

# Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview

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## Summary

A number of federal statutes aim to combat fraud and abuse in federally funded health care programs such as Medicare and Medicaid. Using these statutes, the federal government has been able to recover billions of dollars lost due to fraudulent activities. In March 2010, Congress enacted comprehensive health care reform legislation. One focus of this legislation, the Patient Protection and Affordable Care Act (PPACA) as amended, is improved health care fraud and abuse enforcement. PPACA, among other things, creates new health care fraud enforcement tools and expands upon the types of prohibited conduct. This report provides an overview of some of the more commonly used statutes used to fight health care fraud and abuse and discusses some of the changes made to these statutes by PPACA.

Title XI of the Social Security Act contains Medicare and Medicaid program-related anti-fraud provisions, which impose civil penalties, criminal penalties, as well as exclusions from federal health care programs on persons who engage in certain types of misconduct. PPACA amends these administrative sanctions and authorizes the imposition of several new civil monetary penalties and exclusions.

Under the federal anti-kickback statute, it is a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value (i.e., "remuneration") in return for a referral or to induce generation of business reimbursable under a federal health care program. The statute prohibits both the offer or payment of remuneration for patient referrals, as well as the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or ordering of any item or service that is reimbursable by a federal health care program. PPACA revises the evidentiary standard under the anti-kickback statute and eliminates the requirement of actual knowledge of, or specific intent to commit a violation of the statute. This amendment may make it easier for the government to prove its case.

The Stark law and its implementing regulations prohibit physician self-referrals for certain health services that may be paid for by Medicare or Medicaid. Under the Stark law, if (1) a physician (or an immediate family member of a physician) has a "financial relationship" with an entity, the physician may not make a referral to the entity for the furnishing of these health services for which payment may be made under Medicare or Medicaid, and (2) the entity may not bill the federal health care program or any individual or entity for services furnished pursuant to a prohibited referral. PPACA limits certain exceptions to the Stark law.

The federal False Claims Act (FCA) imposes civil liability on persons who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving federal government money or property. Health care program false claims often arise in billing, including billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or billing for services at a higher rate than provided ("upcoding"). Civil actions may be brought in federal district court under the FCA by the Attorney General or by a person known as a relator (i.e., a "whistleblower"), for the person and for the U.S. Government, in what is termed a *qui tam* action. PPACA appears to make it easier for certain relators to bring qui tam actions, thus potentially allowing some FCA actions to proceed that would have been dismissed under prior law.

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The issue of health care fraud and abuse<sup>1</sup> has attracted a lot of attention in recent years, primarily because the financial losses attributed to it are estimated to be billions of dollars annually.<sup>2</sup> Based on the fact that the Medicare and Medicaid programs make up the largest single purchaser of health care in the world and over 20% of all U.S. federal government spending, it is not surprising that these federal health programs have been considered prime targets for fraudulent activity.<sup>3</sup> Thus, efforts to address this fraud and abuse continue to be a priority for Congress.

Prior to the enactment of comprehensive health reform legislation this year,<sup>4</sup> the federal government had an array of statutes that it used to fight health care fraud. The Patient Protection and Affordable Care Act (PPACA), among other things, expanded upon a number of the existing provisions. This report provides a brief overview of some of the key federal statutes, including program-related civil and criminal penalties, the anti-kickback statute, the Stark law, and the False Claims Act, that are used to combat fraud and abuse in federal health care programs.<sup>5</sup> This report also addresses some of the amendments made to these statutes by PPACA.<sup>6</sup>

## **Basic Civil and Criminal Penalties and Exclusions**

#### Overview

Title XI of the Social Security Act contains Medicare and Medicaid program-related anti-fraud provisions, which impose penalties and exclusions from federal health care programs on persons who engage in certain types of misconduct.<sup>7</sup> Under Section 1128A of the Social Security Act, the

<sup>&</sup>lt;sup>1</sup> Health care "fraud" has been described as an intentional attempt to wrongfully collect money relating to medical services, while "abuse" has been described as actions which are inconsistent with acceptable business and medical practices. *See* Alice G. Gosfield, MEDICARE AND MEDICAID FRAUD AND ABUSE 6 (2008).

<sup>&</sup>lt;sup>2</sup> FBI reports estimate that fraudulent billings to both public and private health care programs make up between three and ten percent of total health care expenditures. Federal Bureau of Investigation, Financial Crimes Report to the Public: Fiscal Year 2009, available at http://www.fbi.gov/publications/financial/fcs\_report2009/ financial\_crime\_2009.htm#health.

