

# Health Care Compliance Professional's Manual

## Health Care Fraud and Abuse Laws

### ¶20,300 Introduction

At least some of the more than four billion health insurance benefit transactions processed in the United States each year are fraudulent.\* Although they may constitute only a small percentage, such fraudulent claims carry a very high price tag. Every six months the Office of Inspector General (OIG) conducts a formal audit of the Medicare program's fee-for-service claim payments. It is estimated that of the \$308.4 billion paid in Medicare's fiscal year 2009 fee-for-service program, 7.8 percent of claims - representing \$24.1 billion in payments were improperly paid due to erroneous billing, inadequate provider documentation of services to back up the claims, or outright fraud.<sup>1</sup> It is of note, that the error rate in the previous year (fiscal year 2008) was 3.6 percent representing \$10.4 billion in improper payments.<sup>2</sup> According to the National Health Care Anti-Fraud Association, \$68 billion of the nation's annual health care outlay is lost to fraud,<sup>3</sup> and other estimates by government and law enforcement agencies place the loss as high as \$226 billion each year.<sup>4</sup>

The subject of health care fraud and abuse has undergone significant growth in the past decade as the result of the expanding reach of both federal and state legislation and stepped-up enforcement efforts on the part of the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and state Medicaid Fraud Control Units (MFCUs). Increasingly, health care providers have had to grapple with restrictions legislating not only how they conduct business but also how they structure relationships among themselves. Determining the boundaries of permissible conduct under a myriad of statutes at both the federal and state levels is a difficult undertaking.

Much of the complexity of this body of law relates to the statutory language in both the Medicare and Medicaid Statute<sup>5</sup> and Limitation on Certain Physician Referrals, referred to as the Stark Law<sup>6</sup> and the difficulty in defining the specific conduct that is subject to these broadly worded fraud and abuse prohibitions. In addition, many of the prohibitions are subject themselves to numerous safe harbors and exceptions, especially in the area of kickbacks and referral arrangements. Indeed, the Stark Law has been referred to as a statute of exception because it broadly bans some physician referrals and then proceeds to list the circumstances in which the bans do not apply. Finally, the wide range of both criminal and civil sanctions available to enforce the prohibitions, under the statutes themselves or under a variety of other federal laws that apply to fraud and abuse, adds additional complexity to this somewhat formidable subject area.

### Footnotes

- \* This chapter was edited in May 2010 by Ritu Kaur Singh, Esq. of Jones Day. Ms. Singh would like to acknowledge the assistance of Michael Shaheen, Esq. of Jones Day.
- 1 CMS Report, Centers for Medicare & Medicaid Services, Improper Medicare Fee-for-Service Payments Report (Nov. 2009), [http://www.cms.hhs.gov/apps/er\\_report/](http://www.cms.hhs.gov/apps/er_report/).
- 2 CMS Report, Centers for Medicare & Medicaid Services, Improper Medicare Fee-for-Service Payments Report—November 2009 Long Report, [http://www.cms.hhs.gov/apps/er\\_report/](http://www.cms.hhs.gov/apps/er_report/). This substantial increase in errors is partly due to a change in the Centers for Medicare & Medicaid Services (CMS) use of a different error rate measurement methodology.
- 3 National Health Care Anti-Fraud Association, The Problem of Health Care Fraud, [http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti\\_fraud\\_resource\\_centra&wpscode=TheProblemOfHCFraud](http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centra&wpscode=TheProblemOfHCFraud).
- 4 FBI Report, Financial Crimes Report to the Public, Fiscal Year 2008, [http://www.fbi.gov/publications/financial/fcs\\_report2008/financial\\_crime\\_2008.htm#health](http://www.fbi.gov/publications/financial/fcs_report2008/financial_crime_2008.htm#health).
- 5 [42 U.S.C. §1320a-7b](#).
- 6 [42 U.S.C. §1395nn](#).

## ¶20,302 Fraud and Abuse Prohibitions

The types of health care provider activities that fall within the federal fraud and abuse prohibitions are largely defined in the Medicare and Medicaid statute, the civil False Claims Act (FCA), the Anti-Kickback statute, and the Limitation on Physician Self-Referral statute, known as the Stark Law.<sup>7</sup> Very generally, these prohibitions relate to:

- false claims or other fraudulent billing activities.
- bribes or kickbacks, including a complex array of discounts, rebates, profit-sharing agreements, or other business arrangements.
- illegal referrals, prohibiting physicians from referring patients for health care services to entities in which the physician has a financial interest.

### Recent Enforcement Activity

Recent fraud and abuse enforcement activity has focused on specific areas of relationships between providers and industry, prescription drugs, and durable medical equipment and supplies (DME).<sup>8</sup> Arrangements between providers and companies in the pharmaceutical and biotechnology industries have been scrutinized under the federal Anti-Kickback Statute. Prescription drug cases generally involve companies charging inflated prices to Medicaid, offering illegal kickbacks to physicians, marketing drugs for off-label uses, billing for drugs not delivered to beneficiaries, or switching drugs to maximize Medicare reimbursement.<sup>9</sup> Medical equipment and supplies enforcement has focused on fraudulent billing in the DME field.

