

## IN THE WAKE OF THE COLUMBIA/HCA INVESTIGATIONS: PLOTTING A COURSE FOR MEDICARE COMPLIANCE

Jamie R. Welton

*Reports of widespread criminal abuse of the Medicare system have resulted in the creation of new legislation and regulations interpreted as broad mandates to clean up the financially unstable Medicare system. The federal government's recent investigation and prosecution of Columbia/HCA for Medicare fraud served as a wake-up call to health-care providers participating in the Medicare system. As a result, in order to avoid a similar fate as Columbia/HCA, health-care providers are now more energetically guarding against noncompliance with Medicare requirements.*

*In this note, Mr. Welton analyzes Medicare reimbursement requirements, Medicare procedures for reviewing reimbursement requests, specific areas of reimbursement often investigated, and the effects of such investigations. Mr. Welton also examines the statutes used by the government to punish noncompliance, exemptions to the statutes, and the elements required for establishing a good-faith defense to a charge of noncompliance. Lastly, Mr. Welton recommends several strategies on how health-care providers may avoid the initiation of an investigation and discusses various means of recourse if the government initiates an investigation.*

### I. Introduction

The federal government's investigations of Columbia/HCA<sup>1</sup> have caused health-care industry administrators and

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Jamie R. Welton is a member of the University of Illinois College of Law class of 1999 and of The Elder Law Journal.

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1. Federal law enforcement authorities indicted three mid-level Columbia/HCA executives for Medicare fraud in Florida in late July 1997. See Kurt Eichenwald & Martin Gottlieb, *Healthcare's Giant—When Hospitals Play Hardball; A Hospital Chain's Brass Knuckles, and the Backlash*, N.Y. TIMES, May 11, 1997, at A1

executives to reevaluate the risk of fraud charges and exclusion from the Medicare program.<sup>2</sup> By turning hospitals operating at record losses into profitable and efficient facilities, Columbia executives, with their Wall Street savvy, took the health-care industry by storm.<sup>3</sup> Columbia sliced into the market share of not-for-profits with aggressive marketing strategies, hospital takeovers, cost-reduction, high-volume purchasing, intricate pricing strategies, and monetary incentives to managers and physicians who met the company's financial goals.<sup>4</sup> Under Columbia/HCA's control, the quality of services provided often increased as well.<sup>5</sup> Columbia's strategies made it the largest of for-profit hospital chains and the ninth-largest employer in the country, employing more people than McDonald's and General Electric.<sup>6</sup> Prior to the federal investigations, Columbia/HCA owned 342 hospitals, 150 outpatient surgical centers, 570 home-health-care centers, and produced over \$20 billion in annual revenues.<sup>7</sup>

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[hereinafter Eichenwald, *Healthcare's Giant*]. Doug Molloy, a U.S. Attorney in Fort Meyers, indicated that one more person is likely to be similarly charged. See *Another Indictment Expected in HCA Case*, TAMPA TRIB., Feb. 14, 1998, at Bus. & Fin. 1. State investigations in Alabama, Florida, Illinois, and Texas are also ongoing. See *Columbia/HCA Probe Paper Released; Other Developments*, FACTS ON FILE WORLD NEWS DIGEST, Oct. 30, 1997, at 788; Denise Gamino, *Texas Starts Investigation of Columbia*, AUSTIN AMERICAN-STATESMAN, July 26, 1997, at D1. See generally Kurt Eichenwald, *U.S. Looks at Columbia/HCA Elderly Programs*, N.Y. TIMES, Aug. 22, 1997, at D1 [hereinafter Eichenwald, *U.S. Looks at Columbia/HCA*]; *Hospitals Funnel Patients to Their Home-Care Clinics; Issue One Target of Columbia/HCA Probe*, ST. LOUIS POST-DISPATCH, Sept. 3, 1997, at 5C; *Hospitals Say Relator Lacked Cause of Action Under False Claims Act*, HEALTHCARE FRAUD LIT. REP., Mar. 1997, at 12; Kris Hundley, *As Columbia/HCA Grows, So Do the Questions*, ST. PETERSBURG TIMES, Apr. 20, 1997, at 1A [hereinafter Hundley, *As Columbia/HCA Grows*]. In addition to the above-mentioned states, search warrants have also been served in North Carolina, Tennessee, and Utah. See Michael Casey, *Columbia: A Year Later, Bad News Continues*, MED. INDUSTRY TODAY, Apr. 7, 1998, at Managed Care News Perspectives. In addition, the Securities and Exchange Commission (SEC) announced in April 1998 that it is investigating Columbia/HCA for alleged violations of federal securities laws. See *id.* The SEC often investigates the targets of fraud investigations to determine if reported earnings and other submissions are accurate. See *id.*

2. See Kurt Eichenwald, *For Hospitals, a New Prognosis on Fraud-Charge Exposure*, N.Y. TIMES, Aug. 1, 1997, at D2.

3. See Hundley, *As Columbia/HCA Grows*, *supra* note 1.

4. See Eichenwald, *Healthcare's Giant*, *supra* note 1. Columbia has grown from 2 hospitals to 350 hospitals, 555 home health-care centers, 150 nursing homes, and \$20 billion in annual revenues in less than 10 years. See *id.*

5. See Hundley, *As Columbia/HCA Grows*, *supra* note 1.

6. See Larry Amsel, *Corporate Healthcare*, TIKKUN, May 15, 1997, at 19.

7. See *Columbia/HCA Healthcare Executives Indicted; More Expected*, MED. INDUSTRY TODAY, July 31, 1997, at Payer & Provider News; see also <<http://www.columbia.net>>. Thomas (Tommy) F. Frist, Jr., new CEO of Columbia/HCA, former head of HCA prior to its merger with Columbia, and brother of Senator Frist (R-TN), has recently set forth plans to spin-off divisions of Columbia/HCA to



On October 5, 1998, the government joined a whistle-blower action that was already underway in Tampa, Florida, against Columbia/HCA and Quorum Health Group, a former asset of HCA.<sup>8</sup> The whistle-blower, James F. Alderson, who was the Chief Financial Officer for North Valley Hospital in Whitefish, Montana, stands to receive up to twenty-five percent of the estimated one-billion-dollar recovery.<sup>9</sup> This litigation marks a substantial change in the way companies conduct business with federal and state health-care programs.<sup>10</sup>

Since the notion of a national health-care system died at the altar of public opinion in 1994, opponents of for-profit health care shifted the attack to a core weakness of profitable health-care companies: Medicare reimbursement. It is no secret that, in 1997, thirty percent of Columbia's \$20 billion in annual revenues was from Medicare reimbursements (a relatively low percentage by industry standards).<sup>11</sup> Over the past five years, the Department of Health and Human Services' Office of the Inspector General (OIG), as well as contractors, fiscal intermediaries, and private insurance payors, targeted numerous health-care companies. Using recently granted resources,<sup>12</sup> the OIG,

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shareholders, keeping 232 hospitals that annually produce roughly \$14.2 billion in revenue. See Lucette Lagnado, *Columbia Unveils Restructuring Plan; 32% of Its Hospitals to be Spun Off*, WALL ST. J., Nov. 18, 1997, at A4.

8. HCA sold Quorum in the late 1980's, prior to Columbia's 1994 purchase of HCA. Quorum Health Group is primarily a hospital management company, operating more than 200 hospitals in 37 states. See Kurt Eichenwald, *U.S. Suit Charges Fraud by 2 Big Hospital Chains*, N.Y. TIMES, Oct. 6, 1998, at A1 [hereinafter Eichenwald, *U.S. Suit Charges Fraud*].

9. See *id.*; see also 31 U.S.C. § 3730(d) (1994). North Valley Hospital is one of hundreds of hospitals managed by Quorum. See Eichenwald, *U.S. Suit Charges Fraud*, *supra* note 8.

10. Michael M. Mustokoff & Stephen A. Mallozzi, *Columbia/HCA Learns Nothing Is Sacred*, LEGAL INTELLIGENCER, Sept. 30, 1998, at 7 (suggesting that the health-care providers' surprise at the Columbia/HCA investigations is unwarranted considering two 11th Circuit cases applying the False Claims Act to aggressive cost reports).

11. See Michael J. Stoil, *Rumors of Fraud—and Real Budget Cuts; Healthcare Fraud Investigated*, NURSING HOMES, Sept. 1997, at 10.

12. See *Medicare at Risk: Hearings Before the Permanent Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 105th Cong. 100 (1997) [hereinafter Aronovitz, *Medicare at Risk*] (statement of Leslie G. Aronovitz, Associate Director of the Health Financing and Systems Issues in Health, Education, and Human Services Division of the U.S. General Accounting Office). The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936, allocated \$104 million between the HHS and the Department of Justice (DOJ). See Aronovitz, *Medicare at Risk*, *supra*. The OIG allocated \$70 million to hire 250 additional investigators, attorneys, auditors, and analysts to investigate health-care providers. See *id.* at 101. The DOJ spent \$24 million to hire 120 additional prosecutors exclusively devoted to health-care fraud. See *id.*

with the aid of the Federal Bureau of Investigation (FBI), Department of Justice (DOJ), and Health Care Financing Administration (HCFA), launched an attack on health-care providers under the guise of cleaning up fraud and abuse. As a result, individuals and corporations have lost their livelihood,<sup>13</sup> financial security,<sup>14</sup> rights,<sup>15</sup> and respect by

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13. General exclusion functionally prevents an organization from operating, and certainly prevents continued employment and/or operations involving Medicare reimbursement. See generally 31 U.S.C. § 3729 (1994); 42 U.S.C.A. §§ 1320a-7a, -7b (West Supp. 1998). The principal may be excluded from Medicare due to acts of its agents. See 18 U.S.C. § 2 (1994); 42 U.S.C.A. § 1320a-7a(l) (West Supp. 1998). Conversely, managing employees and officers may personally be excluded from participation if the entity which employed them is found guilty of noncompliance, even if the employees and officers did not participate in any wrongdoing. See HIPAA § 213, Pub. L. No. 104-191, 110 Stat. 1936; see also 42 U.S.C. § 1395 (1994, Supp. 1996 & West Supp. 1998). Once excluded, reinstatement is discretionary and employers risk exclusion by hiring any person who has been excluded. See 42 C.F.R. §§ 1001.3002, .951 (1998).

14. The fines are imposed per billing violation, and often result in huge penalties. See, e.g., *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 965 n.10, 966 (Del. Ch. 1996) (holding Caremark liable for \$29 million in criminal fines, \$129.9 million in civil fines, \$3.5 million under the Controlled Substances Act, and a donation of \$2 million, Caremark also settled an ancillary suit by private insurance company payors for \$98.5 million, and paid substantial legal fees to defend five ancillary shareholder derivative suits). The exclusion prevents any future reimbursement, thereby cutting off a substantial stream of revenue. Any purchaser of the excluded company risks exclusion as well. See 42 C.F.R. § 1001.1001; *infra* notes 132-34. If the fines do not bankrupt the entity and/or individual(s) involved, then spin-off litigation surely will. Typically, suits on behalf of fiscal intermediaries, contractors, private insurance payors, and shareholders are brought upon exclusion from Medicare. See, e.g., *In re Caremark*, 698 A.2d at 965 n.10, 966.

15. Administrative remedies must be exhausted before a federal court may review an OIG finding, however, the Administrative Law Judge does not have the authority to review discretionary OIG decisions or to enjoin an OIG decision. See 42 U.S.C. § 405(h) (1994); 42 C.F.R. §§ 1005.2(c)(5), (7), 1005.2(c)(4), 1001.2007(d) (1998). Assets may be frozen pending administrative and judicial review, thus making it difficult to pay legal fees and continue operations. See 18 U.S.C. § 1345 (1994); *United States v. Brown*, 988 F.2d 658, 663 (6th Cir. 1993) (holding that 18 U.S.C. § 1345 asset freezes are not limited to banking-law violations and may be applied to assets traceable to Medicare fraud). The inability to enjoin and obtain review of discretionary OIG decisions often violates liberty rights guaranteed by the Due Process Clause. See *Erickson v. Great Falls Eye Surgery Ctr.*, 67 F.3d 858, 863 (9th Cir. 1995) (holding that a protectible liberty interest is at stake when a recognized participant in the Medicare program is excluded); *Vanelli v. Reynolds Sch. Dist. No. 7*, 667 F.2d 773, 778 (9th Cir. 1982) (holding that there is a protectible liberty interest if the exclusion from a program is made in connection with the alteration of a status recognized by law). In order to seek pre-exhaustion judicial review in a federal court of competent jurisdiction a litigant must show (1) a colorable constitutional claim, (2) irreparable harm, and (3) the purpose of the exhaustion requirement would not be served by additional ALJ/DAB review. See *Lavapies v. Bowen*, 883 F.2d 465, 467 (6th Cir. 1989) (citing *Mattews v. Eldridge*, 424 U.S. 319 (1976)). The standard for judicial review is the same as it is for the ALJ: whether the OIG determination to exclude was based on substantial evidence. See *Papendick v. Sullivan*, 969 F.2d 298, 302 (7th Cir. 1992). No federal court has granted pre-exhaustion judicial review. See *W. Bruce Shirk & Stephanie*

being demonized and associated with criminals who actively and willfully engage in defrauding the Medicare system.<sup>16</sup> Until the OIG uses its broad discretion to delineate between criminals who intend to defraud the government and health-care providers who unwittingly fail to comply with technical and discretionary billing requirements, health-care providers must take active steps to protect their right to participate<sup>17</sup> in the Medicare system.

The Columbia investigation, and other similar investigations, serve as a wake-up call to health-care providers. The substantial amount of political capital generated from hearings over the rampant criminal abuse and financial instability of the Medicare system has resulted in legislation and regulations that give the OIG broad powers to “clean-up” the system.<sup>18</sup> The only form of OIG success that is consistently recognized is the recovery of large sums of expended capital, often making profitable health-care companies greater targets than smaller criminal schemes. Part II of this note examines Medicare reimbursement requirements, how requests are reviewed, special areas of OIG attention, and the ramifications of OIG investigations. Part III analyzes the statutes used to enforce compliance, pertinent exemptions (“safe harbors”), and the elements of establishing a “good faith” defense. Finally, part IV offers practical suggestions on how to avoid an OIG investigation, and legal avenues of recourse if an OIG investigation is instigated.

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Pontzer Gilson, *Procedure, Term and Judicial Review*, in HEALTHCARE EXCLUSIONS: A COMPREHENSIVE GUIDE 113, 125 (1997).

16. See generally *Medicare Fraud Prevention: The Medicare Enrollment Process: Hearing Before the Permanent Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 105th Cong. 401 (1998) [hereinafter *Convicted Medicare Fraud Felon*] (statement of Convicted Medicare Fraud Felon). The testimony reveals the ease at which politicians label Medicare reimbursement issues synonymously with criminal activity. See also *Improper Medicare Billings by Hospitals Nationwide for Investigational Devices and Procedures: Hearings Before the Permanent Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 104th Cong. 5 (1996) [hereinafter *Roth Statement*] (statement of Senator Roth (R-DE) revealing the congressional focus on criminal activity).

17. The “right to participate” is a normative claim. Although there is case law and theories that support such a contention, there is also case law to the contrary. The issue is one that should certainly be raised by Medicare participants who are subjected to permissive exclusion by the OIG. See 42 C.F.R. §§ 1001.201, 1001.901, 1001.951.