<sup>&</sup>lt;sup>3</sup> Stephen M. Blank, Justin Alexander Kaspisin and Allison C. White, *Health Care Fraud*, 46 Am. Crim. L. Rev. 701 (2009) (citing A Closer Look: Inspectors General Address Waste, Fraud, Abuse in Federal Mandatory Programs: Hearing Before the House Comm. on Budget, 108<sup>th</sup> Cong. 82 (2003) (testimony of Dara Corrigan, Acting Principal Deputy Inspector General, Department of Health and Human Services). See also CRS Report RL34217, *Medicare Program Integrity: Activities to Protect Medicare from Payment Errors, Fraud, and Abuse*, by Holly Stockdale.

<sup>&</sup>lt;sup>4</sup> P.L. 111-148 (2010). PPACA was amended by the Health Care Education and Reconciliation Act of 2010, P.L. 111-152 (2010). (HCERA). These Acts will be collectively referred to in this report as "PPACA."

<sup>&</sup>lt;sup>5</sup> This report only addresses some of the more commonly invoked statutes used to address fraud and abuse in federal health care programs. For example, this report does not address federal health care program integrity activities, certain administrative initiatives designed to fight fraud, waste, and abuse. For general information on Medicare Program Integrity, see CRS Report RL34217, *Medicare Program Integrity: Activities to Protect Medicare from Payment Errors, Fraud, and Abuse*, by Holly Stockdale. It is also important to note that many states have enacted fraud and abuse legislation. This report does not address state law.

<sup>&</sup>lt;sup>6</sup> It should also be noted that PPACA contains numerous provisions relating to health care fraud enforcement that are not addressed in this report. For a discussion of some of these additional provisions, see CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*, coordinated by Patricia A. Davis, and CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in PPACA*, coordinated by Julie Stone.

<sup>&</sup>lt;sup>7</sup> "Federal health care program" is defined as (1) any plan or program that provides health benefits, whether directly, (continued...)

Office of the Inspector General at the Department of Health and Human Services (OIG) is authorized to impose civil penalties and assessments on a person, including an organization, agency, or other entity, who engages in various types of improper conduct with respect to federal health care programs, including the imposition penalties against a person who knowingly presents or causes to be presented to a federal or state employee or agent certain false or fraudulent claims.<sup>8</sup> For example, penalties apply to services that were not provided as claimed, or claims that were part of a pattern of providing items or services that a person knows or should know are not medically necessary.<sup>9</sup> In addition, certain payments made to physicians to reduce or limit services are also prohibited. This section provides for monetary penalties of up to \$10,000 for each item or service claimed, up to \$50,000 under certain additional circumstances, as well as treble damages.

Section 1128B of the Social Security Act provides for criminal penalties involving federal health care programs. Under this section, certain false statements and representations, made knowingly and willfully, are criminal offenses. For example, it is unlawful to make or cause to be made false statements or representations in either applying for benefits or payments, or determining rights to benefits or payments under a federal health care program. In addition, persons who conceal any event affecting an individual's right to receive a benefit or payment with the intent to either fraudulently receive the benefit or payment (in an amount or quantity greater than that which is due), or convert a benefit or payment to use other than for the benefit of the person for which it was intended may be criminally liable. Persons who have violated the statute and have furnished an item or service under which payment could be made under a federal health program may be guilty of a felony, punishable by a fine of up to \$25,000, up to five years imprisonment, or both. Other persons involved in connection with the provision of false information to a federal health program may be guilty of a misdemeanor and may be fined up to \$10,000 and imprisoned for up to one year.<sup>10</sup>

One of the most severe sanctions available under the Social Security Act is the ability to exclude individuals and entities from participation in federal health care programs.<sup>11</sup> Under Section 1128 of the Social Security Act, exclusions from federal health programs are mandatory under certain circumstances, and "permissive" in others (i.e., OIG has discretion in whether to exclude an entity or individual).<sup>12</sup> Exclusion is mandatory for those convicted of certain offenses, including (1) a criminal offense related to the delivery of an item or service under Medicare, Medicaid, or a state health care program; (2) a criminal offense relating to neglect or abuse of patients in connection

<sup>12</sup> 42 U.S.C. § 1320-7.

