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HEALTH CARE LAW MONTHLY welcomes your comments and opinions. Please direct all correspondence and editorial questions to: Adriana Sciortino, LexisNexis Matthew Bender, 121 Chanlon Road, New Providence, NJ 07974 (1-908-771-8662); e-mail: adriana.sciortino@lexisnexis.com. For all other questions, call 1-800-833-9844. NOTE: The information herein should not be construed as legal advice, nor utilized to resolve legal problems.

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The Federal Government's Heightened False Claims Act Enforcement and Prosecution – Recent Trends and Practical Solutions

By
Patricia S. Hofstra¹ and Elinor L. Hart²

Introduction

Several recent developments in the health care enforcement environment have increased the capacity of the federal government to detect and punish health care fraud. The Affordable Care Act (“ACA”) enhanced the federal government’s ability to combat fraud and abuse by creating a public and private partnership between private and public insurers, permitting stiffer sentences for health care fraud, and creating enhanced screening of Medicare and Medicaid providers for potential fraudulent activity.³ In addition, relatively new Medicare fraud strike force has harnessed the capacities of federal, state and local investigators to use Medicare data analysis techniques and increased focus on community policing to combat fraud.⁴ The federal government has not delayed acting on this new authority. Within just the last two months, the federal government implemented its “sixth national Medicare fraud takedown,”⁵ raising

the government’s arrest and charge record to more than 1,500 individual providers across nine major Medicare networks with recoveries of nearly \$2 billion since the 2007 inception of Medicare fraud strike force operations.⁶

The False Claims Acts (“FCA”) is at the forefront of this resurgence in enforcement and prosecution by the federal government, with many recent lawsuits alleging a variety of improper billing practices based on the submission of medically unnecessary claims⁷ or claims for services that were not rendered.⁸ Recent trends suggest that these aggressive enforcement activities are not coming to an end. Even more disconcerting for health care providers is the public and private partnership between the federal government and private insurers, which presents a unique risk that federal investigations will be followed by overpayment demands, claims of insurance fraud, or other adverse conduct by private insurers.⁹ As a result, anyone representing providers in the health care industry must understand the severe penalties that may be imposed for potentially improper billing and the practical solutions built into the healthcare laws that can help alleviate exposure.

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³ The ACA created a first-ever private and public partnership to combat health care fraud that will allow for data sharing between State and Federal government agencies and private health insurance companies. The new initiative was announced in July 2012. Press Release, Dep’t of Health & Human Servs., Obama administration announces groundbreaking public-private partnership to prevent health care fraud (July 26, 2012), available at <http://www.hhs.gov/news/press/2012pres/07/20120726a.html>.

⁴ <http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/index.html>.

⁵ Press Release, Dep’t of Justice Office of Public Affairs, Medicare Fraud Strike Force Charges 89 Individuals for Approximately \$223 Million in False Billing (May 14, 2013), available at <http://www.justice.gov/opa/pr/2013/May/13-crm-553.html>. These takedowns are being conducted as part of the Medicare Health Care Fraud Prevention & Enforcement Team, otherwise known as “HEAT.” *Id.* HEAT was established in 2009 by the Department of Health and Human Services and the Department of Justice.

⁶ *Id.*

⁷ See 42 U.S.C. § 1395y(a)(1)(A) (stating that Medicare pays only for services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”).

⁸ See Press Release, *supra* note 4.

⁹ By way of limited example, Amerigroup Corporation, BCBS, Humana, Travelers, and WellPoint all joined the federal government’s public and private partnership. See Press Release, *supra* note 3. As HHS details, one of the primary purposes of the public/private partnership is to share information on “specific schemes, utilized billing codes and geographical fraud hotspots.” *Id.* Longer term goals include a partnership that spots and stops payments billed to different insurers, and a quicker response in identifying and responding to health care fraud. *Id.*

False Claims Act – The Basics

The federal civil FCA¹⁰ imposes liability on anyone who knowingly submits or causes the submission of a false or fraudulent claim to the government. “The purpose of the FCA is to discourage fraud against the government.”¹¹ Specifically, the FCA, in relevant part, imposes liability on:

[A]ny 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 . . .¹²

The FCA only applies to offenses committed “knowingly,” which the FCA defines as actions where the person: “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” Specific intent to defraud is not required.¹³

A “claim” under the FCA is equally as broad. Under the FCA a “claim”:

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded¹⁴

In addition to the civil FCA, there is also a criminal FCA that contains similar provisions.¹⁵ Claims under the criminal FCA have three elements:

- (1) a false or fraudulent claim;
- (2) presented to an agency of the government;
- (3) and the defendant had knowledge of the claim’s falsity.

