ Nonetheless, the CIA was an attempt to accomplish via litigation

³³⁶ *Id.* at § II.D.2.a

³³⁷ *Id.*

³³⁸ *Id.* at § III.D.2.d. The information may also be used by state Medicaid programs in establishing reimbursement rates, subject to the provisions of TAP’s individual state settlement agreements. *Id.*

³³⁹ A number of other pharmaceutical companies are under investigation for similar practices. *See, e.g.*, Press Release, Dep’t of Justice, Bayer to Pay \$14 Million to Settle Claims for Causing Providers to Submit Fraudulent Claims to 45 State Medicaid Programs, Jan. 23, 2001, *available at* <http://www.usdoj.gov/opa/pr/2001/January/039civ.htm>. *See also* Reed Abelson & Jonathan D. Glater, *New York Will Sue 2 Big Drug Makers on Doctor Discount*, N.Y. TIMES, Feb. 13, 2003, at A1 (reporting spokeswoman for Aventis as stating “the company voluntarily stopped reporting an average wholesale price in August 2001”).

³⁴⁰ *See* 42 U.S.C. § 1395u(o)(1) (2003); 42 C.F.R. § 405.517(b) (2003).

something the legislative and regulatory processes had thus far failed to achieve: a revision of the Medicare drug reimbursement methodology to more accurately reflect the prices paid by customers. As one observer has argued, prosecutors “are trying to use litigation to force companies to change their practices, not just to win damages.”³⁴¹

And it was clear that these efforts would not be limited to TAP. In the subsequent *Compliance Guidance for Pharmaceutical Manufacturers*, the OIG identified the “Integrity of Data Used to Establish or Determine Governmental Reimbursement” as one of the key risk areas for pharmaceutical manufacturers.³⁴² As the OIG noted, “[t]he government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable.”³⁴³ Given reports of similar investigations against many other large pharmaceutical companies, it was quite possible that the OIG would be able to use the CIA process to induce pricing changes for many of the products reimbursed by the Medicare program—thus, as a practical matter, facilitating the underlying goal without resorting to contentious legal or regulatory actions.³⁴⁴

These suspicions were borne out in December 2003, when Congress finally passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.³⁴⁵ Under the new legislation, reimbursement for outpatient prescription drugs in 2004 generally will be set at 85 percent of AWP, subject to adjustments based on market surveys.³⁴⁶ Beginning in 2005,

³⁴¹ See Abelson & Glater, *supra* note 339 (quoting law professor Jennifer Arlen).

³⁴² OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,733 (May 5, 2003) (identifying key risk areas).

³⁴³ *Id.* at 23,733.

³⁴⁴ See, e.g., *TAP Pharmaceuticals, Bristol-Myers Squibb Targets of Federal Marketing, Pricing Probe*, 4 HEALTH CARE FRAUD REP. (BNA) 207 (2001) (describing investigations against other large pharmaceutical companies).

³⁴⁵ Pub. L. No. 108-173 § 303, 117 Stat. 2066, 2233 (2003) (“Payment Reform for Covered Outpatient Drugs and Biologicals”).

³⁴⁶ *Id.* at § 303(b)(2), 117 Stat. 2238-39 (to be codified at 42 U.S.C. §

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payment for single-source drugs will be based on the lesser of: (1) the “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.³⁴⁷ The OIG will be required to conduct surveys to monitor the market prices of drugs, and reimbursement may be adjusted accordingly; manufacturers who misrepresent a drug’s average sales price will be subject to civil monetary penalties, as well as FCA liability.³⁴⁸ Beginning in 2006, physicians will also have the option to obtain outpatient drugs through a competitive acquisition system.³⁴⁹ In order to address the oncology issues mentioned above, the drug pricing revisions are explicitly linked to an increase in practice expense reimbursement for drug administration, with such revisions exempted from the budget neutrality requirement.³⁵⁰

It is far too soon to determine whether the new provisions will resolve this long-standing debate. Despite the practice expense revisions, oncologists have already complained that the post-2005 reimbursement methodology will disadvantage them economically.³⁵¹ Moreover, the complexity of both the pricing and

1395u(o)(4).

³⁴⁷ *Id.* at § 303(c), 117 Stat. 2239-42 (to be codified at 42 U.S.C. § 1395w-3a(b)(4), (c)). Moreover, the definition of average sales price is similar to the definition of ASP found in the TAP CIA. *Id.*; Corporate Integrity Agreement, *supra* note 335, at § II.D.2.d.