<sup>(...</sup>continued)

through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government [not including health insurance provided to federal government employees] or (2) any state health care program, as defined in section 1128(h) [42 U.S.C. § 1320a-7(h)]. 42 U.S.C. § 1320a-7b(f). Federal health care programs include Medicare and Medicaid.

 $<sup>^{8}</sup>$  42 U.S.C. § 1320a-7a. Civil penalties do not apply to beneficiaries under this provision. Under 42 U.S.C. § 1320a-7a(i)(5), a beneficiary is defined as an individual who is eligible to receive items or services for which payment may be made under a federal health care program, but excludes any providers, suppliers, or practitioners. However, it may be noted that beneficiaries still may be subject to criminal penalties under 42 U.S.C. § 1320a-7b.

<sup>&</sup>lt;sup>9</sup> Several other types of prohibited conduct subject to civil penalties are specified by the statute. See 42 U.S.C. § 1320a-7a(a)-(b).

<sup>&</sup>lt;sup>10</sup> 42 U.S.C. § 1320a-7b(a)(6).

<sup>&</sup>lt;sup>11</sup> It has been stated that exclusion from federal health care programs can be a "financial death sentence" for those in the health care industry who depend on these programs for business. HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, 32 (Linda Baumann ed. 2002).

with the delivery of a health care item or service; or (3) a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. OIG has "permissive" authority to exclude an entity or an individual from a federal health program under numerous circumstances, including conviction of certain misdemeanors relating to fraud, theft, embezzlement, breach of fiduciary duty or other financial misconduct; a conviction based on an interference with or obstruction of an investigation into a criminal offense; and revocation or suspension of a health care practitioner's license for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.<sup>13</sup>

### **New Civil Monetary Penalties and Exclusions**

PPACA amends the administrative sanctions and authorizes the imposition of new civil monetary penalties for persons who knowingly

- order or prescribe a medical or other item or service during a period in which the person was excluded from a federal health care program when the person knows or should know that a claim for the item or service will be made under the program;<sup>14</sup>
- make or cause to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a federal health care program;
- fail to report and return an overpayment within specified time limits;
- fail to grant the OIG timely access (upon reasonable request) for the purpose of audits, investigations, evaluations, or other statutory functions; and
- make or use a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program.<sup>15</sup>

As with other misconduct for which a civil monetary penalty may be imposed, the Secretary may also exclude from participation in federal health care programs persons who engage in these activities.<sup>16</sup>

## The Anti-Kickback Statute

### Overview

In light of the concern that decisions of health care providers can be improperly influenced by a profit motive,<sup>17</sup> and in order to protect federal health care programs from additional costs and overutilization, Congress enacted the anti-kickback statute. Under this criminal statute, it is a

<sup>&</sup>lt;sup>13</sup> See 42 U.S.C. § 1320-7a(b) for additional circumstances under which OIG has permissive authority to exclude individuals and other entities from a federal health care program.

<sup>&</sup>lt;sup>14</sup> 42 U.S.C. § 1320a-7a(a)(8).

<sup>&</sup>lt;sup>15</sup> P.L. 111-148, §§ 6402(d); 6408(a).

<sup>&</sup>lt;sup>16</sup> 42 U.S.C. § 1320a-7(b)(7).

<sup>&</sup>lt;sup>17</sup> 63 Fed. Reg. 1659, 1662 (Jan. 9, 1998).

felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value (i.e., "remuneration") in return for a referral or to induce generation of business reimbursable under a federal health care program.<sup>18</sup> The statute prohibits both the offer or payment of remuneration for patient referrals, as well as the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or ordering of any item or service that is reimbursable by a federal health care program. Persons found guilty of violating the anti-kickback statute may be subject to a fine of up to \$25,000, imprisonment of up to five years, and exclusion from participation in federal health care programs for up to one year.

