



HEALTH CARE REFORM INCLUDES AGGRESSIVE FRAUD INITIATIVE: HHS OIG, DOJ, AND CONGRESS RAMP UP ENFORCEMENT AND PREVENTION EFFORTS

Health care fraud and abuse enforcement has not escaped the health care reform sweeping the country. In recent years, billions of dollars have been recovered through settlements and judgments related to health care fraud investigations, and government officials, facing reform-related budget concerns, are looking to continue with the aggressive fraud recovery efforts. According to Tony West, the Assistant Attorney General for the Department of Justice’s (“DoJ”) Civil Division, “[f]ederal and state spending on Medicare and Medicaid exceeds \$800 billion per year,” and “external estimates project the amount [of health care fraud] at three to ten percent (3% - 10%) of total spending.”¹

Although health care is already a highly regulated area of expenditure, the repercussions of recent legislation and policy changes related to fraud enforcement have yet to be seen. This legislation includes enhanced federal enforcement tools, program integrity initiatives, industry-related transparency requirements, and increased funding for health care fraud enforcement and prevention. This *Commentary* focuses on the amendments to current federal enforcement tools, including the False Claims Act² (“FCA”) and the federal anti-kickback statute,³ that significantly increase the exposure of health care providers, pharmaceutical companies, and medical device manufacturers to civil and criminal liability.

In addition to the legislative changes, the DoJ has announced that other enforcement efforts will focus on actively analyzing Medicare data to identify fraud

1 Statement of Assistant Attorney General Tony West Before the Senate Judiciary Committee Entitled “Effective Strategies for Preventing Health Care Fraud,” Wednesday, October 28, 2009. <http://www.justice.gov/dag/testimony/2009/dag-testimony-091028.html>.

2 31 U.S.C. §§ 3729-33.

3 42 U.S.C. § 1320a-7b.

“hot spots” and expanding strike force operations to those areas, enhanced training programs on enforcement measures for prosecutors and investigators, increased compliance training for providers to help stop potential fraud before it happens, and increased interagency coordination and state enforcement efforts.

FEDERAL FRAUD ENFORCEMENT STATUTES

The False Claims Act (“FCA”). The FCA is the government’s primary civil tool to combat fraud and abuse in federal funding and procurement. In the health care arena, this usually relates to false or fraudulent claims for Medicare and Medicaid reimbursement. The aggressive pursuit of health care fraud by the Office of the Inspector General of the Department of Health and Human Services (“HHS OIG”) and the DoJ includes using the FCA to prosecute a variety of acts relating to Medicare and Medicaid claims, including unlawful marketing and distribution of misbranded and adulterated drugs, kickbacks to providers, and inflated drug pricing. Under the qui tam provisions, private citizens, or “relators,” may file suit on behalf of the United States against those who have falsely or fraudulently claimed federal funds. The DoJ must then decide on behalf of the government whether to intervene or allow the relator to pursue the action alone.

Recovery under the FCA includes three times the government’s loss plus a civil penalty of \$5,500 to \$11,000. Of this recovery, a relator may claim 15 to 25 percent if the government intervenes in the qui tam action, or up to 30 percent if the government declines to intervene. In the fiscal year ending September 30, 2009, the United States government collected \$2.4 billion in settlements and judgments in cases involving fraud against the government.⁴ Almost \$2 billion was obtained through lawsuits filed under the qui tam provisions of the FCA related to fraudulent claims for Medicare reimbursement for services that were not medically necessary or, in some circumstances, never provided.

4 *Justice Department Recovers \$2.4 Billion in False Claims Cases in Fiscal Year 2009; More Than \$24 Billion Since 1986.* Department of Justice News Release. November 19, 2009. <http://www.prnewswire.com/news-releases/justice-department-recovers-24-billion-in-false-claims-cases-in-fiscal-year-2009-more-than-24-billion-since-1986-70521362.html>

The Anti-Kickback Statute and Stark Laws. The Anti-Kickback Statute is a criminal statute that prevents pharmaceutical manufacturers, physicians, and pharmacists from offering or receiving anything of value in return for patient referrals or ordering of goods or services. Violations of the Anti-Kickback Statute are considered felonies, with criminal penalties of up to \$25,000 in fines and five years in prison.

The Stark Laws⁵ are civil statutes that similarly prohibit health care providers from profiting from referrals of patients for specific “designated health services” that are made by a physician with whom the provider has an improper compensation arrangement. Violations of the Stark Laws can result in denial of payment for the prohibited services, refunding of payments, monetary penalties ranging from \$15,000 to \$100,000, and exclusion from federal program participation.

FCA and the Implied False Certification Theory. In recent years, the HHS OIG and the DoJ have been pushing to extend the reach of the FCA under an implied false certification theory. The HHS OIG and the DoJ are wielding the FCA as a tool to extend the reach of the Anti-Kickback Statute and the physician referral prohibition statutes, collectively known as the Stark Laws. Under this theory, in submitting a claim for reimbursement to Medicare, a health care provider impliedly certifies that it has not violated any Medicare statutes and regulations, including the Anti-Kickback Statute. Thus, Anti-Kickback violations may be sufficient to trigger FCA liability if payment was made by the health care provider as an inducement to refer Medicare patients or to order goods or services reimbursable by Medicare. Even if a referral was not actually induced, the health care provider may still be liable. Moreover, even if the health care provider actually provided the services for which it billed Medicare, the services may be considered tainted by the fraud (Anti-Kickback violation), and thus the reimbursement claims are considered false. Under this interpretation of the law, the government or relator does not have to demonstrate actual damages in order to state a claim under the FCA. False certification theory has also been applied to Stark Law violations. For example, if a health care provider leases office space to a physician at a rate below fair-market value or compensates a physician at rates above fair-market

5 42 C.F.R. §§ 411.350-89.

value, all “designated health services” provided to patients referred by that physician are considered tainted and fall under False Claims Act liability.