Results of recent Office of Inspector General (OIG) investigations and settlements reveal the following specific examples of these and other areas of fraud:

- **Kickbacks disguised as consulting and other arrangements:** The OIG entered into a settlement under which five orthopedic implant vendors agreed to pay \$311 million to resolve allegations of anti-kickback and FCA violations related to alleged sham consulting and other payments to physicians that were disguised kickbacks. Four of the five companies also entered into deferred prosecution agreements, and one company entered into a non-prosecution agreement. They also entered into 5-year corporate integrity agreements (CIAs) with the federal government.<sup>10</sup>
- **Illegal marketing and pricing practices:** A large pharmaceutical company agreed to pay \$2.3 billion related to illegal promotions of certain pharmaceuticals and payment of illegal kickbacks to health care providers in September 2009,<sup>11</sup> another large pharmaceutical company settled claims that it paid illegal kickbacks and failed to pay rebates to Medicaid for \$650 million in February 2008,<sup>12</sup> and yet a third pharmaceutical company paid \$515 million in September 2007 to settle a variety of claims over its marketing and pricing practices.<sup>13</sup>
- **Switching drugs:** In 2008, the OIG entered into settlements with several nationwide pharmacies in which the pharmacies agreed to pay \$49.5 million, \$36.7 million, and \$35 million, respectively, for allegedly switching capsules for tablets to receive greater reimbursement from Medicaid.<sup>14</sup>
- **Kickbacks for equipment and supplies:** A variety of DME providers have engaged in alleged schemes to defraud the Medicare program by billing for durable medical equipment and supplies, such as motorized wheelchairs, that were not provided to beneficiaries or not medically necessary.<sup>15</sup> Twenty defendants were recently arrested and charged with participating in multiple Medicare fraud schemes that allegedly resulted in the submission of \$26 million in fraudulent bills; the defendants were DME company owners and marketers who purportedly filed false orders for wheelchairs, orthotics, and medical beds.<sup>16</sup>
- **Medically unnecessary services:** Medtronic Spine LLC agreed to pay \$75 million to settle allegations that it engaged in a seven-year scheme that resulted in hospitals billing Medicare for kyphoplasty procedures as inpatients.<sup>17</sup> The government alleged that it is more appropriate to bill kyphoplasty procedures as outpatients (which is less expensive for Medicare). A dental management company paid \$24 million to settle allegations that it performed medically unnecessary dental services on children insured by Medicaid.<sup>18</sup> Quest Diagnostics paid \$302 million over allegations that one of its subsidiaries knowingly sold test kits that did not provide accurate results.<sup>19</sup> A Minnesota Hospital agreed to pay \$846,461 to settle claims that it admitted patients and kept others admitted to acute care when it was not medically necessary.<sup>20</sup>
- **Outlier payments:** A hospital system paid more than \$788 million, as part of a \$900 million settlement in total, to resolve claims that it received excessive outlier payments (which are intended to be limited to

particularly expensive episodes of care), as a result of inflating its charges substantially in excess of any increase in the costs associated with patient care and billing for services and supplies not provided to patients.<sup>21</sup> Since 2006, several other New Jersey and Pennsylvania hospitals have settled outlier claims, including Saint Barnabas Corporation, the largest health care system in New Jersey, for \$265 million.<sup>22</sup>

#### Footnotes

- 7 [31 U.S.C. §3729](#), et. seq., [42 U.S.C. §1320a-7b\(b\)](#) and [42 U.S.C. §1395nn](#).
- 8 OIG Testimony, *Testimony of Daniel R. Levinson, Inspector General*, given before the U.S. House of Representatives House Energy and Commerce Committee Subcommittee on Health, June 25, 2009, *see also* OIG Testimony, *Testimony of Lewis Morris, Chief Counsel to the Inspector General*, given before the U.S. House of Representatives House Oversight and Government Reform Committee, Feb. 9, 2007; *see also* OIG Testimony, *Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs*,. OIG Testimony, Testimony of Dara Corrigan, Acting Principal Deputy Inspector General, July 9, 2003, <http://www.oig.hhs.gov>.
- 9 [42 U.S.C. § 1320a-7b\(b\)](#).
- 10 Press Release, U.S. Dept. of Justice, Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring (Sept. 27, 2007), <http://www.usdoj.gov/usao/nj/press/files/pdf/hips0927.rel.pdf>.
- 11 Press Release, U.S. Dept. of Justice, Justice Department Announces Largest Health Care Fraud Settlement in its History (Sept. 2, 2009), [http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/Pfizer%20-%20PR%20\(Final\).pdf](http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/Pfizer%20-%20PR%20(Final).pdf).
- 12 Press Release, U.S. Dept. of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), [http://www.usdoj.gov/opa/pr/2008/February/08\\_civ\\_094.html](http://www.usdoj.gov/opa/pr/2008/February/08_civ_094.html).
- 13 Press Release, U.S. Dept. of Justice, Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), [http://www.usdoj.gov/opa/pr/2007/September/07\\_civ\\_782.html](http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html).
- 14 *United States et al., ex rel. Bernard Lisitza v. Omnicare, Inc.*, 01 C 7433, and *United States ex rel. David Kammerer v. Omnicare, Inc.*, 04-C-2074 (N.D. Ill.), [http://www.usdoj.gov/usao/iln/indict/2006/01c7433\\_settlement\\_agreement.pdf](http://www.usdoj.gov/usao/iln/indict/2006/01c7433_settlement_agreement.pdf); *see also* Press Release, U.S. Dept. of Justice, CVS Caremark Settlement (Mar. 18, 2008), [http://www.usdoj.gov/usao/iln/pr/chicago/2008/pr0318\\_01.pdf](http://www.usdoj.gov/usao/iln/pr/chicago/2008/pr0318_01.pdf); *see also* Press Release, U.S. Dept. of Justice, Walgreens Settlement, June 4, 2008, [http://www.usdoj.gov/usao/iln/pr/chicago/2008/pr0604\\_01.pdf](http://www.usdoj.gov/usao/iln/pr/chicago/2008/pr0604_01.pdf).
- 15 OIG Testimony, *Testimony of Dana Corrigan, Acting Principal Deputy Inspector General*, given before the United States Senate Committee on Finance, Apr. 28, 2004, <http://www.oig.hhs.gov/testimony/docs/2004/042804fin.pdf>.
- 16 Press Release, U.S. Dept. of Justice, Los Angeles Medicare Fraud Strike Force Charges 20 in Health Care Fraud Cases Involving Durable Medical Equipment (Oct. 21, 2009), <http://www.justice.gov/opa/pr/2009/October/09-crm-1131.html>.
- 17 Press Release, U.S. Dept. of Justice, Medtronic Spine, Formerly Kyphon Inc., to Pay U.S. \$75 Million to Resolve Allegations of Defrauding Medicare (May 22, 2008), <http://www.justice.gov/opa/pr/2008/May/08-civ-455.html>.
- 18 Press Release, U.S. Dept. of Justice, National Dental Management Company Pays \$24 Million to Resolve Fraud Allegations (Jan. 20, 2010), <http://www.justice.gov/opa/pr/2010/January/10-civ-052.html>.
- 19 Press Release, U.S. Dept. of Justice, Quest Diagnostics to Pay U.S. \$302 Million to Resolve Allegations That a Subsidiary Sold Misbranded Test Kits (Apr. 15, 2009), <http://www.justice.gov/opa/pr/2009/April/09-civ-350.html>.
- 20 Press Release, U.S. Dept. of Justice, Minnesota Hospital to Pay U.S. to Resolve Allegations of False Claims Involving Unnecessary Admissions (Jan. 4, 2010), <http://www.justice.gov/opa/pr/2010/January/10-civ-001.html>.
- 21 Press Release, U.S. Dept. of Justice, Tenet Healthcare Corporation to Pay U.S. more than \$900 Million to Resolve False Claims Act Allegations (June 29, 2006), [http://www.usdoj.gov/opa/pr/2006/June/06\\_civ\\_406.html](http://www.usdoj.gov/opa/pr/2006/June/06_civ_406.html).
- 22 Press Release, U.S. Dept. of Justice, Largest Health Care System in New Jersey to Pay U.S. \$265 Million to Resolve Allegations of Defrauding Medicare (June 15, 2006), <http://www.justice.gov/usao/nj/press/files/pdf/stba0615rel.pdf>.