Like the civil FCA, the criminal FCA uses a “knowledge” requirement that includes:

- (1) knowledge that a claim in question is false;
- (2) avoidance of knowledge that a claim is false; or
- (3) acting in reckless disregard of the truth of a claim.

The criminal FCA, however, does not authorize the government to prosecute health care providers and entities for mistakes, honest errors, or negligence even if they result in billing errors or erroneous claims.¹⁶ In cases of mistake, honest error, or negligence, the provider must still refund the monies, but the provider will not be subject to civil, administrative, or criminal penalties under the civil or criminal FCA.

Penalties for FCA violations may be stiff. An individual—including individual providers—found liable under the civil FCA may be subject to fines of \$5,000 to \$10,000 *per claim*, plus 3 times the amount of damages which the government sustains because of the acts.¹⁷ Violations of the criminal FCA

¹⁰ 31 U.S.C. § 3729–3731.

¹¹ *Cell Therapeutics Inc. v. Lash Group Inc.*, 2009 U.S. App. LEXIS 25297, at *3 (9th Cir. Nov. 18, 2009).

¹² 31 U.S.C. § 3729.

¹³ 31 U.S.C. § 3729(b); *see also* *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 2005 U.S. Dist. LEXIS 36427, at *24–*25 (D.N.J. Dec. 21, 2005):

[T]he term “knowingly” means that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or the falsity of the information. . . . Congress specifically amended the FCA in 1986 to include this definition of scienter, to make “firm . . . its intention that the Act does not punish honest mistakes or incorrect claims submitted through mere negligence.”

¹⁴ A claim does not include, however, “requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property.” 31 U.S.C. § 3729(b).

¹⁵ 18 U.S.C. § 287.

¹⁶ *See, e.g.*, Remarks of then Deputy Attorney General Eric H. Holder, Jr. to the American Hospital Association, February 1, 1999, *available at* <http://www.usdoj.gov/archive/dag/speeches/1999/holderahaspeech.htm>; <http://www.justice.gov/dag/readingroom/chcm.htm>; *see also* *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995) (“Innocent mistakes or negligence are not actionable under this section.”).

¹⁷ 31 U.S.C. § 3729(a).

also carry the risk of incarceration for up to five years, as well as fines.¹⁸

FCA Trends in Enforcement and Prosecution

The federal government has aggressively used the FCA over the last several years to enforce and prosecute alleged violations of various federal laws. These efforts have resulted in several significant settlements and claims, and recent cases illustrate that the government is targeting services and providers for submitting claims that were not medically necessary.

For example, on June 28, 2012 the Health and Human Services Office of Inspector General (“OIG”) announced a settlement with Bethany Lutheran Homes, Inc., a skilled nursing facility.¹⁹ The federal government alleged that Bethany Lutheran Homes had provided medically unnecessary physical, occupational and speech therapy, and had improperly billed Medicare for such services.²⁰ Bethany Lutheran Homes paid a \$675,000 settlement, and entered into a Corporate Integrity Agreement (“CIA”), which is an agreement with the OIG that typically involves the settlement of allegations and contains agreement from the provider to implement certain business practices, as well as an

agreement from the OIG not to seek Medicare or Medicaid exclusion or other certain penalties.²¹ A similar settlement was reached with the Fairfax Nursing Center in February 2013, after allegations by the federal government that Fairfax Nursing Center provided “excessive, medically unnecessary, or otherwise non-reimbursable physical, occupational, and speech therapy services. . . .”²² Fairfax Nursing Center settled the claims for \$700,000.²³

On May 2, 2013, the federal government also filed an FCA lawsuit against Chemed Corporation, the largest for-profit hospice chain in the United States.²⁴ The complaint covers conduct that allegedly occurred in 18 states, and alleges that Chemed Corporation and its various subsidiaries knowingly submitted claims for services that were (1) not medically necessary, (2) not actually provided, or (3) not performed in accordance with Medicare requirements.²⁵

Laboratories and individual providers have also been subject to allegations that their claims were for medically unnecessary services. For example, in April 2012, the OIG settled an FCA case against Calloway Laboratories, a clinical toxicological laboratory that perform urine drug testing services.²⁶ The United States alleged that Calloway Labs impermissibly paid kickbacks to health care providers, falsified provider signatures on requisition forms, and received payment from federal health care

¹⁸ 18 U.S.C. § 287.