18. See Aronovitz, *Medicare at Risk*, *supra* note 12.

## II. Complying with Medicare Reimbursement Requirements and the Impact of Noncompliance

The HCFA and the OIG report that there are approximately 38 million Medicare beneficiaries.<sup>19</sup> In addition, they report that over 800 million claims for roughly \$250 billion are filed annually.<sup>20</sup> The Department of Health and Human Services (HHS) estimates that \$27 billion is lost to waste, fraud, and abuse, roughly \$1.2 billion of which is recovered through prosecuting Medicare noncompliance.<sup>21</sup> Considering Columbia's intent to settle with the government by 1999 and the specter of one-billion-dollar liability, the money received from prosecuting noncompliance claims will skyrocket into the next millennium.<sup>22</sup> The HCFA and OIG audit over nine percent of all claims filed.<sup>23</sup> Because of the additional resources allocated to compliance enforcement, the number of claims audited, and the amounts recovered, the number of investigations is likely to increase substantially in the near future. By examining the methods of reimbursement, review and detection of noncompliance, special areas of OIG enforcement, and the ability of the OIG to exclude providers from participation in Medicare, it becomes apparent that achieving effective compliance is necessary.

### A. Methods of Medicare Reimbursement

The Social Security Amendments of 1965 established Medicare in order to provide hospital and medical insurance for the elderly.<sup>24</sup> Medicare is a two-part program of hospital insurance (Part A—inpatient services and home health care) and supplementary medical insurance (Part B—outpatient services and other services ranging from

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19. See Stephen J. Hedges, *The New Face of Medicare*, U.S. NEWS & WORLD REP., Feb. 2, 1998, at 46. This article is an example of the "criminal abuse" rhetoric that has built the political capital to support broad and stringent OIG enforcement; citing the infamous "laundromat" and "P.O. Box" examples. For a recent example of such rhetoric at congressional hearings, see *Convicted Medicare Fraud Felon*, *supra* note 16.

20. See Hedges, *supra* note 19.

21. See *id.*

22. See Eichenwald, *U.S. Suit Charges Fraud*, *supra* note 8 (analyst estimates a settlement at \$1 billion); Kris Hundley, *Government Joins Columbia Civil Lawsuit*, ST. PETERSBURG TIMES, Oct. 6, 1998, at 1E [hereinafter Hundley, *Government Joins Columbia Civil Suit*] (Columbia hopes to settle in 1999).

23. See Hedges, *supra* note 19.

24. See Health Insurance for the Aged Act, Pub. L. No. 89-97, 79 Stat. 290 (July 30, 1965) (codified as amended at 42 U.S.C. § 1395 (1994, Supp. 1996 & West Supp. 1998)).

lab testing to ambulances).<sup>25</sup> The HCFA, acting under the HHS, is in charge of the administration of Medicare.<sup>26</sup> Health-care providers and Health Maintenance Organizations (HMOs) treat beneficiaries and receive reimbursement from Medicare under either the HCFA's fee-for-service (FFS) program or the managed-care program.<sup>27</sup>

The FFS program covers almost ninety percent of all Medicare beneficiaries.<sup>28</sup> A network of claims processing contractors, such as Blue Cross/Blue Shield and CIGNA, process and pay Medicare claims.<sup>29</sup> Medical contractors use federal funds to pay health-care providers for the costs of providing items and services to beneficiaries.<sup>30</sup> In return, Medicare reimburses contractors for their costs and for safeguarding the administrative payments.<sup>31</sup> Contractors have broad discretion in safeguarding payment practices.<sup>32</sup>

The managed-care program covers almost five million people enrolled in HMOs for medical care.<sup>33</sup> HMOs enroll beneficiaries in either a risk contract or a cost contract.<sup>34</sup> Under a risk contract, Medicare pays an HMO a fixed monthly amount per beneficiary in advance, rather than reimbursing the HMO for each particular service as in the FFS program.<sup>35</sup> The HMO assumes the responsibility of providing all of the medical needs of its beneficiaries in return for the set lump-sum amount paid by Medicare.<sup>36</sup> If the costs of the medical services provided in a given month are less than the predetermined Medicare payment, the HMO profits.<sup>37</sup> Conversely, if costs exceed the Medicare payment, the HMO bears the loss.<sup>38</sup> Cost contracts, on the other hand, allow Medicare beneficiaries to choose services provided by their HMO or outside services which bill under the FFS program.<sup>39</sup>

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25. See Aronovitz, *Medicare at Risk*, *supra* note 12, at 88.

26. See *id.*

27. See *id.*

28. See *id.*

29. See *id.*

30. See *id.*

31. See *id.*

32. See *id.*; see also 42 U.S.C. § 202 (1994).

33. See Aronovitz, *Medicare at Risk*, *supra* note 12, at 89.

34. See *id.* at 89, 89 n.2.

35. See *id.* at 89.

36. See *id.*

37. See *id.*

38. See *id.*

39. See *id.* at 89 n.2.

Medicare then deducts any amount of FFS reimbursement from the monthly fixed rate for the beneficiary.<sup>40</sup>

Both the FFS and managed-care programs are victims of fraud and abuse.<sup>41</sup> Medicare is an honor system that relies on the ethical integrity of the providers to bill Medicare accurately.<sup>42</sup> The financial incentives for providers clash with the quality of care for beneficiaries.<sup>43</sup> Under the FFS program, the provider has an incentive to perform more services and bill at higher rates.<sup>44</sup> Under the managed-care program, the provider has an incentive to minimize services and bill at lower rates.<sup>45</sup> Under these programs, it is easy to understand how criminals can reap financial rewards and how billing errors can result in billions of lost dollars annually. Federal and state investigators have begun to tighten Medicare reimbursement enforcement as a means to increase compliance with required billing procedures.<sup>46</sup> As Medicare races toward bankruptcy, the efforts aimed at enforcement and compliance attempt to recover billions of misallocated funds and save additional money through greater compliance.<sup>47</sup>

## B. Methods of Review and Detecting Noncompliance

One reason for the exploitation of Medicare is the HCFA's method of reviewing claims.<sup>48</sup> The processing controls and automated

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40. *See id.*

41. *See id.*

42. *See Roth Statement, supra* note 16. Senator Roth used the abuse statistics as justification for enhancing enforcement measures. *See id.* Senator Roth wanted "to put some teeth into the program and make those who would abuse the system think twice before attempting to defraud Medicare." *Id.* Although the enforcement measures are directed at criminal activity, many of the activities that result in "abuse" lack a criminal intent, and may be subjected to sanction in order to encourage compliance.

43. *See id.*

44. *See Aronovitz, Medicare at Risk, supra* note 12, at 96.

45. *See id.*

46. Medicare has become a top priority for the FBI and DOJ. *See New Top Prosecutor Takes Over: Thomas Scott Has Declared Medicare Fraud One of His Top Priorities*, BROWARD DAILY BUS. REV., Oct. 31, 1997, at A5. Several states have also been prosecuting fraudulent and abusive Medicare billing practices. *See supra* note 1 and accompanying text.

47. The HCFA launched Operation Restore Trust, a pilot five-state crackdown on Medicare fraud and abuse. This highly acclaimed program has recovered \$180 million and returned \$23 for every \$1 spent on the enforcement measures. *See* Press Release from Senator Richard Durbin, *Durbin to Propose 'Zero Tolerance' Initiative to Combat Medicare Fraud*, CONG. PRESS RELEASES (Jan. 29, 1998). Compare this with the OIG's Project Jumpstart which failed to produce a single dollar in recoupment. *See Roth Statement, supra* note 16, at 30.

48. *See Aronovitz, Medicare at Risk, supra* note 12, at 93.

information systems of the HCFA warrant criticism.<sup>49</sup> The HCFA's new multimillion dollar Medicare Transaction System (MTS) has yet to be tested due to delays and increased cost projections, forcing the HCFA to postpone the system's development.<sup>50</sup> To detect questionable payments, Medicare relies predominantly on its contractors who have a financial stake in the outcome.<sup>51</sup>

HCFA also relies on beneficiaries to provide leads based on the review of their Explanation of Medicare Benefits (EOMB) statement, which comes to beneficiaries once a bill is submitted to Medicare for payment.<sup>52</sup> As an additional means of illuminating instances of Medicare fraud and abuse, federal and state hot lines encourage and facilitate communication between beneficiaries and authorities.<sup>53</sup> The HHS and organizations, such as Citizens Against Government Waste (CAGW), participate in educational outreach programs to raise awareness among the elderly. In addition, the programs encourage notification of authorities when an EOMB does not match the services received or when beneficiaries are offered compensation for disclosing their Medicare number.<sup>54</sup>

The HCFA conducts both prepayment and postpayment reviews.<sup>55</sup> Prepayment reviews audit claims for compliance with regulatory procedures and the established criteria for reimbursement.<sup>56</sup> A computer edit will automatically deny duplicate claims and will hold claims for manual review that do not appear to comply with the required criteria.<sup>57</sup> Postpayment reviews consist of focused reviews of medical records, comprehensive audits of claims, and audits of providers' cost reports.<sup>58</sup> Focused medical reviews consist of matching

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49. See *id.*

50. See *id.* at 95. Y2K compliance pressures have also contributed significantly to the system's delay.

51. See *id.* at 90.

52. See *id.* at 91.

53. See *HHS Program Uses Retired Professionals to Help Spot Medicare Fraud*, U.S. Newswire, June 23, 1997, available in LEXIS, News Library, USNWR File. The OIG has set up toll-free hotlines to encourage the public to report suspicions of fraud and abuse. See *Medicare Fraud Hotline Improved and Expanded, Says HHS*, U.S. Newswire, July 16, 1997, available in LEXIS, News Library, USNWR File (toll-free hotline number is 1-800-HHS-TIPS; hearing impaired number is 1-800-377-4950; fax number is 1-800-223-8164).

54. See Aronovitz, *Medicare at Risk*, *supra* note 12, at 91; *Medicare Fraud*, *SUNDAY GAZETTE MAIL*, June 23, 1996, at 8B.

55. See Aronovitz, *Medicare at Risk*, *supra* note 12, at 91.

56. See *id.*

57. See *id.*

58. See *id.*

medical records with the services billed and with relevant billing codes available for particular services.<sup>59</sup> Analysts compare one provider's claims against those of other providers to determine whether any one provider is an unusually high biller per volume of services provided.<sup>60</sup> Analysts also attempt to identify medical services that make up a large number of claims.<sup>61</sup> After considerable postpayment reviews reveal a pattern or a consistent error, the HHS develops new medical review policies for reimbursement of the problematic items or services.<sup>62</sup> As a result, the volume of claims received for the particular items or services affected by the policy change decrease dramatically.<sup>63</sup>

Flagged claims undergo a comprehensive claim audit, which examines providers' billing records for irregularities in greater depth.<sup>64</sup> Auditing cost reports is another means of enforcement. Auditors examine cost reports from particular providers and assess the reasonableness of the costs of services relative to the corresponding reimbursement.<sup>65</sup> When an audit determines that Medicare has overpaid, contractors attempt to recover overpayments from providers.<sup>66</sup> However, the audits are very resource intensive, involving detailed comparisons of a particular patient's medical records to particular claims and interviews with the staff of providers.<sup>67</sup>

Federal and state investigators also have several means to detect and to enforce Medicare fraud and abuse. Investigators obtain information by issuing subpoenas, seizing documents with search warrants, wiretapping offices, pressuring employees to become government witnesses or informants, and utilizing other means avail-

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59. *See id.* Among other things, a postpayment review will examine whether the service provided was reasonably necessary, whether the service was excessive or substandard, and whether the particular service meets professionally recognized standards of health care. *See id.*; *see also* 42 C.F.R. § 1001.701 (1998).

60. *See* 42 C.F.R. § 1001.701. For example, a provider-targeted medical review focuses on which providers are billing the highest amounts, and compares data from several similar providers to determine whether any provider is a disproportionately high biller per volume.

61. For example, if a particular service increases ten-fold over a two-year period, a contractor may become suspicious. *See* Aronovitz, *Medicare at Risk*, *supra* note 12, at 90.

62. *See id.* at 91.

63. *See id.* at 93.

64. *See id.* at 91.

65. *See id.* at 92.

66. *See id.*

67. *See id.*



able in the realm of criminal-law enforcement.<sup>68</sup> Seminars train special agents, prosecutors, investigators, and law-enforcement officers to read cost reports and to understand the providers' methods of compiling records and altering documents.<sup>69</sup> The financial success of Operation Restore Trust (ORT) continues to pressure the HCFA to extend similar law-enforcement programs nationwide.<sup>70</sup>

### C. Special Risk Areas Targeted by the OIG for Investigation

Compliance issues vary depending on the particular segment of the health-care industry; for the purpose of this section, some examples are cross-referenced from other segments of the industry in order to highlight many of the compliance issues specifically targeted by enforcing agencies.<sup>71</sup> The OIG issued the *Publication of the OIG Compliance Program Guidance for Hospitals* in late February 1998.<sup>72</sup> The notice expands upon previous compliance recommendations made to clinical laboratories in March of 1997 and serves as a guide for organizations to develop voluntary compliance programs.<sup>73</sup> Since then, the

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68. See Kurt Eichenwald, *Federal Agents Step Up Pressure in Columbia/HCA Investigation*, N.Y. TIMES, Aug. 20, 1997, at D1.

69. See Kurt Eichenwald, *Columbia Inquiries Said to Look at Olsten Dealings*, N.Y. TIMES, July 22, 1997, at D1.

70. See *supra* note 47.

71. For specific and exhaustive discussion of OIG target areas within particular segments of the industry, the following compliance guidelines have been set forth by the OIG as of February 21, 1999: Clinical Laboratories, Hospitals, Home Health Agencies, and Third Party Medical Billing Companies. See 62 Fed. Reg. 9435 (Mar. 3, 1997) (clinical laboratories); 63 Fed. Reg. 8987 (Feb. 23, 1998) (hospitals); 63 Fed. Reg. 42,410 (Aug. 7, 1998) (home health); 63 Fed. Reg. 70,138 (Dec. 18, 1998) (third-party medical billing). Draft compliance guidelines have been issued for Durable Medical Equipment, Prosthetics, Orthotics, and Supply. See 64 Fed. Reg. 4435 (Jan. 28, 1999). The OIG has also solicited information and recommendations for Nursing Homes and the Hospice industry. See 63 Fed. Reg. 70,7137 (Dec. 18, 1998) (nursing homes); 64 Fed. Reg. 2228 (Jan. 13, 1999) (hospice). The OIG has also recently amended Chapter IV of C.F.R. title 42, which sets forth 45 particular practices that warrant permissive exclusion. See 42 C.F.R. § 402.1(c)(1)-(30) (as amended in 63 Fed. Reg. 68,687, 68,689-92 (Dec. 14, 1998)). The OIG also issues Special Fraud Alerts that further develop particular target areas, which are available at <<http://www.dhhs.gov/progorg/oig/frdalrt/index.htm>> See, e.g., 64 Fed. Reg. 1813 (Jan. 12, 1999) (physician liability for certifications in the provision of medical equipment, supplies, and home health services).

72. Department of Health and Human Services Office of Inspector General *Publication of the OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. 8987 (1998).