## ¶20,304 HIPAA and the Extension of the Medicare/Medicaid Statute in 1996

Until passage of the [Health Insurance Portability and Accountability Act \(HIPAA\)](#) in August 1996,<sup>23</sup> the Medicare and Medicaid Statute targeted health care payment practices and business arrangements only in connection with the Medicare and Medicaid programs.<sup>24</sup> The legislation prohibited fraudulent billing activities under the Medicare program or state health care programs. Amendments contained in the 1996 health insurance reform statute extend both civil monetary and criminal penalties for fraudulent billing activities to *all* federal health care programs, defined as any plan or program that provides health benefits, directly through insurance or otherwise, that are funded in part by the federal government (with the exception of the Federal Employee Health Benefit Program).<sup>25</sup> The statute also amended the U.S. criminal code to specifically delineate health care fraud offenses against any health benefit program (*i.e.* public or private health benefit programs) and grant the Department of Justice (DOJ) authority to enjoin and seize assets derived from health care fraud.<sup>26</sup>

Specifically, federal law prohibits claims for payment under any federal health care program for any item or service provided by a person who:

- has knowingly and willfully made or caused to be made any false statement or representation of a material fact in application for payment, or
- has furnished services or supplies determined to be substantially in excess of those needed or so lacking as to be worthless.

This language prohibits much more than billing for services not rendered. It can include billing for a more expensive covered item than that provided, misrepresentation of a patient's condition for billing purposes, claiming costs for nonchargeable services, and so forth. The vast majority of enforcement efforts are directed at fraudulent billing activities, and more recently many of the enforcement initiatives relating to false claims have been taken under the auspices of the FCA.<sup>27</sup>

Title XIII of the American Recovery and Reinvestment Act of 2009 ([ARRA](#)), otherwise known as the Health Information Technology for Economic and Clinical Health Act ([HITECH Act](#)),<sup>28</sup> significantly increased fines and the scope of remedies for violations of HIPAA and breaches of the security of electronic health records and, if certain procedures and technologies are not in place, requires disclosure to affected individuals, news media, and HHS in the event security of protected information is breached. Criminal penalties are enforceable against persons who obtain or disclose protected health information without authorization. In addition, a state's Attorney General can bring civil actions against a person on behalf of residents adversely affected by violations of either HIPAA or the HITECH Act. The Attorney General can either seek to enjoin further violations or obtain money damages on behalf of the residents harmed. HHS is beginning to perform periodic audits of health care providers to ensure that required policies under the HITECH Act are in place. Individuals harmed by violations of HIPAA and the HITECH Act will be able to recover a percentage of monetary penalties or a monetary settlement based upon methods to be established by HHS for this private recovery in the next three years.

A detailed discussion of the HIPAA Privacy and Security Rules as well as enforcement and penalties is in the chapter entitled "A Compliance Officer's Guide to HIPAA Privacy and Security Rules at ¶20,760 - ¶20,800, ¶20,810 - ¶20,836, and ¶20,838, respectively.