There are certain statutory exceptions to the anti-kickback statute. Under one exception, "remuneration" does not include a discount or other reduction in price obtained by a provider of services or other entity if the reduction in price is properly disclosed and reflected in the costs claimed or charges made by the provider or entity under a federal health care program.<sup>19</sup> Another exception includes, under certain circumstances, amounts paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals that furnish services reimbursable by a federal health program. In addition to these exceptions, the Department of Health and Human Services' Office of Inspector General (OIG) has promulgated regulations that contain several "safe harbors" to prevent common business arrangements from being considered kickbacks.<sup>20</sup> Safe harbors listed by regulation include certain types of investment interests, personal services and management contracts, referral services, and space rental or equipment rental arrangements. OIG has indicated that the safe harbor provisions are not indicative of the only acceptable business arrangements, and that business arrangements that do not comply with a safe harbor are not necessarily considered "suspect."<sup>21</sup>

### **Revising the Intent Requirement**

Prior to PPACA, courts reached varying conclusions as to what it meant for a defendant to "knowingly and willfully" violate the anti-kickback statute. For example, the Ninth Circuit found that "knowingly and willfully" meant that the government must prove that defendants (1) knew their conduct was a violation of the anti-kickback statute and (2) still engaged in the conduct with the "specific intent" to disobey the law.<sup>22</sup> Conversely, in *United States v. Starks*, the Eleventh Circuit found that the "knowingly and willfully" standard was met if defendants knew their conduct was generally unlawful, regardless of whether the defendants knew they were violating the anti-kickback statute.<sup>23</sup>

Section 6402(f) of PPACA revises the evidentiary standard under the anti-kickback statute.<sup>24</sup> PPACA states that in order to establish a violation of Section 1128B of the Social Security Act, including the anti-kickback statute, a defendant does not have to have actual knowledge of, or

<sup>&</sup>lt;sup>18</sup> 42 U.S.C. § 1320a-7b(b).

<sup>&</sup>lt;sup>19</sup> See 42 U.S.C. § 1320a-7b(b)(3) for additional exceptions to the anti-kickback statute.

<sup>&</sup>lt;sup>20</sup> See 42 C.F.R. § 1001.952 for the safe harbor provisions. For a discussion of each of the safe harbors, see Dan McGuire and Mac Scheider, HEALTH CARE FRAUD, 46 Am. Crim. L. Rev. 701 (2009).

<sup>&</sup>lt;sup>21</sup> 64 Fed. Reg. 63,518, 63,521 (Nov. 19, 1999).

<sup>&</sup>lt;sup>22</sup> Hanlester Network v. Shalala 51 F.3d 1390, 1399-1400 (9<sup>th</sup> Cir. 1995).

<sup>&</sup>lt;sup>23</sup> United States v. Starks, 157 F.3d 833 (11<sup>th</sup> Cir. 1998).

<sup>&</sup>lt;sup>24</sup> It should be noted that this new intent requirement of PPACA may apply to all of section 1128B of the Social Security Act, not just the anti-kickback statute. The implications of changing the intent requirement for other subsections of section 1128B is outside the scope of this report.

specific intent to commit a violation of, the anti-kickback statute. However, it should be noted that PPACA did not remove the requirement that a defendant must still "knowingly and willfully" offer or pay remuneration to induce prohibited referrals or other business under the anti-kickback statute. Thus, the government may still have to prove that the defendant knew that the conduct in question was unlawful,<sup>25</sup> but not that it was a violation of the anti-kickback statute per se. Still, it appears that the amendments made by PPACA may make it easier for the government to prove an anti-kickback statute violation. This may may encourage increased use of the anti-kickback statute.

## Stark Law: Physician Self-Referrals

### Overview

Limitations on physician self-referrals were enacted into law in 1989 under the Ethics in Patient Referrals Act, commonly referred to as the "Stark law."<sup>26</sup> The Stark law, as amended, and its implementing regulations prohibit certain physician self-referrals<sup>27</sup> for designated health services (DHS) that may be paid for by Medicare or Medicaid. In its basic application, the Stark law provides that if (1) a physician (or an immediate family member of a physician) has a "financial relationship" with an entity, the physician may not make a referral to the entity for the furnishing of designated health services (DHS)<sup>28</sup> for which payment may be made under Medicare or Medicaid, and (2) the entity may not present (or cause to be presented) a claim to the federal health care program or bill to any individual or entity for DHS furnished pursuant to a prohibited referral.<sup>29</sup> It has been noted that the general idea behind the prohibitions in the Stark law is to prevent physicians from making referrals based on financial gain, thus preventing overutilization and increases in health care costs.<sup>30</sup>

<sup>&</sup>lt;sup>25</sup> See, e.g., Bryan v. U.S., 524 U.S. 184 (1998) ("As a general matter, when used in the criminal context, "willful" act is one undertaken with a "bad purpose." In other words, in order to establish a "willful" violation of a statute, "the Government must prove that the defendant acted with knowledge that his conduct was unlawful." (footnotes omitted)

<sup>&</sup>lt;sup>26</sup> The Stark law, created as Section 1877 of the Social Security Act and codified at 42 U.S.C. § 1395nn, was created by the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, 103 Stat. 2423 (1989). The Stark law was significantly amended by the Omnibus Budget Reconciliation Act of 1993, P.L. 103-66, §13562, 107 Stat. 312 (1993) and is commonly referred to as "Stark II." Regulations for Stark II have been issued by the Centers for Medicare and Medicaid Services (CMS) and are comprehensive. *See* 42 C.F.R. § 411.350 et seq.