³⁴⁸ Pub. L. No. 108-173, § 303(c), 117 Stat. 2243-44 (to be codified at 42 U.S.C. § 1395w-3a(d)). H.R. CONF. REP. NO. 108-391, at 592 (2003) (“The Conferees intend that if a manufacturer knowingly . . . submits 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.).

³⁴⁹ Pub. L. No. 108-173 § 303(d), 117 Stat. 2245-52 (to be codified at 42 U.S.C. § 1395w-3B).

³⁵⁰ *Id.* at §§ 303(a), 117 Stat. 2234-37, 2253 (providing for practice expense adjustments), (f) (prohibiting the Secretary of HHS from revising drug payment amounts in 2004 unless concurrent practice expense adjustments are made).

³⁵¹ *See, e.g.,* Darrin Schlegel, *US Oncology Says Medicare Changes Threat to Profits*, HOUSTON CHRON., Dec. 3, 2003, at Business, p. 1.

the practice expense revisions is likely to require extensive rulemaking by CMS, which—similar to other anti-fraud initiatives described in this article—may result in an unanticipated delay in implementation. For our purposes, however, it is significant that both these legislative changes and the most recent round of proposed regulatory amendments came about only *after* the widely publicized AWP fraud investigations and settlements demonstrated that the issue could be resolved. In this way, the litigation process not only foreshadowed, but in many ways provided a model for, the necessary statutory and regulatory changes.

IV. THE EFFECTS OF THE CURRENT REGIME

A. *Regulatory Ambiguity and Prosecutorial Discretion*

The resolution of regulatory ambiguity through selective litigation might not be of concern if all parties trusted the process to be fair. Unfortunately, the health care industry has alleged that the potential for astronomical FCA liability, combined with the threat of exclusion from federal health care programs, leaves providers virtually no choice but to settle disputes in which they might well prevail at trial. As one author has argued, “[p]roviders 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.”³⁵² Provider organizations have gone further, characterizing recent fraud enforcement initiatives as “border[ing] on extortion.”³⁵³ There is indeed some evidence to support these complaints, including a GAO report concluding that the United States Attorneys’ Offices participating in the “Operation Bad

³⁵² Hyman, *supra* note 1, at 155. *See also id.* at 166 (arguing that “settling these cases, at almost any price, became the only viable option” for hospitals targeted by the PATH initiative).

³⁵³ GEN. ACCOUNTING OFFICE, [Untitled Report], B-279893 (July 22, 1998), at 15 n.30 (describing comments made by the Louisiana Hospital Association).

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Bundle” laboratory initiative had no evidentiary basis for targeting the hospitals they selected for investigation.³⁵⁴ And even the courts have acknowledged that the government’s enforcement efforts have, on occasion, been “rather draconian.”³⁵⁵

That regulators wield significant power to encourage settlements—even in situations in which abstract legal analysis might favor the defendant—is not a novel proposition. Administrative law scholars have long acknowledged that, where not constrained by judicial review, the balance of power favors the government in settlement negotiations.³⁵⁶ As one commentator notes, “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.”³⁵⁷ Characterizing the process as “administrative arm-twisting,” another commentator argues that the practice “succeeds, and evades judicial or other scrutiny, in part because companies in pervasively regulated industries believe that they cannot afford to resist agency demands.”³⁵⁸

In addition to raising concerns about fairness to the industry,³⁵⁹ this approach also promotes a form of “regulation by litigation”—the agency’s ability to demand compliance with conditions of participation that are not required, and perhaps not permitted, under current law. This danger arises under any enforcement scheme that permits the *ex ante* imposition of negotiated conditions before a regulated entity is permitted to participate (or

³⁵⁴ See GEN. ACCOUNTING OFFICE, *MEDICARE FRAUD AND ABUSE: DOJ’S IMPLEMENTATION OF FALSE CLAIMS ACT GUIDANCE IN NATIONAL INITIATIVES VARIES*, GAO/HEHS-99-170 (Aug. 1999), at 4 (analyzing investigations); Hyman, *supra* note 1, at 165-66 (describing laboratory bundling investigations).

³⁵⁵ *Ass’n. of Am. Med. Coll. v. United States*, 217 F.3d 770, 781 (9th Cir. 2000) (noting that the “OIG could still modify its rather draconian view of the [Medicare] Act’s requirements for Part B billing”).

³⁵⁶ See, e.g., Bhagwat, *supra* note 8; Noah, *supra* note 274.

³⁵⁷ Bhagwat, *supra* note 8, at 1299.