### Footnotes

23 The Health Insurance Portability and Accountability Act (HIPAA) ([PubLNo. 104-191](#)).

24 [42 U.S.C. §1320a-7b](#).

25 HIPAA, (PubLNo. 104-191) (amending [42 U.S.C. §§1320a-7a](#) & [1320a-7b\(a\)](#)).

26 See [18 U.S.C. §669](#), §1035, [§1345](#), [§1347](#), and [§1518](#).

27 [31 U.S.C. §§3729](#) through [3733](#).

28 American Recovery and Reinvestment Act of 2009 (ARRA) ([PubLNo. 111-5](#)), 123 Stat. 115, Title XIII (codified in scattered sections of 42 U.S.C.).

## ¶20,306 False Claims Act

The False Claim Act (FCA) imposes liability for knowingly presenting, or causing to be presented, a false or fraudulent claim for payment from the federal government. Under the FCA, no specific intent to defraud is necessary; rather knowing means actual knowledge, reckless disregard for, or deliberate ignorance of the truth or falsity of the information.<sup>29</sup> The Fraud Enforcement Recovery Act of 2009 ([FERA](#)) expands exposure under the FCA, making parties liable for any false claims paid with government funds<sup>30</sup> and for the retention of money owed to the government.<sup>31</sup> The Patient Protection and Affordable Care Act (PPACA), enacted March 23, 2010, states that FCA liability will arise if an actor does not repay any identified overpayment within sixty days.<sup>32</sup>

The federal government, state attorneys general, or private individuals, via *qui tam* action (a suit to recover damages sustained by the government, a percentage of which is awarded to the individual), may bring a lawsuit under the FCA.

To bring a *qui tam* action, the individual, referred to as a relator, must be an original source of the information concerning the false claim.<sup>33</sup> The FCA was recently amended by PPACA, which now requires that to qualify as an original source, the relator must provide independent and material information to the government before such information has been publicly disclosed.<sup>34</sup>

Additionally, the PPACA altered the FCA to provide that if the government opposes dismissal, the public disclosure bar is not jurisdictional and does not require dismissal. Moreover, public disclosure is now limited to federal suits and does not apply to state proceedings or private litigation.<sup>35</sup> Previously, lawsuits based on the prior public disclosure of allegations or transactions were jurisdictionally barred.<sup>36</sup>

The statute of limitations for a FCA action is either six years from the date of the violation, or three years after the date when facts material to the right of action are known or reasonably should have been known to the U. S. official charged with responsibility to act, whichever occurs later, but in no case longer than ten years after the violation.<sup>37</sup>

For a more detailed discussion of the False Claims Act, see the chapter entitled "False Claims Act and Quit Tam Suits," at [¶20,330-¶20,340](#).

### Footnotes

29 [31 U.S.C. §3729\(b\)](#).

30 31 U.S.C. §3729(a)(1)(A).

31 31 U.S.C. §3729(a)(1)(G).

32 The Patient Protection and Affordable Care Act § 6402(d) ([PubLNo 111-148](#)) (2010),

33 [31 U.S.C. §3730\(e\)\(4\)\(A\)](#).

34 The Patient Protection and Affordable Care Act § 10104(j) ([PubLNo 111-148](#)) (2010); 31 U.S.C. §3730(3)(4)(B).

35 The Patient Protection and Affordable Care Act § 10104(j) ([PubLNo 111-148](#)) (2010).

36 31 U.S.C. §3730(e)(4)(A).

37 [31 U.S.C. §3731\(b\)](#).

## ¶20,308 Anti-Kickback Statute and Physician Self Referral Prohibition

The Medicare and Medicaid Statute prohibits specific categories of referral payments, including kickbacks, bribes, or rebates. Indeed, this particular part of the Medicare and Medicaid Statute is often referred to as the Anti-Kickback Statute. Specifically, [42 U.S.C. §1320a-7b\(b\)](#) forbids any knowing and willful conduct involving the solicitation, receipt, offer, or payment of any kind of remuneration in return for referring an individual or recommending or arranging the purchase, lease, or ordering of an item or service that may be wholly or partially paid for under a federal health care program. The U. S. Court of Appeals for the Third Circuit has concluded that the Anti-Kickback Statute is violated if one purpose of a payment or remuneration to a provider is to induce referrals.<sup>38</sup> The prohibition is intended to curb the corrupting monetary influence on a physician's decision as to when and where to refer patients.

To determine whether a patient selects the services offered by a physician or other provider as a result of a referral, it is necessary to examine the source of the alleged referral. Most patients rely heavily on direction from their treating physicians in selecting a facility or health care professional. In examining any business arrangement that directs the flow of health care to any specific provider, therefore, the ability of any one of the parties to the arrangement to exercise undue influence over a patient's health care decision can be a key issue.

The Patient Protection and Affordable Care Act (PPACA) amended a number of provisions under the Anti-Kickback Statute. One such amendment provides that an Anti-Kickback Statute violation may be established without showing that an individual knew of the statute's proscriptions or acted with specific intent to violate the Anti-Kickback Statute. The new standard could significantly expand criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the Anti-Kickback Statute.<sup>39</sup> This amendment relaxes the specific intent requirement judicially recognized in *Hanlester Network v. Shalala*.<sup>40</sup> PPACA further amended the Anti-Kickback Statute to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act (FCA).<sup>41</sup>

In addition to enumerated statutory exceptions, the Office of Inspector General (OIG) has published regulations outlining certain categories of activities referred to as safe harbors that are deemed not to violate the Anti-Kickback Statute. The failure of a particular business arrangement to comply with a safe harbor, however, does not make the conduct or activity illegal. Furthermore, the OIG has published a number of advisory opinions in response to particular facts and proposed transactions in which the OIG advises on how the Medicare and Medicaid Statute will be applied to the proposed transaction or facts. While advisory opinions are not to be relied on as precedent, they nevertheless serve as guidance.

