

# REFLECTIONS ON THE GOVERNMENT'S STICK AND CARROT APPROACH TO FIGHTING HEALTH CARE FRAUD

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## I. INTRODUCTION

Society devotes a tremendous amount of its resources to promoting the health of its citizens. More than any other single event, the creation of the Medicare and Medicaid programs in 1965 marked the federal government's entrance into the field of health care delivery. As the single largest payer of health care services, the federal government has influenced the health care system greatly by regulating how and what items and services will be reimbursed. As these two programs have grown, the government has also become increasingly involved in protecting the integrity of the programs from internal mismanagement, as well as provider fraud and abuse.

While a number of different federal and state agencies share the responsibility of protecting the Medicare program and its beneficiaries, the Office of Inspector General ("OIG") for the Department of Health and Human Services ("DHHS") retains primary authority. Established in 1976 as the first statutory inspector general, the office was created largely in response to scandals in the Medicare and Medicaid programs and the former Department of Health, Education and Welfare's inability to deter fraud and abuse in those programs.<sup>1</sup> The OIG is charged

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1. S. REP. NO. 94-1324, at 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5420, 5422.

with providing leadership and recommending policies designed to promote efficiency and to prevent fraud and abuse in the operation of the federal health care programs.<sup>2</sup>

Fulfilling this mandate is enormously challenging because the health care industry provides an environment that is ripe for abuse. The coverage and reimbursement of medical services are governed by a complex and often inconsistent set of rules which create countless loopholes that can easily be abused. The ambiguous nature of medical treatment, combined with patients who are often weak and vulnerable, enable health care providers to bill unnecessary tests and useless equipment to the programs. Additionally, defrauders will exploit the relationship of trust between physician and patient by rewarding the doctor for referring patients inappropriately. Whether a cash bribe or an inflated return on the doctor's investment in the scheme's joint venture, the objective is to override the physician's ethical and fiduciary duties at the expense of the patient and the health care programs.

Moreover, federal health care program reimbursement traditionally has been based primarily on a "pay and chase" system. In other words, government contractors, i.e., carriers and fiscal intermediaries that process Medicare and Medicaid payments, have processed and paid claims based on their facial representations with a limited amount of pre-payment review. To the extent that contractors have identified inappropriate billings, they generally have done so only after the money has been paid to the provider.

While these characteristics of the health care industry have always made it vulnerable to fraudulent schemes and abuses, recent years have seen a surge in complex schemes which often span several states and implicate millions of health care dollars. In response to this burgeoning problem, the federal government has developed a two-pronged approach that relies on a mix of traditional law enforcement tools to prosecute defrauders and creative measures to promote program integrity through collaboration with honest health care providers. This Article will explore the background of the current fight against health care fraud, the enhanced enforcement authorities, resources and

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2. *Id.*

initiatives available to the government, and the different collaborative efforts undertaken with the industry to strengthen the integrity of the government's health care programs. The enforcement/collaboration mix that will be used in the future to combat health care fraud will be influenced largely by an understanding of what has worked and what has not.

## II. THE RISE OF GOVERNMENT ENFORCEMENT AGAINST HEALTH CARE FRAUD

One prong of the government's efforts to protect the integrity of federal health care programs has been through the utilization of traditional law enforcement. The increased role of law enforcement in combating health care fraud is due largely to the recognition by policymakers that throughout the 1990s, fraud in federal health care programs became an enormous problem. Hardly a month passes when the news fails to carry a story concerning the government's investigation of a health care provider. Indeed, health care fraud has been described as the "crime of the nineties."<sup>3</sup>

Various government studies have supported the view that the country has been plagued with a health care fraud epidemic over the past decade. For instance, in 1992 the Government Accounting Office ("GAO") estimated that ten percent of all health care spending might be lost to fraud and abuse.<sup>4</sup> More recently, comprehensive audits of Medicare financial statements performed by the OIG found \$23 billion in overpayments in fiscal year ("FY") 1996 and \$20.3 billion in FY 1997.<sup>5</sup> While these audits were not intended to quantify the portion of the overpayments attributable to fraud, even if a relatively small

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3. 1995-1996 U.S. DEPT OF JUSTICE, HEALTH CARE FRAUD REP. 2 (1996).

4. George Anders & Laurie McGinley, *Surgical Strike: A New Brand of Crime Now Stirs the Feds: Health-Care Fraud*, WALL ST. J., May 6, 1997, at A1.

5. U.S. DEPT OF HEALTH & HUMAN SERVICES, AUDIT OF THE HCFA 1997 FINANCIAL STATEMENTS (1998). However, the most recent 1998 audit indicated that overpayments have been reduced 45% to \$12.6 billion, or an error rate of 7.1%, compared with an error rate of 11% in FY 1997 and 14% in FY 1996. DEPARTMENT OF HEALTH & HUMAN SERVICES-OFFICE OF INSPECTOR GENERAL, IMPROPER FISCAL YEAR 1998 MEDICARE FEE-FOR-SERVICE PAYMENTS 1 (1999) (visited Sept. 23, 1999) <[http://www.waisgate.hhs.gov/cgi-bin/waisgate?WAISdocID=5790111939\\_310\\_0\\_0&WAISaction=retrieve](http://www.waisgate.hhs.gov/cgi-bin/waisgate?WAISdocID=5790111939_310_0_0&WAISaction=retrieve)>.

portion of these overpayments are due to fraud, the amount is unacceptable. Furthermore, Malcolm Sparrow, a well-known researcher and commentator on health care fraud, believes that most insurers, public and private, have failed to adequately measure the true extent of the problem.<sup>6</sup> According to Sparrow, official reports of fraud may reflect just the tip of the iceberg.<sup>7</sup>

Alongside official views of the problem, the public shares the view that there is widespread health care fraud. In a 1997 Association of American Retired Persons ("AARP") survey, ninety-three percent of Americans believed fraud to be widespread in the health care system; seventy percent believed the Medicare program would be saved if fraud were eliminated; and eighty percent believed something can and should be done about health care fraud and that Congress should spend more money to combat it.<sup>8</sup> Naturally, the health care industry has taken exception to broad indictments of the provider community, and government spokespersons have continuously acknowledged that most providers deal with the federal health care programs in an honest and ethical manner.

Leaving aside the unanswerable question of what exact level of fraud exists in the system, one central fact clearly emerges. In response to the problem during the 1990s, the government launched a systematic and unprecedented enforcement effort to combat health care fraud. A number of significant interrelated developments over the course of the 1990s mark this effort, including: (1) a series of high profile, multi-million dollar recoveries against major health care corporations; (2) the increased use of the False Claims Act ("FCA") by the government, partly through *qui tam* lawsuits filed by private citizens; (3) the passage of major anti-fraud health care legislation and the corresponding growth and enhancement of law enforcement resources and evolution of enforcement strategies; (4) the development of National Project enforcement initiatives; and (5) the imposition of Corporate Integrity Agreements ("CIA"s) on providers that have abused the health care system.

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6. Malcolm K. Sparrow, *Fraud Control in the Health Care Industry: Assessing the State of the Art*, NAT'L INST. OF JUST. RES. IN BRIEF, Dec. 1998, at 1.

7. *Id.*

8. *AARP Survey Shows Public Attitudes Toward Health Care Fraud, Stronger Efforts Needed to Educate Consumers*, OLD PRESS, Mar. 6, 1997.

### A. Multi-Million Dollar Recoveries as a Sign of the Times

Perhaps the most visible sign of the government's vigorous anti-fraud enforcement activities is the series of high profile, multi-million dollar recoveries against major health care providers that occurred during the 1990s. While these cases represent a small percentage of the many important civil and criminal prosecutions brought by the government over the last decade, their ability to grab the headlines sent an unmistakable message: health care fraud will not be tolerated.<sup>9</sup>

1. *Operation LabScam.*—Undoubtedly, the “shot heard around the world” in the battle against Medicare fraud was the government's announcement in 1992 that National Health Laboratories, Inc. (“NHL”) agreed to pay \$110 million as part of a global settlement.<sup>10</sup> The payment was part of a settlement of fraud allegations that NHL engaged in abusive marketing practices that caused physicians to order medically unnecessary laboratory tests.<sup>11</sup> At the time, the civil settlement was one of the largest in the health care industry. Equally unprecedented, the laboratory and its president pled guilty to criminal charges relating to the laboratory's billing practices.<sup>12</sup>

In the aftermath of the NHL investigation and settlement, the government assembled a task force and launched a larger investigation and enforcement initiative known as Operation LabScam. LabScam targeted conduct similar to the wrongdoing at issue in the NHL case and focused on the country's largest

9. Although as of the date of this writing it has not yet been fully resolved through settlement or otherwise, perhaps no case has received as much media attention as the Columbia/HCA investigation, publicized in 1997 by law enforcement's seizure of records at an El Paso, Texas facility. See, e.g., Kris Hundley, *U.S. Expands Investigation of Columbia*, ST. PETERSBURG TIMES, Apr. 29, 1997, at E1. To date, the Department of Justice has intervened in at least three different *qui tam* suits against Columbia and has issued complaints against certain Columbia/HCA executives. See Lucette Lagnado, *U.S. Joins Whistleblower in Suit Against Columbia/HCA*, WALL ST. J., Apr. 12, 1999, at B4; Lucette Lagnado, *U.S. Amends Suit Against Columbia and Quorum, Alleging Pattern of Fraud*, WALL. ST. J., Feb. 3, 1999, at B2.

10. *NHL Will Pay U.S. \$100 Million to Settle Largest Medicare Fraud Case Ever*, DOJ PRESS RELEASE, Dec. 18, 1992.

11. *Id.*

12. *Id.*

independent clinical laboratories.<sup>13</sup> The OIG, in coordination with the Department of Justice ("DOJ") and other law enforcement agencies, including State Medicaid Fraud Control Units ("MFCU"s), formed this task force to promote interagency cooperation and proactive investigations.<sup>14</sup> This approach enabled the government to pursue simultaneously criminal, civil and administrative actions on a national level and recover millions of dollars.<sup>15</sup>

One of the achievements of Operation LabScam was reached in 1997 when the government announced that SmithKline Beecham Clinical Laboratories, Inc. ("SmithKline") had agreed to pay \$325 million to settle fraud allegations of unnecessary tests and billing and marketing fraud similar to those alleged in NHL.<sup>16</sup> As part of the global settlement of the case, SmithKline agreed to institute a comprehensive compliance program.<sup>17</sup> In addition to the NHL and SmithKline settlements, substantial settlements were reached with other major independent clinical laboratories.<sup>18</sup> Through Operation LabScam, the government recovered approximately \$800 million for the Medicare Trust Fund and the U.S. Treasury Operation.<sup>19</sup>

In addition to achieving record levels of fines and penalties, Operation LabScam spotlighted the need for improved compliance within the industry. In the wake of the lab initiative settlements, the clinical laboratory industry held a conference focused on the government's enforcement initiatives and appropriate compliance measures.<sup>20</sup> To facilitate and promote compliance within the laboratory industry, the OIG took the occasion of the SmithKline settlement to announce the release of its model compliance guidance for clinical laboratories.<sup>21</sup> Finally, another

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13. Dep't of Justice U.S. Attorney, E.D. of Pa., *DOJ & DHHS Highlight Latest Efforts to Fight Fraud by Clinical Laboratories*, DOJ PRESS RELEASE (Feb. 24, 1997) <<http://www.usdoj.gov/opa/pr/1997/February97/082ag.htm>> [hereinafter *Latest Efforts to Fight Fraud*].

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Latest Efforts to Fight Fraud by Clinical Laboratories*, *supra* note 13.

19. *Id.*

20. *Medicare Compliance Showdown for Hospital and Labs*, NATIONAL INTELLIGENCE REP., Feb. 26, 1997, at 1.

21. See *infra* notes 113-16 and accompanying text for discussion of the OIG

outgrowth of the initiative was that the Health Care Financing Administration ("HCFA") implemented programmatic changes regarding billing and reimbursement of laboratory claims.<sup>22</sup>

2. *National Medical Enterprises, Inc.*— In June 1994, another shock wave throughout the industry occurred when the government announced that National Medical Enterprises ("NME"), owner of over sixty psychiatric hospitals and substance abuse centers nationwide, agreed to pay the government \$379 million in criminal fines, civil damages and penalties.<sup>23</sup> The government alleged that NME committed fraud by admitting and treating patients unnecessarily, keeping patients hospitalized longer than was necessary in order to use up available insurance coverage, double billing and billing for services not performed.<sup>24</sup> In addition to paying the largest health care settlement in history, an NME subsidiary, Psychiatric Hospitals, Inc., agreed to plead guilty to making unlawful payments to induce doctors and other professionals to refer Medicare and Medicaid patients.<sup>25</sup> Significantly, NME agreed to divest itself of practically all its psychiatric hospitals and substance abuse business and to put its remaining hospitals and other NME health services under a "corporate integrity plan" to assure better patient care and compliance with regulations.<sup>26</sup>

The NME case implicitly highlighted the government's focus on quality of care as a fraud issue. NME's alleged conduct not only harmed Medicare financially, but it also victimized patients by exposing them to mental treatment services that were not needed or by denying them treatment that was needed. In short, when a provider delivers substandard care to a Medicare beneficiary, the government is not getting its benefit of the bargain. This focus on substandard care as fraud has become explicitly evident in the various nursing home fraud settlements reached

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compliance guidances.

22. *HCFA Urges Switch to New CPT Automated Test Panels*, NATIONAL INTELLIGENCE REP., Mar. 26, 1997, at 1.