¹⁹ In November 2012 the OIG released a report targeting skilled nursing facilities (“SNFs”) and highlighting the federal government’s concerns that SNFs are billing a quarter of their claims in error and are costing the federal government over \$1 billion per year. Dep’t of Health & Human Servs., Office of Inspector General, *Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars in 2009* (Nov. 2012), available at <http://oig.hhs.gov/oei/reports/oei-02-09-00200.pdf>. The report also found that SNFs misreported information on approximately 47% of claims submitted to Medicare, and that the majority of inappropriate claims resulted from improper upcoding for services provided. *Id.* at p. 14.

²⁰ Press Release, United States Attorney’s Office for the Southern District of Iowa, *Council Bluffs Area Nursing Home Reaches Settlement Agreement on Allegations of Fraudulent Billing to Medicare for Physical, Occupational, and Speech Therapy Services* (June 28, 2012) available at <http://www.justice.gov/usao/ias/news/2012/Bethany%20Lutheran%20Homes%206-28-2012.html>.

²¹ U.S. Dep’t of Health & Human Servs., Office of Inspector General, <http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> (last visited July 28, 2012). Examples of recent CIAs include a CIA for Pinnacle Medical Solutions, http://oig.hhs.gov/fraud/cia/agreements/Pinnacle_Medical_Solutions_062120102.pdf, Abbott Laboratories, http://oig.hhs.gov/fraud/cia/agreements/Abbott_Laboratories_05072012.pdf, and Harmon Memorial Hospital, http://oig.hhs.gov/fraud/cia/agreements/Harmon_County_Healthcare_Authority_dba_Harmon_Memorial_Hospital_and_or_Harmon_County_Healthcare_Trust_06132012.pdf.

²² Press Release, Dep’t of Justice Office of Public Affairs, *Northern Virginia Therapy Provider to Pay \$700,000 to Resolve False Claims Act Allegations* (Feb. 13, 2013) available at <http://www.justice.gov/opa/pr/2013/February/13-civ-193.html>.

²³ *Id.*

²⁴ Press Release, Dep’t of Justice Office of Public Affairs, *United States Files False Claims Act Lawsuit Against the Largest For-Profit Hospice Chain in the United States* (May 2, 2013) available at <http://www.justice.gov/opa/pr/2013/May/13-civ-500.html>.

²⁵ *Id.*

²⁶ Press Release, United States Attorney’s Office for the District of Massachusetts, *Calloway Laboratories to Pay Over \$7.71 Million to Resolve False Claims Act Allegations* (Apr. 3, 2012) available at <http://www.justice.gov/usao/ma/news/2012/April/CallowayPR.html>.

programs for medically unnecessary urine drug tests.²⁷ Calloway Laboratories paid \$7.71 million to resolve the federal government's claims, and entered into a CIA with the OIG which specified mandatory procedures for correcting Calloway's billing and other practices that had led to the improper billing.²⁸

Dr. Steven J. Wasserman suffered a similar fate. In February 2013, the OIG announced that it and Dr. Wasserman settled the federal government's FCA case for a staggering \$26.1 million, one of the largest individual FCA settlements in history.²⁹ The FCA accused Dr. Wasserman, a dermatologist, of having an illegal kickback arrangement with Tampa Pathology Laboratory, under which Dr. Wasserman sent biopsy specimens for testing and diagnosis to the laboratory.³⁰ Through allegedly falsified records, Dr. Wasserman would then bill Medicare for the laboratory testing as if he had done the work.³¹ Dr. Wasserman was also accused of performing "thousands of unnecessary skin surgeries" for the sole purpose of obtaining reimbursement, even though the surgeries were not medically necessary.³²

On the morning of August 6, 2013, the DOJ also arrested and charged Dr. Farid Fata in a criminal FCA case alleging that Dr. Fata submitted over \$35 million in medically unnecessary claims to Medicare.³³ Specifically, the complaint alleges that Dr. Fata, by way of example: (1) submitted fraudulent claims to Medicare for medically unnecessary services (i.e. chemotherapy treatments); (2) falsified and directed others to falsify documents to justify cancer treatments for billing purposes; (3) performed unnecessary chemotherapy on patients in remission;

(4) deliberately misdiagnosed patients as having cancer to justify unnecessary cancer treatment; and (5) distributed controlled substances to patients without medical necessity.³⁴