Kickbacks have become a significant enforcement target for the federal government. In *United States v. Weinbaum*,<sup>42</sup> sponsors of incentive programs for physician relocation came under scrutiny. In this indictment, a hospital was charged with violating the Anti-Kickback Statute by paying more than \$10 million over ten years to physicians and group practices in exchange for referrals. Allegedly, the recipients of the relocation payments were physicians who were either married or related to doctors established in the hospital's service area as further incentive for them to refer patients. Ultimately, the hospital paid \$21 million to resolve these kickback allegations.<sup>43</sup> In 2006, the same hospital system agreed to pay over \$47 million, as part of a \$900 million FCA settlement, to resolve allegations that the hospital system paid kickbacks to physicians for Medicare patient referrals and billed Medicare for services that were ordered or referred by physicians with whom the hospital system had an improper financial relationship.<sup>44</sup>

### Physician Self-Referral Prohibition Statute

The Stark Law<sup>45</sup> generally prohibits a physician from referring Medicare patients for certain designated health services (DHS) when those services are furnished by a DHS entity with which the physician has a financial relationship extending the general prohibition on referrals for remuneration in the Anti-Kickback Statute to self-referrals. A financial relationship under the Stark Law includes direct or indirect compensation or ownership/investment interests.<sup>46</sup> The Stark Law stems from the same concerns that both patients' interests and cost-containment initiatives are better served if physician referral decisions are isolated from any financial incentives arising from a physician's investment interests in a health care entity. Unlike the Anti-Kickback Statute, the Stark Law is a strict liability statute. The Stark Law works by prohibiting all referrals from physicians to DHS entities and then excepting certain categories of arrangements from that broad general prohibition. The numerous statutory exceptions to the ban and its overlap with the anti-kickback prohibition add significant complexity to the simplicity of the basic self-referral ban.

Final regulations governing the Stark Law were promulgated in January 2001 (Phase I), March 2004 (Phase II), September 2007 (Phase III), and August 2008. Additionally, in July 2007, April, 2008, and July, 2008, Centers for Medicare & Medicaid Services (CMS) proposed other revisions and additions to the Stark Law regulations.<sup>47</sup>

The Stark Law has been increasingly invoked by whistleblowers bringing federal FCA cases. For example, a health

services corporation paid \$7.5 million in January 2007 to resolve allegations that it made illegal payments to physicians in violation of the Stark Law, and in March 2004, a hospital paid \$22.5 million to resolve claims that the compensation that it had paid to physician employees did not represent fair market value in violation of the Stark law.

The Stark Law is discussed in detail in the chapter entitled "A Compliance Officer's Guide to the Stark Law and Regulations" at ¶20,950 - ¶20,980.

#### Footnotes

- 38 *United States v. Greber*, [760 F.2d 68](#) (3d Cir. 1985).
- 39 The Patient Protection and Affordable Care Act § 6402 ([PubLNo 111-148](#)) (2010).
- 40 *See Hanlester v. Shalala*, [51 F.3d 1390](#) (9th Cir. 1995).
- 41 The Patient Protection and Affordable Care Act § 6402 ([PubLNo 111-148](#)) (2010).
- 42 *United States v. Weinbaum*, 03CR-1587L (SD Cal. June 6, 2003).
- 43 [Summary, Office of the United States Attorney for the Southern District of California, May 17, 2006.](#)
- 44 Press Release, U.S. Dept. of Justice, Tenet Healthcare Corporation to Pay U.S. more than \$900 Million to Resolve False Claims Act Allegations (June 29, 2006), [http://www.usdoj.gov/opa/pr/2006/June/06\\_civ\\_406.html](http://www.usdoj.gov/opa/pr/2006/June/06_civ_406.html).
- 45 [42 U.S.C. §1395nn](#); [42 C.F.R. §411.350](#), et. seq.
- 46 42 U.S.C. §1395nn(a)(2).
- 47 *Proposed rules*, [72 FR 38122](#), July 12, 2007; [73 FR 23529](#), April 30, 2008; [73 FR 38502](#), July 7, 2008.

## ¶20,310 Civil Monetary Penalties Statute

Another federal law governing financial relationships between physicians and health care entities is the Civil Monetary Penalties Statute (CMP Law).<sup>48</sup> The CMP Law prohibits an entity from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care.<sup>49</sup> The Office of Inspector General guidance has stated that the payment does not have to be tied to a specific patient or a reduction in medically necessary care.<sup>50</sup> Violation of this provision subjects the entity and the offending physician to civil monetary penalties of up to \$2,000 per patient.<sup>51</sup>

Additionally, the CMP Law imposes monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary that the person knows, or should know, is likely to influence the beneficiary's choice of a provider or supplier of an item or service paid for by a federal health care program.<sup>52</sup>

### Footnotes

48 [42 U.S.C. §1320a-7a.](#)

49 42 U.S.C. §1320a-7(b).

50 [OIG Advisory Opinion No. 07-22 \(2008\).](#)

51 42 U.S.C. §1320a-7(b)(2).

52 42 U.S.C. §1320a-7(a).