73. *Publication of the OIG Compliance Program Guidance for Clinical Laboratories*, 62 Fed. Reg. 9435 (1997). The compliance guidelines for hospitals reiterate and expand upon the clinical laboratories' recommendations and serve as a model for similar guidance programs to be developed for other specialized areas of health care to be issued at a later date. 63 Fed. Reg. at 8990.

OIG has continued to set forth compliance guidelines for particular segments of the health-care industry, using the earlier issued compliance guidelines as models for compliance programs.<sup>74</sup> The compliance guidelines set forth several special risk areas that the OIG routinely investigates. The OIG also issues Special Fraud Alerts which reveal practices that the OIG finds questionable and seeks to investigate.<sup>75</sup>

One such practice, a common billing error known as "phantom services," occurs when Medicare is billed for items and services not actually rendered.<sup>76</sup> Phantom services are easy to detect because medical records plainly reveal the items and services provided. As a billing scheme, however, they are difficult to detect because such bills are lumped with similar items and services and often match a pattern of patient treatment.

To qualify for reimbursement, the items and services provided must be medically necessary.<sup>77</sup> A physician must certify each HCFA claim as reasonable and necessary.<sup>78</sup> Upon investigation, the OIG may determine in hindsight that the physician's medical decision was inappropriate.<sup>79</sup> Although there is a general prohibition against federal officers exercising any type of supervision or control over the practice of medicine, such subsequent decisions may limit a physician's options when treating patients.<sup>80</sup>

The OIG also targets the billing scheme known as "upcoding."<sup>81</sup> Upcoding is the practice of providing a higher payment rate than the

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74. See *supra* note 71.

75. Special Fraud Alerts are available at <<http://www.dhhs.gov/progorg/org/frdalrt/index.htm>>. See *supra* note 71.

76. See 63 Fed. Reg. at 8990 n.13. This form of billing error represents a significant part of the OIG caseload. See *id.*

77. See 42 U.S.C. § 1320a-7a(a)(1)(E) (1994 & Supp. 1996) (condemns billing items/services not medically necessary); see also § 1395y(a)(1)(A) (1994) (establishing that no payment shall be made for items/services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"); 42 C.F.R. § 1001.701 (1998) (prohibiting excessive or unacceptable quality of services as determined by a local PRO, state or local licensing board, fiscal intermediary, contractor, private insurance carrier, professional society, or any other source the OIG deems appropriate).

78. See 63 Fed. Reg. at 8990 n.14.

79. See 42 C.F.R. § 1001.701 (for standards on quality of care).

80. See, e.g., 42 U.S.C. § 1395 (1994, Supp. 1996 & West Supp. 1998).

81. See 63 Fed. Reg. at 8990 n.15. Upcoding was the focus on the Columbia/HCA investigation. Columbia/HCA allegedly upcoded the severity of patients' conditions and treatments as a means of receiving larger reimbursements from Medicare. See *More Indictments Expected in Fraud Case Against Columbia/HCA*, MED. INDUSTRY TODAY, Feb. 18, 1998, at Payer and Provider News. Examples that the

billing code that more accurately reflects the items and services performed.<sup>82</sup> The Health Insurance Portability and Accountability Act of 1996<sup>83</sup> specifically added additional sanctions for upcoding.<sup>84</sup> The "DRG creep" is a scheme similar to upcoding, where a provider bills a Diagnosis Related Group (DRG) code that allows greater reimbursement than a code that more accurately reflects the services performed.<sup>85</sup> Cost reports are often seized and scrutinized along with corresponding medical records to determine whether upcoding was an intentional attempt to obtain a greater Medicare reimbursement.<sup>86</sup>

The strategies are the same under a managed-care program where the incentive is to underbill rather than overbill the beneficiary.<sup>87</sup> Failure to provide reasonably necessary items and services to beneficiaries may warrant an OIG investigation and is one risk area that deserves greater attention to ensure that beneficiaries are receiving the medical care to which they are entitled.<sup>88</sup> Similarly, the OIG investigates reports of patient dumping by requiring that emergency departments perform screenings to determine whether a person has an emergency medical condition which requires immediate treatment or transfer.<sup>89</sup> Providers are also investigated for providing substandard care for items reimbursed in full.<sup>90</sup>

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OIG points to range from unnecessarily altering a treatment path to qualify for an upcoded treatment to billing a lower-coded treatment as an upcoded treatment. See 63 Fed. Reg. at 8990 n.15.

82. See 63 Fed. Reg. at 8990 n.15.

83. Pub. L. No. 104-191, 110 Stat. 1936.

84. See 63 Fed. Reg. at 8990 n.15; see also 42 U.S.C. § 1320a-7a(a)(1)(A) (1994 & Supp. 1996) (an improperly filed claim includes any claim "for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to any item or service actually provided").

85. See 63 Fed. Reg. at 8990 n.16.

86. See *id.* at 8990 nn.15, 19; see also Aronovitz, *Medicare at Risk*, *supra* note 12, at 89.

87. See Aronovitz, *Medicare at Risk*, *supra* note 12, at 89.

88. See 42 C.F.R. § 1001.701 (1998); 63 Fed. Reg. at 8990 n.14.

89. See 42 U.S.C.A. § 1395dd(a)-(b) (West Supp. 1998); 63 Fed. Reg. at 8990 n.26.

90. See 42 C.F.R. § 1001.701(a)-(b) (prohibiting excessive or unacceptable quality of services as determined by a local PRO, state and local licensing board, fiscal intermediary, contractor, private insurance carrier, professional society, or any other source the OIG deems appropriate.). An example of full reimbursement for substandard care exists in what the FBI's George Clow calls the case of "nutritional milk." Clow indicated that providers had "nutritional milk" sent to nursing homes with residents being told that the government wanted them to have milk. In return for the milk, providers acquired the nursing home residents' Medicare beneficiary numbers and billed the milk as a "reasonable and necessary" expense. Even if the "nutritional milk" was reasonable and necessary, providing ordinary milk

Because items and services must be “reasonable and necessary,” providers often engage in upcoding to provide services that are necessary but not reasonable. For example, experimental procedures not yet approved by the Food and Drug Administration (FDA) do not qualify for reimbursement.<sup>91</sup> In order to gain FDA approval, pharmaceutical and medical supply companies need clinical trials by health-care providers.<sup>92</sup> Financial incentives, such as stock options and referrals,<sup>93</sup> influence providers to forego billing such services to Medicare, but such incentives raise troubling issues under the broad antikickback statutes.<sup>94</sup> As such, many providers who seek to engage in clinical trials are left with purposefully miscoding the procedure to qualify for Medicare reimbursement in order to avoid the risk of violating the antikickback statute. As a result, procedures are often altered for the sole reason of obtaining an otherwise unavailable coded bill.<sup>95</sup>

Duplicate billing is another chronic problem that the OIG investigates.<sup>96</sup> In addition to providers submitting duplicate bills, they often submit those bills to more than one primary payor.<sup>97</sup> The OIG may, as a discretionary matter, view many duplicate billing mistakes as simple errors. However, the OIG has discretionary powers and may view repeated double billing as a false claim.<sup>98</sup> Duplicate billing may also occur where a provider submits a bill for outpatient services

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and submitting a claim for “nutritional milk” may subject the provider to penalties for offering substandard care. *See NewsHour with Jim Lehrer: Medicare Fraud* (PBS television broadcast, May 15, 1996) (transcript no. 5228). Providing substandard care is based on the “you should get what you pay for” theory of sales, making any determination outside of such a blatant case as Clow’s “nutritional milk” example a tedious and often arbitrary determination.

91. *See Roth Statement*, *supra* note 16, at 5.

92. *See id.*

93. *See id.* at 7. Providers often receive stock options or cash to use experimental products and stand to reap the benefits of numerous referrals and additional revenues upon FDA approval. *See id.*

94. *See* 42 U.S.C.A. § 1320a-7a (West Supp. 1998) (prohibiting billing for items and services from entities which do not qualify for reimbursement). *See generally* 63 Fed. Reg. at 8990 n.23; *see also* Casey, *supra* note 1 (summarizing the OIG investigation of Columbia regarding stock options to physicians).

95. For example, to qualify an experimental arthrectomy as a reimbursable angioplasty, a patient may unnecessarily have an angioplasty balloon ran up the artery and expanded for an x-ray to put in the file. The procedure was so common physicians joked when it was time for a “reimbursement balloon.” *See Roth Statement*, *supra* note 16, at 9.

96. 63 Fed. Reg. at 8990 n.18.

97. *See id.*

98. *See id.*

furnished during an inpatient stay when the service is also billed as an inpatient service.<sup>99</sup>

Another targeted practice is known as “unbundling.” Unbundling is the claiming of items and services in a fragmented fashion when, in actuality, they are required to be billed as a single item.<sup>100</sup> Thus, unbundling enables providers to increase the amount of reimbursement.<sup>101</sup> The converse of unbundling may also warrant investigation. For example, Columbia allegedly failed to separate particular nonreimbursable administrative costs from reimbursable administrative expenses.<sup>102</sup> Hospitals, in particular, often bill the transfer of a patient as a discharge.<sup>103</sup> Medicare regulations only allow the transferee hospital to charge the full DRG, while the transferor hospital may only bill a per diem amount.<sup>104</sup>

“Excessive billing” is a general category that includes the above-mentioned practices, but is associated with patterns or practices designed to coordinate patient care around maximizing reimbursement.<sup>105</sup> A common example of excessive billing is referring patients with a low-cost diagnosis to home-health-care units that receive a higher flat reimbursement rate.<sup>106</sup> In addition to the OIG’s concern

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99. See *id.* at n.17.

100. See *id.* at n.20.

101. See *id.*

102. See Eichenwald, *U.S. Looks at Columbia/HCA*, *supra* note 1, at D1. A portion of administrative expenses are to be allocated to the hospital, such as expenses for running the cafeteria and gift shops. Columbia allegedly received greater reimbursement for administrative expenses by failing to allocate such administrative expenses to a nonreimbursable account.

103. See 63 Fed. Reg. at 8990 n.21.

104. See *id.*

105. See generally 42 C.F.R. § 1001.701 (1998) (setting forth quality of care standards for excessive or unnecessary billing).

106. See *Medicare Home Health, Hearings Before the Subcomm. on Oversight & Investigations of the House Comm. on Commerce*, 105th Cong. 88 (1997) [hereinafter *Cenac Statement*] (statement by David S. Cenac, Chairman of the Board of the Home Care Association of America, which represents 300 free-standing home-health-care agencies; President of Healthcare Management Consulting, Inc., previously employed by Blue Cross of Florida, where he supervised over 100 auditors and over 400 providers) (Mr. Cenac explained that hospital agencies often engage in double-dipping the Medicare system by charging Medicare twice for the same service pertaining to home health care); Hundley, *As Columbia/HCA Grows*, *supra* note 1; see also Eichenwald, *Columbia/HCA Discussions on Cost Shifting Were Secretly Taped by U.S. Informants*, N.Y. TIMES, Sept. 2, 1997, at D2 [hereinafter *Eichenwald, Columbia/HCA Discussions Secretly Taped*]. Eichenwald reported:

A hospital would have [an] enormous incentive to shift costs to a home health care unit because of the way Medicare reimbursement is set up. Under the rules, hospitals receive a fixed payment for the treatment of any of thousands of diagnoses identified by the Govern-

that such billing practices inflate claims, such practices are potential violations of the self-referral statute.<sup>107</sup> The OIG indicates that such practices infringe on a patient's choice and, for that reason alone, warrant treatment as a special risk area.<sup>108</sup>

Another major concern of those enforcing reimbursement rules are potential violations of the antikickback and self-referral statutes, which prohibit offering, soliciting, paying, or receiving "any remuneration" for which any part of payment may be made under a federal health-care program.<sup>109</sup> The scope of antikickback and self-referral enforcement covers a broad number of situations.<sup>110</sup> For example, investigators of Columbia contend that providing physicians with stock options and encouraging them to refer patients to hospitals and clinics owned by Columbia is remuneration.<sup>111</sup> As examples that raise an antikickback/self-referral eyebrow, the OIG lists agreements providing payment for medical directorships, discounted rents or fees for services, interest-free loans, and payments for goodwill ancillary to the acquisition of a physician's practice.<sup>112</sup>

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ment, regardless of how much it actually costs the hospitals to treat the illness. In that way, the Government hopes to push hospitals to hold down expenses. . . .

In recent years, reimbursement for outpatient services has been the fastest growing portion of the Medicare program.

107. See *Cenac Statement*, *supra* note 106, at 88; see also 42 U.S.C. § 1320a-7b(b) (1994 & Supp. 1996) (criminal penalties associated with illegal payments related to federal health care programs).

108. See 63 Fed. Reg. at 8990 n.22. This is a particularly significant issue for the acute care industry; hospitals have had to put significant safeguards in place to ensure the patient is well informed about their need to continue care after discharge with home health and that they have the right to choose the agency for care.

109. See 42 U.S.C. § 1320a-7b(b).

110. See generally *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20 (1st Cir. 1989); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985) (holding that even if a referral is merely ancillary to an agreement, the relationship violates the antikickback statute); *United States v. Porter*, 591 F.2d 1048, 1054 (5th Cir. 1979) (reversing convictions on a fee-sharing arrangement between a laboratory and the physicians who referred specimens; the antikickback and self-referral statutes as well as other regulations have since amended the law to condemn such practices); James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health care Marketplace: Life in the Health care Speakeasy*, 22 AM. J.L. & MED. 205, 207-20 (1996).

111. See 42 U.S.C. § 1320a-7b(b). Columbia contends that offering physicians limited partnerships in health networks is within a safe harbor that allows doctors to invest in hospitals (the original purpose of the exemption was to encourage the development of hospitals in rural areas). See Blumstein, *supra* note 110.

112. See 63 Fed. Reg. at 8990 n.23.

Joint ventures and arrangements between hospitals and hospital-based physicians also draw the attention of investigators.<sup>113</sup> Any arrangement between a provider in a position to refer business may draw scrutiny, especially arrangements between hospitals and hospital-based physicians where the hospital may not charge the hospital-based physician for use of particular space, equipment, and other administrative services.<sup>114</sup> Similarly, suspicions would be raised by the practice of charging a hospital-based physician a rate higher than fair market value in that it might provide an incentive to refer the patient to the hospital.<sup>115</sup> The OIG Management Advisory Report, *Financial Arrangements Between Hospitals and Hospital-Based Physicians*, elaborates on the inherent risks in such arrangements.<sup>116</sup>

Inaccurate cost reports are especially disfavored because they are often used as a tool to determine the veracity of claims.<sup>117</sup> General accounting principles dictate that health-care providers maintain at least two different sets of cost reports.<sup>118</sup> A Medicare participant will submit one cost report for reimbursement and also maintain a "reserve" report which reflects a more conservative estimate of claims that are guaranteed reimbursement.<sup>119</sup> Claims that are submitted in

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113. See *id.* at 8990 n.24-25.

114. See *id.*

115. See *id.*

116. OIG Management Advisory Report: *Financial Arrangements Between Hospitals and Hospital-Based Physicians*, OEI-09-89-0030, Oct. 1991.

117. See 63 Fed. Reg. at 8990 n.19:

An OIG audit report on the misuse of fringe benefits and general and administrative costs identified millions of dollars in allowable costs that resulted from providers' lack of internal controls over costs included in their Medicare cost reports. In addition, the OIG is aware of practices in which hospitals inappropriately shift certain costs to cost centers that are below their reimbursement cap and shift non-Medicare related costs to Medicare cost centers.