23. *Record Fine for Health Care Fraud and Kickbacks*, DOJ PRESS RELEASE, June 29, 1994, at 1, 2.

24. *Id.* at 3.

25. *Id.* at 2.

26. *Id.*

by the government in the last couple of years.<sup>27</sup>

3. *Caremark, Inc.*—The trend of large publicly traded health care corporations resolving fraud allegations through multi-million dollar settlements has expanded to all types of providers. For instance, in June 1995, Caremark, Inc. agreed to pay \$161 million to settle criminal and civil liabilities for paying kickbacks to physicians for referrals to its home infusion oncology, hemophilia and human growth hormone businesses, submitting improper billings, and failing to keep accurate records at some of its pharmacies.<sup>28</sup> The company entered criminal pleas in Ohio and Minnesota and entered into a corporate integrity plan for five years.<sup>29</sup> Significantly, the Caremark case led to a private shareholder derivative suit, in which a court found that corporate directors may have a duty to establish compliance programs,<sup>30</sup> thus illustrating how law enforcement can play an indirect role in causing the industry to embrace compliance.

4. *University of Pennsylvania Teaching Hospital.*—The \$30 million 1995 settlement with the Clinical Practices of the University of Pennsylvania ("CPUP") in 1995 did not equal the financial magnitude of the NHL, SmithKline, NME or Caremark settlements; however, the case sent an important new signal to the health care industry. For the first time, a government investigation focused on a prestigious teaching hospital and its faculty physician billing practices.<sup>31</sup> Among other charges, the government alleged that CPUP faculty physicians billed for services actually performed by resident physicians in training.<sup>32</sup> Under Medicare rules, the government already pays for a substantial

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27. See, e.g., U.S. GEN. ACCOUNTING OFFICE, CALIFORNIA NURSING HOMES: CARE PROBLEMS PERSIST DESPITE FEDERAL AND STATE OVERSIGHT (1998).

28. *Caremark to Pay \$161 Million in Fraud and Kickback Cases*, DOJ PRESS RELEASE (June 16, 1995) <[http://www.usdoj.gov/opa/pr/Pre\\_96/June95/342txt.html](http://www.usdoj.gov/opa/pr/Pre_96/June95/342txt.html)>.

29. *Id.*

30. *In re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959, 970-72 (Del. Ch. 1996).

31. *Penn Will Pay for Medicare Overcharges*, PITT POST GAZETTE, Dec. 13, 1995, at B2.

32. *Id.* See also David K. Johnston, *University Agrees to Pay in Settlement on Medicare*, N.Y. TIMES ABSTRACTS, Dec. 13, 1995, available in WL, ABS Database 1995 WL 9681824.

portion of the residents' training and salaries, and their services cannot be billed on a fee-for-service basis.<sup>33</sup> The government also alleged that faculty physicians billed for higher levels of patient evaluation and management than was actually provided and that the physicians' documentation for such services was inadequate.<sup>34</sup>

The publicity surrounding the size of the civil settlements and the criminal pleas focused the industry on the need for voluntary compliance. This need was also highlighted by the inclusion of mandatory compliance obligations as part of the global settlements. Furthermore, the success of these cases demonstrate to government policymakers the growing importance of multi-district, multi-agency task forces as an integral part of law enforcement strategy and tactics.<sup>35</sup>

### *B. Government's Use of the False Claims Act and the Escalating Role of Qui Tam*

*1. The False Claims Act: the Government's Primary Weapon Against Fraud.*—The health care settlements discussed in the prior section resolved, among other issues, the health care providers' liability under the civil False Claims Act ("FCA"), one of the integral weapons in the government's anti-fraud arsenal. For over a century, the federal government has used the FCA as its "primary litigative tool" to combat fraud against federally-funded programs.<sup>36</sup> Although originally intended to counter fraud by army contractors, the law was written in general terms and became a tool to combat fraud perpetrated against all federal government programs.<sup>37</sup> Thus, as Medicare and Medicaid fraud moved to the forefront of concern, the DOJ quite naturally turned this powerful legal tool toward health care defrauders.<sup>38</sup>

33. DEPARTMENT OF HEALTH & HUMAN SERVICES-OFFICE OF INSPECTOR GENERAL, SEMI-ANNUAL REP., OCT. 1, 1998-MAR. 31, 1999, at 3-4.

34. See Johnston, *supra* note 31; *Penn Will Pay for Medicare Overcharges*, *supra* note 30, at B2.

35. See *infra* notes 13-22 and accompanying text.

36. S. REP. NO. 99-345, at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5266. The law was originally passed in 1863 during the Civil War and was signed by President Abraham Lincoln. Act of Mar. 2, 1863, ch. 67, 12 Stat. 696.

37. S. REP. NO. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5273.

38. See *Peterson v. Weinberger*, 508 F.2d 45 (5th Cir. 1975) (holding that Medi-

In general, the FCA is violated when a person or entity deceives the federal government in order to improperly obtain money from the government or to be improperly relieved from paying money to the government.<sup>39</sup> In short, the FCA prohibits, among other things: (1) knowingly submitting (or causing to be submitted) to the federal government a false or fraudulent claim for payment; (2) knowingly using (or causing to be used) a false record or statement to get a false or fraudulent claim paid by the government; (3) conspiring with others to get a false or fraudulent claim paid by the government; and (4) knowingly using (or causing to be used) a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government ("reverse false claim").<sup>40</sup> Despite the FCA's long history, it had fallen into relative disuse until 1986 when Congress dramatically strengthened the law amid reports of escalating fraud against the government. At that time, the GAO and the DOJ estimated that fraud was draining up to 10% of the entire federal budget.<sup>41</sup> Among other things, the 1986 amendments (1) increased the cost of violating the law to treble damages and mandatory civil penalties of between \$5,000 and \$10,000 for each false claim; (2) clarified the knowledge standard so that defendants would be liable for submitting claims in "deliberate ignorance" or "reckless disregard" of the truth or falsity of the claims; (3) eliminated the need to prove specific intent; (4) codified the normal civil action "preponderance of the evidence" standard of proof into the FCA; and (5) made sweeping changes to the private enforcement mechanism in the law known as *qui tam*, which has played an integral part in the dramatic rise in anti-fraud enforcement.<sup>42</sup>

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care and Medicaid claims are directly or indirectly paid from federal government funds, thus false claims to those programs trigger liability under the FCA).

39. False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. § 3729 (1994)).

40. 31 U.S.C. § 3729(a)(1)-(7).

41. See S. REP. NO. 99-345, at 2-3 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5266-68.

42. See *id.*

2. *The Escalating Role of Qui Tam in Health Care Fraud Enforcement.*—One common thread underlying some of the highlighted settlements, as well as many other subsequent major settlements, is their genesis in the filing of private whistleblower suits, properly known as *qui tam* lawsuits. The term "*qui tam*" stands for a longer Latin phrase that is translated as "who as well for the king as for himself sues in this matter."<sup>43</sup> In short, the *qui tam* provisions of the FCA allow private parties (known as relators) to bring lawsuits alleging FCA violations on behalf of the federal government and to share in any recovery made either by the government or by the *qui tam* plaintiff on his or her own.<sup>44</sup>

In 1986, as noted above, amid widespread reports of "pervasive" fraud against the government, Congress sought to revitalize the *qui tam* provisions because it believed that "only a coordinated effort of both the government and the citizenry [would] decrease this wave of defrauding public funds."<sup>45</sup> According to Congress, it intended "to encourage more private enforcement suits" under the FCA.<sup>46</sup> Among other things, the 1986 *qui tam* amendments (1) guaranteed relators a share of between 15% and 30% of the funds recovered from the defendant in a successful case; (2) entitled relators to reasonable attorneys' fees and expenses; (3) allowed relators to remain as parties in the suits that the government joined or to pursue their own cases if the government declined; (4) eliminated the restrictive "government possession of information" bar against *qui tam* suits and replaced it with a less restrictive "public disclosure" bar; and (5) protected whistleblowers from employer retaliation.<sup>47</sup>

Eventually, private relators responded to Congress' action, and *qui tam* filings began a yearly and steady climb. For instance, *qui tam* filing increased from 33 in FY 1987 to 131 in FY 1993, and then to 530 in FY 1997.<sup>48</sup> Moreover, private citizens

43. See BLACK'S LAW DICTIONARY 1251 (6th ed. 1990).

44. 144 CONG. REC. D416-01 (daily ed. Apr. 28, 1998) (statement of Lewis Morris, Assistant Inspector General for Legal Affairs).

45. See S. REP. NO. 99-345 at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5267.

46. See *id.* at 23-24, reprinted in 1986 U.S.C.C.A.N. at 5288-89.

47. See *id.* at 23-25, reprinted in 1986 U.S.C.C.A.N. at 5288-300.

48. THE FALSE CLAIMS ACT LEGAL CENTER, 12 TAXPAYERS AGAINST FRAUD Q. REV. 41 (1998).

joined the health care anti-fraud effort in dramatically increasing numbers. By 1996, the majority of *qui tam* suits were, and continue to be, filed against health care providers.<sup>49</sup>

*Qui tam* lawsuits have long been accompanied by heated debate. Whether one views *qui tam* as a positive or negative influence, there is little dispute that *qui tam* lawsuits have had a dramatic impact on the health care industry and will likely continue to do so for the foreseeable future.<sup>50</sup> For instance, under the threat of potential *qui tam* actions, providers must, out of sheer necessity to protect themselves, take employee complaints alleging fraud seriously and respond appropriately when they find it, thereby hopefully reducing the likelihood of employees filing *qui tam* suits. To do otherwise leaves the provider open to *qui tam* suits by employees who believe the company cares little about preventing fraud and encourages abuse. The *qui tam* phenomena highlights that the industry's best protection against the "stick" of government enforcement is to embrace compliance and to try to prevent fraud and abuse from occurring in the first place.

### C. Anti-Fraud Health Care Legislation, Increased Resources and Evolving Enforcement Strategies

Headline-making settlements under the FCA and its *qui tam* provisions were not the only signal that health care fraud enforcement had become a chief focus of public policy makers and the law enforcement community. Indeed, as early as 1993, United States Attorney General Janet Reno declared that health care fraud enforcement would be one of the top priorities at the DOJ.<sup>51</sup> Congress, too, focused on the problem and eventually

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49. *Id.* (noting that the percentage of *qui tam* cases involving the DHHS as the client agency increased from 12% in FY 1987 to a majority, 56% by FY 1996 and 54% in FY 1997).

50. See *Justice Department Recovers More Than \$2 Billion in False Claims Act Awards and Settlements*, DOJ PRESS RELEASE, Oct. 23, 1998. Taking into account all federal programs, not just health care, there have been more than 2400 *qui tam* suits filed since the 1986 amendments, leading to total recoveries of \$2.249 billion. *Id.* Significantly, it took until 1995 to reach the first \$1 billion mark and then only three more years to reach the \$2 billion mark. *Id.*

51. 1995-1996 HEALTH CARE FRAUD REP. 1, *supra* note 3, at 1.

passed major anti-fraud measures through the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")<sup>52</sup> and the Balanced Budget Act of 1997 ("BBA").<sup>53</sup> These statutes expanded the OIG's administrative authorities and created new health care fraud crime provisions. Moreover, the HIPAA provided substantial and secure funding for anti-fraud enforcement through the creation of the Health Care Fraud and Abuse Control Program ("Program"). Armed with these additional legislative tools and resources, the OIG, DOJ and other law enforcement agencies were able to dramatically increase personnel and to expand their use of previously developed interagency enforcement strategies.

*1. New or Enhanced Anti-Fraud Statutes.*—Prior to the HIPAA, the OIG had authority to impose either mandatory or permissive exclusion from the Medicare and Medicaid programs for any one of a number of specific acts or omissions.<sup>54</sup> Among other things, the HIPAA added as two new bases for mandatory exclusion the felony conviction involving the delivery of a health care item or service and the felony conviction relating to controlled substances.<sup>55</sup> The HIPAA also added two new bases for permissive exclusion relating to ownership, controlling interest or management responsibility in sanctioned entities.<sup>56</sup>

More recently, in the BBA, Congress further expanded the OIG's exclusion authority. First, in response to continuing reports of fraud and abuse, Congress added a "three strikes and you're out" provision to the mandatory exclusion authority.<sup>57</sup> In other words, a provider who is convicted on three or more occa-

52. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

53. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251.

54. See 42 U.S.C. § 1320a-7 (1994 & Supp. III 1997). Exclusion is an administrative remedy possessed by the Secretary of Health and Human Services and delegated to the Office of Inspector General by which health care entities or individuals are barred from participating in the federal health care programs as providers. *Id.* In other words, if excluded, a provider may not submit claims for reimbursement to the federal health care programs for any services rendered to federal health care program beneficiaries. See *id.*

55. *Id.* §§ 1320a-7(a)(3), -7(a)(4).