³⁵⁸ Noah, *supra* note 274, at 922.

³⁵⁹ See Krause, *supra* note 49, at 210-12 (describing the importance of fair FCA enforcement to the perceived legitimacy of the anti-fraud agenda).

in this case to continue participating) in the relevant market:

The basic substantive concern . . . is that agencies and agency personnel will use the relatively unfettered authority they enjoy . . . in order to coerce compliance from regulated entities with substantive rules and interpretations which are of their own creation and are inconsistent with the norms laid out by the legislature or the courts.³⁶⁰

Of course, the bare fact that an administrative agency interprets (or even makes) law is not improper; indeed, the whole of administrative law is predicated on the premise that agency expertise is necessary to give meaning to the broad laws passed by Congress.³⁶¹ Moreover, the ability of an administrative agency to make law via means other than the traditional notice-and-comment or adjudicatory processes—such as through informal guidelines, advisory opinions, and public statements by agency officials—has been well-documented.³⁶² The use of such informal processes, however, necessarily means that a great deal of agency lawmaking takes place outside the established process for judicial review of administrative actions.³⁶³ This is particularly troubling in light of the fact that courts often defer to the positions expressed by the agency in such informal guidance.³⁶⁴ The above discussion

³⁶⁰ Bhagwat, *supra* note 8, at 1304.

³⁶¹ See *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (deferring to an agency's interpretation of its own statutory mandate).

³⁶² See, e.g., Waller, *supra* note 175, at 1404-05 (describing the development of antitrust guidelines); Bhagwat, *supra* note 8, at 1304-05 (describing the scope of delegated rulemaking authority).

³⁶³ See Bhagwat, *supra* note 8, at 1304-05 (noting that traditional rulemaking and adjudicatory processes occur in the context of judicial review, whereas "coerc[ed] . . . compliance [occurs] in a context where outside supervision is lacking"); Noah, *supra* note 274, at 936-37 (arguing that "[t]he opportunity to challenge agency action in court provides a critical deterrent to arbitrary action").

³⁶⁴ See, e.g., Waller, *supra* note 175, at 1407-08 (noting that courts defer to the antitrust guidelines); *Zimmer, Inc. v. Nu-Tech Med., Inc.*, 54 F. Supp. 2d 850, 862 (N.D. Ind. 1999) (agreeing with an OIG Advisory Opinion that found that an arrangement potentially violated the Anti-Kickback Statute); *supra* Part III.B.2.

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suggests that all of these concerns may be present in current health care fraud enforcement.

Similar concerns arise with regard to the exercise of prosecutorial discretion outside the regulatory context, such as with the DOJ's enforcement of the FCA in health care cases. Given the broad contours of the FCA and Anti-Kickback Statute, perhaps the extent of prosecutorial innovation in health care should not be surprising. As Charles Ruff once noted, "[l]ike Nature, the federal prosecutor abhors a vacuum. Given a statutory grant of jurisdiction, he will seek to bring within it any offense he finds unattended or even, in his view, inadequately attended."³⁶⁵ Congress is incapable of predicting all situations in which a new law may be invoked; instead, it enacts broad prohibitions which "are brought into contact with the real world only through the mediation of intricate judge-made doctrines that specify what these laws actually prohibit."³⁶⁶ Where a statute leaves room for interpretation as to the prohibited conduct, as with the anti-fraud statutes, prosecutors will be motivated to "bring previously undefined conduct to trial in the hope that the court will criminalize it."³⁶⁷ But while prosecutors play a necessary role in interpreting broad statutes, they must take care not to undertake the heart of the legislative function: defining the contours of prohibited public behavior.³⁶⁸

Although understandable from the perspective of law enforcement, this process proves to be less than ideal for providing

³⁶⁵ Charles F.C. Ruff, *Federal Prosecution of Local Corruption: A Case Study in the Making of Law Enforcement Policy*, 65 GEO. L.J. 1171, 1228 (1977).

³⁶⁶ Dan M. Kahan, *Is Chevron Relevant to Federal Criminal Law?*, 110 HARV. L. REV. 469, 471 (1996). As Kahan 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 when it does." *Id.*

³⁶⁷ Geraldine Szott Moohr, *Mail Fraud and the Intangible Rights Doctrine: Someone to Watch Over Us*, 31 HARV. J. ON LEGIS. 153, 179 (1994).