<sup>&</sup>lt;sup>27</sup> "Referral," as defined by the Stark law, includes the request of a physician for an item or service, as well as an establishment of a plan of care that involves furnishing DHS. 42 U.S.C. §1395nn(h)(5).

<sup>&</sup>lt;sup>28</sup> A list of "designated health services" can be found at 42 U.S.C. § 1395nn(h)(6). Services include clinical laboratory services, physical therapy services, and inpatient and outpatient hospital services.

<sup>&</sup>lt;sup>29</sup> While both the anti-kickback statute and the Stark law may apply to physician self-referrals, the statutes differ "in scope and structural approach." 64 Fed. Reg. 63518, 63520 (Nov. 19, 1999). The anti-kickback statute is a criminal law that requires improper intent for a violation and has statutory and regulatory "safe harbors" that do not aim to define the full range of lawful activity. *Id.; see also* Linda A. Baumann, *Navigating the New Safe Harbors to the Anti-Kickback Statute*, 12 Health Lawyer 1, 4 (2000). The Stark law, on the other hand, is a civil law, and a transaction must fall entirely within an exception to be lawful, regardless of the parties' intent. *Id.* Therefore, even if an arrangement is acceptable under the Stark law, it may violate the anti-kickback statute if there is improper intent to induce referrals. Baumann, 12 Health Lawyer at 4.

<sup>&</sup>lt;sup>30</sup> See, e.g., 66 Fed. Reg. 856, 859 (Jan. 4, 2001) ("Prior to enactment of section 1877 [of the Social Security Act], there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships (some of these studies involved compensation as well). Increased utilization occurred whether the (continued...)

A "financial relationship" under the Stark law consists of either (1) an "ownership or investment interest" in the entity or (2) a "compensation arrangement" between the physician (or immediate family member) and the entity. An "ownership or investment interest" includes "equity, debt, or other means," as well as "an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." A "compensation arrangement" is generally defined as an arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity, other than certain arrangements that are specifically mentioned as being excluded from the reach of the statute. The Stark law includes a large number of exceptions, which have been added and expanded upon by a series of regulations. These exceptions may apply to ownership interests,<sup>31</sup> compensation arrangements,<sup>32</sup>

Violators of the Stark law may be subject to various sanctions, including a denial of payment for relevant services and a required refund of any amount billed in violation of the statute that had been collected. In addition, civil monetary penalties and exclusion from participation in Medicaid and Medicare programs may apply. A civil penalty not to exceed \$15,000, and in certain cases not to exceed \$100,000, per violation may be imposed if the person who bills or presents the claim "knows or should know" that the bill or claim violates the statute.<sup>34</sup>

### **PPACA Amendments to Stark Law Exceptions**

#### Whole Hospital Exception

Under the "whole hospital exception" to the Stark law existing prior to PPACA, a physician could have referred a patient to a hospital in which the physician had an investment or ownership interest, and a hospital could have presented claims for DHS to Medicare or Medicaid, so long as (1) the referring physician was authorized to perform services at the hospital, and (2) the ownership or investment interest was in the whole hospital, and not just a subdivision of it.<sup>35</sup> Legislative history accompanying the new health reform legislation described the reasoning behind this exception:

35 42 U.S.C. § 1395nn(d)(3).

<sup>(...</sup>continued)

physician owned shares in a separate company that provided ancillary services or owned the equipment and provided the services as part of his or her medical practice. This correlation between financial ties and increased utilization was the impetus for section 1877 of the Act.").

<sup>&</sup>lt;sup>31</sup> Exceptions applicable to ownership arrangements include arrangements involving rural providers, hospital ownership, and ownership of publicly traded securities and mutual funds. *See* 42 U.S.C. § 1395nn(c) and implementing regulations.