56. *Id.* § 1320a-7(b)(15) (1994)

57. 42 U.S.C. § 1320a-7(c)(3)(G)(ii) (1994 & Supp. III 1997).

sions of mandatory exclusion offenses would be permanently excluded. Congress also expanded the scope of exclusion from Medicare, Medicaid and other state health care programs to all "[f]ederal health care programs," which is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government."<sup>58</sup>

Congress also enacted a number of enhancements to the OIG-administered Civil Monetary Penalty ("CMP") authorities through the HIPAA and the BBA. For instance, under the HIPAA, Congress raised the amount of authorized penalties and assessments to \$10,000 per false item or service claimed and treble the amount improperly claimed.<sup>59</sup> Second, it "clarified" the standard of knowledge required to impose liability as "knowing" presentment of false or fraudulent claims, and it defined the term "should know" to mean acting with "deliberate ignorance" or "reckless disregard of the truth or falsity of the information" submitted, which is consistent with the "knowledge" standard of the FCA.<sup>60</sup>

Congress also added new CMP authorities in the BBA. For instance, it authorized a CMP remedy for violations of the anti-kickback statute by providing for a CMP of up to \$50,000 per violation and an assessment of up to treble the amount of improper remuneration.<sup>61</sup> It also authorized a \$10,000 penalty and treble the amount claimed CMP for contracting with an excluded individual and submitting claims for those services while the person knew or should have known about that individual's exclusion.<sup>62</sup>

In addition to strengthening the OIG's administrative authorities to combat fraud, the HIPAA also created a variety of new criminal sanctions that applied to Medicare and Medicaid fraud and that extended to fraud perpetrated against any health care benefit program, including private payor plans. These new criminal provisions included health care fraud, embezzlement of

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58. *Id.* § 1320a-7b(f)(1) (Supp. III 1997).

59. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 § 231(c), 110 Stat. 1936.

60. *Id.* § 231(d).

61. 42 U.S.C. § 1320a-7a(a)(7).

62. *See id.*

health care funds, false statements relating to health care, obstruction of criminal investigations of health care offenses, and money-laundering of proceeds of health care offenses.<sup>63</sup>

2. *Health Care Fraud and Abuse Control Program.*—As previously mentioned, one of the most crucial aspects of the HIPAA was the creation of a statutorily mandated Program.<sup>64</sup> Under the joint direction of the Attorney General and the Secretary of DHHS acting through the OIG, the Program was designed to achieve certain statutory goals, including (1) coordinating federal, state and local law enforcement efforts relating to health care fraud, (2) conducting investigations, audits and evaluations relating to the delivery of and payment for health care in the United States, (3) facilitating enforcement of the civil, criminal and administrative statutes applicable to health care, (4) providing industry guidance, including advisory opinions, the promulgation of safe harbor regulations and special fraud alerts relating to potentially fraudulent health care practices, and (5) establishing a national data bank to report final adverse actions against health care providers.<sup>65</sup>

To fund the coordinated anti-fraud effort of the Program, the HIPAA directs that an amount equaling recoveries derived from health care cases—including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution, compensation to the victim agency and relators' shares—is deposited in the Medicare Trust Fund.<sup>66</sup> Moreover, monies are appropriated from the Trust Fund to a newly created expenditure account, called the Health Care

63. Colleen M. Faddick, *Health Care Fraud and Abuse: New Weapons, New Penalties, and New Fears for Providers Created by the Health Insurance Portability and Accountability Act of 1996*, 6 ANNALS HEALTH L. 77, 91-95 (1997).

64. U.S. OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH & HUMAN SERVICES, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM AND GUIDELINES: AS MANDATED BY THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, at 2 (1997). The overall goal of the HCFAC Program is to further enable the identification, investigation, and where appropriate, prosecution of those individuals and entities who commit fraud against the nation's health care delivery system. See *id.*

65. *Id.*

66. See DEPT OF HEALTH & HUMAN SERVICES & DEPT OF JUSTICE, ANNUAL REP.: HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, FY 1998, at 3 (1999) [hereinafter 1998 HCFACP ANNUAL REP.].

Fraud and Abuse Control Account ("Account"), in amounts the Secretary and Attorney General annually certify are necessary to finance anti-fraud activities.<sup>67</sup> The amounts appropriated are completely independent of what is deposited through recoveries.<sup>68</sup> In other words, Congress has established that a fixed and increasing amount of funds shall be transferred from the Trust Fund to the Account.<sup>69</sup>

*3. Increased Coordination in Government Enforcement Efforts.*—As mandated by the HIPAA, coordination of law enforcement is a key aspect of the Program. Such coordination is based largely on the early success achieved in an interagency enforcement initiative known as Operation Restore Trust ("ORT"), a two-year demonstration project initiated in March 1995.<sup>70</sup> ORT was designed to bring together the talents and expertise of a wide range of federal and state officials and to concentrate their combined energies on fraud and abuse in home health agencies and nursing homes.<sup>71</sup> A multidisciplinary team of auditors, program managers, evaluators, utilization review experts, investigators and advocates focused on fraud in five states, which represented a major share of Medicare and Medicaid expenditures and beneficiaries.<sup>72</sup>

Another important aspect of ORT, and one that continues today, is the OIG's development of "auditgators," whereby OIG auditors work even more closely with its investigators when

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67. *Id.* at 3-5.

68. *Id.*

69. *Id.* at 3. There are maximum amounts available for expenditure each year. In the first year of operation under the new Program (FY 1997), the Secretary and Attorney General certified \$104 million for appropriation to the Account. *See id.* In the second year of the Program, the Attorney General and the Secretary certified \$119.6 million for appropriation to the Account, and the amount increases every year until 2003, at which point it will remain stable at \$240.6 million. 1998 HCFA CP ANNUAL REP., *supra* note 66, at 3.

70. U.S. OFFICE OF INSPECTOR GENERAL, SEMIANNUAL REP., OCT. 1, 1994-MAR. 21, 1995, at 23 (1995) [hereinafter SEMIANNUAL REP., OCT. 1, 1994-MAR. 21, 1995].

71. *See id.*

72. *Id.* Ultimately, ORT resulted in \$187.5 million of program savings through restitution, fines, settlements and other overpayment recoveries, providing a \$23 to \$1 saving to expenditure ratio. *See id.* Specifically, ORT produced 74 criminal convictions, 58 civil actions and 218 exclusions. *Id.*; *see also Secretary Shalala Launches New "Operation Restore Trust,"* DHHS PRESS RELEASE (May 20, 1997) <<http://www.hcfa.gov/news/pr1997/n970520.htm>>.

audit findings suggest criminal or civil fraud.<sup>73</sup> Additionally, OIG evaluators use their analyses to identify program vulnerabilities, giving auditors and investigators targets for further development, as well as case-specific data for existing investigations.<sup>74</sup>

While interagency coordination existed prior to the HIPAA,<sup>75</sup> as a result of that legislation, the government has continued its use of coordinated enforcement groups, expanding their membership and scope as necessary to address fraud and abuse throughout the health care industry at the investigation, prosecution and policymaking levels.<sup>76</sup> These national groups, among other things, sponsor training of enforcement personnel on detecting and prosecuting complex health care schemes.<sup>77</sup> Finally, another feature of the new health care fraud enforcement environment is the government's employment of parallel proceedings in which criminal and civil prosecutors closely coordinate the criminal, civil and administrative aspects of all white-collar crime matters under investigation.<sup>78</sup>

73. SEMIANNUAL REP., OCT. 1, 1994-MAR. 21, 1995, *supra* note 70, at 23.

74. *Id.*

75. *Latest Efforts to Fight Fraud*, *supra* note 13. For instance, Operation LabScam included coordination among the DOJ, several U.S. Attorneys Offices, numerous Medicaid Fraud Control Units, the FBI, the Postal Inspection Service, the Defense Criminal Investigative Service, the OIG and the HCFA. *See id.* Several of the other cases highlighted in section II.A also featured inter-agency coordination and cooperation across numerous federal districts.

76. 1998 HCFCP ANNUAL REP., *supra* note 66, at 10. The government continues to have cases under investigation against major health care providers whose operations span numerous states, thus requiring multi-district, multi-agency task forces to conduct the investigations. Nationally, the Executive Level Health Care Fraud Policy Group (composed of DHHS, OIG, HCFA, DHHS Office of General Counsel, FBI and DOJ civil and criminal prosecutors), the National Health Care Fraud Working Group (composed of DHHS, DOJ, Department of Defense ("DOD"), Department of Labor ("DOL"), Veterans Administration ("VA"), Treasury, Office of Personnel Management ("OPM"), United States Railroad Retirement Board, United States Postal Service and the National Association of Attorneys General) and other bodies share information on both specific cases and overall trends.

77. *Id.* For example, the OIG and the FBI together sponsored four interagency training sessions regarding health care fraud and abuse in order to enhance the agencies' understanding of the complexities of the federal health care programs. *Id.* at 21. These initial training programs focused on managed care, durable medical equipment, ambulance payments and home health care. *Id.* In addition, the HCFA, in collaboration with the OIG and the FBI, provided training sessions on basic Medicare and Medicaid program issues to new agents and investigators to enable them to understand Medicare and Medicaid program policies and operation. *Id.*

78. *Coordination of Parallel Criminal, Civil, and Administrative Proceedings*,

None of these new statutes or strategies, however, would have had the impact they have without the requisite law enforcement personnel to put them into effect. And, due to the stable funding provided under the HIPAA and the Program, the DOJ and the FBI added significant numbers of new personnel, including agents, attorneys, auditors and other support personnel to carry out enforcement actions.<sup>79</sup> Finally, public participation has played a role in the government's evolving enforcement strategies. For instance, in ORT, the OIG enlisted the support and participation of the public and the industries that the initiative targeted through a hotline (1-800-HHS-TIPS) established to receive allegations of fraud and abuse on a confidential basis.<sup>80</sup> The OIG enlisted public support primarily by working with the Administration on Aging ("AOA"), state Ombudsman and patient advocacy groups

OFFICE OF ATTORNEY GENERAL MEMORANDUM (visited Sept. 26, 1999)

<<http://www.usdoj.gov/ag/readingroom/970728.htm>>

79. DHS & DOJ ANNUAL REP.: HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, FY 1997, at 13 (1998) [hereinafter 1997 HCFACP ANNUAL REP.]. OIG increased its staff levels from a little over 900 to 1258 and opened eleven new investigative offices and three new audit offices. *Id.*; 1998 HCFACP ANNUAL REP., *supra* note 66, at 10.

In 1997, the Attorney General announced that 167 new positions for health care fraud enforcement were authorized to be filled in United States Attorneys' Offices ("USAOs"). 1997 HCFACP ANNUAL REP., *supra*, at 22. These included 60 criminal civil Assistant United States Attorneys ("AUSAs"), 30 civil AUSAs, 23 paralegals, 30 auditor/investigators, 23 support positions and a full time Health Care Fraud Coordinator in the Legal Programs Section of the Executive Office of United States Attorneys. *Id.*

In 1996, more than 60% of Civil Division Commercial Litigation Branch attorneys who did civil fraud cases worked on health care fraud cases. 1997 FY DOJ HEALTH CARE FRAUD REP. 14; 1997 HCFACP ANNUAL REP., *supra*, at 25. In 1997, the Civil Division received authorization for an additional 33 positions, and an attorney was selected in 1996 to serve as the Civil Division's health care fraud coordinator. 1997 FY DOJ HEALTH CARE FRAUD REP., *supra*, at 14; 1997 HCFACP ANNUAL REP., *supra*, at 25.

The HIPAA specified mandatory funding to the FBI for health care fraud enforcement. 1997 HCFACP ANNUAL REP., *supra*, at 29. The law provided the FBI with \$47 million in 1997 for its health care fraud efforts. *Id.* The FBI used this funding, in large part, to fund an additional 46 agents and 31 support positions for health care fraud and to create several new dedicated health care fraud squads. *Id.* This increase in personnel resources increased the number of FBI agents addressing health care fraud in 1997 to the equivalent of 370 agents, as compared to 112 in 1992. *Id.*

80. *Who Pays? You Pay*, DHS PRESS RELEASE (Sept. 15, 1999) <<http://www.hhs.gov/progorg/oe/outreach/campaign>>

who did outreach to beneficiaries through public service announcements, community education events, training sessions and educational brochures as part of "fraud buster projects."<sup>81</sup>

More recently, Medicare beneficiaries have been included in a public campaign to ferret-out fraud, co-sponsored by the DHHS, the DOJ and the AARP, called "Who Pays? You Pay."<sup>82</sup> Different sites around the country were chosen to host "fraud fighter rallies," in which federal officials educated beneficiaries on how to decipher their medical bills.<sup>83</sup> The campaign also advertised the OIG's hotline but counseled that beneficiaries should only use it after they have worked with health care providers or Medicare insurance companies to get a satisfactory answer to their complaints.<sup>84</sup>

Medicare beneficiaries not only have a vested interest in protecting the solvency of the Medicare Trust Fund by reducing waste, but they can also realize a direct and tangible benefit from identifying abusive practices. Pursuant to the HIPAA, the DHHS has created a Medicare fraud and abuse Incentive Reward Program ("IRP") to encourage the reporting of any information about providers engaged in fraudulent activities. The Medicare program will make a monetary reward only for information that leads to a minimum recovery of \$100 of Medicare funds from individuals and entities that the HCFA determines have committed sanctionable offenses.<sup>85</sup> The amount of the reward will not exceed ten percent of the overpayments recovered in the case, or \$1000, whichever is less.<sup>86</sup> Rewards will not be given for information relating to matters that, at the time the information is provided, are already the subject of a review by the program or law enforcement agencies.<sup>87</sup> Labeled a "mini

81. *A Comprehensive Strategy to Fight Health Care Waste, Fraud and Abuse*, U.S. DEPT OF HEALTH & HUMAN SERVICES FACT SHEET (visited Feb. 10, 1999) <<http://www.hhs.gov/nes/press/1999pres/99210.html>> [hereinafter *Comprehensive Strategy*].

82. *Who Pays? You Pay*, *supra* note 80.