## ¶20,312 Mail Fraud, Wire Fraud, Money Laundering, and Obstruction of Federal Audit Statutes

Other federal statutes that are used to prosecute individuals or entities that submit false health care claims include mail fraud, wire fraud, money laundering, and obstruction of federal audit statutes.

### Mail and Wire Fraud

As health care schemes invariably involve the mailing of invoices, bills, reimbursement checks, and numerous other documents, the mail fraud statute is also used to prosecute false health care claims.<sup>53</sup> The statute essentially prohibits anyone who has devised a scheme to defraud the government from using the mail to further that scheme. Case law provides that the concept of fraud under the statute is to be construed very broadly and that the definition of fraud also is to be liberally construed to further the purpose of the statute, which is to prohibit the misuse of the mail to further fraudulent enterprises.<sup>54</sup>

There are two elements required to prove mail fraud: (1) a scheme to defraud, and (2) use of the mail for the purpose of executing the scheme. The statute is applicable even when the only use of the mail involves the transmittal of insurance claims or the checks by which those claims were paid. For example, in *United States v. Collins*,<sup>55</sup> the owner and operator of several nursing homes was convicted of mail fraud for sending falsely inflated Medicaid cost reports to a state administrative agency.

Because the prerequisite elements of a scheme to defraud the government under both the mail fraud and the wire fraud statutes are identical, cases construing mail fraud apply to wire fraud as well. The only difference is that mail fraud requires the use of the mail, while wire fraud requires an interstate or foreign electronic transmission. Mail fraud can occur even if the mailing took place entirely within one state. Violation of the mail and wire fraud statutes involves severe penalties, including up to \$250,000 and imprisonment for up to five years.<sup>56</sup>

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended the mail fraud statute to allow the preindictment freezing of assets in federal health care investigations.<sup>57</sup>

### Money Laundering

In the battle against health care fraud, the government has successfully brought charges against defendants for money laundering.<sup>58</sup> If a health care provider obtains \$10,000 or more from a specified unlawful activity, such as from Medicare through submitting false claims, and later uses that money in a monetary transaction within the United States involving at least \$10,000 to or from an account in which the illegally obtained funds have been deposited, then the provider can be found guilty of money laundering.<sup>59</sup>

Although criminal penalties attach to violations of this statute, it is most frequently used to seize any property involved in the transaction.

### Federal Audit Statute

The obstruction of the federal audit statute is of particular importance to health care providers because audits are a main tool used by the government to monitor provider performance. Audits are usually the first step in any criminal investigation. The statute imposes substantial penalties upon any person or entity that receives in excess of \$100,000 from the government in any year and with intent to deceive or defraud the United States, endeavors to influence, obstruct, or impede a federal auditor in the performance of official duties relating to that person or entity.<sup>60</sup>

### Footnotes

<sup>53</sup> 18 U.S.C. §1341.

<sup>54</sup> See, e.g., *United States v. States*, [488 F.2d 761](#) (8th Cir. 1973).

<sup>55</sup> *United States v. Collins*, [596 F.2d 166](#) (6th Cir. 1979).

<sup>56</sup> 18 U.S.C. §1341 (mail fraud), §1343 (wire fraud), [§1347](#) (health care fraud), and §3571 (standard fines).

<sup>57</sup> HIPAA ([PubLNo. 104-191](#)), §247 codified at 18 U.S.C. § 1345. See also *United States v. Fang*, [937 F. Supp. 1186](#) (D. Md. 1996), in which prosecutors sought a preliminary injunction under the mail fraud statute to terminate a physician's scheme to defraud private health insurers and to freeze a significant portion of his assets.

<sup>58</sup> 18 U.S.C. §§1956 through 1957. See, e.g., *United States v. White*, [492 F.3d 380](#) (6th Cir. 2007); *United States v. Medina*, [485 F.3d 1291](#) (11th Cir. 2007); *United States v. Suba*, [132 F.3d 662](#) (11th Cir. 1998); *United States v. Contents of Four Bank Accounts*, [330 F. Supp. 2d 1299](#) (M.D. Ala. 2004).

<sup>59</sup> 18 U.S.C. §1957.

60 18 U.S.C. §1516.

## ¶20,314 RICO

Another statute that is used in health care fraud cases is the Racketeer Influenced and Corrupt Organizations Act (RICO). Four activities are prohibited under RICO:

- investing income that is derived directly or indirectly from a pattern of racketeering activity or through the collection of unlawful debt, in which the person has participated as a principal, to acquire an interest in or establish or operate an enterprise that is engaged in or affects interstate foreign commerce;
- acquiring or maintaining, directly or indirectly, through a pattern of racketeering activity or the collection of unlawful debt, any interest in or control of any enterprise that is engaged in or affects interstate or foreign commerce;
- for any person employed by or associated with an enterprise that is engaged in or affects interstate or foreign commerce, conducting or participating, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or the collection of unlawful debt;
- conspiring to commit any of the prohibited acts listed above.<sup>61</sup>

Racketeering activity includes specified federal and state crimes, including mail fraud and wire fraud. A pattern of racketeering activity requires at least two acts of racketeering activity, the most recent of which must have occurred within ten years after the commission of a prior act of racketeering activity.<sup>62</sup>

The statute of limitations for civil RICO actions is four years from the accrual of the cause of action, which begins to run when the plaintiff first knew or should have known of his or her injury.<sup>63</sup>

### Footnotes

61 [18 U.S.C. §1962](#).

62 [18 U.S.C. §1961\(a\)\(5\)](#).