118. See Mustokoff & Mallozzi, *supra* note 10, at 7.

Let there be any doubt as to the government's legal authority, the search warrant probable cause affidavit states: "In a recent Eleventh Circuit Court of Appeals decision [*Calhoon*], the Court stated: 'While it is true that a provider may submit claims for costs it knows to be presumptively nonreimbursable [sic], it must do so openly and honestly, describing them accurately while challenging the presumption and seeking reimbursement. Nothing less is required if the Medicare reimbursement system is not to be turned into a cat and mouse game in which clever providers could, with impunity, practice fraud on the government.'"

See *id.*

119. See *United States v. Calhoon*, 97 F.3d 518 (11th Cir. 1996); Eichenwald, *U.S. Suit Charges Fraud*, *supra* note 8; Hundley, *Government Joins Columbia Civil Lawsuit*, *supra* note 22; Mustokoff & Mallozzi, *supra* note 10.

the reimbursable cost report but are excluded from the reserve report are deemed presumptively nonreimbursable.<sup>120</sup> Federal investigators rely on the Eleventh Circuit opinion in *United States v. Calhoon*,<sup>121</sup> which held that a failure to flag the “presumptively nonreimbursable” claims excluded from the reserve report in the submitted cost report constitutes a false claim.<sup>122</sup> The failure to red flag any particular claim may taint an entire cost report.<sup>123</sup> In the civil suit against Columbia, the government stands to recover \$210 million from the “presumptively nonreimbursable” claims submitted in 1996 alone.<sup>124</sup>

If a cost report is inaccurate, all claims become suspicious and may warrant a further investigation and audit.<sup>125</sup> The failure to disclose information upon a reasonable request of the OIG, or a mere failure to disclose information necessary to determine the legitimacy of a given claim, may warrant an independent exclusion, in addition to a more detailed investigation.<sup>126</sup> Individuals and entities may be held liable for mistakes on the part of contractors, fiscal in-

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120. See *Calhoon*, 97 F.3d at 518; Mustokoff & Mallozzi, *supra* note 10, at 7 (regarding *Calhoon*'s holding that Medicare is not a discretionary system that allows participants to maximize reimbursement, and requires presumptively nonreimbursable claims seek reimbursement as such). The maintenance of a reserve cost report suffices to support the crucial intent standard of the False Claims Act and is deemed sufficient evidence to establish a presumption that the claim was not reimbursable. Although abandoning reserve cost reports might limit the prosecutorial repertoire, it may also risk a breach of fiduciary duty. The OIG voluntary compliance guidelines, consistent with the 11th Circuit's reasoning, mandates a “reserve” cost report-like analysis be done and that any questionable claims be singled out by the participant. Ironically, the act of internal review creates the perfect conspiracy elements where the act of review itself may trigger the operation of the False Claims Act if the outcome of any such review is not disclosed to the Medicare payor. The sheer volume of claims virtually overwhelms Medicare payors at present rates. A slew of tagged questionable claims increases the likelihood that resources expended on the tagged claims will divert focus from nonreimbursable claims filed along with the other presumably reimbursable claims (assuming the average Medicare thief would not tag their bogus claims). The uncertainty of reimbursement for particular claims tagged by the participant's affirmative duty may adversely affect the quality of patient care if providers are unable to assure Medicare payment. On a larger level, the spell cast on for-profit health care may indicate that the Stark witch-hunt has reached an executive level.

121. 97 F.3d 518 (11th Cir. 1996).

122. See *id.* at 529; Mustokoff & Mallozzi, *supra* note 10, at 7 (regarding *Calhoon*'s holding that Medicare is not a discretionary system that allows participants to maximize reimbursement, and requires presumptively nonreimbursable claims seek reimbursement as such); see also *supra* text accompanying notes 118-20.

123. See 63 Fed. Reg. 8987, 8990 n.19.

124. See generally Mustokoff & Mallozzi, *supra* note 10, at 7.

125. See 63 Fed. Reg. at 8990 n.19.

126. See 42 C.F.R. §§ 1001.1101-1201 (1998); see, e.g., *United States v. Data Translation*, 984 F.2d 1256 (1st Cir. 1992).



intermediaries, and other government agents, as well as for the failure to correct an auditor's error.<sup>127</sup> Similarly, the failure to refund credit balances may warrant greater scrutiny of cost reports and raise suspicions of a failure to inform the government of a reimbursement error.<sup>128</sup>

Once the OIG or other investigatory agency begins an investigation, the failure to grant immediate access to investigators warrants exclusion from the Medicare program and greater investigatory procedures.<sup>129</sup> Furthermore, if the investigatory agency feels that the target of an investigation is interfering or obstructing the investigation in any way, the OIG may exclude the target from Medicare and continue its investigation.<sup>130</sup> The patient-physician privilege provides no defense; the failure or refusal to provide patient information upon reasonable request may also warrant immediate exclusion and further investigation.<sup>131</sup>

An investigation may also delve into relationships with entities or individuals excluded from the program, as well as with those fines assessed for reimbursement violations.<sup>132</sup> If a sanctioned or excluded entity has an ownership interest of five percent or more, holds five percent or more of the total assets, or is a director, partner, managing employee, or agent of the entity, then the entity risks exclusion from Medicare on the basis of the relationship.<sup>133</sup> The risk of exclusion raises potential problems in the acquisition of sanctioned entities and in the employment of sanctioned individuals with authority to obligate or act on behalf of the employer.<sup>134</sup>

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127. The failure to disclose knowledge of a government misappropriation originates from the adoption of the Social Security Act of 1934 and may also be within the scope of 42 C.F.R. § 1001.1101 for failure to disclose pertinent information. See, e.g., Kurt Eichenwald, *For Hospitals, a New Prognosis on Fraud-Charge Exposure*, N.Y. TIMES, Aug. 1, 1997, at D2 (referring to the charges against the indicted Columbia officers for failing to notify the HHS of an auditor error that resulted in an excessive payment).

128. See 63 Fed. Reg. at 8990 n.19.

129. See 42 C.F.R. § 1001.1301.

130. See §§ 1001.301, 1101-.1201.

131. See § 1001.1201. See generally *Brillantes v. People*, 51 Cal. App. 4th 323 (1996); *People v. Bhatt*, 611 N.Y.S.2d 447 (Sup. Ct. 1994).

132. See 42 C.F.R. § 1001.1001.

133. See *id.*

134. See *id.*

#### D. The Scope of Investigational Inquiries and the Means to Exclude Entities and Individuals from Participation in the Medicare Program

Standard due process limits associated with subpoenas and search warrants, in addition to the procedural limitations set forth in regulations, apply to OIG investigatory techniques.<sup>135</sup> However, investigational inquiries are nonpublic proceedings.<sup>136</sup> Witnesses are entitled to counsel, but nonwitness attendance is left to the discretion of the OIG.<sup>137</sup> In addition, any claim of privilege or objection is waived if not claimed at an investigational inquiry.<sup>138</sup> The powers of the OIG also apply to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts that review OIG, ALJ, and DAB decisions.<sup>139</sup>

The OIG must exclude any individual or entity that is convicted of a criminal offense related to the delivery of an item or service to a federal health-care program for reimbursement.<sup>140</sup> A federal health-care program 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 . . . [or] any State health-care program."<sup>141</sup> As later discussed in part III, there are several statutory means to enforce Medicare reimbursement requirements. Private contractors, insurance companies, fiscal intermediaries, or other governmental agencies may also seek civil sanctions against entities for themselves and for the government, any of which would qualify for OIG exclusion.<sup>142</sup>

A criminal conviction or civil penalty related to Medicare billing is not necessarily required for the OIG to exclude an entity or individual from participation in the program.<sup>143</sup> The OIG may determine on

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135. See § 1006.1-.5. See generally *United States v. Abrams*, 615 F.2d 541 (1st Cir. 1980).

136. See 42 C.F.R. § 1006.4(b).

137. See *id.*

138. See § 1006.4(e).

139. See § 1001.1(b).

140. See § 1001.101.

141. 42 U.S.C. § 1320a-7b(f)(1)-(2) (1994 & Supp. 1996).

142. See 31 U.S.C. § 3730(b) (1994); 42 U.S.C.A. § 1320a-7a (West Supp. 1998) ("In addition [to fines and treble damages] the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal healthcare programs . . . and to direct the appropriate State agency to exclude the person from participation in any State healthcare program.").

143. See 42 C.F.R. pt. 1001—Program Integrity—Medicare and State Healthcare Programs, subpt. C—Permissive Exclusions (1998).

its own that an entity or individual has submitted a false or improper claim, or has engaged in an act of remuneration.<sup>144</sup> The OIG has permissive authority to exclude entities or individuals convicted of any offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with health-care or government agencies.<sup>145</sup> The evidentiary basis for permissive OIG exclusion derives from information received from local PRO's, state or local licensing boards, fiscal agents, contractors, private insurance companies, state or local professional societies, or any other source that the OIG deems appropriate.<sup>146</sup>

An entity or individual may be subjected to exclusion from state and federal health-care programs, substantial fines per violation, and treble damages.<sup>147</sup> To obtain a federal court review of a determination by the OIG, an ALJ, the DAB, contractor, fiscal intermediary, or private insurance company, the entity or individual must first exhaust all administrative remedies.<sup>148</sup> The ALJ, however, does not have the authority to review discretionary OIG decisions or to enjoin an OIG decision.<sup>149</sup> Pending review and appeal, assets of an entity or individual may be frozen,<sup>150</sup> and injunctions are not often granted for the exclusion from state and federal health-care programs.<sup>151</sup>

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144. See 42 C.F.R. §§ 1001.901-.951.

145. See § 1001.201(a). The OIG recently proposed moving this category from permissive to mandatory exclusion, adopting a minimum five-year exclusion. See *Healthcare Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191*, 62 Fed. Reg. 47,182, 47,183 (1997).

146. See 42 C.F.R. §§ 1001.701(b)(1)-(5), .801(b)(1)-(6).

147. See 42 U.S.C.A. §§ 1320a-7a, -7b (West Supp. 1998).

148. See 42 C.F.R. §§ 1005.2(c)(4)-(5), (7), 1001.2007(d).

149. See § 1005.4(c)(5), (7).

150. Assets may be frozen pending administrative and judicial review making it difficult to pay legal fees and continue operations. See 18 U.S.C. § 1345 (1994); *United States v. Brown*, 988 F.2d 658, 663 (6th Cir. 1993) (holding that 18 U.S.C. § 1345 asset freezes are not limited to banking law violations and may be applied to assets traceable to Medicare fraud). The Secretary may also enjoin any activity or person from "concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief." See 42 U.S.C. § 1320a-7a(k).

151. In response to an exclusion, entities and individuals often seek an injunction pending review or criminal trial. Considering the authority the Secretary has to enjoin activities and freeze assets, most entities and individuals fail to obtain an injunction against the Secretary pending review. See *supra* notes 15, 150; *infra* text accompanying notes 333-49; see also, e.g., *Erickson v. Great Falls Eye Surgery Ctr.*, 67 F.3d 858 (9th Cir. 1995) (reversing a district court's grant of an injunction against exclusion from participation in federal health-care programs); cf. *Ram v. Heckler*, 617 F. Supp. 612 (W.D.N.C. 1985) (enjoining a 42 U.S.C. § 1320a exclusion pending appeal).

General exclusion from the program prevents an organization from operating and prevents continued operations and employment involving Medicare reimbursement.<sup>152</sup> The principal may be excluded from Medicare due to the acts of its agents.<sup>153</sup> Managing employees and officers may be personally excluded from participation if the entity which employed them is found guilty of noncompliance, even if they did not participate in any wrongdoing.<sup>154</sup> Once excluded, reinstatement is discretionary and employers risk exclusion by hiring any person who has been excluded.<sup>155</sup> Because fines are imposed on a per billing violation basis, penalties are often astronomically large and may result in substantial spin-off litigation.<sup>156</sup> For example, Caremark International was held liable for \$29 million in criminal fines, \$129.9 million in civil fines, \$3.5 million under the Controlled Substances Act, and was required to make a donation of \$2 million.<sup>157</sup> In addition to the fines, Caremark International settled an ancillary suit brought by private insurance company payors for \$98.5 million and paid substantial legal fees to defend five ancillary shareholder derivative suits.<sup>158</sup> *Caremark International* pales in comparison to the civil suit against Columbia, as analysts estimate that Columbia faces approximately one billion dollars of liability.<sup>159</sup> Exclusion prevents any future reimbursement, thereby cutting off a substantial stream of revenue and making it difficult to pay legal fees.<sup>160</sup> The financial risk of a potential legal battle can be quite coercive and often prevents an entity or individual from adequately responding to the allegations.<sup>161</sup>

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152. See generally 31 U.S.C. § 3729 (1994); 42 U.S.C.A. §§ 1320a-7a, -7b (West Supp. 1998).

153. See 18 U.S.C. § 2 (1994); HIPAA § 213, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended at 42 U.S.C. § 1320a-7a(l) (West Supp. 1998)).

154. See generally 31 U.S.C. § 3729; 42 U.S.C. §§ 1320a-7a, -7b.

155. See 42 C.F.R. §§ 1001.3002, .951; see also 62 Fed. Reg. 47,182, 47,185-87 (1997) (examining discretionary reinstatement).

156. See, e.g., 31 U.S.C. § 3729(a)(1)-(7); *infra* notes 159-60.

157. See *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 965 n.10, 966 (Del. Ch. 1996); *supra* notes 13-14.

158. See *In re Caremark*, 698 A.2d at 965-66.

159. See generally Eichenwald, *U.S. Suit Charges Fraud*, *supra* note 8.

160. See *Cenac Statement*, *supra* note 106 (discussing CSM Home Health Serv., Inc. v. HCFA, DAB No. CR440, 1996 WL 599839 (HHS Oct. 11, 1996)).

161. See, e.g., *CSM Home Health Serv. Inc. v. HCFA*, DAB No. CR440, 1996 WL 599839 (HHS Oct. 11, 1996) (where the HCFA continued to pursue claims against CSM despite several favorable rulings acquitting CSM from any wrongdoing).

The stakes are high. Mandatory exclusions last five years.<sup>162</sup> Most permissive exclusions are from one to three years.<sup>163</sup> The OIG proposed that no permissive exclusion be for less than one year and that permissive exclusion for fraud offenses, obstruction of an investigation, and misdemeanor violations of the Controlled Substances Act be for no less than three years, unless the Secretary determines that mitigating circumstances justify a shorter period.<sup>164</sup> The OIG also proposed that excluded individuals must be excluded at least as long as the entity is excluded in connection with the individual.<sup>165</sup> The OMB rejected the OIG's proposals in accordance with Executive Order 12866 and the Regulatory Flexibility Act;<sup>166</sup> however, the OIG's position reflects the common length of permissive exclusions.<sup>167</sup>

Considering the different methods of reimbursement, the discretionary and arbitrary nature of investigations, special risk areas, and the potential impact of investigational inquiries, the health-care industry must respond. The next section examines the statutory means that governmental agencies, contractors, fiscal intermediaries, and private insurers may use to enforce billing requirements, as well as expressly recognized exemptions and defenses. In addition, part III discusses the arduous appeals process, focusing on the tools available for those seeking to recover and the legal options available for the wrongly accused.