³⁶⁸ See Kahan, *supra* note 366, at 479-81 (explaining why "prosecutors end up with a significant share of delegated lawmaking authority"); Moohr, *supra* note 367, at 179 (noting that in such circumstances, "lawmaking devolves to law enforcers").

notice to potential defendants. As scholars have long acknowledged, federal prosecutors have strong personal incentives to apply the law in ways that benefit their personal agendas rather than the public good.³⁶⁹ Moreover, individual prosecutors may “internalize the political benefits and externalize the practical and human costs of adventurous readings of federal criminal law.”³⁷⁰ Nowhere are those costs greater than in disputes over the proper scope “of statutes that mark the boundary line between socially desirable and socially undesirable behavior.”³⁷¹ Health care anti-fraud statutes mark such a boundary: they protect against improper financial activities, while at the same time encouraging the provision of legitimate medical services and providing the flexibility necessary for the development of more efficient and higher quality delivery mechanisms. It is precisely in such circumstances where clear guidance is crucial in order to “avoid deterring desirable conduct.”³⁷²

The danger is that an overemphasis on enforcement may lull regulators into complacency, where they seek to delay difficult policy decisions in the hopes that the desired results instead may be achieved through the litigation process. There is some evidence that this has occurred in health care. As one judge recently observed in the nursing home context, “although extensive regulatory authority exists for punishing unscrupulous facilities, the Government has increasingly opted for the expedited results of lawsuits under the FCA’s powerful threats of significant fines, treble damages, and costly litigation fees.”³⁷³ Similarly, the

³⁶⁹ See Kahan, *supra* note 366, at 486-87 (noting the phenomenon of “prosecutorial overreaching”).

³⁷⁰ *Id.* at 487-88.

³⁷¹ *Id.* at 485.

³⁷² Hyman, *supra* note 1, at 539. See also Kahan, *supra* note 366, at 485 (arguing that “‘fair warning’ or notice” is most important in such situations); Noah, *supra* note 274, at 936 (arguing that “reliance on individualized bargaining undermines consistency and invites the standardless (and largely unaccountable) exercise of agency discretion”).

³⁷³ *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1152 (W.D. Mo. 2000). A similar process appears to be underway in the Environmental Protection Agency, where commentators argue that “[w]ith the

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ongoing pharmaceutical pricing investigations arose after more than thirty years of government awareness that the Medicare drug reimbursement system was flawed, during which time neither Congress nor HCFA/CMS was able to muster the political will to make the necessary changes.³⁷⁴ From both an academic and a practical perspective, it is problematic when enforcement is given a higher priority than clarifying the applicable regulations. So long as providers feel compelled to settle these allegations, however, there appears to be little incentive for regulators to make these necessary, and often controversial, policy revisions.

B. The Role of Private Relators

The fraud enforcement environment is complicated significantly by the presence of private relators under the FCA, who are free to bring suit even when the government declines to pursue the allegations.³⁷⁵ It is one thing to provide government prosecutors with the discretion to pursue novel interpretations of a broad statute; it is quite another to permit private individuals to reap multi-million dollar recoveries by using the FCA to pursue violations of ambiguous program rules containing no private rights of action.³⁷⁶ Although the drafters of the 1986 FCA amendments envisioned *qui tam* relators as helpful sources of information that otherwise would not have been available to the government, the reality has been quite different.³⁷⁷ The Supreme Court has

priority on meeting referral targets and collecting fines, enforcement officials forego opportunities to assist in diagnosing and solving the technical or production problems that can lead to noncompliance. This approach to enforcement robs the regulatory process of important feedback concerning how well the rules work.” Freeman, *supra* note 149, at 17.

³⁷⁴ See *supra* Part III.C.2.b. See also Patrick 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 policy-makers are delegating by default substantial policy-making authority to enforcement agencies and prosecutors”).

³⁷⁵ 31 U.S.C. § 3730(b) (2003).

³⁷⁶ Cf. *Sedima v. Imrex Co., Inc.*, 473 U.S. 479, 504 (Marshall, J., dissenting) (decrying the expansion of civil RICO cases by private litigants).

³⁷⁷ See S. REP. NO. 99-345, at 4, 23 (1986) *reprinted in* 1986 U.S.C.C.A.N.

acknowledged this, cynically concluding that “*qui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good.”³⁷⁸ Critics have argued that the FCA *qui tam* provisions undermine prosecutorial discretion by permitting relators to maintain suits that the government has declined to join, and by requiring the government to expend significant resources to review voluminous *qui tam* filings.³⁷⁹ While prosecutorial discretion may be an imperfect screen for preventing unjustified expansion of the FCA, it is infinitely preferable to a bounty system enforced by private individuals who have no obligation to further the government’s—or for that matter the patient’s—health care interests.³⁸⁰

These observations are not unique to the health care industry. Statutory enforcement by private parties has long been subject to allegations of abuse. Indeed, the FCA *qui tam* provisions are now unique in American law in part because such statutes fell out of favor in England in the 1600s, “due in large part to abuses by the informers, such as fraudulent prosecutions and extortion.”³⁸¹ Indeed, concern over the role of private parties in regulatory

at 5269, 5288 (“Detecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity.”).