Finally, several recent settlements emphasize that certain higher volume procedures or products are particularly suspect in the eyes of the federal government, and are at risk of being categorized as "medically unnecessary." By way of limited example, in July 2013 the OIG settled a claim for \$4 million based on allegations that Jackson Cardiology Associates and its owner, Dr. Jashu Patel, improperly submitted claims for procedures that were medically unnecessary.³⁵ The government alleged that Dr. Patel ordered catheterizations for patients based on tests that he read incorrectly, even though 75% of the patients had no medical need for a catheterization. The settlement also covered allegations that Allegiance Health, a nearby hospital, improperly performed medically unnecessary peripheral stents.³⁶ RS Medical, a durable medical equipment company, also paid the federal government \$1.2 million to settle allegations that RS Medical billed Medicare for medically unnecessary medical equipment.³⁷

These recent cases show a trend: the federal government is maximizing its fraud and abuse recoveries under the FCA by focusing on industries and services that typically generate higher volumes of claims, making testing laboratories, skilled nursing facilities, and other related service providers at the greatest risk for enforcement activity.

Practical Solutions – Preventing Improper Billing Practices and Minimizing Exposure

Providers on the federal government's FCA enforcement radar are not without options. HHS has

²⁷ *Id.*

²⁸ *Id.*

²⁹ Press Release, Dep't of Justice Office of Public Affairs, Florida Physician to Pay \$26.1 Million to Resolve False Claims Allegations (Feb. 11, 2013) available at <http://www.justice.gov/opa/pr/2013/February/13-civ-183.html>.

³⁰ *Id.*

³¹ *Id.*

³² *Id.* See also United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., 2005 U.S. Dist. LEXIS 36427, at *22 (D.N.J. Dec. 23, 2005) (noting that "[m]ore common examples of falsity include the billing of the government for medically unnecessary care, or billing for more hours than that for which care was actually rendered.").

³³ Press Release, Dep't of Justice Office of Public Affairs, Oakland County Doctor and Owner of Michigan Hematology [sic] and Oncology Centers Charged in \$35 Million Medicare Fraud Scheme (Aug. 6, 2013), available at <http://www.justice.gov/opa/pr/2013/August/13-crm-885.html>.

³⁴ *Id.*

³⁵ Press Release, United States Attorney's Office for the Eastern District of Michigan, United States Intervenes in Health Care Fraud Action And Obtains \$4 Million in Settlement (July 10, 2013) available at http://www.justice.gov/usao/mie/news/2013/2013_7_10_jpatel_HCF.html.

³⁶ *Id.*

³⁷ Press Release, United States Attorney's Office for South Carolina, \$1.2 Million Settlement With Durable Medical Equipment Company, International Rehabilitative Sciences D/B/A RS Medical Resolves South Carolina False Claims Act Lawsuit (May 16, 2013), available at <http://www.justice.gov/usao/sc/news/5.16.13.rsmedical.html>.

developed three tools that can assist providers to identify improper billing concerns, prevent improper billing practices, and minimize exposure: compliance plans, voluntary refunds of overpayments and, if appropriate, self-disclosure.

Compliance Plans

Well developed and appropriately implemented compliance programs are a key to preventing improper billing practices. In fact, pursuant to a mandate in the ACA, all skilled nursing and nursing facilities were to “have in operation a compliance and ethics program” as of March 23, 2013.³⁸ The compliance and ethics programs assist facilities in preventing and detecting criminal, civil, and administrative violations—such as those under the FCA—and to promote quality of care within the facility.³⁹ The ACA further requires that each compliance and ethics program contain eight components:

- (1) Establish procedures that are reasonably capable of reducing the prospect of civil, criminal, and administrative violations;
- (2) Assign specific high-level individuals with overall responsibility to oversee compliance (including having sufficient resources and appropriate authority);
- (3) Use due care not to delegate substantial discretionary authority to an individual the organization knows or should know has a propensity to engage in civil, criminal, or administrative violations;
- (4) Implement effective communication of standards and procedures to all employees and agents of the organization
- (5) Take reasonable steps to maintain compliance with standards, including regular monitoring and auditing of processes and systems and refunds of overpayments, if necessary;

³⁸ Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, Section 6102 (Mar. 23, 2010). Although the ACA also required CMS to promulgate regulations under Section 6102, to date CMS has not yet done so. Nonetheless, the statutory mandate still exists, so affected facilities refusing to comply do so at their own risk.