### III. The Statutory Means to Enforce Medicare Reimbursement Requirements, Safe Harbors, and Legal Defenses

There are several statutory means to enforce compliance with Medicare reimbursement requirements. If convicted or assessed civil penalties, entities and individuals are subjected to the exclusionary penalties discussed above. Several "safe harbors" establish exemptions from exclusionary penalties. By structuring compliance programs and conduct to fall within the safe harbor exemptions, entities and individuals have much greater leeway to challenge the OIG and its agents' determination. Also, the OIG has set forth a voluntary

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162. See 42 C.F.R. pt. 1001, subpt. B; 62 Fed. Reg. at 47,182 (1997).

163. See 62 Fed. Reg. 47,182, 47,183 (Sept. 8, 1997).

164. See *id.* at 47,183-84.

165. See *id.*

166. See 5 U.S.C. §§ 601-612 (Supp. 1996).

167. See 62 Fed. Reg. at 47,187.

compliance program for hospitals that may be used as a model to fashion a good-faith defense to allegations of Medicare fraud and abuse. Litigation over these issues may take place in a variety of forums; however, understanding the process of administrative review and temporary procedural remedies is essential to protecting the interests of those charged.

### A. The Statutory Means to Enforce Medicare Billing Requirements

Compliance with Medicare billing requirements may take several forms, thus giving authorities several tools to employ. The variety of statutory options differ with respect to intent requirements, scope of penalty, and effect on spin-off litigation. The following details the most common means of enforcing Medicare billing requirements.

#### 1. FALSE CLAIMS AND STATEMENTS

The Federal False Claims Act establishes liability for any person who "knowingly" makes a false or fraudulent claim to the federal government.<sup>168</sup> Government agencies or private persons—such as fiscal intermediaries, contractors, or private insurers—may bring a claim; private persons may receive up to twenty-five percent of the government's recovery.<sup>169</sup> The whistle-blower in the civil suit against Columbia, James F. Alderson, stands to recover \$250 million.<sup>170</sup>

Liability may take several forms: (1) knowingly making a false claim for payment; (2) knowingly making use of a false record or statement to get a false claim paid; (3) conspiring to defraud by getting a false claim paid; (4) possessing or controlling money used or to be used by a federal health-care program and intending to defraud or willfully conceal the property from the government, thus delivering or causing to be delivered less property than the amount for which the person received a receipt; (5) delivering receipt intending to defraud the government without "completely knowing" whether the information on the receipt is true; (6) knowingly billing the government with-

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168. See 31 U.S.C. § 3729(a) (1994).

169. See § 3730(b), (d)(1).

170. See Eichenwald, *U.S. Suit Charges Fraud*, *supra* note 8 (Alderson stands to recover 15-25% of an estimated billion dollars). Alderson is a former Chief Financial Officer of North Valley Hospital in Whitefish, Montana, one of over 200 hospitals managed by Quorum, and his attorneys have stated that Alderson was terminated for refusing to submit Quorum cost reports because the reserve reports reflected the proper reimbursement claims. See *id.*

out license to do so; and (7) knowingly using or causing to use a false record to reduce a debt owed to the government.<sup>171</sup> If convicted, any such person may receive a fine between \$5,000 and \$10,000 per violation and is liable for up to three times the amount of damage sustained.<sup>172</sup>

Conviction rests on proof that an individual "knowingly" committed any of the acts alleged. "Knowingly" in regard to the information exchanged is (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information.<sup>173</sup> Proof of specific intent to defraud the government is not necessary to establish liability.<sup>174</sup> Some courts take a narrow view of "knowingly." For example, in *Hagood v. Sonoma County Water Agency*<sup>175</sup> and *Anderson v. Northern Telecom, Inc.*,<sup>176</sup> the courts held that proof of mistakes are not enough on the ground that the phrase "known to be false" requires more than inaccuracy, it requires a lie.<sup>177</sup> The "reckless disregard" standard, however, encompasses acts that are less than a "lie."<sup>178</sup> Based on the OIG's voluntary compliance guidelines for hospitals, officers risk liability for submitting claims without taking adequate measures to ensure the veracity of claims.<sup>179</sup>

The civil suit against Columbia highlights the intent standard as applied to cost reports. Entities keeping a reserve cost report, a generally accepted accounting principle, that fail to disclose claims submitted in the cost report which are excluded from the internal reserve cost report, are liable for a false claim if any of those undisclosed "presumably [sic] nonreimbursable" claims are denied.<sup>180</sup> Participants have an affirmative duty to flag questionable reimbursement claims in the submitted cost report.<sup>181</sup> Courts may find reserve cost

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171. See 31 U.S.C. § 3729(a)(1)-(7).

172. See *id.*

173. See § 3729(b)(1)-(3).

174. See *id.*

175. 81 F.3d 1465 (9th Cir. 1996).

176. 52 F.3d 810, 815-16 (9th Cir. 1995).

177. See *Hagood*, 81 F.3d at 1478 (quoting parts of *Anderson*); *Anderson*, 52 F.3d at 815-16.

178. See, e.g., *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).

179. See 63 Fed. Reg. 8987, 8996 (Feb. 23, 1998).

180. *United States v. Calhoon*, 97 F.3d 518, 530 (11th Cir. 1998).

181. See *id.*

In fact, the government has initiated at least three additional cases since the onset of the Columbia investigation where it has relied on

reports to be tacit confessions that the participant knowingly submitted certain claims that were most likely nonreimbursable.<sup>182</sup>

False claims and statements are also within the scope of Title 18.<sup>183</sup> Presenting a claim to a person in civil service with knowledge that such claim is false, fictitious, or fraudulent risks imprisonment for up to five years, in addition to fines.<sup>184</sup> Additionally, any person who knowingly and willfully conceals or covers up material facts, makes materially false representations, or makes use of any false statement risks imprisonment for up to five years and fines.<sup>185</sup> Conspiracy to defraud the government may also be applied to Medicare billing, bringing in a number of individuals who share in the purpose but take no independent actions to effect the conspiracy.<sup>186</sup>

## 2. MEDICARE FRAUD AND ABUSE STATUTES

Liability may also occur under the Medicare fraud and abuse language in the Social Security Act.<sup>187</sup> Under § 1320a-7a, which sets forth civil penalties, any person who improperly files a claim or makes payments to induce a reduction or limitation of services risks fines, damage awards up to three times the amount of damages, and a mandatory five-year exclusion from participation in any federal health program.<sup>188</sup> A claim is improperly filed if a person knowingly

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cost reports to impose criminal liability on health care providers and their employees. In all three cases, the government relied upon discrepancies between the cost reports submitted to the fiscal intermediaries and the internal accounting records of the provider to establish that health care fraud had, in fact, occurred. It is becoming increasingly clear that the new affirmative duty to red-flag attempts to obtain reimbursement for presumptively nonreimbursable [sic] costs has turned what was once an unassailable into easy prey for government prosecutors. Cost reports are sacred no more. The affirmative duty to disclose aggressive accounting is now the rule.

Mustokoff & Mallozzi, *supra* note 10, at 7.

182. See *supra* notes 180-81. Courts reason that because the provider did not include the claim in its reserve cost report it must have presumed the claim as nonreimbursable. See *Calhoun*, 97 F.3d at 530; *United States v. Mills*, Medicare & Medicaid Guide (CCH) ¶ 44,670 (D. Ga. May 1, 1996), *aff'd in part, rev'd in part*, 138 F.3d 928 (11th Cir. 1998). Providers should challenge the 11th Circuit's conclusion considering the other legitimate and reasonable inferences that exist as to why the claim was excluded from the reserve cost report.

183. See 18 U.S.C. §§ 287, 1001 (1994).

184. See § 287.

185. See § 1001.

186. See § 371; see also 42 C.F.R. § 402.1(f) (as amended in 63 Fed. Reg. 68,687 (Dec. 14, 1998)) (Medicare fraud and abuse counterpart).

187. 42 U.S.C.A. §§ 1320a-7a, -7b (West Supp. 1998).

188. See § 1320a-7a(a)-(b).



presents to an officer of the government a claim determined as an item or service a "person knows or should know" is not reimbursable.<sup>189</sup> Claims that are not reimbursable are: (1) claims based on a code that results in greater payment than a more applicable code, (2) claims which are false or fraudulent, (3) claims based on services furnished by an unlicensed physician, where a physician falsely represents to a patient the physician's medical specialty, and (4) claims that are not medically necessary.<sup>190</sup>

Liability is also based on submitting: (1) claims that a person knows or should know are generally excessive, (2) claims that contain false and misleading information meant to influence the decision of a beneficiary, (3) claims that involve any remuneration that may influence the choice of beneficiaries' providers, and (4) claims made on behalf of excluded persons or, if a person arranges or contracts with excluded persons, for items and services for which payments are made under a federal health-care program.<sup>191</sup> A person is also civilly liable if any illegal remuneration under § 1320a-7b(b) occurs.<sup>192</sup> Recent amendments to 42 C.F.R. § 402.1(c) declare forty-five particular acts that may warrant permissive exclusion.<sup>193</sup>

Fines quickly add up. In addition to any other lawful penalties, fines for such conduct are typically \$10,000 for each item or service provided, \$15,000 for each improperly influenced beneficiary, \$10,000 a day for each day a person engages in prohibited activities with excluded persons, and \$50,000 for each illegal act of remuneration.<sup>194</sup> Fines are independent of damages sustained by a federal health-care program, which may be no more than three times the amount claimed for each item or service and no more than three times the amount of remuneration.<sup>195</sup> Mandatory and permissive exclusion also apply, subjecting a party to at least a one-year exclusion and up to a five-year exclusion, with reinstatement based on the discretionary authority of the OIG.<sup>196</sup>

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189. See § 1320a-7a(a).

190. See § 1320a-7a(a)(1).

191. See § 1320a-7a(a)(1)-(6).

192. See § 1320a-7a(a)(7).

193. See 42 C.F.R. 402.1(C)(1)-(30) (as amended by 63 Fed. Reg. 68,687 (Dec. 14, 1998)).

194. See 42 U.S.C.A. § 1320a-7a(a)(7).

195. See *id.*

196. See *id.*

Under § 1320a-7b, a person risks criminal penalties for making or causing false statements or representations to be made,<sup>197</sup> illegal remunerations,<sup>198</sup> false statements or representations with respect to conditions or operation of institutions,<sup>199</sup> illegal patient admittance and retention policies,<sup>200</sup> and violation of assignment terms.<sup>201</sup> A person makes or causes to be made false statements or representations by (1) knowingly and willfully making false representations of material fact in any application for benefits, (2) knowingly and willfully making false representations of material fact for use in determining rights to benefits or payments, (3) having knowledge of events affecting any right to benefits or payments and concealing or failing to disclose such event with an intent to fraudulently secure a greater amount than ordinarily due, (4) knowingly and willfully converting any part of a benefit or payment for a use other than the beneficiary, (5) submitting a claim based on items/services furnished by a party known not to be a licensed physician, or (6) helping patients qualify for benefits not otherwise received.<sup>202</sup> A conviction is classified as a felony, incurring fines up to \$25,000 and/or five years' imprisonment for each violation as well as exclusion from Medicare benefits.<sup>203</sup>

Illegal remunerations occur where a party knowingly and willfully solicits, receives, offers or pays any remuneration in any form in return for referring an individual to a person for the furnishing or arranging of an item or service paid by a federal health-care program, or in return for aiding in the acquisition of any item or service for which payment by a federal health-care program occurs.<sup>204</sup> A conviction for illegal remuneration is a felony with a fine up to \$25,000 per violation and/or five years' imprisonment.<sup>205</sup> More specifically, offer-

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197. See 42 U.S.C.A. § 1320a-7b(a).

198. See 42 U.S.C. § 1320a-7b(b) (1994 & Supp. 1996).

199. This paragraph is primarily concerned with making false representations of material fact in order to qualify for a status for which certification is required under subchapter XVIII. A felony punishable with fines of up to \$25,000 or up to five years imprisonment. See 42 U.S.C.A. § 1320a-7b(c) (West Supp. 1998).

200. This paragraph is primarily concerned with excessive charges and the tacking on of additional fees, a felony punishable with up to \$25,000 or five years imprisonment. See 42 U.S.C. § 1320a-7b(d).

201. This paragraph is primarily concerned with accepting 42 U.S.C. § 1395u(b)(3)(B)(ii) or § 1395u(h)(1) assignments and making knowing and willful violations of the terms of assignment, which is a misdemeanor punishable with up to \$2000 or six months imprisonment. See 42 U.S.C. § 1320a-7b(e) (1994).

202. See 42 U.S.C.A. § 1320a-7b(a)(1)-(6) (West Supp. 1998).

203. See *id.*

204. See 42 U.S.C. § 1320a-7b(b)(1)-(2) (1994 & Supp. 1996).

205. See *id.*

ing, accepting, or soliciting any item of value in an attempt to influence operations of an employee benefit plan is a violation of 18 U.S.C. § 1954 and additionally subjects a person to racketeering charges.<sup>206</sup>

The intent element is the key in all Medicare fraud and abuse statutes. The reach of the antikickback provisions are broad, incorporating relationships where any such agreement is entirely ancillary to a lawful purpose.<sup>207</sup> The breadth of the statutory language continues to expand, and many courts find the language sufficiently broad to incorporate secondary acts, such as the re-referral of an individual's test samples to a second laboratory.<sup>208</sup> Although the Ninth Circuit requires a specific intent to violate the antikickback statute,<sup>209</sup> recent regulatory changes give enforcement agencies broad discretionary authority.<sup>210</sup> Subsequent decisions reinforce the notion that ignorance of the law is no defense to charges under §§ 1320a-7a, -7b. The Eighth Circuit follows a "heightened intent" approach, which defines "willfully" as conduct the defendant knows is unjustifiable and wrong.<sup>211</sup> Given the broad discretionary authority of enforcement agencies and the permissive ability to exclude absent a conviction or assessment of civil penalty, greater consideration should be given to safe harbor application and the establishment of a good-faith defense that incorporates the intent element of the charge.

### 3. RACKETEERING

Racketeering includes bribery, dealing in a controlled substance (non-over-the-counter drugs), acts relating to fraud and identification documents (Medicare beneficiary numbers), access devices, mail fraud, wire fraud, obstruction of justice, obstruction of criminal inves-

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206. See 18 U.S.C. § 1954 (1994).

207. See *United States v. Greber*, 760 F.2d 68, 72-73 (3d Cir. 1985) (holding that even if a referral is merely ancillary to an agreement, the relationship violates the antikickback statute). See generally Tamsen Douglass Love, Note, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti-Kickback Statute*, 50 VAND. L. REV. 1029 (1997).

208. See, e.g., *Modern Med. Lab., Inc. v. Smith, Kline, Beecham Clinical Lab., Inc.*, 1994 U.S. Dist. LEXIS 7838 (N.D. Ill. 1994).

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

210. See 42 C.F.R. § 402.3 (as amended by 63 Fed. Reg. 68,687 (Dec. 14, 1998)) (defining "knowingly and willfully" as (1) actual knowledge, (2) deliberate ignorance, or (3) reckless disregard, and expressly declaring that no specific intent is required).