<sup>&</sup>lt;sup>32</sup> Exceptions applicable to compensation arrangements include office space and equipment rental arrangements, physician recruitment, as well as bona fide employment relationships. *See* 42 U.S.C. § 1395nn (e) and implementing regulations.

<sup>&</sup>lt;sup>33</sup> Exceptions applicable to both types of financial relationships under the Stark law include physician services performed by another physician in the same group practice, in-office ancillary services, and certain services performed under a prepaid plan. *See* 42 U.S.C. § 1395nn(b) and implementing regulations.

<sup>&</sup>lt;sup>34</sup> For additional information on the Stark law and description of each of the Stark law exceptions, *see* CRS Report RL32494, *Medicare: Physician Self-Referral ("Stark I and II")*, by Jennifer O'Sullivan.

When originally enacted, the physician self-referral laws included an allowance for physicians to have ownership in a whole hospital. It was included because, at the time, there were a number of rural hospitals in particular where such ownership arrangements were in effect. Ownership in a whole hospital was not then viewed as a significant incentive for self-referral because these hospitals were usually the only hospitals in the area and they provided a breadth of services. The original physician self-referral law did explicitly prohibit ownership in "a subdivision of a hospital" because of the concern that if physicians owned only their particular part of a hospital—like a cardiac wing—there would be an incentive for self-referral.<sup>36</sup>

The legislative history also suggests that the whole hospital exception promotes the growth of physician-owned specialty hospitals, which typically provide a limited range of hospital services. It noted that these specialty hospitals "too often focus on high-profit services, fail to have fully-staffed emergency rooms, and treat low percentages of Medicaid patients or uncompensated care patients compared to other hospitals in their communities."<sup>37</sup>

Section 6001 of PPACA made changes to the Stark law by placing new restrictions on the hospitals elgible for the whole hospital exception.<sup>38</sup> For example, under this section, the whole hospital exception cannot be met unless the hospital has (1) physician ownership or investment as of December 31, 2010, and (2) a Medicare provider agreement in effect on that date. Thus, beginning December 31, 2010, new physician-owned hospitals may be prohibited from meeting the whole hospital exception. In addition, after the enactment date of PPACA (i.e., March 23, 2010), existing physician-owned hospitals may not add new beds, operating rooms or procedure rooms unless the hospital meets certain specified criteria. Existing hospitals must also meet additional requirements requirements regarding conflicts of interest, bona fide investments, and patient safety issues. Further, a facility cannot convert from an ambulatory surgical center to a hospital after the date of enactment of PPACA.

#### **In-Office Ancillary Services**

The Stark law includes a general exception permitting physicians and group practices to order and provide certain DHS in their offices when they meet certain statutory requirements. Under this exception, the statute limits who can furnish the service, designates where the service must be performed, and limits who can bill for the service.<sup>39</sup> Although it was intended to protect the convenience of patients and to allow patients to receive certain services during their doctor visits, some were concerned that this exception has the potential to promote the overuse of these services.<sup>40</sup>

<sup>&</sup>lt;sup>36</sup> H.R. Rep. No. 111–443, H.R. 4872, The Reconciliation Act of 2010 (2010) at 355.

<sup>&</sup>lt;sup>37</sup> Id.

 $<sup>^{38}</sup>$  It should be noted that the new restrictions on physician-owned hospitals also apply to rural providers. 42 U.S.C.  $\$  1395nn(d)(2)(C).

<sup>&</sup>lt;sup>39</sup> 75 Fed. Reg. 40040 (July 13, 2010).

<sup>&</sup>lt;sup>40</sup> As pointed out in a recent Medpac report: "[0]n the one hand, proponents of the [in-office ancillary services] exception argue that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. On the other hand, there is evidence that physician investment in ancillary services leads to higher volume through greater overall capacity and financial incentives for physicians to order additional services. In addition, there are concerns that physician ownership could skew clinical decisions." Medicare Payment Advisory Commission, Report to the Congress, Alligning Incentives in Medicare, June 2010, available at http://www.medpac.gov/documents/ (continued...)

Section 6003 of PPACA addresses these concerns by adding new disclosure requirements to the in-office ancillary services exception. Wth respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services determined by the Secretary, the referring physician must inform the individual in writing at the time of the referral that the individual may obtain the services from a person other than the referring physician, or an individual who is directly supervised by the physician or by another physician in the group practice. The individual must be provided with a written list of suppliers who furnish these services in the area in which the individual resides.