³⁹ *Id.*

- (6) Consistently enforce standards through appropriate disciplinary mechanisms;
- (7) Take corrective measures to modify practices and procedures if an offense is discovered; and,
- (8) Periodically reassess the compliance program.⁴⁰

The issues targeted by compliance and ethics programs—quality of care billing issues, medical necessity, and upcoding—are precisely the issues the OIG is targeting in its heightened enforcement efforts. All providers, and not only skilled nursing facilities, are therefore well-advised to implement a meaningful and effective compliance and ethics program that involves employee training and education, standard operating procedures for employees to anonymously report suspected abuses, and high-level managerial oversight over the program and suspected violations.

Refunds of Overpayments

If a provider’s compliance plan or other audit reveals an overpayment for any reason, including a lack of medical necessity, a new provision under the ACA⁴¹ also requires providers to report and return the overpayment. While CMS has not yet issued final regulations under this new section, providers are still subject to the statutory requirements. Proposed regulations issued in February 2012⁴² shed light on how CMS intends the refund process works. In short, any person who receives an overpayment must report and return the overpayment and provide written notification of the reason for the overpayment within 60 days after the date on which the overpayment was identified or the date any corresponding cost reports are due.⁴³

The procedure for reporting and returning overpayments under the ACA will take the same form as the existing voluntary refund process, but with the new name of “self-reported overpayment refund process.” This process requires providers to submit a form identifying the affected claims; how the error was discovered; corrective action plans implemented

⁴⁰ *Id.*

⁴¹ *Id.* Section 6402(a).

⁴² Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (Feb. 16, 2012).

⁴³ *Id.*

to prevent future errors; the reason for the refund; whether a corporate integrity agreement is in place; the time frame and total refund for the period in which the error occurred; certain claim-identifying information; and a description of statistical sampling methodology used to identify the overpayment, if any.⁴⁴

The obligation to report and return an overpayment is triggered when a person has “identified” an overpayment, *i.e.* if the person has actual knowledge of or acts in reckless disregard or deliberate ignorance of the overpayment.⁴⁵ Once an overpayment is identified, the failure to report and return overpayments can subject a provider or supplier to civil monetary penalties, potential liability under the FCA or even exclusion from the Medicare program.⁴⁶

Self-Disclosure

Finally, providers seeking to minimize FCA exposure may consider CMS’ self-disclosure protocol. CMS’ recently updated provider self-disclosure protocol provides a mechanism for providers, nursing facilities, testing laboratories, and other affected entities to disclose potential violations of federal laws including the FCA, the Federal anti-kickback statute, or other Federal criminal, civil, or administrative laws for which civil monetary penalties are authorized.⁴⁷ The self-disclosure protocol generally requires a disclosing party to disclose: (1) the potential violation, (2) the law that was potentially violated, (3) the details of the violation and potential damages, (4) an acknowledgement that the conduct constituted a potential violation, and (5) a description of the corrective action taken, among other basic information about the disclosing party.⁴⁸ For potential damages relating to improper claims, such as

claims lacking medical necessity or the required quality of care, the self-disclosure protocol also requires the offending party to review either all affected claims, or select a statistically valid random sample of claims.⁴⁹

The risks and benefits of self-disclosure must be carefully weighed prior to disclosure, including whether self-disclosure will trigger additional investigations into other areas of the provider’s practice. The OIG’s self-disclosure protocol evidences the OIG’s belief that self-disclosure shows the effectiveness of a compliance program, that cooperative individuals or entities deserve a lower multiplier for damages than would otherwise be used in a government-initiated investigation, and that self-disclosure may result in timelier resolution of potentially problematic practices.⁵⁰ All providers considering self-disclosure must carefully analyze whether it is appropriate in any given case.

Conclusion

Health care fraud and abuse is of increasingly significant concern, and even alleged violations have the potential to adversely affect a health care provider’s business. The federal government’s expanded efforts to combat health care fraud and abuse under the FCA therefore raise new and unique questions for providers and managers of health care providers, particularly in light of the public and private partnership that could create simultaneous liability from public and private payors. As recent trends show, the failure to adequately understand and support claims may subject providers to the full panoply of penalties, monetary and criminal, under the Federal FCA, and more is expected to come.

⁴⁴ *Id.* at 9181.

⁴⁵ *Id.* at 9180.

⁴⁶ *Id.* at 9181.

⁴⁷ U.S. Dep’t of Health & Human Servs., Office of Inspector General, OIG’s Provider Self-Disclosure Protocol (Apr. 17, 2013), *available at* <http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*