211. See *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996). See generally Love, *supra* note 207. Love pointed out that the district court derived this definition of willfully from 2 EDWARD J. DEVITT ET AL., *FEDERAL JURY PRACTICE AND INSTRUCTIONS* 30.05 (West 4th ed. 1990). See Love, *supra* note 207.

tigations or any law enforcement investigation, and acts relating to monetary transactions in property derived from unlawful activity or laundering.<sup>212</sup> Racketeering laws give enforcement agencies other means to combat Medicare fraud and abuse, often creating greater leverage because of the larger fines and terms of imprisonment, in addition to the implications for spin-off litigation.

Under 18 U.S.C. § 1956, any financial transaction involving the proceeds of a specified unlawful activity with the intent to promote the unlawful activity or disguise the nature of the proceeds is a violation, warranting a fine of \$500,000 or twice the value of the property, whichever is greater, and imprisonment of up to twenty years.<sup>213</sup> For example, Columbia created a fund of revenues specifically designed to pay for Medicare reimbursement fines and assessments if liable. Arguably, as the government contends in the case against Columbia, such funds are the direct or indirect proceeds of unlawful Medicare billing practices and are proof of the criminal intent to defraud. The mere monetary transaction of "clean" funds linked to funds inappropriately derived from a federal health-care program qualifies for racketeering treatment if in excess of \$10,000.<sup>214</sup> This broader provision carries a similar fine and a prison sentence up to ten years.<sup>215</sup> Any racketeering conviction warrants exclusion from federal health-care programs under 42 C.F.R. § 1001.1001, on the ground that it is deceptive behavior.<sup>216</sup>

#### 4. MAIL AND WIRE FRAUD

Charges of mail and wire fraud go hand in hand with a conviction of Medicare fraud and abuse. Mail fraud occurs when a person uses the Postal Service to achieve an unlawful end.<sup>217</sup> Wire fraud occurs when a person uses wire, radio, or television communication to achieve an unlawful end.<sup>218</sup> Mail and wire fraud consists of (1) intentional participation in a scheme to defraud and (2) use of mail or wire communication to execute the scheme.<sup>219</sup>

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212. See 18 U.S.C. § 1961(1) (1994 & Supp. 1996) (definition of racketeering activity).

213. See § 1956(a)(1).

214. See 18 U.S.C. § 1957(a) (1994).

215. See § 1957(b).

216. See 42 C.F.R. § 1001.1001 (1998).

217. See 18 U.S.C. § 1341 (1994).

218. See § 1343.

219. See *United States v. Hooshmand*, 931 F.2d 725, 731 (11th Cir. 1990).

Most convictions under the Federal False Claims Act or other Medicare fraud and abuse statutes are sufficient to establish a mail or wire fraud violation as long as a party uses mail or wire communication to submit a claim, report, or any other document used to evaluate the legitimacy of a Medicare claim.<sup>220</sup> The intent requirement differs, however, and provides avenues to escape mail or wire fraud conviction. Arguably, mail and wire fraud require an intent to defraud.<sup>221</sup> However, other language within the statutes suggests that a criminal intent is not necessary. For example, "obtaining money or property by means of false or fraudulent pretenses" does not necessarily imply that obtaining reimbursement on false pretenses suffices.<sup>222</sup> Several cases hold that circumstantial evidence of criminal intent suffices by requiring only that a fraudulent scheme exist.<sup>223</sup> Under such an interpretation, "deliberate ignorance" may qualify, while "reckless disregard" may not. Conviction of mail or wire fraud can result in additional fines and prison sentences up to five years (greater penalties exist if the transaction involves a financial institution).<sup>224</sup>

## 5. BREACH OF FIDUCIARY DUTY

Although there is no statutory duty to develop voluntary compliance programs, officers and directors may be liable for breach of fiduciary duty to the company for failing to take steps to reduce the risk of Medicare noncompliance. The case *In re Caremark* established that directors may be liable if (1) a negligent decision resulted in a loss or (2) there was a failure to act where due attention would have prevented the loss.<sup>225</sup>

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220. Compare 18 U.S.C. § 287, with §§ 1341, 1343.

221. Virtually all of the frauds used in the mail and wire fraud statutes indicate an intent requirement. For example, language such as "having devised or intending to devise any scheme or artifice to defraud," "procure for unlawful use," and "for the purpose of executing such scheme" implies that an unlawful purpose must be present. §§ 1341, 1343.

222. *Id.*

223. See *United States v. Suba*, 132 F.3d 662 (11th Cir. 1998) (found mail fraud based on breach of fiduciary duty and evidence that money used to pay nonreimbursable claims out of a trust was comprised of Medicare reimbursement money); *United States v. Wingate*, 997 F.2d 1429 (11th Cir. 1993) (success of the fraudulent scheme not necessary); *United States v. Desmarais*, 938 F.2d 347 (1st Cir. 1991) (guilty knowledge difficult to prove due to its nature, especially in fraud cases); *United States v. Hawkins*, 905 F.2d 1489 (11th Cir. 1990) (circumstantial proof of criminal intent suffices).

224. See 18 U.S.C. §§ 1341, 1343.

225. See *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 965 n.10, 966 (Del. Ch. 1996) (*Caremark* held liable for \$29 million in criminal fines, \$129.9 mil-

Under the holding in *Caremark*, a director's duties include "a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under the circumstances may, in theory at least, render a director liable for losses caused by noncompliance with applicable legal standards."<sup>226</sup> If the directors make a good-faith effort to be reasonably informed in the exercise of judgment, there is most likely no breach of fiduciary duty.<sup>227</sup> Directors are not liable for bad decisions, nor does the duty to act in good faith require that directors possess particular knowledge about every aspect of the entity's operations.<sup>228</sup> The scope of liability often depends on the size of the organization and the scope of the detailed information required to avoid the loss.<sup>229</sup> The mere fact that a loss is due to a criminal violation does not suffice.<sup>230</sup>

The role that a breach of fiduciary duty plays is important; it may be a result of a permissive exclusion and may also warrant permissive exclusion.<sup>231</sup> *Caremark* had an internal audit plan to ensure compliance: an outside auditor, a continuing education program, a hot line for whistle-blowers, and disciplinary avenues for enforcement.<sup>232</sup> *Caremark's* initiative did not save them from liability under the antikickback statute; however, it provided a good-faith defense to the charge of breach of fiduciary duty.<sup>233</sup> Providers that have not disclosed claims excluded from any internal estimate of reimbursable claims risk breach of fiduciary claims in the event of investigation.<sup>234</sup> Ironically, as *Caremark* details, the failure to make such internal review of submitted claims may support a breach of fiduciary duty claim as well.<sup>235</sup>

The Controlled Substances Act and ERISA also have application in Medicare fraud and abuse enforcement. However, liability for such

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lion in civil fines, \$3.5 million under the Controlled Substances Act; required to make a donation of \$2 million; settled an ancillary suit by private insurance company payors for \$98.5 million; and paid substantial legal fees to defend five ancillary shareholder derivative suits).

226. *Id.* at 970.

227. *See id.* at 968.

228. *See id.* at 970-71.

229. *See id.*

230. *See id.*

231. *See* 42 C.F.R. § 1001.201(c) (1998); 62 Fed. Reg. 47,182, 47,187 (1997).

232. *See In re Caremark*, 698 A.2d at 962-63.

233. *See id.*

234. *See id.*; *see also* *United States v. Calhoun*, 97 F.3d 518 (11th Cir. 1996).

235. *See In re Caremark*, 698 A.2d at 967.

acts stems from violations of the Federal False Claims Act and the antikickback statute. The Securities Exchange Commission (SEC) also investigates the targets of fraud investigations to determine if reported earnings and other submissions are accurate.<sup>236</sup> Safe harbors provided in the regulations may exempt organizations and entities. These warrant examination as they may provide a sea wall to hold off the broad powers available to parties seeking to enforce Medicare billing requirements.

## **B. The “Not So” Safe Harbors: Coming Within the Scope of Exceptions**

Many Medicare fraud and abuse statutes have express exceptions within the statutes. In addition, there are thirteen safe harbors expressly set forth in 42 C.F.R. § 1001.952 that are payment practices not considered criminal offenses. Structuring payment practices to qualify for safe harbor treatment is necessary to combat the broad tools available to enforce Medicare billing requirements.

Under the antikickback statute, there are two provisions that can aid a defense against billing enforcement: (1) the six-year statute of limitations and (2) exceptions to “illegal remunerations.”<sup>237</sup> The first provision requires that the Secretary initiate civil enforcement within six years after the presentation of the claim, request for payment, or occurrence of the act which allegedly violates the statute.<sup>238</sup>

The second provision lists six items that are expressly excluded from “illegal remunerations.”<sup>239</sup> First, properly disclosed discounts or reductions in price, if appropriately reflected in the costs submitted for reimbursement, are not an illegal remuneration.<sup>240</sup> Second, payment by an employer to an employee for services within the scope of the items or services provided to the beneficiary and reimbursed by Medicare is not an illegal remuneration.<sup>241</sup> Third, any amount paid by a vendor to a purchasing agent for individuals or entities furnishing reimbursable services is not an illegal remuneration if there is a writ-

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236. Richard S. Bednar & Stanley R. Soya, *Collateral Consequences*, in *HEALTH-CARE EXCLUSIONS: A COMPREHENSIVE GUIDE* 135, 140-45 (1997) (addressing several collateral consequences of noncompliance); Casey, *supra* note 1 (Columbia/HCA's securities problems as a result of noncompliance).

237. See 42 U.S.C. §§ 1320a-7a(c)(1), 7b(b)(3) (1994 & Supp. 1996).

238. See § 1320a-7a(c)(1).

239. See § 1320a-7b(b)(3).

240. See § 1320a-7b(b)(3)(A).

241. See 42 U.S.C. § 1320a-7b(b)(3)(B) (1994).

ten contract.<sup>242</sup> The written contract must specify the amount to be paid, either by a fixed amount or percentage of the value of the purchase made under the contract.<sup>243</sup> In addition, and if the entity is a provider, a disclosure must be made to the entity and to the Secretary as to the amount received by each vendor.<sup>244</sup> Fourth, a waiver of coinsurance under Part B with respect to individuals who qualify under the Public Health Service Act is not considered an illegal remuneration.<sup>245</sup> Fifth, any practice specified by the Secretary in the regulations escapes criminal enforcement.<sup>246</sup> Sixth, remuneration between an organization and individual or entity through a risk-sharing agreement is not illegal.<sup>247</sup>

In addition to the provisions just described, several safe harbors exist that may provide an exception to acts otherwise illegal under Medicare fraud and abuse statutes. They are as follows:

(1) *Investment Interests*. The OIG proposed to delete this provision. However, the proposal was rejected by the OMB on grounds not related to the provision, suggesting that the investment interest safe harbor will not be safe for very long.<sup>248</sup> The provision excludes from the definition of "remuneration" any payment that is a return on investment, as long as several applicable standards are met.<sup>249</sup>

(2) *Space Rentals*. Remuneration does not include any payments made by a lessee to a lessor for the use of premises as long as the lease agreement: (1) is in writing, (2) specifies the premises, (3) provides the schedule of periodic access intervals and their length if there are such periodic access intervals, (4) has a lease term of greater than one year, and (5) contains an aggregate rental charge that is set in advance at arm's length for the fair market value and not determined in a manner that takes into account the value or volume of any referrals or generated business.<sup>250</sup>

(3) *Equipment Rentals*. "Remuneration" does not include payments made by a lessee to a lessor if made under the same conditions as a space rental safe harbor lease.<sup>251</sup> One focus in the Columbia in-

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242. See § 1320a-7b(b)(3)(c).

243. See § 1320a-7b(b)(3)(c)(i).

244. See § 1320a-7b(b)(3)(C)(ii).

245. See § 1320a-7b(b)(3)(D).

246. See § 1320a-7b(b)(3)(E).

247. See § 1320a-7b(b)(3)(F).

248. See 62 Fed. Reg. 47,182, 47,186 (1997).

249. See 42 C.F.R. § 1001.952(a) (1998).

250. See § 1001.952(b).

251. See § 1001.952(c).



vestigation is the financial incentives and other financial achievement goals given to physicians that the government claims are remuneration under the antikickback statute. A personal services safe harbor may provide an exemption for such agreements.

(4) *Personal Services and Management.* Remuneration does not include a principal's payments to an agent as compensation for services as long as: (1) the agreement is in writing, (2) it specifies the services performed, (3) it sets out any periodic access intervals that exist as to schedule and length of the intervals, (4) the term of the agreement is at least one year, (5) aggregate compensation paid is set in advance and not determined in a manner that takes into account the value or volume of any referrals or generated business, and (6) the services do not involve counseling or promotion in violation of federal or state law.<sup>252</sup>

(5) *Employees.* Similar to the professional services safe harbor, remuneration does not include compensation to employees with a bona fide employment relationship with the employer.<sup>253</sup>

(6) *Sale of Practice.* Remuneration does not include any payment made to a practitioner for the sale of a practice, as long as the completion of sale occurs within one year of the first sale agreement.<sup>254</sup> Additionally, the practitioner selling the practice cannot be in a position to make referrals or to otherwise generate business reimbursable under a federal health-care program for the purchasing practitioner within a year following the date of the first sale agreement.<sup>255</sup>

(7) *Referral Services.* Remuneration does not include any payment between a participant and a referral service as long as the referral service does not exclude any other Medicare participants.<sup>256</sup> The payment made to the referral service must also be equally assessed to all participants, and the referral service cannot impose requirements on the manner in which the participant provides services to a referred person.<sup>257</sup> The referral service must also require written disclosures to each person seeking a referral.<sup>258</sup>

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252. See § 1001.952(d).

253. See § 1001.952(i).

254. See § 1001.952(c)(1).

255. See § 1001.952(e).

256. See § 1001.952(f)(1).

257. See § 1001.952(f)(2).

258. See § 1001.952(f). Except that the referral service may require the participant to charge the person referred the same rate as nonreferred patients. See § 1001.952(f)(3). There are five elements in the mandated disclosure: (1) manner in which it selects participants, (2) fee to the referral service, (3) manner in which

(8) *Warranties*. Warranties are not remuneration if the buyer (1) fully and accurately discloses any price reduction obtained as part of the warranty and (2) provides to the Secretary, upon request, information supplied by the manufacturers and/or suppliers pursuant to the exemption.<sup>259</sup> Manufacturers and suppliers must also fully and accurately report any price reduction as a result of a warranty or, if a price reduction is unavailable, disclose the existence of a warranty on the invoice.<sup>260</sup> The exemption does not apply if manufacturers or suppliers pay any remuneration other than the cost of the item itself.<sup>261</sup>

(9) *Discounts*. A discount is a reduction in the amount a seller charges a buyer in an arm's length transaction.<sup>262</sup> A discount may include a rebate credit (check or coupon) directly redeemable from the seller only to the extent the reductions in price are attributable to the original item or service.<sup>263</sup> The definition of discount does not include a cash payment, a reduced price in exchange for an agreement to buy, a reduction applicable to a payor but not Medicare, waiver of coinsurance, a warranty, compensation for a personal service, or any other remuneration not expressly defined as a discount.<sup>264</sup> Generally, a discount must stem from the purchase of the same good discounted, must be reported in the same or following year, disclosed in a cost report, and provided to the Secretary upon request.<sup>265</sup>

(10) *Group Purchasing Organizations*. Remuneration does not include any payment made to a group purchasing organization (GPO) as part of an agreement to supply items or services, as long as there is a written agreement with each entity or individual disclosing the fee as less than three percent of the purchase price.<sup>266</sup> If there is not a fixed rate less than three percent of the purchase price, the written agreement must set a maximum rate or amount taken from the total purchase price.<sup>267</sup> If the receiver of items or services is a health-care

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participants are selected, (4) nature of relationship between participants and the referral service, and (5) nature of any restriction that may exclude a participant. See § 1001.952(f)(4)(i)-(v).