83. *Id.*

84. *Id.*; Robert Pear, *Anti-Fraud Initiative Enlisting Medicare Recipients; But Policing Bills Rules Some Doctors*, COMMERCIAL APPEAL, Feb. 21, 1999, at A1.

85. *Comprehensive Strategy*, *supra* note 81.

86. *Id.*

87. Department of Health & Human Services, Health Care Financing Administration, Program Integrity: Medicare, 63 Fed. Reg. 31,123 (June 8, 1998) (to be codi-

*qui-tam*" by some commentators, the incentive program has only recently been implemented, and there are no reports of awards having yet been issued.

#### D. National Projects

Contemporaneous with the new enforcement strategies noted above, the government also established national project enforcement initiatives against certain types of fraudulent health care practices.<sup>88</sup> These national projects target a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers. There are several objectives for each of the national projects, including restitution to the Medicare program, penalizing providers who submitted false claims with knowledge of their falsity and imposing appropriate integrity measures to deter future misconduct.

1. *72-Hour Window Project*.—In 1995, the OIG and the DOJ launched a national project to recover overpayments made to hospitals as a result of claims submitted for non-physician outpatient services that were already included in the hospital's inpatient payment under the Prospective Payment System ("PPS").<sup>89</sup> Hospitals that submit claims for outpatient service in addition to inpatient admission are, in effect, submitting duplicate claims for the outpatient services. OIG audits identified a prevalent pattern of abuse of hospital claims for inpatient services under PPS.

2. *Hospital Outpatient Laboratory Project*.—In 1994, the

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fied at 42 C.F.R. pt. 420).

88. DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL PROJECT PROTOCOLS—BEST PRACTICE GUIDELINES (1998) (promoting a consistent approach to national enforcement projects). These guidelines are used by the OIG when developing and participating in national project efforts and when addressing the assessment of legal sufficiency, minimum parameters, equitable treatment of providers and collection of overpayments. While the OIG guidelines are generally applicable to national projects, not every element in the guidelines is necessarily appropriate for a particular enforcement initiative. *See id.* At the same time, each national project is expected to conform to the OIG Protocol, and any deviations from the guidelines must be approved in advance of the project's initiation. *See id.*

89. SEMIANNUAL REP., OCT. 1 1998-MAR. 31, 1999, *supra* note 33, at 4.

OIG and several United States Attorneys' Offices ("USAO"s) recognized that blood chemistry unbundling (billing for multiple codes when a single all-inclusive code was required) and other abusive practices in independent clinical laboratories also occurred in hospital outpatient clinical laboratories. In 1996, with the assistance of the OIG and state auditors, the two USAOs in Ohio initiated a fraud investigation to determine if hospital outpatient laboratories in Ohio knowingly (1) improperly unbundled or double billed blood chemistry and hematology claims or (2) filed claims for medically unnecessary tests.<sup>90</sup> Subsequently, other USAOs began to investigate similar conduct by hospitals in their districts.

3. *Physicians at Teaching Hospitals ("PATH")*.—Based on previous OIG audits and investigations, the OIG's Office of Audit Services launched the PATH initiative to measure the level of compliance with Medicare reimbursement requirements at various teaching hospitals throughout the country. There are two components in a PATH audit. The first component is related to the requirement, pursuant to law, regulations, agency policy issuances and Medicare carrier guidance, that Medicare Part B payment in the teaching hospital setting be conditioned on a physician personally providing a service to a patient or personally supervising the services rendered by a resident or intern in the attending physician's presence.<sup>91</sup> For the second component, PATH audits are designed to review evaluation and management ("E/M") service claims for coding errors based on the E/M codes established by the HCFA in 1992. The purpose of this review is to identify any patterns of upcoding of E/M services by institutions.<sup>92</sup>

4. *Pneumonia Upcoding Project*.—Medicare inpatient hospital stays are reimbursed based on the diagnosis-related group ("DRG") that is assigned to the patient's stay.<sup>93</sup> Most pneumonia cases are grouped into one of four DRGs, one of which (DRG

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90. See *id.* at 5.

91. *Id.* at 3-4.

92. *Id.*

93. *Id.* at 6.

79) results in significantly more payment to the hospital than do the others.<sup>94</sup> Most pneumonia cases fall into the lower-paying DRGs. The OIG has found that a relatively small percentage of hospitals across the country have assigned diagnosis codes which are used for very specific types of pneumonia much more frequently than would be justified based on epidemiology, resulting in cases being assigned DRG 79.<sup>95</sup>

Prior to the initiation of this national project, experts reviewed the medical records at a number of hospitals with disproportionately high use of the identified codes. These reviews found that in a high percentage of cases, the medical records did not support the diagnosis codes assigned to cases reimbursed as DRG 79.<sup>96</sup> The government also reviewed the official guidelines for coding, including the coding clinic,<sup>97</sup> and concluded that they form a strong basis for asserting that hospitals were adequately informed of the correct way to code the cases in question.

These national projects have been an important success not only for the total amount of funds returned to the Medicare Trust Fund, but also because they have, arguably, played a major role in moving the hospital industry to adopt voluntary compliance plans. The "heightened enforcement environment" was among the reasons cited by hospitals for implementing compliance programs in a recent GAO study.<sup>98</sup> Moreover, any FCA settlement under any of the national projects listed above includes mandatory compliance obligations on the provider. Thus, national projects provide another example where the use of the enforcement stick against some in the health care industry led many others to adopt voluntary compliance measures.

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94. SEMIANNUAL REP., OCT. 1, 1998-MAR. 31, 1999, *supra* note 33, at 6.

95. *Id.*

96. *Id.*

97. Department of Health & Human Services, Health Care Financing Administration, Medicare Program; Diagnosis Codes on Physician Bills, 54 Fed. Reg. 30,558 (1989) (to be codified at 42 C.F.R. pt. 424). *Coding Clinic* is published quarterly by the American Hospital Association and is the only publication and source of coding advice that is endorsed by the HCFA.

98. See *infra* notes 203-06 and accompanying text.

*E. Mandating Compliance Through Corporate Integrity Agreements*

Simultaneous with all of the government's heightened enforcement initiatives, the OIG initiated the concept of corporate integrity programs ("CIA"s) as a necessary and important tool to ensure the continued integrity of the Medicare program. The OIG imposes corporate integrity obligations on health care providers as part of global settlements of OIG and other governmental investigations and audits arising under a variety of false claims statutes.<sup>99</sup> A provider consents to these obligations in exchange for the OIG's agreement not to exclude that health care provider from participation in federal health care programs under the OIG's permissive exclusion authorities.<sup>100</sup> In short, CIAs are instituted to ensure that providers maintain the necessary "trustworthiness" to participate in federal health care programs. First imposed in 1994, agreements with corporate integrity obligations have steadily increased from four in 1994 to 231 in 1998, for a current total of more than 350 such agreements.<sup>101</sup> Although most of the CIAs are with hospitals, virtually all types of health care providers have negotiated such agreements with the OIG.

Over the years, CIAs have become much more comprehensive. Early CIAs simply required that the provider attend training and certify such training to the OIG.<sup>102</sup> In contrast, today's most comprehensive CIAs are in effect for five years and require a provider to implement the following compliance measures: "[h]ire a compliance officer and/or appoint a compliance committee; [d]evelop written standards and policies; [i]mplement a comprehensive employee training program; [a]udit billings to Medicare; [e]stablish a confidential disclosure program; [r]estrict employment of ineligible persons; and [s]ubmit a variety of reports to the [OIG]." While there are common elements in all CIAs, each CIA is tailored to the specific provider and deals with

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99. See Barbara Frederickson, *Corporate Integrity Agreements Impose Additional Obligations on Providers*, 1 J. OF HEALTH CARE COMPLIANCE 26-27 (1999) [hereinafter *Corporate Integrity Agreements*].

100. *Id.*

101. *Id.*

102. *Id.*

the particular facts of the conduct at issue.<sup>103</sup> The OIG also monitors compliance by providers who are subject to CIAs by evaluating each component of the provider's compliance program and assessing whether the program is fulfilling the letter and spirit of the CIA.

One key feature of CIAs is auditing. An ongoing evaluation process of a compliance program is the only way that the OIG and the provider can determine whether the claim submission process is being conducted appropriately and whether the provider is in compliance with the terms of the CIA. Accordingly, the review procedures in many recent CIAs require that the provider engage an Independent Review Organization ("IRO"), such as an accounting, auditing or consulting firm, to assess the adequacy of the provider's performance under the CIA. Requiring that the review be done by an outside organization ensures that the review is completely objective. CIAs contain detailed requirements about the review of the provider's billing practices. For example, they require a review of a statistically valid sample of claims and contain specific requirements regarding the methodology used.<sup>104</sup> Overpayments and material deficiencies discovered during the audit must be reported to the HCFA contractor and the OIG, as necessary.<sup>105</sup> The provider is required to take appropriate corrective action in response to any discovered errors.<sup>106</sup>

Providers subject to CIAs are required to report to the OIG if they discover credible evidence of misconduct and have reason to believe that the misconduct may violate criminal, civil or administrative law.<sup>107</sup> The report, which generally must be made within 30 days of the discovery of the alleged violation, must include the findings regarding the violation, the provider's actions to correct the specific violation and further steps it will take to ensure that the same or similar conduct does not arise in the future.<sup>108</sup>

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103. *Id.*

104. *Corporate Integrity Agreements*, *supra* note 99, at 26-27.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

Providers subject to CIAs are also required to submit comprehensive implementation and annual reports detailing fulfillment of their CIA obligations.<sup>109</sup> Required items include the audit report prepared by the IRO, information about the confidential disclosure system (including a record and summary of each allegation received, the status of the respective investigations and any corrective action taken in response to the investigation) and a certification from the compliance officer that all requirements have been met.<sup>110</sup>

The OIG is expanding its review for certain providers by conducting an increased number of on-site visits. Typical activities in an on-site visit include interviews so that the OIG can assess whether the compliance message has reached all levels of employees. Audit work papers are reviewed to determine whether the prescribed methodologies were followed and the results were accurately reported. On-site review of Medicare claims is conducted in cooperation with HCFA contractors to ensure that claims are being accurately submitted.

Finally, failure to fulfill the requirements in the CIA can lead to significant monetary penalties or exclusion. Under recent CIAs, providers are subject to the imposition of specific monetary penalties (called stipulated penalties) for failure to comply with the basic obligations under the agreement, for example, appointing a compliance officer or developing policies and procedures.

More significantly, a material breach of the CIA (e.g., failure to report a material deficiency, take corrective action and pay appropriate refunds) constitutes an independent basis for exclusion.<sup>111</sup> The provider is afforded appropriate due process and review rights when this provision is invoked, as is true with the imposition of stipulated penalties. The exclusion remedy is necessary since the primary reason that the OIG releases a provider from liability for submitting false claims is because the provider agreed to implement compliance measures. If the provider fails to follow through on its promises, exclusion of the provider is an appropriate remedy.

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109. *Corporate Integrity Agreements*, *supra* note 99, at 26-27.

110. *Id.*

111. *Id.*

*F. Summary of Enforcement Developments*

The results of all these enforcement developments (strengthened FCA, increased *qui tams*, new statutes, secure and increased funding, evolving enforcement strategies, additional personnel and imposition of CIAs) have been dramatic, with increases in criminal and civil investigations, prosecutions, convictions, judgments, settlements and exclusions throughout the 1990s.<sup>112</sup>

In addition to the high profile settlements and the national projects against hospitals, the government has achieved decisive results against providers of all sizes and types, including, among others, durable medical equipment suppliers, home health agencies, nursing homes, hospice providers, third-party billing agents, carriers and fiscal intermediaries. Additionally, the government has expanded its focus beyond simple fraud schemes involving billing for services not performed to combat such conduct as cost report fraud, substandard quality of care and man-

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112. Health care fraud investigations by the FBI increased from 657 in FY 1992 to 2200 in FY 1996. U.S. DEPT OF JUSTICE, HEALTH CARE FRAUD REP.: FISCAL YEAR 1998 (visited Oct. 10, 1999) <<http://www.usdoj.gov/dag/health98.htm>> [hereinafter 1998 HCFR]. Criminal prosecutions went from 83 cases involving 116 defendants to 246 cases involving 450 defendants. *Id.* Convictions (guilty pleas and verdicts) increased from 90 defendants to 307. *Id.* Civil health care fraud investigations handled by the DOJ increased from 270 to 2488 during the same time span. *Id.* Most of these numbers increased again over FY 1997 and FY 1998. 1998 HCFACP ANNUAL REP., *supra* note 66, at 22. For instance, federal prosecutors filed 322 criminal health care fraud cases in 1998, and 326 defendants were convicted. *Id.* Also in 1998, 107 civil cases were filed, and at the end of the year 3471 civil matters were pending. *Id.* at 21-23.

In 1997, more than 2700 individuals and entities were excluded from federally sponsored health care programs—a 93% increase over 1996. 1997 HCFACP ANNUAL REP., *supra* note 79, at 5. In 1998, the DHHS excluded 3021 individuals and entities, an increase of 11% over 1997. 1998 HCFACP ANNUAL REP., *supra* note 66, at 10.