³⁷⁸ Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 949 (1997).

³⁷⁹ As Professor James Blumstein has argued, permitting such *qui tam* suits in the Anti-Kickback context “allows the pursuit of a suit for civil liability without the restraining influence of a government official’s exercise of prosecutorial discretion.” Blumstein, *supra* note 154, at 218. See also Marsha J. Ferziger & Daniel G. Currell, *Snitching for Dollars: The Economics and Public Policy of Federal Civil Bounty Programs*, 1999 U. ILL. L. REV. 1141, 1171, 1185 (1999) (noting that “private enforcers have no incentive to engage in discretionary nonenforcement” and that false “tips” can be costly because they consume scarce agency resources).

³⁸⁰ See William E. Kovacic, *Whistleblower Bounty Suits as Monitoring Devices in Government Contracting*, 29 LOY. L.A. L. REV. 1799, 1825 (1996) (“While the interests of public enforcement officials may not be perfectly congruent with taxpayer interests, it is likely that the aims of *qui tam* relators and taxpayers also are not invariably congruent.”).

³⁸¹ Bales, *supra* note 270, at 386.

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decisionmaking permeates administrative law. As Professor Jody Freeman has explained:

Private actors exacerbate all of the concerns that make the exercise of agency discretion so problematic. They are one step further removed from direct accountability to the electorate As nonstate actors, they remain relatively insulated from the legislative, executive, and judicial oversights to which agencies must submit [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.³⁸²

Thus, there is a long-standing perception that it is improper for agencies to delegate substantial enforcement authority to private entities.

Compelling as it may be, however, this view of agency authority is far too simplistic. Private parties are given a role in enforcement precisely because experience has also shown us that administrative agencies, left to their own devices, are apt to be “captured by the interests they purport to regulate.”³⁸³ As Professor Spencer Weber Waller has noted, “[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.”³⁸⁴ In this context, the role of private “watchdogs” is crucial—as it was in fifteenth century England, where *qui tam* provisions first developed to counter disincentives for government officials to enforce the

³⁸² Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 574 (2000) [hereinafter, Freeman, *Private Role*]; Kovacic, *supra* note 380, at 1831-32 (explaining reasons why relators may “attack conduct that is benign”).

³⁸³ Waller, *supra* note 175, at 1428. Moreover, private relators may be able to provide “inside information” that the government otherwise might not be able to obtain. See Pamela H. Bucy, *Information as a Commodity in the Regulatory World*, 39 HOUS. L. REV. 905, 940 (2002) (“Complex economic wrongdoing cannot be detected or deterred effectively without the help of those who are intimately familiar with it.”).

³⁸⁴ Waller, *supra* note 175, at 1428.

property laws.³⁸⁵ The need for public oversight was evident in the debates surrounding the 1986 FCA amendments, particularly with regard to the defense industry:

Congress believed that many public officials were active participants in the corruption and therefore were unlikely to enforce the law diligently. Congress wanted to give defense industry functionaries a strong incentive to inform on fraudulent defense contractors, and create an enforcement mechanism that was independent of the Department of Justice officials who often were part of the problem.³⁸⁶

By providing an alternative source of information to supplement government investigations—and an alternate means of enforcement to counter government inertia—the *qui tam* provisions establish a mechanism for independent assessment of the government's enforcement priorities.³⁸⁷ Thus, while private enforcement may impose significant costs, it also offers much-needed oversight.³⁸⁸

The dangers of restricting the private role in enforcement can be illustrated by an all-too-recent example from the securities industry. During the 1990s, Congress became concerned with the volume of private securities fraud litigation, which critics characterized as “scandalous” and “legalized extortion by the plaintiffs bar.”³⁸⁹ In response, Congress sought to restrict the primary vehicle through which such private litigation had been brought: the civil provisions of the Racketeer Influenced and Corrupt Organizations Act (RICO), which permit “[a]ny person injured in his business or property” to bring suit for treble

³⁸⁵ Bales, *supra* note 270, at 386.