63 *Agency Holding Corp. v. Malley-Duff & Assoc., Inc.*, 483 U.S. 143 (1987).

## ¶20,316 Fraud and Abuse Sanctions

The area of health care fraud and abuse is further complicated by the array of sanctions—criminal, civil, and administrative—that are available to curb fraudulent activities in the health care industry. Federal statutory authority over fraudulent billing arises from a variety of sources. Criminal penalties are available under the Medicare and Medicaid Statute itself for submitting false claims and engaging in other fraudulent billing activities. A violation of the Anti-Kickback Statute is also defined as a felony with penalties ranging from fines of \$25,000 to five years' imprisonment.<sup>64</sup>

In addition, federal officials can invoke statutes previously used against organized crime to battle fraud and abuse in the health care industry. Penalties that apply to false claims and fraudulent billing are available under some provisions of the mail and wire fraud provisions of the U.S. Criminal Code.<sup>65</sup> For example, the code prohibits the use of the mail for the purpose of executing any scheme by means of false or fraudulent representations. This statute can be used to prosecute false Medicare claims because it allows a court to issue an injunction to stop the activity and seize the defendant's assets.

Mail and wire fraud violations also may trigger the application of Racketeer Influenced and Corrupt Organizations Act (RICO).<sup>66</sup> RICO prohibits a person from receiving any income, directly or indirectly, from a pattern of racketeering activity involving the commission of a predicate act, such as mail or wire fraud. Under RICO, the fraudulent activity does not have to involve a violation of federal law, and accordingly, private insurance fraud also may be prosecuted under this statute.

The U.S. Criminal Code also prohibits what is commonly known as money laundering, and the government has prosecuted Medicaid and Medicare false claims under this provision.<sup>67</sup> The sanction for money laundering is a fine of up to \$500,000 and imprisonment for up to twenty years.<sup>68</sup>

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established five new criminal offenses related to health care fraud:

- knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money owned by, or under the custody or control of, any health care benefit program;<sup>69</sup>
- knowingly and willfully embezzling or stealing or converting to the use of any person, other than the rightful owner, or intentionally misapplying, any money or other assets of a health care benefit plan;<sup>70</sup>
- knowingly and willfully lying or covering up a material fact or making false statements in connection with the delivery of, or payment for, health care benefits;<sup>71</sup>
- willfully preventing, obstructing, misleading, delaying, or attempting to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a federal health care offense to a criminal investigator;<sup>72</sup>
- money laundering.

Civil, rather than criminal, sanctions, however, are the norm with respect to incidents of fraud and abuse in the health care industry. An entity or individual that commits an act in violation of the Anti-Kickback Statute is subject to a civil monetary penalty of not more than \$50,000 for each such act and an assessment of not more than three times the total amount of remuneration offered, paid, solicited, or received.<sup>73</sup> Additionally, the individual or entity can be excluded from participation in federal health care programs and subject to liability under the False Claims Act (FCA).<sup>74</sup>

Violations of the Stark Law can result in the repayment of all claims billed pursuant to improper referrals, civil monetary penalties up to \$15,000 for specified infractions and \$100,000 for a circumvention scheme, potential exclusion from federal health care programs, and FCA liability.<sup>75</sup>

The Office of Inspector General (OIG) has stated that self-disclosure of Anti-Kickback Statute and Stark Law violations can mitigate or resolve administrative liability.<sup>76</sup> The OIG developed its Provider Self-Disclosure Protocol (Protocol) in 1998<sup>77</sup> for providers not currently under investigation for the conduct to be disclosed and subsequently issued two open letters - in April 2006 and April 2008 - to health care providers encouraging the use of the Protocol to resolve violations of the Stark Law and the Anti-Kickback Statute. On March 24, 2009, the OIG announced two policy changes that served to (1) clarify when the Protocol should be used to address potential Stark Law violations; and (2) narrow the applicability of the OIG's April 24, 2006 Open Letter.<sup>78</sup> In the March 2009 guidance, the OIG encouraged health care providers to resort to the Protocol for potential Stark Law violations only if there were also potential Anti-Kickback

Statute violations. The OIG also stated that it will impose a minimum civil monetary penalty of \$50,000 for noncompliance with the Stark Law and the Anti-Kickback Statute reported under the Protocol. The OIG has stated that self-disclosure can result in a resolution of Anti-Kickback Statute violations at the lower end of the damages continuum and without a corporate integrity agreement (CIA) or corporate compliance agreement (CCA).<sup>79</sup>

The Patient Protection and Affordable Care Act (PPACA) creates a statutory protocol for violations of the Stark Law, especially for those categories that do not fall within the purview of the OIG Protocol.<sup>80</sup> This new protocol will provide for agency discretion to resolve Stark Law violations and authorizes HHS to reduce the amount due and owing for all violations under the Stark Law. HHS may consider such factors as the nature and extent of the improper practice, the timeliness of the disclosure, cooperation by the disclosing party, and other factors within HHS' discretion. PPACA requires CMS to develop the process and procedures for the self-disclosure protocol by the end of September 2010.

Fraudulent billing practices may be the object of civil claims under the FCA.<sup>81</sup> Under this statute, any person who knowingly presents a false or fraudulent claim for payment to the government is liable for damages of up to three times the amount of damages sustained by the federal government in addition to civil penalties ranging between \$5,500 and \$11,000.<sup>82</sup> Case law has established that each false claim is a separate violation of the law and generates liability for a separate penalty. The government has had some major successes in recovering civil monetary damages under the FCA. Health care providers need to be aware that false bills, or even erroneous bills resulting from clinical errors, especially if they are repeated over time, can have severe financial consequences under the FCA.