Under the first full year of the Program (FY 1997), \$1.087 billion was collected in criminal fines, civil judgments, settlements and administrative impositions; \$968 million was returned to the Medicare Trust Fund; and \$31 million was recovered as the federal share of Medicaid restitution. 1997 HCFACP ANNUAL REP., *supra* note 79, at 7. “In 1998, the Federal Government won or negotiated more than \$480 million in judgments, settlements, and administrative impositions. . . . As a result of these activities, as well as prior-year judgments, settlements, and administrative impositions, the federal government in 1998 collected \$296 million.” 1998 HCFACP ANNUAL REP., *supra* note 66, at 10.

aged care fraud. Such results signal that if it must, the government is prepared and has the tools at its disposal to wage another ten-year battle against health care fraud.

Equally as important as the immediate impact of returning funds to the treasury and eliminating fraudulent providers from the programs, the ultimate effect of these myriad enforcement developments has been to convince the health care industry of the need to develop and implement voluntary compliance programs in order to protect the integrity of the nation's health care system.

### III. GOVERNMENT COLLABORATION/COOPERATION WITH HEALTH CARE PROVIDERS

At the same time the federal government has increased its capacity to prosecute health care fraud, there has been a concerted effort to enlist the provider and supplier community in the fight against health care fraud and abuse. In February 1997, Inspector General June Gibbs Brown issued an "Open Letter" to the health care community and urged a joint effort to fight health care fraud:

We need the involvement of you and your fellow health care providers. Through cooperative efforts we can best ensure the success of initiatives to identify and penalize the relatively few dishonest providers whose fraudulent activities are eroding the solvency of the Federal health programs and undermining public confidence in the health care industry.<sup>113</sup>

In keeping with this pledge of cooperation, the OIG has undertaken an unprecedented number of affirmative steps to involve the health care industry in its anti-fraud initiatives. These measures have been as broad in scope as the development of compliance guidances for health care providers and as focused as provider-specific advisory opinions. To help health care providers anticipate and prevent problems, the OIG annually publishes its work plan and specifies the program vulnerabilities on which it will direct its resources. In addition, the OIG issues

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113. June Gibbs Brown, *Open Letter to Health Care Providers* (visited Sept. 27, 1999) <<http://www.dhhs.gov/progorg/oig/modcomp/ltrhcp.html>>.

fraud alerts targeted at specific abusive practices in the belief that honest providers will use the information to modify behavior. Also, the OIG has established a mechanism that rewards those companies that self-disclose fraudulent or abusive practices to the OIG to encourage further self-policing by providers and suppliers.

If we are to anticipate where the fight against health care fraud will lead, it is helpful to evaluate the opportunities for government/industry collaboration. A review of the OIG initiatives and the health care industry's response to them may give some indication whether future anti-fraud efforts will be based on confrontation or cooperation.

#### *A. Promoting Program Integrity Through Compliance Guidance*

As part of the effort to involve the industry in the fight against health care fraud and abuse, the OIG began meeting with provider groups in order to develop compliance program guidances for health care providers. Initially, these meetings were informal efforts to gather insights into the industry sector that would be the subject of the OIG guidance. It soon became apparent, however, that there was broad interest in the content of the guidances. Thus, the OIG expanded its outreach efforts through the use of the Federal Register. By publishing notices of upcoming compliance program guidances in the Federal Register, the OIG solicits input and recommendations from both the provider community and the general public.

The development of these compliance program guidances has become a major part of the OIG's activities to engage the health care industry in addressing health care fraud. The OIG has issued guidances for hospitals,<sup>114</sup> clinical laboratories,<sup>115</sup> home health agencies<sup>116</sup> and third-party medical billing companies.<sup>117</sup> Additional guidances are under development for

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114. Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (1998).

115. Publication of the OIG Model Compliance Plan for Clinical Laboratories, 62 Fed. Reg. 9435 (1997), *as revised* in 63 Fed. Reg. 45,076 (1998).

116. Publication of the OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410 (1998).

117. Publication of the OIG Compliance Program Guidance for Third-Party Medi-

hospice providers, durable medical equipment suppliers, nursing homes and Medicare+Choice organizations.<sup>118</sup> The guidances represent the culmination of the OIG's suggestions on how providers can most effectively establish internal controls and implement monitoring procedures to identify, correct and prevent fraudulent and wasteful activities. While the documents present basic procedural and structural guidance for designing a compliance program, they do not constitute a compliance program. Rather, they are a set of guidelines to be considered by a provider interested in establishing a culture that promotes prevention, detection and resolution of instances of misconduct.

As expressly noted in the guidances, they are not mandatory,<sup>119</sup> nor do they represent an exclusive set of advisable elements of a compliance program. Each has retained, however, the seven elements based on the United States Sentencing Guidelines, which the OIG considers necessary for a comprehensive compliance program. These seven elements are: (1) the development of written policies, (2) the designation of a compliance officer and other appropriate bodies, (3) the development and implementation of effective training and education, (4) the development and maintenance of effective lines of communication, (5) the enforcement of standards through well-publicized disciplinary guidelines, (6) the use of audits and other evaluation techniques to monitor compliance, and (7) the development of procedures to respond to detected offenses and to initiate corrective action.<sup>120</sup> In addition to these seven components of a comprehensive compliance program, each guidance highlights "risk areas" that the OIG has identified through its audits and investigations and that should be addressed by the provider's internal policies and procedures.<sup>121</sup>

The OIG believes that there are a number of reasons why health care providers should implement and maintain a compli-

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cal Billing Companies, 63 Fed. Reg. 70,138 (1998).

118. The HCFA regulations implementing the Medicare+Choice program require Medicare+Choice organizations to implement compliance plans by January 1, 2000. See 42 C.F.R. § 422.501 (1999). The regulations require that the plan include the seven elements identified in the OIG guidances. *Id.*

119. See *supra* notes 114-17.

120. See 42 C.F.R. § 422.501.

121. See *supra* notes 114-17.

ance plan.<sup>122</sup> Foremost, an effective plan reduces the potential liability of the entity and its managers.<sup>123</sup> In the context of criminal health care fraud, the government must prove intent to commit the illegal act. The existence of a comprehensive and effective compliance program can serve to mitigate that intent by demonstrating that the company has taken affirmative steps to comply with the law. The existence of an effective compliance plan also will be taken into account by both the OIG and the DOJ in evaluating whether a health care entity has made reasonable efforts to avoid and detect misconduct.<sup>124</sup> In short, the provider's compliance measures will be taken into account in calculating the civil and administrative sanctions that may be pursued.

An effective compliance program also can provide a health care company a defense against shareholder derivative actions and may protect corporate directors from personal liability.<sup>125</sup> The fiduciary duties of corporate directors require that they keep themselves adequately informed concerning the operations of the company.<sup>126</sup> A compliance program designed to assure compliance with applicable legal requirements has been recognized as meeting this duty of care.<sup>127</sup>

Since the Inspector General believes that the vast majority of health care providers and suppliers want to strengthen the integrity of the health care system, she has put a premium on promoting voluntary compliance plans. In addition to using the Federal Register to solicit input on the content of the guidances, the OIG also has engaged in other outreach efforts to promote corporate compliance. On March 22, 1999, the OIG and the Health Care Compliance Association ("HCCA") co-sponsored a first-of-its-kind government/industry compliance roundtable.<sup>128</sup>

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122. Lewis Morris, *The Top 10 Reasons to Implement a Compliance Program*, 1 J. HEALTH CARE COMPLIANCE 1 (1999).

123. See DEPARTMENT OF HEALTH & HUMAN SERVICES, DHHS MODEL COMPLIANCE PLAN (visited Oct. 12, 1999) <[http://waisgate.hhs.gov/cgiID=57036521\\_2\\_0\\_0&WAI\\_Saction=retrieve](http://waisgate.hhs.gov/cgiID=57036521_2_0_0&WAI_Saction=retrieve)>.-bin/waisgate?waisdoc

124. U.S. Deputy Attorney General, *Guidance on the Use of the Civil False Claims Act in Civil Health Care Matters* (visited June 3, 1998)<<http://www.usdoj.gov/04foia/readingrooms/chcm.htm>>.

125. *In re Caremark Int'l*, 698 A.2d 959, 970-72 (Del. Ch. 1996).

126. *In re Caremark Int'l*, 698 A.2d at 970-72.

127. *Id.*

128. OFFICE OF INSPECTOR GENERAL OF THE U.S. DEPT' OF HEALTH & HUMAN

The day-long discussions were an opportunity for the health care compliance industry to inform the OIG of issues surrounding the implementation and maintenance of compliance programs. The meeting was also an opportunity for the OIG to present the policy objectives underlying its corporate integrity initiatives and compliance program guidances.

The roundtable was devoted to discussion of a series of compliance-related topics proposed in advance by the participants. Over 125 compliance officers, health care compliance consultants and government representatives attended the event. The participants represented a wide spectrum of institutional and individual provider organizations. Because the objective of this collaboration was to share perspectives on creating and implementing an effective compliance program, the participants did not attempt to reach consensus on the many issues that surround compliance with health care program requirements. However, the participants gained new insights into the challenges associated with creating effective compliance programs. To share these insights with a large audience, the roundtable moderators prepared a written summary of the discussions that took place at their respective breakout sessions.<sup>129</sup>

#### *B. Additional Means to Prevent Fraud: Advisory Opinions and Fraud Alerts*

One of the most significant features of each of the OIG's compliance program guidances is the enumeration of specific fraud risk areas. Armed with this information, a health care provider can construct a compliance program that can anticipate most fraud and abuse problems likely to arise in the course of participating in the government's health care programs. However, new schemes are continually emerging, and the evolving Medicare reimbursement system requires a provider to continually reassess its practices. Because the OIG prefers to have pro-

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SERVICES & HEALTH CARE COMPLIANCE ASS'N, BUILDING A PARTNERSHIP FOR EFFECTIVE COMPLIANCE: A REPORT ON THE GOVERNMENT INDUSTRY ROUNDTABLE (visited Oct. 11, 1999) <<http://www.dhhs.gov/progorg/oig/modcomp/roundtable.htm>> [hereinafter REPORT ON THE GOVERNMENT INDUSTRY ROUNDTABLE].

129. *Id.*

viders take preventative measures to avoid potentially abusive practices, it has undertaken two additional collaborative efforts to promote program integrity—advisory opinions and fraud alerts.

*1. Advisory Opinions.*—In the HIPAA, Congress sought to balance the impact of significantly increased penalties for health care fraud and abuse with new provisions mandating that the OIG provide more guidance to the industry. The centerpiece of the HIPAA guidance initiatives is an advisory opinion process pursuant to which parties to existing or proposed health care business transactions can obtain binding legal guidance as to whether their arrangements may run afoul of the anti-kickback statute,<sup>130</sup> the civil money penalties ("CMP") law<sup>131</sup> or the exclusion provisions.<sup>132</sup>

Historically, law enforcement has objected to providing guidance on criminal statutes because of the risk that such guidance may be misused to protect the guilty. Determinations of culpability under criminal statutes ultimately depend on inquiries into the specific facts of particular circumstances, especially with respect to the question of intent. Thus, one concern is that the government's burden of proving its case could be hampered by claims that a defendant lacked criminal intent because he or she relied on prior guidance issued by the enforcement agency in a different matter. In most cases, there will be factual differences between the arrangements being compared, and even where the facts are superficially similar, the intent of the parties may be quite different. A further concern is that insight into the government's interpretation of criminal statutes might assist the criminally-minded in designing schemes that circumvent the law.

Nevertheless, in a complex regulatory environment, ambiguity often favors the dishonest. An absence of guidance may discourage innocuous and beneficial conduct by those who are honest but risk-averse ("the law seems unclear, so we'd better play it safe"), while encouraging the unscrupulous and reckless to

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130. Social Security Act § 1128B, 42 U.S.C. § 1320a-7b (1994 & Supp. III 1997).

131. See *id.* § 1320a-7a.

132. See *id.* § 1320a-7.

engage in fraudulent and abusive schemes with abandon ("the law seems unclear, so here's our chance"). The criminals defend themselves with claims that they could not have had unlawful intent because they could not have known what the law requires.

In these circumstances, advisory opinions can be an effective means of leveling the playing field between the minority of malefactors and the overwhelming majority of lawful providers. Individual providers need not guess anymore whether their business arrangements will be subject to applicable sanctions. In addition, the industry as a whole benefits from the reasoning contained in the opinions. In particular, advisory opinions sometimes afford the OIG the opportunity to provide further clarity and benchmarks in specific areas that have been of concern to the health care industry.<sup>133</sup>

The OIG intends to offer meaningful guidance through the advisory opinion mechanism. Thus, the Inspector General has placed the function within her Office of Counsel and staffed it with attorneys familiar with industry commercial practices and transactions. To receive substantive guidance, parties are required to submit detailed descriptions of their arrangements, including operating and financial documents.<sup>134</sup> Occasionally, a request is submitted that clearly cannot be approved; the requesting parties are contacted and given an opportunity to withdraw the request before incurring additional fees.<sup>135</sup> Most requests, however, involve arrangements that are scrutinized on a case-by-case basis to determine whether, based on a totality of facts and circumstances, they pose a risk of fraud or abuse, irrespective of the parties' actual intent.<sup>136</sup>

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133. See, e.g., DHHS-OIG, Op. 98-10 (1998) (listing specific factors used in evaluating commission sales arrangements); DHHS-OIG, Op. 98-16 (1998) (stating hallmarks of disfavored arrangements for free or below fair market value goods and services); DHHS-OIG, Op. 99-2 (1999) (noting benchmarks for determining suspect discounts in contracts with skilled nursing facilities).

134. 42 C.F.R. § 1008.31 (1998), *as amended in* 63 Fed. Reg. 38,311, 38,312 (1998).