³⁸⁶ *Id.* at 388.

³⁸⁷ See Freeman, *Private Role*, *supra* note 382, at 663-64 (identifying advantages of private attorneys general); Ferziger & Currell, *supra* note 379, at 1200 (arguing in favor of properly constructed bounty systems).

³⁸⁸ See Bales, *supra* note 270, at 430 (arguing that “Congress made the policy choice, when it passed the FCA, that the benefits of vigorous enforcement of the laws prohibiting fraud against the government outweigh the drawbacks of dispersing prosecutorial power among the public”).

³⁸⁹ 141 CONG. REC. H.15215 (daily ed. Dec. 20, 1995) (remarks of Rep. Bliley in favor of overriding presidential veto of legislation).

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damages.³⁹⁰ In the Private Securities Litigation Reform Act of 1995 (PSLRA), Congress prohibited civil RICO suits based on allegations of fraud in the purchase or sale of securities.³⁹¹ While the amendment was an efficient method of preventing frivolous suits in the short term, the long-term consequences of abolishing this mechanism of private oversight of the securities industry did not become apparent for several years. In hindsight, some commentators attribute the recent Enron debacle, in part, to the significant reduction in legal risks faced by auditors and other “gatekeepers” once such private litigation was no longer permitted.³⁹² Thus, the health care industry should take a lesson from the securities industry: in our zeal to level the playing field for health care providers relative to *qui tam* relators, we must take care not to enact similarly counterproductive measures that allow fraud to flourish undetected, with similarly disastrous consequences.

C. Reconceptualizing Our Approach to Fraud

As the above discussion demonstrates, the current federal approach to health care fraud rests on an untenable combination of regulatory inertia, a proliferation of informal non-binding guidance, and an increasing amount of public and private litigation. Yet while deep dissatisfaction within the provider community is a legitimate concern, we cannot simply foreclose the litigation route—neither for government officials, nor for the private relators who both revitalize and complicate the enforcement process. How, then, can we increase fairness in health care fraud enforcement, while not sacrificing efficiency?

First and foremost, it is important to clarify key regulatory

³⁹⁰ 18 U.S.C. § 1964(c) (2003) (defining RICO remedies).

³⁹¹ Pub. L. No. 104-67, 109 Stat. 758, Tit. I., § 107 (1995) (codified at 18 U.S.C. § 1964(c) (2003)) (stating, “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).

³⁹² See, e.g., John C. Coffee, *Understanding Enron: “Its 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).

“gray areas.” As Professor Dan Kahan has argued:

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.³⁹³

Recent experience has demonstrated that it is indeed possible to close regulatory loopholes in the health care context. For example, Medicare covers only those items and services that are “reasonable and necessary,” criteria that have been interpreted to preclude coverage of “experimental or investigational” drugs and devices.³⁹⁴ In 1986, HCFA issued instructions denying coverage for medical devices that had not been approved by the Food and Drug Administration (FDA).³⁹⁵ When the OIG began to investigate widespread hospital billing for unapproved devices in the mid-1990s, a group of hospitals challenged the validity of these instructions.³⁹⁶ Although the suit was not successful, a simultaneous lobbying effort persuaded the government to develop a mechanism for covering a limited group of non-approved devices that are designated by the FDA as “non-experimental/investigational” in nature.³⁹⁷ Similar clarifications in regulatory “gray areas,” as may be occurring with pharmaceutical pricing, would go a long way towards assuaging industry concerns.

Second, even in the absence of regulatory clarification,

³⁹³ Kahan, *supra* note 366, at 493-94.

³⁹⁴ See 42 U.S.C. § 1395y(a)(1)(A) (2003) (reasonable and necessary criteria); Medicare Part A Intermediary Letter, No. 77-4 (Jan. 1977), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 28,152 (excluding coverage of experimental or investigational items and services).

³⁹⁵ See, e.g., Medicare Hospital Manual § 260.1, *reprinted in* Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp 1457, 1462 (C.D. Cal. 1996).

³⁹⁶ *Cedars-Sinai*, 939 F. Supp. at 1457.