The most damaging sanction available in the area of health care fraud and abuse is exclusion from federal health care programs. In accordance with the Balanced Budget Act of 1997, the OIG enacted a final rule in 2002 to expand the scope of exclusion beyond Medicare and state health care programs to all federal health care programs.<sup>83</sup> Federal program exclusion can be either mandatory or permissive. Certain violations of the Medicare and Medicaid statute, including a conviction for patient neglect or abuse, are subject to mandatory exclusions of a minimum of five years. Any felony conviction for the offense of health care fraud created in HIPAA<sup>84</sup> is also subject to mandatory exclusion. The statute enumerates a number of activities that could subject a provider or entity to permissive exclusion. Briefly, under the statutory list, the OIG has the authority to exclude a provider on the basis of either a previous action by a court, licensing board, or agency, or its own administrative finding of wrongdoing. Notably, in *Inspector General v. Hanlester Network*,<sup>85</sup> the OIG exercised its civil sanction authority with respect to alleged violations of the Anti-Kickback Statute without relying on a previous conviction.

#### Footnotes

64 [42 U.S.C. §1320a-7b\(a\)](#).

65 18 U.S.C. §§1341 and 1343.

66 [18 U.S.C. §1961\(a\)\(1\)](#).

67 18 U.S.C. §§1956; *see United States v. States*, 488 F.2d 761 (8th Cir. 1973).

68 18 U.S.C. §1956.

69 HIPAA ([PubLNo. 104-191](#)).

70 *See* [18 U.S.C. §669](#).

71 *See* 18 U.S.C. §1035.

72 *See* [18 U.S.C. §1518](#).

73 [42 U.S.C. §1320a-7a\(a\)](#).

74 42 U.S.C. §1320a-7a(a).

75 [42 U.S.C. 1395nn\(g\)](#).

76 [OIG Open Letter to Providers, April 24, 2006](#). [See also OIG Open Letter to Providers, April 15, 2008](#).

77 *See Notice*, 63 FR 5839, Oct. 30, 1998.

78 [OIG Open Letter to Providers, March 24, 2009](#).

79 *See* 42 U.S.C. § 1320a-7a(a)(7). CMPs for Anti-Kickback Statute violations are based on the number and dollar value of improper payments or remuneration between the parties.

80 The Patient Protection and Affordable Care Act § 6409 ([PubLNo 111-148](#)) (2010).

81 [31 U.S.C. §§ 3729](#) through [3733](#).

82 28 C.F.R. § 85.3(a)(9).

- 83 *Final rule*, [67 FR 11928](#), March 18, 2002; [42 C.F.R. §§ 1001.102\(c\), 1001.951, and 1001.952](#).
- 84 HIPAA ([Pub. L. No. 104-191](#)).
- 85 Departmental Appeals Board, Civil Remedies Division, Docket Nos. C-186-C-192, C-208, C-213, March 1, 1991.

## ¶20,318 State Fraud and Abuse Laws

At the state level, many legislatures have enacted statutes that parallel the federal government's initiatives in combating health care fraud and abuse. This legislation frequently prohibits provider self-referral of patients to health care facilities in which the provider has a financial interest. State legislation also regulates certain financial transactions between health care practitioners, banning remuneration in the form of kickbacks or bribes in exchange for the referral of patients. State law also governs fraudulent billing practices, with false claims acts and insurance fraud statutes in some jurisdictions.

In *State v. Harden*,<sup>86</sup> the Florida Court of Appeals concluded that the federal Anti-Kickback Statute preempted the stricter Florida Medicaid anti-kickback statute of 2000, which prohibited conduct legal under the federal statute. The Florida statute did not contain any safe harbors, and it contained a lower *mens rea* standard, which permitted a violation based on negligence. The court found that the Florida statute was preempted and, thus, unconstitutional under the Supremacy Clause. The Supreme Court of the United States denied review in April 2007. Although the decision in *Harden* is limited to the interpretation of the Florida statute, it suggests that, to the extent that state anti-kickback statutes are more restrictive than the federal statute, they may be subject to a successful challenge.

The Deficit Reduction Act of 2005 (DRA)<sup>87</sup> mandates that states ensure that any entity receiving annual Medicaid payments of at least \$5 million educate its employees on the FCA and its whistleblower provisions. Additionally, the DRA contained financial incentives for states to pass their own versions of the federal FCA. If a state false claims act is determined by the OIG to meet certain requirements, the state is entitled to an increase of ten percentage points in its share of any amounts recovered under a state action brought under such a law. As of May 2010, the OIG had approved the false claims acts of fourteen states - California, Georgia, Hawaii, Illinois, Indiana, Massachusetts, Michigan, Nevada, New York, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.<sup>88</sup> For a description of state false claim laws see the chapter entitled "Summary of State Civil False Claims Laws," in the Basics of the Law section at ¶20,376 - ¶20,378.

### Footnotes

- 86 *State v. Harden*, [873 So.2d 352](#) (Fla. Dist. Ct. App. 2004), *aff'd*, [938 So.2d 480](#) (Fla. 2006), *cert. denied*, 127 S. Ct. 2097 (2007).
- 87 [Deficit Reduction Act of 2005](#), § 6031(a), 42 U.S.C.A. §1396h (2007).
- 88 OIG State False Claims Act Reviews, <http://www.oig.hhs.gov/fraud/falseclaimsact.asp>.