135. The advisory opinion statute requires the OIG to charge a requesting party a fee equal to the actual cost of preparing the opinion. 42 C.F.R. § 1008.31 (1998), *as amended in* 63 Fed. Reg. 38,311, 38,312 (1998).

136. Determinations of intent, an essential element of criminal liability, cannot be made based solely on documentary submissions in the absence of a full investigation.

The analysis of an arrangement under the anti-kickback statute generally involves an inquiry into five aspects of the arrangement: the basic facts, the applicable federal program reimbursement principles, the associated risks, the proffered safeguards, and the potential benefits. An arrangement that technically violates the anti-kickback statute may be approved if the risk to the federal health care programs is minimal and offsetting benefits exist for federal beneficiaries or the public.<sup>137</sup> While the OIG will assume theoretical risks, benefits must be real and substantiated. In assessing an arrangement's risks, the OIG first considers the potential for the four "evils" underlying the enactment of the anti-kickback statute: overutilization, increased program costs, corruption of medical decision-making and unfair competition. If there is any likelihood that one or more of these evils may result, the OIG examines the arrangement to determine whether sufficient safeguards exist to prevent harm to the federal programs or their beneficiaries.

In sum, the advisory opinion process is an effective tool for providing increased guidance to the vast majority of honest health care providers regarding the anti-kickback statute and other fraud laws. The process is designed to produce meaningful and informed opinions that will help parties to structure lawful arrangements. The benefit of an effective OIG advisory opinion process does not, however, inure solely to industry. Preventing fraud at the outset reduces the government's enforcement costs and program losses. In addition, advisory opinions are an important tool for providing notice to the provider community as to the meaning of the law. Such notice may assist law enforcement in prosecuting future offenders.

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Hence, the OIG should disregard intent in an advisory opinion analysis, as a negative opinion is merely a determination that an arrangement could potentially violate the anti-kickback statute if the parties have the requisite criminal intent.

137. See, e.g., DHHS-OIG, Op. 98-3 (1998) (discussing donation of an ambulance to a municipality); DHHS-OIG, Op. No. 98-7 (1998) (discussing ambulance restocking pursuant to a regional emergency medical services program); DHHS-OIG, Op. 99-6 (1999) (articulating waivers of co-payments for children in a pediatric oncology research program).

2. *Special Fraud Alerts and Advisory Bulletins.*—While advisory opinions offer one-on-one guidance, OIG special fraud alerts and advisory bulletins sweep more broadly by identifying practices in particular segments of the health care industry that are particularly vulnerable to fraud as well as national trends in health care fraud. These documents are published in the Federal Register, in keeping with the OIG's goal of publicizing its concerns about possibly widespread, abusive health care practices and providing wider distribution of this information to the general public. The questionable practices identified in these alerts include joint venture arrangements, the routine waiver of co-payments and deductibles, physician authorization of medically unnecessary services, the interrelationship of nursing homes and hospices, the provision of medical supplies in nursing homes, and prescription drug marketing practices.<sup>138</sup>

In addition to providing insight into the concerns of the OIG and other law enforcement agencies, the fraud alerts and bulletins are often used by the marketing and sales staff of providers and suppliers to educate their customers. For example, according to representatives of the clinical laboratory industry, the special fraud alert on laboratory inducements is often used by a laboratory sales force to explain to a physician client why the laboratory will not provide free goods or other inducements that could be construed as illegal remuneration. The fraud alert also may cause the physician to think twice about continuing to do business with a laboratory that engages in the identified practices, thus helping to level the playing field to the benefit of the honest supplier of services.

Consistent with the collaborative nature of the fraud alerts, the OIG has made a practice of providing drafts of a proposed fraud alert to representatives of the affected industry sector. For instance, OIG representatives consulted extensively with representatives of the American Medical Association ("AMA") and other professional physician associations in preparing the most recent fraud alert on the physician's role in certificates of medi-

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138. See, e.g., Home Health Fraud, and Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities, 60 Fed. Reg. 40,847 (1995). The Special Fraud Alerts are also available on the OIG's website, visited Sept. 23, 1999, <<http://www.dhhs.gov/progorg/oig/frdalrt/index.htm>>.

cal necessity ("CMN"s).<sup>139</sup> In order to make sure its membership appreciates its responsibilities in the areas outlined in the fraud alert, the AMA has indicated that it will help disseminate the alert by reproducing it in the association's publications.<sup>140</sup>

### *C. Encouraging Provider Self-Disclosure of Errors and Misconduct*

With an increase in the prevalence of corporate compliance programs and the monitoring of risk areas, there is an increasing likelihood that providers will identify overpayments as well as misconduct. The OIG compliance program guidelines, as well as the Sentencing Guidelines for Organizations, state that self-identified misconduct should be reported to the OIG or the DOJ. At the same time, these agencies have made it clear that simple billing errors are not the subject of law enforcement efforts and should be reported to the appropriate program agency representative or contractor.

A provider has a powerful incentive to return funds that it has determined it is not entitled to keep. First, the Social Security Act provides for criminal sanctions against

Whoever . . . having knowledge of the occurrence of any event affecting . . . his initial or continued right to any . . . benefit or payment [under Medicare or Medicaid] . . . conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized.<sup>141</sup>

Two of the new criminal statutes created by the HIPAA also punish the continued concealment of health care program overpayments. The first of these statutes, 18 U.S.C. § 1035, is patterned after the criminal false statement statute<sup>142</sup> and provides, in part, "[w]hoever in any manner involving a health care benefit program, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact . . .

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139. See OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERVICES, HEALTH CARE FRAUD AND ABUSE AND THE FALSE CLAIMS ACT 13 (1998).

140. See *id.*

141. 42 U.S.C. § 1320a-7b(a)(3) (1994 & Supp. III 1997).

142. 18 U.S.C. § 1001 (1994 & Supp. III 1997).

shall be fined under this title or imprisoned not more than five years, or both."<sup>143</sup>

A second new HIPAA criminal statute, 18 U.S.C. § 669, also is targeted at providers that wrongfully convert program funds. Significantly, this statute makes clear that there is not a *de minimus* amount of improperly paid health care benefits which a provider may retain once the payment error has been identified.<sup>144</sup> The statute applies to *all* health care programs and states, in part:

Whoever knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program, shall be fined under this title or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of \$100 the defendant shall be fined under this title or imprisoned not more than one year, or both.<sup>145</sup>

Whether a billing error rises to the level of misconduct warranting disclosure to law enforcement is often a source of dispute. During the previously referenced OIG/HCCA Compliance Roundtable, extensive discussion was devoted to the issue, and several principles were identified by the participants.<sup>146</sup> While the distinction between an "innocent billing error" and a scheme to defraud is often fact-dependent, fraud requires that the provider "knowingly" submit a false claim or "knowingly" make false statements to get a false claim paid.<sup>147</sup> Some of the variables that may establish evidence of knowledge include whether the provider was on actual or constructive notice of the rule or policy, the clarity of the policy, whether there had been prior audits or similar notice to the provider concerning the practice, and whether the pervasiveness of the erroneous claims is sufficient to support an inference that they arose from intentional conduct.

While these factors can help a provider to evaluate the seri-

143. 18 U.S.C.A. § 1035(a) (West Supp. 1999).

144. *Id.* § 669(a).

145. *Id.*

146. See REPORT ON THE GOVERNMENT INDUSTRY ROUNDTABLE, *supra* note 128.

147. See 18 U.S.C.A. § 669(2).

ousness of a billing problem or other questionable practice, ultimately the decision of how to respond to a finding of non-compliance rests with the provider. At the same time, the government has a responsibility to have in place effective and appropriate mechanisms that allow a provider to report instances of non-compliance and get them resolved.

The traditional process for resolving improper billings has been to make a refund of the overpayment to Medicare. While this may be the correct procedure when the matter involves a simple billing error, the government is concerned that some providers are inappropriately using the contractor refund process to circumvent a fraud investigation. Some providers apparently believe that returning the ill-gotten funds negates an element of the FCA, or at least reduces the case's appeal. Occasionally, HCFA contractors report receiving unsolicited checks from providers with conditional endorsements, such as "paid in full," on the face of the check or within the correspondence. These conditional endorsements are an attempt by the provider to cause the contractor to inadvertently agree to accept in full payment an amount less than the amount due.

In response to these attempts to circumvent the contractor's program integrity the functions, the HCFA has issued instructions for handling unsolicited refunds where there is a strong suspicion of fraud or an active investigation.<sup>148</sup> The contractors are directed to deposit any check submitted by a provider or supplier, compile the data on these voluntary refunds, and furnish reports to the HCFA's Division of Financial Integrity on a quarterly basis.<sup>149</sup> In order to more readily identify providers that make voluntary refunds while under a CIA, the OIG periodically provides the HCFA's regional offices with a list of entities which have agreements with the OIG. In addition, the HCFA has issued a Program Memorandum to its contractors in which it reiterates the obligation of the contractors to determine the basis of all overpayments.<sup>150</sup>

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148. HEALTH CARE FINANCING ADMINISTRATION, U.S. DEP'T. OF HEALTH & HUMAN SERVICES, CARRIER MANUAL-PART. 2 § 14017 (1998); INTERMEDIARY PART. 2 § 3974 (1998).

149. HEALTH CARE FINANCING ADMINISTRATION, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PROGRAM MEMORANDUM INTERMEDIARIES, Trans. No. A-98-42 (1998) (visited Oct. 11, 1999) <<http://www.hfca.gov/pubforms/transmit/a984260.htm>>.

150. HEALTH CARE FINANCING ADMINISTRATION, U.S. DEP'T OF HEALTH & HUMAN

At the same time that it is scrutinizing repayments and other submissions made by providers to the program, the government has established a mechanism for providers to report non-compliance with program requirements—the OIG's "Provider Self-Disclosure Protocol ("Protocol.")"<sup>151</sup> Pursuant to the Protocol, the health care provider is encouraged to submit a preliminary report that describes the nature of the matter being disclosed, the reasons why the provider believes that a violation of federal law may have occurred, and an indication of whether the provider has knowledge that the matter is currently under review by a government agency or contractor.<sup>152</sup> "As part of its participation in the disclosure process," the provider is also "expected to conduct an internal investigation and a self-assessment" after the initial disclosure of the matter.<sup>153</sup> The OIG will generally agree, for a reasonable time, to forego an investigation of the matter if the provider agrees that it will conduct the review in accordance with the Protocol's guidelines.<sup>154</sup>

Upon receipt of the internal investigative report, the OIG will take steps to verify the disclosure information. The extent of the OIG's verification effort will depend in large part upon the quality and thoroughness of the internal investigative and financial impact reports. In the normal course of verification, the OIG will not request production of written communications subject to the attorney-client privilege.<sup>155</sup> However, if outside counsel has been retained to conduct the internal investigation, there may be substantive documents or other materials critical to resolving the disclosure that may be covered by the work product doctrine. The OIG is prepared to discuss with the company's counsel ways to gain access to the underlying information without the need to waive the protections provided by an appropriately asserted claim of privilege. At the same time, the company's compliance officer and management should participate in deciding which documents and materials will be withheld from production to

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SERVICES, PROGRAM MEMORANDUM, Trans. No. AB 98-24 (1998) (visited Oct. 11, 1999) <<http://www.hfca.gov/pubforms/transmit/26982460.htm>>.

151. Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399 (1998).

152. *Id.* at 58,400.

153. *Id.* at 58,401.

154. *Id.* at 58,402.

155. *Id.* at 58,403.

the OIG.

In order to be eligible for the program, the provider must make the initial disclosure to the OIG through the Office of Investigations ("OI").<sup>156</sup> Prior to admitting a health care provider to the OIG's self-disclosure program, the OI conducts a survey of law enforcement agencies to ensure that the matter is not under investigation.<sup>157</sup> In most cases, upon acceptance into the program, the provider is given an opportunity to conduct its own investigation of the matter. In all cases, the entity must provide sufficient information in the form of audit work papers and supporting documentation to quantify the harm to the federal health care programs.<sup>158</sup> The volunteer may also elect to provide the OIG a report of its internal investigation which may be shared with other law enforcement agencies.<sup>159</sup>

On an expedited basis, the OI conducts a verification of the matter disclosed by the volunteer, with the OIG's Office of Audit Services ("OAS") having responsibility for quantifying the loss to the federal health care programs.<sup>160</sup> The extent of the verification depends largely on the quality of any investigative report provided by the volunteer and the cooperation of those who have information concerning the practices under review. Upon conclusion of the verification process, the Office of Counsel to the Inspector General ("OCIG") will have responsibility for negotiating an equitable resolution of the matter. As discussed above, if the matter involves a violation of civil or criminal law, the OIG will bring the affected USAO into the process.

The current self-disclosure Protocol is the outgrowth of an earlier effort by the OIG and the DOJ to create a structured program to encourage disclosures of fraud by health care providers. The initial disclosure program began on a pilot basis, limited to specified industry segments and geographic areas that coincided with the DHHS' development of the ORT initiative. In addition to limiting the pilot to the providers targeted by the anti-fraud initiative, the self-disclosure pilot program was further limited by two strict prerequisites. First, the disclosure had

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156. Provider Self-Disclosure Protocol, 63 Fed. Reg. at 58,401.

157. *Id.* at 58,400, 58,403.

158. *Id.* at 58,402.