³⁹⁷ See 42 C.F.R. § 405.201-15 (2003). This category includes low-risk devices and newer generations of previously approved devices that present only incremental risks over their predecessors. *Id.*

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prosecutorial discretion should be exercised so as to minimize the unfairness resulting from fraud investigations based on good faith interpretations of ambiguous provisions. For example, in the mid-1990s, the OIG undertook the nationwide PATH initiative to investigate whether hospitals had improperly billed for “physician” services that were actually rendered by interns and residents.³⁹⁸ Although regulations clarified in 1995 that Medicare would pay only when the attending physician was physically present at the time services were rendered, hospitals argued that the policy prior to that time had been unclear.³⁹⁹ HHS eventually admitted that the standards had “not been consistently and clearly articulated,” and limited future audits to hospitals in regions where the Medicare carrier had clearly explained the rules prior to 1993.⁴⁰⁰ As positive as this resolution may have been, however, it suffers from a significant limitation: it does not apply to suits brought by *qui tam* relators, who need not abide by the government’s prosecution decisions.⁴⁰¹

Third, as the author has suggested elsewhere, it might be possible to devise a format in which the critical legal issue—a

³⁹⁸ See generally, Bucy, *supra* note 34 (describing the initiative). Medicare Part B pays for patient care services by attending physicians in hospitals; interns and residents are funded by general graduate medical education payments made to the hospital under Medicare Part A, and may not bill for services to individual patients. *Id.* at 4.

³⁹⁹ See *id.* at 7-13 (describing the history of HHS guidance on this issue); 42 C.F.R. § 415.172 (2003) (final regulations). The hospitals were so convinced of the unfairness of the government’s position that they brought suit against HHS to prevent further enforcement. See *Assn. of Am. Med. Coll. v. United States*, 217 F.3d 770 (9th Cir. 2000) (affirming the dismissal of suit for want of jurisdiction, but without prejudice).

⁴⁰⁰ See Letter from Harriet S. Rabb, General Counsel of HHS, to Jordan J. Cohen, President of the Association of American Medical Colleges (July 11, 1997) (admitting lack of clarity and limiting future audits), *available at* <http://www.aamc.org/hlthcare/path/oig711.htm>. The OIG later withdrew from PATH audits at sixteen facilities whose communications with carriers had been unclear. See *Aussprung*, *supra* note 37, at 24.

⁴⁰¹ See Kovacic, *supra* note 380, at 1848 (calling for the DOJ to exercise its screening function more vigorously “to eliminate erroneous or frivolous suits” by *qui tam* relators); 31 U.S.C. § 3730(c)(3) (2003) (describing the procedure if the United States elects not to intervene in the suit).

novel theory of falsity or fraud—could be tested without subjecting the defendant to the full range of FCA liability.⁴⁰² For example, the parties might stipulate to the scope of liability, such as the number and value of claims submitted, and agree to test the legal theory in a bench trial.⁴⁰³ If the judge found the legal theory to be valid, the defendant would be subject to damages and penalties in the stipulated amounts. A ruling against the government, on the other hand, would serve as binding precedent that the defendant had not violated the FCA. If feasible, such a mechanism could provide judicial oversight of the theory of falsity, the crucial ingredient missing from current FCA enforcement. Again, however, this approach would be of limited utility if it did not apply to *qui tam* suits as well as government actions.

Finally, it may be time to rethink the current *qui tam* incentive structure, at least as it pertains to health care fraud. The number of *qui tam* cases filed since the 1986 amendments suggests that the drafters' strategy is working, perhaps better than anyone anticipated.⁴⁰⁴ Yet the success of a private bounty system should be measured by more than just the sheer number of cases filed; rather, it should be measured by the number of filings that identify *actual* fraud. This in turn requires that the incentive structure be neither too remote to induce participation from insiders, nor so generous as to tempt them to file meritless suits.

Good informant tips alert an agency to clear violations of law for which a high monetary penalty can be imposed; the worst tips alert agencies to actions that appear to be violations but are not. In these latter cases, the agency invests enforcement costs, and the defendant incurs defense costs, to engage in litigation yielding no penalty. These tips are not just “noise” in the system; they cost the agency

⁴⁰² See Krause, *supra* note 49, at 215-16.

⁴⁰³ A similar approach has been used to avoid litigating thousands of individual claims in FCA cases. See, e.g., *United States v. Krizek*, 859 F. Supp. 5 (D.D.C. 1994) (trying FCA case involving eight thousand claims on the basis of two hundred representative claims for seven representative patients).

⁴⁰⁴ See FCA Statistics, *supra* note 61 (stating that in 1998, approximately two-thirds of *qui tam* suits involved the federal health care programs).