259. See § 1001.952(g)(1)-(2).

260. See § 1001.952(g)(3)(i)-(ii).

261. See § 1001.952(g)(4).

262. See § 1001.952(h)(3).

263. See *id.*

264. See *id.*

265. There are specific requirements depending on the type of buyer (entity, HMO, nonentity). Meeting the above listed criteria suffices for each. See § 1001.952(h).

266. See § 1001.952(j).

267. See § 1001.952(j)(1)(ii).

provider, the GPO must annually disclose the amount received from the purchasers with respect to the items or services supplied.<sup>268</sup>

(11) *Waiver of Beneficiary Coinsurance and Deductible Amounts.* Remuneration does not include any reduction or waiver of a beneficiary's duty to make coinsurance or deductible payments, so long as such payments are owed to a hospital for inpatient services or owed by an individual who qualified under the Public Health Services Act (PHSA).<sup>269</sup> Waiver of a beneficiary copayment or deductible owed to a hospital for inpatient services, where the beneficiary does not qualify under the PHSA, requires that the hospital abstain from shifting the burden of the reduction or waiver to Medicare.<sup>270</sup> The hospital must also offer to reduce or waive the payments without regard to admission, length of stay, or DRG code, and must not make the reduction pursuant to a price reduction agreement between a hospital and third-party payor.<sup>271</sup>

Finally, remuneration does not include (12) increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans,<sup>272</sup> or (13) price reductions offered to health plans.<sup>273</sup> There are several standards that these reductions must meet to qualify for nonremuneration treatment depending on the type of contract at issue.<sup>274</sup> To qualify, generally, the reductions must apply to all Medicare enrollees unless otherwise provided and must not shift the burden to other federal health-care programs.<sup>275</sup> The OIG annually solicits proposals and recommendations for developing new safe harbor provisions and modifications to current safe harbors.<sup>276</sup>

### C. Establishing a Good-Faith Defense to Charges of Medicare Fraud and Abuse

Because the intent standards are so broad under Medicare fraud and abuse statutes, establishing a good-faith defense is essential to challenging a claim of Medicare fraud and abuse. Until courts adopt a

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268. See § 1001.952(j)(2).

269. See § 1001.952(k).

270. See § 1001.952(k)(1)(i).

271. See § 1001.952(k)(1)(ii).

272. See § 1001.952(l).

273. See § 1001.952(m).

274. See *supra* notes 268-69 and accompanying text.

275. See *supra* notes 268-69 and accompany text.

276. See Solicitation of New Safe Harbors and Special Fraud Alerts, 63 Fed. Reg. 68,223 (Dec. 10, 1998).

heightened intent standard, *United States v. Greber*<sup>277</sup> illuminates the breadth of the antikickback statutes and the need to prepare and challenge allegations of knowingly and willfully violating the statute.<sup>278</sup> Considering the sheer magnitude of claims and the ability to err, the same holds true for allegations of false claims, which require solid good-faith defenses to overcome the low standard of “reckless disregard” and “deliberate ignorance.”<sup>279</sup> The OIG recently published guidelines for hospitals to follow in voluntarily developing compliance programs.<sup>280</sup> The OIG indicated that the existence of effective compliance programs that predate investigations is considered when addressing administrative penalties and has continued to reiterate that promise in the compliance guidelines that followed.<sup>281</sup> As *Caremark* indicates, such steps are essential to fulfilling a fiduciary duty and may offer a resource to distinguish errors from fraud and abuse.<sup>282</sup>

The OIG sets forth seven guidelines to establish a good-faith defense: (1) developing and distributing written standards of conduct, (2) the designation of a Chief Compliance Officer, (3) providing a system of compliance education for all employees, (4) creating incentives and avenues for whistle-blowers to report suspected violations, (5) developing a system to address allegations and enforce disciplinary action, (6) using audits and other techniques to monitor compliance, and (7) establishing investigation and remediation of identified systematic problems and developing policies addressing sanctioned individuals.<sup>283</sup> Although many of the guidelines are not practical to achieve, the guidelines offer a way out from broad condemnation under Medicare fraud and abuse statutes.

#### 1. THE DEVELOPMENT AND DISTRIBUTION OF WRITTEN STANDARDS OF CONDUCT

The OIG strongly encourages high-level involvement on the part of officers and directors, as well as large bodies such as nursing facilities, home health-care businesses, psychology and rehabilitation de-

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277. 760 F.2d 68 (3d Cir. 1985).

278. See generally Love, *supra* note 207.

279. See *supra* notes 173-79 and accompanying text.

280. See 63 Fed. Reg. 8987, 8990 (1978).

281. See 63 Fed. Reg. at 8988; *supra* note 71.

282. See *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 962-63 (Del. Ch. 1996).

283. See 63 Fed. Reg. at 8989.

partments, outpatient clinics, laboratories, and dialysis groups.<sup>284</sup> Attention to special risk areas go far to overcome a "reckless disregard" standard based on those charges.

The OIG suggests a written claim development and submission process.<sup>285</sup> The OIG guidelines model many of the corporate-integrity-agreements (CIAs) put into effect upon settlement, indicating that the steps advocated are designed to resolve problems that spark investigation.<sup>286</sup> The written policies and procedures should provide proper and timely documentation of billing records to ensure accuracy.<sup>287</sup> Providers should only submit claims when documents support the coded claim and are available for audit and review.<sup>288</sup> Records and bills should be organized to facilitate newly developed compliance procedures, and the potential audit and/or investigation of claims.<sup>289</sup> Policies should ensure the coding staff has access to medical records and other documents necessary to determine the accurate code for the item or service provided.<sup>290</sup> Policies should also provide incentives to billing personnel and coders that counteract tendencies to upcode and prohibit the financial incentive to do so.<sup>291</sup>

In order to stop billing outpatient services rendered in connection with inpatient stays, providers should establish presubmission and postsubmission policies.<sup>292</sup> In the presubmission stage, providers should install software to detect common billing errors that pose special risk to investigation, implement periodic review to determine the appropriateness of claims, and increase scrutiny of all inpatient bills.<sup>293</sup> In the postsubmission stage, policies should establish random testing that reexamine claims and coordination procedures with intermediaries.<sup>294</sup> Written policies should also mandate steps to be taken when errors are detected.<sup>295</sup>

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284. *See id.* at 8990.

285. *See id.* at 8989-93.

286. *See id.* at 8989 n.5. The OIG is attempting to achieve through guidelines what it imposes through corporate integrity agreements with those entities unfortunate enough to have the OIG levy allegations against them. *See* 64 Fed. Reg. 4435, 4438 n.14 (Jan. 28, 1999) (definition of corporate integrity agreement).

287. *See* 63 Fed. Reg. at 8990.

288. *See id.*

289. *See id.*

290. *See id.* at 8991.

291. *See id.*

292. *See id.*

293. *See id.*

294. *See id.*

295. *See id.*

To ensure the accuracy of cost reports, written policies should ensure that basic documentation exists for each cost and that verifiable data supports allocations to various centers.<sup>296</sup> Claims should be double-checked to separate nonreimbursable costs from reimbursable costs.<sup>297</sup> In the case of hospitals owned by a chain, the individual cost report should be cross-reviewed with the chain's cost report.<sup>298</sup> Measures should also be taken to ensure compliance with state and local laws, as well as safe harbor provisions. Claims that providers anticipate, for whatever reason, as not being reimbursable must be flagged as presumptively nonreimbursable claims which the provider is petitioning the Medicare payor to examine.<sup>299</sup>

A compliance program also needs written policies to ensure that only reasonable and necessary services are submitted for reimbursement.<sup>300</sup> The compliance officer should provide procedures and rules to support the medical necessity of services that the hospital provides.<sup>301</sup> The compliance program should also ensure the dissemination of "medical necessity" definitions and procedures.<sup>302</sup>

Antikickback policies must provide strict guidelines on the submission of claims linked to referrals pursuant to agreements designed to generate such referrals.<sup>303</sup> Hospitals should avoid agreements with hospital-based physicians that are designed to provide incentives for a physician's referral of beneficiaries.<sup>304</sup> Safe harbor regulations should also be adopted for structuring arrangements involving any type of remuneration.

To coordinate document and billing reviews, compliance programs should establish procedures regarding the creation, distribution, retention, storage, retrieval, and destruction of documents.<sup>305</sup> All records necessary to protect the integrity of the Medicare billing program should be incorporated into the record storage and retrieval system and should be kept for at least five years.<sup>306</sup>

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296. *See id.* at 8992.

297. *See id.*

298. *See id.*

299. *See United States v. Calhoun*, 97 F.3d 518, 529 (11th Cir. 1996).

300. *See* 63 Fed. Reg. at 8992.

301. *See id.*

302. *See id.*

303. *See id.*

304. *See id.*

305. *See id.* at 8993.

306. *See id.*

Compliance should be considered in evaluating the performance of employees.<sup>307</sup> The OIG looks for an active element of Medicare compliance as an indicator of a workplace culture that emphasizes compliance procedures. Regular discussion of compliance policies, legal requirements, and information regarding strict compliance with program policies, in addition to an awareness that disciplinary action is taken in the event of violations, furthers the goal of a Medicare-friendly environment.<sup>308</sup>

## 2. DESIGNATION OF A CHIEF COMPLIANCE OFFICER

The OIG advocates the appointment of a Chief Compliance Officer (CCO) to operate independently of the CFO and General Counsel and to report directly to the CEO.<sup>309</sup> The CCO, CFO, and General Counsel should work closely together to ensure compliance with safe harbor regulations. However, the CCO should operate independently in implementing and maintaining an effective compliance program.<sup>310</sup> For multiple-entity organizations, there should be a CCO for the parent operation and corresponding positions for each subsidiary that report to the CCO.<sup>311</sup> Compliance reports and periodic visits are stressed as evidence of initiative in enforcing and maintaining effective compliance.<sup>312</sup>

## 3. PROVIDING A SYSTEM OF COMPLIANCE EDUCATION FOR ALL EMPLOYEES

OIG encourages training and educating all officers, managers, and other employees involved in coding, billing, cost reporting, and marketing. It is also important to train and educate employees in other departments who pose a risk of acting without regard to Medicare fraud and abuse statutes and regulations.<sup>313</sup> The CCO has a duty to ensure that such training and education take place, that it is an element of job performance, and that it is required for all new employees in addition to the continual education provided for all employees associated with the CCO's program.<sup>314</sup> The OIG has suggested that a compliance program mandate a minimum number of hours per year

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307. *See id.*

308. *See id.*

309. *See id.* at 8993 n.35.

310. *See id.*

311. *See id.* at 8993 n.36.

312. *See id.* at 8993-94.

313. *See id.* at 8994.

314. *See id.*

of continuing education regarding billing procedures and has hinted that failure to comply with educational requirements may warrant permissive exclusion.<sup>315</sup>

#### 4. CREATING INCENTIVES AND AVENUES FOR WHISTLE-BLOWERS TO REPORT SUSPECTED VIOLATIONS

The CCO's program should establish an internal system of investigation.<sup>316</sup> An effective compliance program should provide confidential and anonymous whistle-blower hotlines, or similar measures, to encourage individuals to report violations.<sup>317</sup> Nonretaliation policies are one way to protect whistle-blowers from harsh treatment by supervisors and reduce the incentives to not report violations.<sup>318</sup> The OIG also suggests that independent reporting paths be created to encourage employees to report violations without fear of reprisal.<sup>319</sup> As a part of both initial and continuing education, the CCO should emphasize the procedures for reporting violations.<sup>320</sup>

#### 5. DEVELOPMENT OF A SYSTEM TO ADDRESS ALLEGATIONS AND ENFORCE DISCIPLINARY ACTION

The CCO should also ensure that there is an adequate system in place to address allegations and enforce violations or compliance program lapses with disciplinary action.<sup>321</sup> In addition to making compliance an element of performance evaluation, new employment policies should explain and mandate ramifications for both the failure to report known violations and the disciplinary consequences for noncompliance.<sup>322</sup> Disciplinary action should protect the rights of employees, but should also verify the organization's commitment to voluntary compliance.<sup>323</sup>

#### 6. THE USE OF AUDITS AND OTHER TECHNIQUES TO MONITOR COMPLIANCE

To ensure continued monitoring of compliance efforts, the CCO should conduct on-site visits and evaluations.<sup>324</sup> The CCO should also

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315. *See id.* at 8995.

316. *See id.*

317. *See id.*

318. *See id.*

319. *See id.* at 8995 n.45.

320. *See id.*

321. *See id.* at 8995-96.

322. *See id.*

323. *See id.* at 8996.

324. *See id.*



conduct interviews, issue and review questionnaires to determine problem areas, and evaluate the effectiveness of the compliance program.<sup>325</sup> The CCO staff should review problem departments and engage in a substantial amount of random claim reviews.<sup>326</sup> The CCO should use reviews to establish trends and focus short-term attention on problem areas.<sup>327</sup> Finally, the CCO should issue evaluation and compliance reports to raise awareness of compliance needs and the attainment of compliance goals.<sup>328</sup>

**7. ESTABLISHING INVESTIGATION AND REMEDIATION OF IDENTIFIED  
SYSTEMATIC PROBLEMS AND DEVELOPMENT OF POLICIES  
ADDRESSING SANCTIONED INDIVIDUALS**

Once aware of internal errors, the compliance program should set forth a plan for responding to detected offenses and developing corrective initiatives.<sup>329</sup> The OIG looks favorably on voluntary disclosures as long as four elements are met: (1) the voluntary disclosure is made on behalf of the entity, and not by an individual, (2) the disclosure is purely voluntary (i.e., no pending investigation exists), (3) the nature of the error and harm to the government is disclosed, and (4) the entity is not subject to bankruptcy proceedings.<sup>330</sup> If credible evidence of misconduct arises, after a reasonable inquiry determines there is reason to believe that a violation occurred, the entity should report the information to the appropriate government agency within sixty days.<sup>331</sup> Prompt reporting demonstrates good faith and a willingness to cooperate with the government. Moreover, if the organization is being targeted by the OIG, it acts as a mitigating factor in the assessment of penalties.<sup>332</sup>

**D. Appeals**

Any party may appeal an exclusion from Medicare benefits or a civil penalty by requesting a hearing before an Administrative Law Judge (ALJ)<sup>333</sup> or by filing a preexhaustion judicial action in a federal

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325. *See id.*

326. *See id.*

327. *See id.*

328. *See id.* at 8996-97.

329. *See id.* at 8997.

330. *See id.* at 8997 n.55.

331. *See id.* at 8997.