159. *Id.*

160. *Id.* at 58,403.

to be made on behalf of a business entity, as opposed to an individual person, officer or employee.<sup>161</sup> Second, the disclosure had to be truly "voluntary."<sup>162</sup> At the time of the disclosure, there could be no pending federal or state criminal prosecution, civil action, or administrative proceeding with respect to the matter disclosed, and the disclosure could not be triggered because the underlying facts were about to be discovered by the government.<sup>163</sup>

Although the OIG received numerous inquiries about the program from representatives of health care providers, only eleven entities actually applied to the program. Of the eleven applications, seven were accepted into the program, and the remaining applicants were rejected because they did not meet one of the conditions for admission. The principle reason for rejecting an applicant was the existence of an ongoing investigation of the matter disclosed.

In order to promote acceptance of the self-disclosure mechanism, the OIG has discussed criticism of both the pilot program and the current self-disclosure Protocol with health care providers and members of the health care bar. One of the most frequently stated objections is the risk of permissive exclusion of the disclosing provider. Although the OIG repeatedly said that it would give substantial consideration to the fact that a provider had self-disclosed the fraudulent practice when making the exclusion decision,<sup>164</sup> there remains a real fear of exclusion by potential volunteers. Some of this concern is based on the scope of the OIG's mandatory exclusion authority, which was further expanded by the HIPAA to include *all* health care-related convictions.<sup>165</sup> It is worth noting, however, that to date, none of the participants in the OIG's self-disclosure initiative have been excluded from government health care programs, an outcome similar to the Defense Department's rate of debarment of participants in its self-disclosure program.

Some commentators urge the OIG to promise to waive per-

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161. Provider Self-Disclosure Protocol, 63 Fed. Reg. at 58,400.

162. *Id.*

163. *Id.*

164. *Id.* at 58,400, 58,403.

165. See Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

missive exclusion of any provider that successfully participates in the disclosure program. While rejecting a blanket waiver of permissive exclusion liability for volunteers, the OIG responded to this concern by publishing the criteria it uses when evaluating whether to impose a permissive exclusion.<sup>166</sup> The exclusion criteria are organized into four general categories of factors bearing on the trustworthiness of a provider that has allegedly engaged in fraud or abuse with respect to government health care programs. These four categories are: the circumstances and seriousness of the underlying misconduct, the defendant's response to the allegations of wrongdoing, the likelihood of a future violation of the law, and the defendant's financial ability to provide quality health care services.<sup>167</sup> In that context, voluntary disclosure of the alleged wrongful conduct is specifically cited among the factors to be considered in evaluating the likelihood that the misconduct will reoccur.

Commentators also observe that when designing the pilot program under ORT, the OIG and the DOJ drew heavily from the experience of the Defense Department's voluntary disclosure program. Unlike defense contractor fraud, however, health care fraud exposes the provider to potential liability to a myriad of federal and state agencies, as well as third-party private insurers and beneficiaries. In recognition of the potential multiple victims of a health care billing scheme, the affected federal agencies, as well as the state MFCUs, are notified by the OIG of the substance of the disclosure. These agencies, however, are not formal participants in the resolution of the entity's liability under the voluntary disclosure program. Providers have objected that by disclosing a fraud matter to the OIG, the MFCUs receive a "road map" for a prosecution but do not formally take part in the negotiated settlement.

A potential solution to this concern is strengthening the participation of other federal and state agencies in the disclosure process, thereby facilitating global settlements. With increasing frequency, the OIG's investigators and auditors are working with their counterparts in other government health care pro-

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166. Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act, 62 Fed. Reg. 67,391 (1997).

167. *Id.*

grams, such as the Defense Department's TriCare program, the Office of Personnel Management's Federal Employees Health Benefits Program and the states' MFCUs. In the appropriate case, it would be to the advantage of the disclosing provider, as well as the government's health care programs, to have more active participation of all investigative agencies affected by the matter disclosed.

It is more difficult to craft a solution to the concern that a provider's disclosure to the OIG may result in collateral lawsuits from private insurers and parasitic suits from *qui tam* relators. The ability of the DHHS to share investigative information with private insurers and thereby include them in the settlement process is limited. Due in part to the restrictions on sharing sensitive patient-related information (i.e., medical records and claims information), as well as investigative techniques, contact between public and private investigative efforts is basically a one-way street. While private insurers may be free to share investigative information with the OIG and the DOJ, the ability of government agencies to reciprocate at present is quite limited. Consistent with the DHHS' Program Guidelines,<sup>168</sup> however, the two departments are continuing to explore ways of collaborating with private insurers in a manner that would allow a broader resolution of a self-disclosing entity's liabilities.

Providers also assert that the FCA presents a disincentive to voluntary disclosure by a company since the disclosure will not necessarily bar a subsequent *qui tam* action. The dramatic increase in health care-related *qui tam* actions may heighten a provider's concern that making a disclosure and conducting an internal investigation of the matter will trigger a *qui tam* action.

While it is true that there is the risk of a collateral lawsuit during the pendency of the disclosure verification and settlement, there are two statutory safeguards in the FCA that may provide some protection to a disclosing provider. The first bars a parasitic suit by a would-be relator who has no independent knowledge of the fraud but instead relies on "publicly disclosed"

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168. See OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH & HUMAN SERVICES, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM AND GUIDELINES: AS MANDATED BY THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ¶ VI.C.4, at 27 (1997).

information.<sup>169</sup> The methods of public disclosure include criminal, civil or administrative hearings, governmental reports, hearings or investigations, or the news media. If the relator's complaint is based on information constituting "allegations or transactions" which has been "publicly disclosed" through these enumerated means, the action is barred unless the relator was the "original source" of the information.<sup>170</sup>

The second means to limit parasitic *qui tams* which are based on self-disclosures may be found in the lesser-referenced bar against actions where the allegations are the subject of a proceeding in which the government is a party. Section 3730(e)(3) of the FCA provides that "[i]n no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party."<sup>171</sup>

It has been suggested that the OIG could provide immunity from a relator's action by simply initiating a civil monetary penalty action pursuant to 42 U.S.C. § 1320a-7a. This administrative authority of the OIG reaches the same false and fraudulent claims that are actionable under the FCA, and it provides comparable penalties. Under this proposal, the amount of the administrative penalties would reflect the estimated damages to the program and could be increased or reduced by agreement of the parties at the conclusion of the disclosure verification process.

The OIG has not engaged in this type of collusive litigation, however, so the merits of this approach have not been tested. Furthermore, there is little concrete evidence to suggest that providers were discouraged from participating in the self-disclosure pilot due to the lack of a bar on subsequent *qui tam* lawsuits. In fact, the Defense Department's voluntary disclosure program has received more than 300 disclosures despite the

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169. 31 U.S.C. § 3730(e)(4)(A) (1994).

170. See *id.* § 3730(e)(4). Public disclosure/original source jurisprudence is very fact specific and quite complicated, and it has generated a number of significant splits in the circuits regarding the various elements of the jurisdictional bar. Whether a disclosure under the Protocol would trigger the bar would depend upon the facts of the case and the circuit in which the *qui tam* action was filed.

171. *Id.* § 3730(e)(3).

discloser's exposure to subsequent *qui tam* actions.<sup>172</sup> In addition, the FCA contains a self-disclosure provision which limits recoveries to double damages and penalties in appropriate circumstances.<sup>173</sup> This provision suggests that the FCA actually provides an incentive to a company considering self-disclosure of the submission of false claims. Secondly, the threat of *qui tams* in the self-disclosure context may protect against dishonest disclosures.<sup>174</sup> Finally, it is also clear that the FCA would need to be amended in order to provide disclosure protection from derivative *qui tam* lawsuits. Such an amendment would likely face legislative obstacles.

#### IV. INDUSTRY RESPONSE TO GOVERNMENT ENFORCEMENT AND COMPLIANCE PROMOTION EFFORTS

Although it appears that the industry as a whole is beginning to embrace voluntary compliance and collaboration with the government as a critical component of operating under the federal health care programs, the industry's initial reaction to the government's heightened enforcement initiatives was anything but cooperative. In fact, the initial reaction of the industry was to attempt to use the legislative and judicial system to stop health care fraud enforcement in its tracks.

##### A. *The Health Care Industry's Attempt to Gut the FCA*

During the 1998 legislative session, the health care industry launched an unprecedented attack and lobbying campaign, spearheaded in large part by the American Hospital Association ("AHA"), against the government's use of the FCA. In short, the

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172. U.S. GENERAL ACCOUNTING OFFICE, DOD PROCUREMENT: USE AND ADMINISTRATION OF DOD'S VOLUNTARY DISCLOSURE PROGRAM (1996).

173. 31 U.S.C. § 3729(a).

174. See *United States ex rel. Keeth v. United Tech. Corp.*, No. H-89-323 (D. Ct. 1994). The company agreed to pay the Government \$150 million where the relator alleged that United Technologies Corp. prematurely billed for work not yet performed and that it attempted to suppress disclosure of improper practices after entering the DOD Voluntary Disclosure Program. THE FALSE CLAIMS ACT LEGAL CENTER, 8 TAXPAYERS AGAINST FRAUD Q. REV. 31 (1994).

AHA sponsored a legislative proposal<sup>175</sup> that would have, in effect, eviscerated the FCA for use against health care fraud by erecting serious legal and practical obstacles to such civil prosecutions. Curiously, these obstacles would not have been imposed on any other defrauders of federal programs. But under the AHA's proposal, members of the health care industry would have enjoyed immunity from the FCA in many situations. The AHA proposal included a "material amount" requirement, a criminal standard of proof, a safe harbor for "substantial" compliance, and a safe harbor for reliance on erroneous agency advice.<sup>176</sup> While all of these measures may have had some superficial appeal, on closer inspection, the government determined that they were seriously flawed, and it vigorously opposed the legislation.

In summary, during hearings on the proposed legislation the government contended that a materiality requirement would create "free for fraud" zones and that a "clear and convincing evidence" standard of proof was inappropriate for civil prosecutions.<sup>177</sup> It also contended that a model compliance plan "safe harbor" was inappropriate given that the OIG issues only non-binding "guidance," not the text of actual compliance plans. Finally, the government asserted that the AHA's suggested safe harbor for reliance on incorrect agency advice encouraged "gaming" of the system, ran counter to a longstanding general principle disallowing estoppel against the United States,<sup>178</sup> would confer immunity even when the provider knew that the person

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

176. H.R. 3523, 105th Cong. § 2 (1998).

177. *Health Care Fraud & Abuse and the False Claims Act: Hearings on H.R. 3523 Before the Subcommittee on Immigration and Claims of the Committee of the Judiciary*, 105th Cong. 7-9 (1998) (statement of Lewis Morris, Assistant Inspector Gen. for Legal Affairs).

178. *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917) (ruling that "the United States is neither bound nor estopped by acts of its officers or agents in entering into an arrangement or agreement to do or cause to be done what the law does not sanction or permit."). See also *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380 (1947) (holding that the government was not bound by the unauthorized representations of its agents in advising a farmer that his crop was insured when, under regulation, over 80% was uninsured). Although more recent case law and the decisions of the Comptroller General have softened this rule of law, a person relying on erroneous advice must show his/her reliance was reasonable under the circumstances.

providing the guidance was acting outside of his or her authority or was providing misinformation, and failed to recognize that the government always takes agency guidance into consideration in its cases.<sup>179</sup>

The AHA proposal picked up more than 200 House co-sponsors, despite opposition from the DOJ, the OIG, public interest groups (including the AARP), Senator Charles Grassley and Representative Howard Berman (the primary sponsors of the 1986 FCA Amendments), and many editorial pages from around the country.<sup>180</sup> Ultimately, support for the bill evaporated when the DOJ issued its guidance on the use of the FCA in health care matters.<sup>181</sup> Rather than waiting for the DOJ to address the AHA's concerns, the AHA pushed the passage of S. 2007/H.R. 3523, which went far beyond the AHA's purported concerns with implementation and effectively immunized the health care industry.

### *B. Industry Lawsuits to Enjoin Enforcement of National Projects*

In addition to attempting to eviscerate the FCA, certain members of the health care industry have also sought to derail the government's national project enforcement initiatives. For instance, the AHA, the Association of American Medical Colleges and the AMA, among others, brought suit to preclude the United States from conducting audits and enforcement efforts pursuant to the OIG's PATH initiative.<sup>182</sup> Specifically, the plaintiffs sought: (1) a declaratory judgment on the specific allegations raised in the complaint and (2) a preliminary injunction to preclude the United States from conducting audits and pursuing

179. *Health Care Fraud & Abuse and the False Claims Act: Hearings on H.R. 3523 Before the Subcommittee on Immigration and Claims of the Committee of the Judiciary*, 105th Cong. 7-9 (1998) (statement of Lewis Morris, Assistant Inspector Gen. for Legal Affairs).

180. See, e.g., *Blown Off: If Government Is Serious About Cutting Down Waste, It Has to Fairly Compensate the Whistle Blowers*, PHIL. INQUIRER, Feb. 5, 1998, at A22; *Fixing Medicare: This "Cure" Could Be Worse Than the Problem*, DALLAS MORNING NEWS, May 1, 1998, at 30A.