After the enactment of PPACA, questions arose as to the effective date of Section 6003, given that the section specifies that it applies to services furnished prior to the enactment of PPACA (i.e., on or after January 1, 2010). However, regulations proposed by CMS have interpreted the section as not being self-effectuating, and propose that this amendment apply only to services rendered after the effective date of the final regulations.<sup>41</sup> CMS has proposed an effective date of January 1, 2011, for the regulations implementing this provision.

## **False Claims Act**

#### Overview

The federal False Claims Act (FCA), codified at 31 U.S.C. §§ 3729-3733, is considered by many to be an important tool for combating fraud against the U.S. government. The FCA is a law of general applicability that is invoked frequently in the health care context.<sup>42</sup> In general, the FCA imposes civil liability on persons who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving federal government money or property.<sup>43</sup> Health care program false claims often arise in terms of billing, including billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or

<sup>43</sup> Under 31 U.S.C. § 3729, the FCA imposes liability on a person who: (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); (D) has possession, custody, or control of property or money used, or to be used, by the government and knowingly delivers, or causes to be delivered, less than all of that money or property; (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the government, makes or delivers the receipt without completely knowing that the information on the receipt is true; (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, 31 U.S.C. § 3729. Additional liability may also flow from any retaliatory action taken against those who seek to stop violations of the False Claims Act. 31 U.S.C. § 3730(h).

<sup>(...</sup>continued)

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<sup>&</sup>lt;sup>41</sup> 75 Fed. Reg. 40040, 40142 (July 13, 2010).

<sup>&</sup>lt;sup>42</sup> The Department of Justice reported that the recovery in health care industry FCA cases accounted for approximately two-thirds of the \$22 billion recovered by the government in FCA cases between 1986 and 2008. United States Department of Justice, Civil Division, "Fraud Statistics, Overview October 1, 1986-September 30, 2008" (Nov. 5, 2008).

billing for services at a higher rate than provided ("upcoding"). Penalties under the FCA include treble damages, plus an additional penalty of \$5,500 to \$11,000 for each false claim filed.

Civil actions may be brought in federal district court under the FCA by the Attorney General or by a person known as a relator (i.e., a "whistleblower"), for the person and for the U.S. Government, in what is termed a *qui tam* action. The ability to initiate a *qui tam* action has been viewed as a powerful weapon against health care fraud, in that it may be initiated by a private party who may have independent knowledge of any wrongdoing.<sup>44</sup> Popularity of *qui tam* actions brought under the FCA may be attributed partially to the fact that successful whistleblowers can receive between 15% and 30% of the monetary proceeds of the action or settlement that are recovered by the government.<sup>45</sup> In 2009, Congress passed the Fraud Enforcement Recovery Act (FERA),<sup>46</sup> which amended the FCA to undo some narrow judicial interpretations and, in general, expand the application of the act.<sup>47</sup>

### PPACA Amendments to the Public Disclosure Bar

The public disclosure bar of the FCA prevents relators from bringing an action based on certain publicly disclosed information. It has been noted that "Congress designed the public disclosure bar to achieve the 'golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own."<sup>48</sup> Prior to the enactment of PPACA, the FCA's public disclosure provision specified that a court does not have jurisdiction over an action that is based upon public disclosure of information in (1) a criminal, civil, or administrative hearing, (2) in a congressional, administrative, or Government Accountability Office (GAO) report, hearing, audit, or investigation, or (3) from the news media, unless the action is brought by the Attorney General or the relator bringing the action is an "original source" of the information.<sup>49</sup> A relator was defined as an original source if the relator had direct and independent knowledge of the information on which the allegations of the FCA claim are based and had voluntarily provided the information to the government before filing an action.<sup>50</sup>

<sup>&</sup>lt;sup>44</sup> HEALTH LAW, 50 (Barry Furrow 2d ed. 2000).

<sup>&</sup>lt;sup>45</sup> Prosecution under the FCA may also be more attractive for the government. It has been pointed out that the terms of the act are relatively simple and straightforward, and can be applied generally to all types of healthcare providers. See Dayna Bowen Matthew, AN ECONOMIC MODEL TO ANALYZE THE IMPACT OF FALSE CLAIMS ACT CASES ON ACCESS TO HEALTHCARE FOR THE ELDERLY, DISABLED, RURAL AND INNER-CITY POOR, 27 Am. J. L. and Med. 439 (2001). Further, because it is a civil statute, there is an easier burden of proof to meet ("preponderance of the evidence") as opposed to a criminal statute ("beyond a reasonable doubt"). *Id.* 

<sup>&</sup>lt;sup>46</sup> P.L. 111-21, 123 Stat. 1617 (2009).