332. *See id.*

333. *See* 42 C.F.R. § 1001.2007.

district court of competent jurisdiction alleging (1) a colorable constitutional claim, (2) irreparable harm, and (3) the purpose of the exhaustion requirement would not be served by additional ALJ/Departmental Appeal Board (DAB) review.<sup>334</sup> The standard for judicial review is the same as it is for the ALJ, whether the OIG determination to exclude was based on substantial evidence.<sup>335</sup> No federal court has granted preexhaustion judicial review.<sup>336</sup> A litigant opposing an OIG exclusion notice before an ALJ must set forth (1) the issues in the notice of proposed exclusion that petitioner disagrees with, (2) the basis for the disagreement, (3) the defenses relied on, (4) any reasons for modification of the exclusion period, and (5) any reasons the public interest in preserving the health and safety of Medicare beneficiaries does not warrant exclusion.<sup>337</sup> The request must be filed within sixty days after notice of the exclusion or assessment of civil penalty.<sup>338</sup> The ALJ may only dismiss an appeal if it fails to raise any issue which may properly be addressed in the hearing.<sup>339</sup> The ALJ has the authority to manage the dispute and rule on motions.<sup>340</sup> However, the ALJ lacks the authority to overrule statutes and regulations as binding precedent, enter a directed verdict, enjoin any act of the Secretary, review the exercise of OIG discretion, set or reduce an exclusion period to zero, or review the exercise of OIG discretion to impose a civil monetary penalty, assessment, or exclusion.<sup>341</sup> The ALJ reviews whether the OIG based their determination on "substantial evidence."<sup>342</sup> The standard rarely goes unmet<sup>343</sup> and has been described as "less than the preponderance of the evidence."<sup>344</sup> The ALJ, DAB, or district court, will not review *de novo*, nor consider or weigh evidence in the rec-

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334. See *Lavapies v. Bowen*, 883 F.2d 465, 467 (6th Cir. 1989) (citing *Mattews v. Eldridge*, 424 U.S. 319 (1976)).

335. See *Papendick v. Sullivan*, 969 F.2d 298, 302 (7th Cir. 1992).

336. See *Shirk & Gilson*, *supra* note 15, at 119-25 (setting forth the applicable case law and distinctions between circuits).

337. See *id.* at 117.

338. See 42 C.F.R. § 1005.2(c) (1998).

339. See § 1005.4(b).

340. See *id.*

341. See § 1005.4(c).

342. See 42 U.S.C. § 405(g) (1994); *Papendick v. Sullivan*, 969 F.2d 298, 300 (7th Cir. 1992); *Myers v. Secretary of HHS*, 893 F.2d 840, 842 (6th Cir. 1990); 42 C.F.R. § 1005.21(h).

343. See *Shirk & Gilson*, *supra* note 15, at 121.

344. *Freemen United Coal Mining Co. v. Stone*, 957 F.2d 360, 362 (7th Cir. 1992).

ord.<sup>345</sup> Rather, the reviewing bodies consider anything in the record that detracts from the reasonableness of the conclusion.<sup>346</sup> The record before the ALJ is critical to post-ALJ review, as both the DAB and any federal district court will only consider issues raised before the ALJ or issues that could not have been raised before the ALJ at the time.<sup>347</sup> Once an ALJ has ruled, all parties are entitled to appeal the ALJ decision to the DAB within thirty days.<sup>348</sup> Once the DAB has ruled, an individual or entity may appeal to a federal district court of competent jurisdiction within sixty days, then the appropriate court of appeals, and then the Supreme Court.<sup>349</sup> Given the circumstances and the lottery-like incentive for whistle-blowers, individuals and entities who anticipate investigation may be better off blowing the whistle on themselves.

#### IV. Protecting Providers from OIG Investigation and Enforcement

Medicare fraud and abuse enforcement is a reality. Given the momentous political capital, broad statutory power, and the enormous financial incentives for whistle-blowers, more health-care entities will be investigated. Investigations can be coercive and abusive, and often result in the exclusion of the entity and individuals involved from Medicare benefits. The impact of exclusions and civil monetary penalties are extreme and are designed to deter noncompliance. The ability to permissively exclude, the inability to obtain review of discretionary decisions, and costly legal expenses to enjoin let alone fight investigatory forces, mandates that entities and individuals take decisive action. Initially, health-care providers and suppliers must play defense, building agreements and practices around safe harbors and attempting to adopt the OIG's arduous suggestions for voluntary compliance. In addition, practitioners must make use of new advisory opinions to shield prosecutorial abuse by future parties. Finally, prac-

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345. See *Papendick*, 969 F.2d at 302; *Garner v. Heckler*, 745 F.2d 383, 387 (6th Cir. 1984).

346. See *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (defining "substantial evidence" as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion").

347. See *Papendick*, 969 F.2d at 302; *Travers v. Sullivan*, 801 F. Supp. 394, 397 (E.D. Wash. 1992) (review limited to final decision, administrative record, and pleadings); see also *Shirk & Gilson*, *supra* note 15, at 119, 126.

348. See *Shirk & Gilson*, *supra* note 15, at 117-21.

349. See *id.* The OIG lacks the authority to appeal beyond the DAB. See *id.*

tioners should challenge the OIG and other government agencies and actors in court and in the public forum.

### A. Playing Defense: Safe Harbors and Voluntary Compliance

The safe harbors and efforts aimed at voluntary compliance provide a frontline defense to allegations of Medicare fraud and abuse. Conduct within the safe harbors, set forth in part III.B above, cannot serve as a basis for exclusion.<sup>350</sup> A safe harbor defense provides defendants with a weapon to combat the permissive powers of the OIG and attack the contractual claims of contractors and fiscal intermediaries that refuse to honor reimbursement agreements.<sup>351</sup> To ensure safe harbor qualification, relevant documents and contracts should model the regulatory requirements and be submitted as part of an advisory opinion to preclude any future liability.<sup>352</sup>

Providers need to develop written long-term plans for compliance.<sup>353</sup> The arduous voluntary compliance program suggested by the OIG is economically and logistically impossible to achieve in the short term.<sup>354</sup> However, initial steps must be taken to raise actions above the threshold of "reckless disregard" and "deliberate ignorance." Significant compliance efforts may also function to shield companies from fiduciary duty and shareholder litigation.<sup>355</sup> In the short term, bringing in a compliance officer, undergoing an internal audit, adopting an OIG-approved claim development and submission process, documenting educational initiatives, and adding compliance as an element considered for hiring and performance purposes all establish a framework and foundation to achieve a compliance culture.<sup>356</sup> Partici-

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350. See 42 C.F.R. § 1001.952 (1998).

351. See *id.*

352. See §§ 1001.952, 1008.1-59; see also § 1008.5(a)(3) (authorizing advisory opinions on whether an arrangement is within a safe harbor).

353. See 63 Fed. Reg. 8987, 8988 (Feb. 23, 1998).

354. The OIG calls for the creation of an entire new industry and expects companies to follow suit. The scope of the plan is not economically feasible in the short term, yet when compared to the risk, justifies substantial expenditures. Practical decisions must be made in plotting a course for compliance to ensure what is economically feasible and achieves an end that shields companies from liability in the short term.

355. See *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 965 n.10, 966 (Del. Ch. 1996).

356. See 63 Fed. Reg. at 8989-93. Documenting initiatives such as spot-checking the work of coding and billing personnel, education and training, personnel interviews, and performance evaluations regarding compliance efforts, helps build a positive preinvestigation record that could prove pivotal at an ALJ evidence sufficiency hearing. See generally 64 Fed. Reg. 4435, 4439 n.20 (Jan. 28, 1999) (implying

pants that are required to submit cost reports should either engage in exhaustive internal compliance and maintain one cost report that will be submitted, or continue to maintain reserve cost reports and submit cost reports flagging claims that internal reviews deem questionable as presumptively nonreimbursable claims.<sup>357</sup> Long-term goals should include a schedule for continuing education, a detailed system of organizing and retrieving documents, as well as an operational compliance department working internally to ensure accuracy and working externally with contractors and fiscal intermediaries to quickly resolve disputes.<sup>358</sup> Although the OIG warns that "hastily constructed" compliance programs "could result in greater harm or liability . . . than no program at all," demonstrable efforts of compliance heighten the intent standard and may shield an organization from civil liability.<sup>359</sup> There are several other strategic avenues to avoid an OIG-imposed exclusion.<sup>360</sup> For example, fashioning plea agreements to avoid mandatory exclusions, and the selection of the crime and entity pleading to the crime may offer comparatively advantageous resolutions to a compliance dilemma.<sup>361</sup> Careful consideration must also be made regarding collateral compliance consequences and spin-off litigation that a plea agreement may trigger.<sup>362</sup>

## B. Shielding Future Prosecution with Advisory Opinions

Advisory opinions prevent the OIG from taking action against the requesting party.<sup>363</sup> A party may seek to acquire an advisory opinion on five different subject matters: (1) what constitutes prohibited remuneration, (2) whether an agreement satisfies statutory exceptions, (3) whether an agreement satisfies a safe harbor, (4) what constitutes an inducement to limit services, and (5) whether any activity warrants

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that spot-checking the work of coding and billing personnel is considered by the OIG when evaluating compliance efforts under a "reckless disregard" or "deliberate ignorance" standard).

357. See Mustokoff & Mallozzi, *supra* note 10, at 7.

358. See 63 Fed. Reg. at 8993.

359. 63 Fed. Reg. at 8988.

360. See Hope S. Foster, *Avoiding OIG-Imposed Exclusion*, in HEALTHCARE EXCLUSIONS: A COMPREHENSIVE GUIDE 87, 87-112 (1997) (setting forth several ground rules a litigant may wish to follow and outlining a variety of options pertaining to particular compliance problems).

361. See *id.*

362. See *id.*; see also Bednar & Soya, *supra* note 236, at 135-52.

363. The OIG is prevented from proceeding against a requestor acting in good-faith reliance upon the OIG opinion where the relevant facts were fully disclosed and accurately presented. See 42 C.F.R. § 1008.45 (1998).

sanction.<sup>364</sup> Advisory opinions are not available to determine the fair market value of any item or service or whether a person qualifies as a bona fide employee.<sup>365</sup> Advisory opinions will be available in the case of presumptively nonreimbursable claims that are excluded in more conservative internal reviews.<sup>366</sup> Requesting parties are responsible for paying an initial \$250 nonrefundable fee, in addition to the costs incurred by the OIG in preparing the advisory opinion.<sup>367</sup> Advisory opinions are yet another tool to check the OIG's broad discretionary power and shield a company from civil liability. For companies making the transition to a more Medicare-friendly system, advisory opinions can provide security for risky maneuvers involving physicians, suppliers, and outpatient services.<sup>368</sup>

### C. Challenging the Legality of OIG Action and Shifting the Medicare Fraud and Abuse Debate Back to Criminals and Away from Good-Faith Operations

Effective compliance programs and the use of advisory opinions are important preinvestigation practices that support a good-faith defense to allegations of Medicare fraud and abuse. Once an investigation begins, or once a contractor or fiscal intermediary refuses payment or demands a refund, providers must be willing to take decisive action. Medicare compliance litigation is analogous to IRS audits, where the financial and legal burdens fall squarely on the citizen.<sup>369</sup> Although cooperation with the investigation is critical, providers should seek an immediate injunction where the investigation lacks basis. The largest concern for some providers is not necessarily the penalties, but the legal fees they steadily incur.<sup>370</sup>

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364. See §§ 1008.5(a)(1)-(5).

365. See §§ 1008.5(b)(1)-(2).

366. See generally 63 Fed. Reg. 38,311 (July 16, 1998) (final rule on advisory opinions). The OIG declared that, in addition, advisory opinions are available regarding the civil money penalty provisions of section 1128A of the Act, which authorizes penalties for a variety of acts, including, among others, presentation of a false or fraudulent Medicare or Medicaid claim and hospital payments to physicians to induce them to reduce or limit care to any Medicare or Medicaid beneficiary under their direct care. See *id.*

367. See 42 C.F.R. § 1008.31; see also § 1008.33 (pertaining to outside experts).

368. For example, Columbia's compliance officer, Alan Yuspeh, continues to debate whether free bagels and pastries in a physicians' lounge constitutes "remuneration." See Casey, *supra* note 1. Through the use of advisory opinions, compliance officers can attempt to narrow OIG expectations to their particular operations.

369. See Cenac Statement, *supra* note 106, at 5.

370. For small, independent companies mounting legal fees can threaten the life of the company. See *id.*

Once a determination of fraud or excess billing is made and payment withheld, the decision is subject to judicial review.<sup>371</sup> Administrative review is inadequate considering that an ALJ lacks the authority to vacate an OIG decision, but such a review is often required prior to judicial review.<sup>372</sup> However, the HCFA may continue to appeal favorable rulings to an ALJ and the DAB.<sup>373</sup> Providers should continue to challenge arbitrary decisions or unnecessary HCFA appeals, and consider actions to recover attorney fees against contractors and fiscal intermediaries that certify reimbursement only to later demand exorbitant refunds. In defending claims based on inaccurate cost reports, the Eleventh Circuit's ruling in *United States v. Calhoun*<sup>374</sup> must be challenged on the ground that reserve cost reports reflect other legitimate and reasonable business determinations and do not conclusively establish that a claim excluded from a reserve cost report is presumptively nonreimbursable.<sup>375</sup>

Outside of the courtroom, health-care providers need to vigorously support Rep. Bill McCollum's (R-FL) proposal to heighten the intent standard and preclude the government from bringing actions under particular circumstances.<sup>376</sup> McCollum's proposal would apply retroactively and prevent the government from taking actions against providers who relied on information supplied by the government.<sup>377</sup> Although many commentators stress complete cooperation with the OIG as a means of limiting exposure and establishing the trustworthiness of a provider,<sup>378</sup> health-care providers and suppliers must continually challenge the overzealous enforcement of Medicare compliance to encourage a reasonable response to the program's billing dilemma.

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371. See 42 U.S.C. § 1395y(d)(3) (1994); *Klein v. Heckler*, 761 F.2d 1304, 1309-10 n.9 (9th Cir. 1985) (holding that when payment is withheld due to a determination of fraud or excess billing, rather than lack of information, the determination is explicitly subject to judicial review).

372. See 42 C.F.R. § 1005.4(c).

373. See, e.g., *CSM Home Health Serv., Inc. v. HCFA*, DAB No. CR440 (1996), 1996 WL 599839 (HHS Oct. 11, 1996)).

374. 97 F.3d 518 (11th Cir. 1996).

375. See *id.* at 529.

376. See *Casey*, *supra* note 1.

377. See *id.*

378. See *Bednar & Soya*, *supra* note 236, at 135-52; *Foster*, *supra* note 360, at 87-112.

## V. Conclusion

The Columbia/HCA investigations serve as a wake-up call and shining example of what may become of those who choose not to comply. Columbia/HCA is also a good pedagogical tool for examining how Medicare compliance is enforced. The focus of the HHS is not on criminals, but rather on those providers who choose to provide service to Medicare beneficiaries. Health-care providers must recognize the initiative as a revenue-generating initiative and respond accordingly.

Medicare continues to serve a vital role in health care and provides necessary medical services to an aging population in need of care. However, Medicare is also a bureaucratic nightmare. Current enforcement is coercive and abusive, threatening good-faith operators and those who receive their quality care. Effective Medicare compliance is an achievable goal if the enforcing agents change the way they view the providers. Unfortunately, as the criminal element continues to evade investigators busy sanctioning legitimate providers, the incentive to remain in health care and provide quality care to Medicare beneficiaries steadily decreases.