181. See 144 CONG. REC. S7675-02, S7676-77 (daily ed. July 8, 1998).

182. *Association of Am. Med. Colleges v. United States*, 34 F. Supp. 2d 1187 (C.D. Cal. 1998).

enforcement actions pursuant to the PATH initiative until a court had the opportunity to rule on the allegations.<sup>183</sup> Generally, the complaint alleged that the federal government intended to coerce teaching hospitals into unfair settlements based upon unlawful and retroactively-applied standards relating to the payment for services of teaching physicians under the Medicare program.<sup>184</sup> However, the court dismissed the lawsuit on the grounds that the plaintiffs failed to establish subject matter jurisdiction over the claims asserted.<sup>185</sup>

First, the court ruled that the plaintiffs' legal challenge of the PATH audits was premature.<sup>186</sup> In the court's view, an OIG audit is not a "final agency" action that would give rise to an appeal right.<sup>187</sup> The court found that the plaintiffs' arguments were based on a series of contingencies that were unascertainable at that time.<sup>188</sup> For example, some of the unknowns included whether there would be any findings at all, whether the OIG would refer the results to the Attorney General or the Secretary, and whether the Secretary or the Attorney General would pursue an action.<sup>189</sup> Notably, the court also emphasized that the plaintiffs did not establish a threat to their ongoing operations.<sup>190</sup> The court concluded that the plaintiffs did not suffer any financial hardship because the OIG assumed the costs of audits unless the hospital chose instead to hire an independent reviewer to conduct a self-audit.<sup>191</sup> Second, citing to a similar case, *Ohio Hospital Association v. Shalala*,<sup>192</sup> the court emphasized that the plaintiffs had an adequate alternative legal remedy.<sup>193</sup> They could obtain judicial review by defending a prosecution under the FCA.<sup>194</sup>

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183. *Association of Am. Med. Colleges*, 34 F. Supp. 2d at 1190 n.5.

184. *Id.* at 1188.

185. *Id.*

186. *Id.* at 1189-90.

187. *Id.*

188. *Association of Am. Med. Colleges*, 34 F. Supp. 2d at 1189-90.

189. *Id.* at 1194.

190. *Id.* at 1195.

191. *Id.*

192. 978 F. Supp. 735 (N.D. Ohio 1997).

193. *Association of Am. Med. Colleges*, 34 F. Supp. 2d at 1189-90.

194. *Id.* at 1190.

The *Ohio Hospital Association* case involved a similar injunctive and declaratory judgment suit filed by the Ohio Hospital Association and the AHA against the Secretary of the DHHS in order to stop the hospital outpatient laboratory project as it was being initially pursued in Ohio.<sup>195</sup> The Associations asserted that the Secretary "was improperly and retroactively enforcing new coding and billing standards in connection with Medicare reimbursement" for outpatient laboratory tests and sought a declaratory judgment.<sup>196</sup> They claimed that "the Secretary did not properly promulgate the new standards," that she could not "retroactively enforce them," and that "the government [could] not hold plaintiffs' member hospitals liable under the [FCA]."<sup>197</sup> As in the PATH related suit, the court dismissed the action for lack of subject matter jurisdiction.<sup>198</sup> In short, regarding the use of the FCA, the court held that it would be improper for the court to issue an "advisory opinion" in advance of the government's potential use of the law.<sup>199</sup> Rather, if a hospital believed that it had valid defenses, it must pursue them by refusing to settle and defending against a specific FCA action.<sup>200</sup> As to the Associations' assertion that the Secretary was improperly imposing new rules, the court held that subject matter jurisdiction did not exist because their claim did not "arise under" the Medicare Act, nor had there been final agency action, as required for judicial review.<sup>201</sup>

The legislative and judicial attacks noted above share a common characteristic. Rather than individual providers defending themselves based on the particular facts of a case, the industry sought to portray the entire government enforcement apparatus as illegitimate and out of control. Such a strategy only served to sow acrimony and mistrust between the industry and the government and to waste valuable resources that could have been put to better use. Fortunately, the industry recently has begun making better use of its resources by embracing the

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195. *Ohio Hosp. Ass'n*, 978 F. Supp. at 736.

196. *Id.*

197. *Id.*

198. *Id.* at 738.

199. *Id.* at 739-40.

200. *Ohio Hosp. Ass'n*, 978 F. Supp. at 739-40.

201. *Id.* at 741-42.

government's call for it to collaborate on preventing fraud.

*C. Industry Response to the Government's Attempts to Promote Compliance Through Collaboration*

The health care industry generally has been very receptive to the government's efforts to enlist providers in improving program integrity. For example, the AHA's Board of Trustees adopted a resolution encouraging its members to adopt "regulatory compliance programs as a way to minimize errors in conforming to the highly technical and complicated rules, and urge[d] all hospitals and health systems to develop and implement or strengthen a formal compliance program to ensure that regulations are accurately followed."<sup>202</sup> Upon release of the OIG's compliance guidance for hospitals, the president of the AHA issued a statement applauding the OIG's effort.<sup>203</sup> The AHA recently concluded a survey of its members to determine the extent of their internal compliance measures. According to the reported results, 99% of the respondents indicated that they had or would have compliance measures in place by the end of 1999.<sup>204</sup>

The GAO also has concluded a preliminary assessment of the prevalence of compliance programs among hospitals and other health care providers.<sup>205</sup> Hospitals in the GAO study cited a number of reasons for the wide-scale adoption of compliance programs, including the heightened enforcement environment, suggestions from the OIG and the expectation that the HCFA and accreditation bodies would soon require compliance pro-

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202. Phillip Dunn, *All Hospitals Should Establish Compliance Programs*, *AHA Says* (Sept. 22, 1997) <<http://www.ahanews.com/cgi-bin/sm40i.exe?docid=100:7293&%50assArticleId=9998>>.

203. Alwyn Cassil, *IG Provides Guidelines for Hospital Compliance Plans* (Feb. 16, 1998) <<http://www.ahanews.com/cgi-bin/sm40i.exe?decid=100:7293&%50assArticleId=11045>>.

204. AMERICAN HOSPITAL ASSOCIATION COMPLIANCE PROGRAM SURVEY (1999) (available from U.S. Dep't of Health & Human Services, Washington, D.C.).

205. U.S. GENERAL ACCOUNTING OFFICE, *MEDICARE: EARLY EVIDENCE OF COMPLIANCE PROGRAM EFFECTIVENESS IS INCONCLUSIVE* (1999) (visited Oct. 12, 1999) <<http://www.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=fihe99059.txt>>.

grams.<sup>206</sup>

Significantly, hospital officials indicated that the benefits of their compliance programs outweighed their costs and said that their compliance efforts were recognized by the federal government when they were the target of an investigation.<sup>207</sup> Recognition of the providers' compliance efforts took several forms, including: (1) the OIG agreeing to allow the providers to use less expensive audit methods as part of the PATH audit initiative, (2) waiver of exclusion from government health care programs, (3) less onerous compliance requirements, and (4) a reduction of FCA monetary liabilities.<sup>208</sup> It should be acknowledged that some of the hospitals interviewed by the GAO researchers expressed concern that they did not receive sufficient credit for their compliance efforts in settlement negotiations with the USAOs.

The industry's response to the revised self-disclosure initiative also has been very positive. The number of providers submitting the results of internal investigations to the OIG has increased significantly since the release of the Protocol. For example, in the first six months since the announcement of the self-disclosure Protocol, over forty providers have submitted applications and information to the OI.<sup>209</sup> By contrast, the OIG received less than a dozen applications during the course of the two-year pilot program.<sup>210</sup> As of April 1999, there have not been any resolutions of matters under the Protocol, due to the time required to finalize the providers' internal investigations and audits and the time required to perform verification of the information.<sup>211</sup>

The health care industry's response to the advisory opinion mechanism also has been favorable. After a slow start, the number of requests for advisory opinions has increased significantly. In the first fiscal year (March 1991-February 1998), the OIG

206. *Id.*

207. *Id.*

208. *Id.* The DOJ has directed that a provider's compliance program be considered when evaluating whether the provider "knowingly" submitted a false claim. *See id.*

209. *See generally* U.S. Office of Inspector General website (visited Oct. 12, 1999) <<http://www.dhhs.gov/progorg/org>>.

210. *Id.*

211. *Id.*

received forty-three requests for advisory opinions and issued six.<sup>212</sup> In the second twelve months of operation, the number of requests for formal guidance increased to sixty-two, and the OIG issued fifteen opinions in FY 1999.<sup>213</sup>

While substantial sectors of the health care industry have embraced the government's efforts to promote collaboration, such a response has not been universal. Most notably, the AMA has been very outspoken in its criticism of the government's fraud-fighting efforts. For example, an *American Medical News* editorial attacked the recent *Who Pays? You Pay* campaign as an unconscionable, ill-considered publicity stunt directed at undermining the patient-physician relationship.<sup>214</sup> In a *Wall Street Journal* editorial entitled *Government to Grandpa: Rat Out Your Doctor*, the President of the AMA decried the education effort as reminiscent of the IRS hounding honest citizens who were on an "enemies list."<sup>215</sup> By contrast, the AHA endorsed the AARP campaign as sound advice and said it would work with the AARP "to responsibly address the issue of health care fraud."<sup>216</sup>

## V. CONCLUSION

Affirmative enforcement, with the objectives of prosecution and recovery of misspent funds, remains a central objective of the government's fight against health care fraud and abuse. With the increased resources provided under the HIPAA, the OIG is expanding its investigative and audit staffs, and in the next few years it will have an enforcement presence in all geographic areas of the country. Similar funding increases have

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212. *Id.*

213. *Id.*

214. *Tampering with Trust*, AM. MEDICAL NEWS (Mar. 15, 1999) <[http://www.ama-assn.org/sci-pubs/amnews/amn\\_99/edit0315.htm](http://www.ama-assn.org/sci-pubs/amnews/amn_99/edit0315.htm)>.

215. Nancy W. Dickey, M.D., *Government to Grandpa: Rat Out Your Doctor*, WALL ST. J., Feb. 24, 1999, at A18.

216. Susan J. Landers, *Feds, Seniors Lobby Targeting Medicare Fraud in New Crusade*, AM. MEDICAL NEWS (Mar. 8, 1999) <[http://www.ama-assn.org/sci-pubs/amnews/pick\\_99/pick0308.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_99/pick0308.htm)>.

allowed the DOJ and the FBI to establish a more comprehensive presence in "fraud hot spots" such as South Florida as well as to expand into new geographic areas.

The results of the heightened enforcement effort have been dramatic. Drawing from the lessons learned in conducting the first multi-agency fraud investigations, investigators and prosecutors are more efficient and better coordinated in their approach to the most complex, multi-jurisdictional cases. The result has been a record number of multi-million dollar settlements, more criminal prosecutions of health care defrauders, and a significant rise in the number of individuals and entities excluded from the government's health care programs. Recommendations to correct systemic weaknesses detected during investigations, audits and evaluations are being made in increasing numbers. These recommendations have produced legislative reforms of services provided by Medicare as well as the elimination of vulnerabilities in agency programs and administrative processes. As a result of these initiatives, billions of dollars in valuable health care funds have been put to better and more effective use.

In addition to increased efforts to uncover existing fraud, the OIG has expanded its preventative efforts. The cornerstone of this effort is the development of voluntary compliance program guidances to encourage the health care industry to fight fraud and abuse. As a condition of settling liability for violations of the FCA, the OIG is requiring providers to execute CIAs which incorporate the principles of the compliance guides. The government's activities to educate the industry also have included the issuance of advisory opinions, fraud alerts and advisory bulletins on fraud risk areas. Each of these outreach measures has been undertaken with the participation and collaboration of the health care industry.

The effectiveness of this dual approach—enforcement and prevention—is becoming apparent. The annual audit of the HCFA's financial statements provides an objective evaluation of

the Medicare program's financial management and internal controls. As discussed earlier, in the last three successive years, the audit report estimates that improper Medicare fee-for-service payments have dropped.<sup>217</sup> While the audits do not attempt to determine what portion of the improper payments are attributable to fraud, as compared to those that are the result of insufficient documentation, lack of medical necessity or other grounds, the results are impressive. There are other indicators that suggest that the efforts to combat fraud are beginning to pay dividends. The HCFA has monitored the average prospective payment system ("PPS") case-mix, which is the discharge-weighted mean of all the DRG relative weights used in the payment formula since the beginning of PPS in FY 1984. The case-mix increased every year since the HCFA began tracking this in 1984.<sup>218</sup> Fiscal Year 1998 saw the first *decrease* in the case-mix, a result that was attributed to the efforts to combat fraud and abuse.<sup>219</sup> Furthermore, the Social Security and Medicare Board of Trustees reported in March, 1999 that the "Hospital Insurance [T]rust Fund, which pays inpatient hospital expenses, is projected to be able to pay full benefits until 2015, seven years longer than projected" the previous year.<sup>220</sup> While the robust economy and changes in reimbursement laws played an important role, the trustees specifically cited the continuing efforts to combat fraud and abuse as a contributing factor.<sup>221</sup>

Whether the improved health of the Medicare program is the consequence of providers paying closer attention to the adequacy of their documentation, implementing effective compliance measures or abandoning abusive practices, the results are positive and indicate that the government's emphasis on enforcement and prevention through collaboration is working. As the

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217. See *supra* note 5.

218. Memorandum of Gregory Savord, *Analysis of PPS Hospital Case-Mix Change Between 1997 and 1998*, to the U.S. Dep't of Health & Human Services (Nov. 19, 1998) (on file with author).

219. *Id.*

220. *Id.*

221. SOCIAL SECURITY AND MEDICARE BOARDS OF TRUSTEES, STATUS OF THE SOCIAL SECURITY AND MEDICARE PROGRAMS, A SUMMARY OF THE 1999 ANNUAL REPORTS (1999).

country's population ages and the demands on the Medicare program grow, we will need creative new ways to preserve the integrity of the health care system. Through aggressive enforcement against untrustworthy providers and collaboration with honest members of the health care industry, the OIG and other law enforcement agencies can develop appropriate solutions to these challenges.