Bootstrapping an Anti-Kickback or Stark action to FCA liability can very quickly escalate potential liability into the \$100 million range. In addition, civil penalties can involve up to \$50,000 in fines and exclusion from federal program participation. Moreover, recovery under the FCA is not limited to false or fraudulent claims. Rather, the government may claim three times the amount of legitimate services of a tainted health care provider that were billed to Medicare and Medicaid for reimbursement. Adding civil penalties of \$5,500 to \$11,000 per occurrence leads to astronomical liability.

AMENDMENTS TO FEDERAL FRAUD ENFORCEMENT STATUTES

Fraud Enforcement and Recovery Act of 2009.⁶ Health care fraud investigations are now bolstered by powerful civil litigation tools aimed at improving health care fraud enforcement and prevention initiatives. For instance, recently enacted legislation provides the DoJ with increased freedom to conduct civil investigations into health care fraud before the entity under investigation is allowed to begin discovery. Under the Fraud Enforcement and Recovery Act of 2009, the Attorney General may delegate the power to issue civil investigative demands (“CIDs”) under the FCA to the Assistant Attorney General for the Civil Division. On January 15, 2010, the Attorney General signed an order delegating this power to Tony West, who was also permitted to redelegate the authority to U.S. Attorneys. These CIDs provide for early discovery and allow U.S. Attorneys to subpoena documents, depositions, and interrogatories before filing a complaint or joining a qui tam action. The Fraud Enforcement and Recovery Act of 2009 also gives the DoJ more freedom to share information obtained using CIDs with whistleblowers and federal and state agencies. This will likely increase government participation in qui tam actions as well as the number of independent government actions.

6 Public Law No: 111-21.

Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010.⁷ These acts (together, the “health care reform legislation”) have the following effects.

Amendments to the FCA. The health care reform legislation has expanded FCA liability. First, regulations on qui tam actions have been greatly expanded.⁸ Previously, a qui tam relator was barred from bringing an action based on information that had been subject to a “public disclosure” unless the relator was the “original source” of the information. The recent legislation removes the jurisdictional bar for allegations based on publicly disclosed information and relaxes the “original source” requirements, making it easier for a qui tam relator to qualify to bring an action. Together, these amendments will enable a greater number of whistleblowers to bring claims, increasing the exposure to qui tam actions. Second, overpayments that are not reported and returned within 60 days after the date identified or the date that a corresponding cost report is due are now considered an “obligation” under the FCA and are the basis for civil monetary penalties.⁹

Amendments to the Anti-Kickback Statute. Amendments to the Anti-Kickback Statute will also increase provider exposure to anti-kickback violations and FCA liability. These amendments codify the false certification theory and provide that a violation under the Anti-Kickback Statute constitutes a false or fraudulent claim that is a sufficient basis for FCA liability.¹⁰ In addition, the health care reform legislation has amended the intent standard under the Anti-Kickback Statute, reducing the burden of proof. Previously, a defendant had to act “knowingly and willfully” to be found liable. Now, “a person need not have actual knowledge or specific intent to commit a violation” to be liable for anti-kickback violations.¹¹

7 H.R. 3590 and H.R. 4872, respectively.

8 H.R. 3590, Sec. 1303.

9 H.R. 3590, Sec. 6402.

10 H.R. 3590, Sec. 6402.

11 H.R. 3590, Secs. 6402, 10606.

Stark Laws. In one area that will potentially help health care providers reduce their exposure to liability, the health care reform legislation addresses the current lack of self-disclosure of Stark Law violations and requires the Secretary of HHS to establish a new self-referral disclosure protocol, while permitting HHS to accept reduced payment of less than the full Stark Law measure of damages in appropriate circumstances.¹²

PRACTICE TIPS

It is important to be aware of the increasingly aggressive pursuit of health care fraud occurring at the federal and state levels. Finally, providers must be prepared for the financial repercussions of a fraud investigation. Under the health care reform legislation, CMS may suspend Medicare payments to providers pending an investigation of a credible allegation of fraud. It is critical to get good professional advice when embarking on a practice or agreement that could touch on a gray area of compliance and to document that advice to reflect the provider's good faith efforts. As always, an ounce of prevention from a rigorous compliance program is far more effective than the pound of cure required to respond to an investigation.

The health care reform legislation has also dramatically changed the compliance landscape. Providers are required to implement compliance programs that must include certain "core elements" to be determined by the Secretary of HHS that are specific to providers and suppliers within each industry or category. Federal legislative changes also provide for increased transparency of financial relationships between industry and providers. In some areas, this pre-empts similar "sunshine laws" enacted by some states, but the overlap is not complete, and providers must analyze compliance under both federal and state laws. As an example, federal reform legislation includes not just physicians but also "teaching hospitals" as providers, and it establishes

12 H.R. 3590, Sec. 6409.

transparency requirements for pharmacy benefit managers, nursing homes, and physicians that provide in-office ancillary services (e.g., MRI, CT, and PET scans).

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