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scarce enforcement resources, driving down the bounty scheme's overall efficiency. More troubling, such tips lead to unwarranted enforcement actions that give rise to the most well-grounded political objections to bounty schemes as a whole.⁴⁰⁵

Commentators suggest that the ideal bounty system is one that combines a relatively small bounty (such as 3 percent of the recovery) with a relatively high degree of certainty that the bounty will be paid.⁴⁰⁶ While a full discussion of the FCA *qui tam* incentive structure is beyond the scope of this article, it is worth noting that the current system appears to do much the opposite: it offers extraordinarily high recoveries for a few successful relators, but leaves the majority with nothing.⁴⁰⁷ Whether a more targeted bounty system might relieve provider anxiety without sacrificing truth and efficiency remains to be seen.

CONCLUSION

Clearly, health care fraud enforcement is flourishing. By emphasizing that fraud is both a *quality* and an *economic* issue—as in the nursing home context—prosecutors have characterized enforcement as protecting both beneficiaries and the public fisc.⁴⁰⁸ Similarly, in the prescription drug context, alleged overpricing has been characterized as harming both the federal health care programs and the patients who are responsible for artificially high copayments.⁴⁰⁹ This has proven to be powerful rhetoric.

⁴⁰⁵ Ferziger & Currell, *supra* note 379, at 1197-98 (describing a model bounty system).

⁴⁰⁶ *Id.*

⁴⁰⁷ *See, e.g.*, Press Release, Dep't of Justice, *supra* note 3 (describing TAP relators' recovery of \$95 million); Kovacic, *supra* note 380, at 1845-46 (objecting to FCA incentives that encourage relators to wait until damages are significant before filing suit, and noting that "[i]t is unwise to tie the firefighter's reward to the total size of the blaze extinguished"); *but see* Ferziger & Currell, *supra* note 379, at 1186 (arguing that several FCA mechanisms exist to deter "overzealous enforcement").

⁴⁰⁸ *See supra* notes 303-309 and accompanying text.

⁴⁰⁹ *See, e.g.*, CMS, Medicare Program: Payment Reform for Part B Drugs,

It seems unlikely that the current Administration will reverse this trend, even in light of the war against terrorism. The individuals who have taken the lead in fraud enforcement at the OIG, the DOJ, and the United States Attorneys' Offices generally are not political appointees. At a time of looming budget deficits, when recent audits still identify \$12 billion a year in improper Medicare payments, the government simply cannot afford to be "soft" on fraud. Moreover, if the new Medicare prescription drug program is ever to become a reality, a continued influx of funds from fraud recoveries (among other sources) is likely to be needed.⁴¹⁰

What will the future hold? This much seems clear: the pharmaceutical industry is back under scrutiny, not only for its sales and marketing activities, but also for its drug pricing methods and sponsorship of medical research.⁴¹¹ Similarly, the quality of care in nursing homes continues to generate a great deal of concern, which has been addressed both through traditional regulatory oversight mechanisms and, more recently, using the FCA.⁴¹² Indeed, the growing reliance on the FCA to enforce nursing home quality standards may signal the broader use of the law to address quality concerns in other health care contexts, such as hospitals and perhaps managed care organizations.⁴¹³

The conceptual model outlined above suggests that we will continue to see three separate mechanisms for reducing health care fraud: traditional notice-and-comment regulation; an ever-

68 Fed. Reg. 50,428, 50,443 (proposed Aug. 20, 2003) (describing how pricing proposals would save money for beneficiaries).

⁴¹⁰ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2066, 2072 (2003) (implementing prescription drug benefit as of January 1, 2006) (to be codified at 42 U.S.C. § 1395w-101(a)(2)).

⁴¹¹ See Notice, Department of Health and Human Services, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 65 Fed. Reg. 23,731 (May 5, 2003) (identifying risk areas for drug manufacturers).

⁴¹² See Notice, Department of Health and Human Services, OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000) (identifying risk areas for the nursing home industry).

⁴¹³ See Joan H. Krause, *Medicare Error as False Claim*, 27 AM. J. L. & MED. 181 (2001) (discussing the potential applicability of the FCA to hospitals).

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increasing variety of informal guidance; and a combination of private and public enforcement brought not simply against providers who engage in “raw fraud,”⁴¹⁴ but also against those who act in accordance with defensible interpretations of ambiguous laws and regulations. Yet experience suggests that this may not be a feasible strategy for the industry in the long run. Instead, the hallmark of an efficient anti-fraud strategy should be *clarity*: clear rules to be followed by those who participate in the federal health care programs, and clear penalties for those who stray.

⁴¹⁴ James F. Blumstein, *What Precisely is “Fraud” in the Health Care Industry?*, WALL ST. J., Dec. 8, 1997, at A25.