<sup>&</sup>lt;sup>47</sup> See S.Rept. 111-10, Fraud Enforcement and Recovery Act of 2009 (Mar. 23, 2009)("The effectiveness of the False Claims Act has recently been undermined by court decisions which limit the scope of the law and, in some cases, allow subcontractors paid with Government money to escape responsibility for proven frauds.") For a general discussion of the amendments made by FERA, *see* CRS Report R40785, *Qui Tam: The False Claims Act and Related Federal Statutes*, by Charles Doyle.

<sup>&</sup>lt;sup>48</sup> H.Rept. 111-97, False Claims Act Correction Act of 2009, (May 5, 2009)(quoting United States ex rel. Springfield Terminal Rwy. Co. v. Quinn, 14 F.3d 645, 649 (D.C. Cir. 1994). As explained in a Senate report, the goal of the public disclosure bar "was to ensure that any individual qui tam relator who came forward with legitimate information that started the government looking into an area it would otherwise not have looked, could proceed with an FCA case." S.Rept. 110-507, The False Claims Act Correction Act of 2008, 110<sup>th</sup> Congress (Sept. 17, 2008) (citations omitted).

<sup>49 31</sup> U.S.C. § 3730(e)(4)(A).

<sup>&</sup>lt;sup>50</sup> 31 U.S.C. § 3730(e)(4)(B).

Section 1313(a)(6) of PPACA amends the FCA's public disclosure bar to limit the application of the bar under certain circumstances, thus potentially allowing some FCA actions to proceed that would have been dismissed under prior law.<sup>51</sup> Among the changes to the public disclosure bar, a court is compelled to dismiss an FCA action or claim, "*unless opposed by the government*, if substantially the same" allegations or transactions had been publicly disclosed (italics added). Thus, PPACA appears to give the federal government some discretion over whether certain actions may be allowed to proceed under the public disclosure bar. The scope of this discretion (e.g., whether a court will be forced to hear a case when the government has opposed a dismissal) is not further addressed by the statute and may be evaluated by the courts.

Further, PPACA provides that an FCA action must be dismissed if the allegations or transactions in question had been publicly disclosed in a congressional, GAO, or other *federal* report, hearing, audit, or investigation (italics added). This language legislatively overruled the Supreme Court's holding in *U.S. ex rel. Wilson v. Graham County Soil & Water Conservation District*,<sup>52</sup> which found that the public disclosure bar of the FCA precluded a relator from bringing an action based on publicly available information in state or local government reports. As amended by PPACA, the public disclosure bar may only place limits on FCA actions based on information disclosed in federal sources or the news media. While the *Wilson* decision was issued after the enactment of PPACA, the Court explained that the changes made by PPACA to the public disclosure bar are not retroactive. Thus, for cases pending prior to the enactment of PPACA, the *Wilson* decision is still relevant.

PPACA also changed the definition of who qualifies as an original source for purposes of the public disclosure bar. Prior to PPACA, a relator was considered an original source if the relator had "direct and independent knowledge" of the information on which the allegations of the FCA claim are based and had voluntarily provided the information to the government before filing an action.<sup>53</sup> Under PPACA, an original source is one who (1) has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or (2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing an action.<sup>54</sup> While it has been noted that this amendment expands the persons that can be an original source, <sup>55</sup> questions may still arise about this definition (e.g., what does it mean to have information that "materially adds" to the publicly disclosed information).

<sup>&</sup>lt;sup>51</sup> See Manager's Amendment to the Patient Protection and Affordable Care Act, Section-by-Section Analysis, prepared by Majority staff, on file with author.

<sup>&</sup>lt;sup>52</sup> 130 S. Ct. 3351 (2010).

<sup>53 31</sup> U.S.C. § 3730(e)(4)(B).

<sup>54 31</sup> U.S.C. § 3730(e)(4)(B).

<sup>&</sup>lt;sup>55</sup> See generally Judith Thorn, Health Care Reform Law Strengthens Government's Ability to Pursue Fraud, Abuse, BNA Health Care Fraud Report (Apr. 7, 2010).

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