

COMPLIANCE PERSPECTIVES



George B. Breen



Rebekah N. Plowman



Emily E. Bajcsi

George B. Breen,
Rebekah N. Plowman,
and Emily E. Bajcsi
are health care
attorneys with the
law firm of Epstein,
Becker & Green

What the Government's Increased Enforcement Efforts Could Mean for Health Care Providers

The first two months of 2010 have seen the political stars align for the passage of stand-alone health care fraud legislation. First came the election of Sen. Scott Brown (R-Mass.) on Jan. 19, 2010, which delivered a serious blow to passage of the Senate's comprehensive health care reform bill and therewith the sweeping health care fraud initiatives contained within that bill. Second came the president's fiscal year 2011 budget, which called for \$1.7 billion for the Department of Health and Human Services (HHS) to fight fraud, including \$561 million in Health Care Fraud and Abuse Control (HCFAC) discretionary funding.¹ This 80 percent increase in discretionary funds² includes \$60.2 million for the Department of Justice (DOJ) to use in the investigation and litigation of health care fraud cases.³

Attorney General Eric Holder and HHS Secretary Kathleen Sebelius announced at the Jan. 28, 2010, National Summit on Health care Fraud that the increased investments called for in the president's FY 2011 budget will be used to support anti-fraud efforts in the field, including the Health Care Prevention and Enforcement Action Team (HEAT) initiative introduced in May 2009.⁴ In keeping with those efforts, DOJ increased the public fisc in FY 2009 by \$2.4 billion as a result of False Claims Act recoveries, with \$1.6 billion contributed by the health care industry, the second largest recovery in U.S. history.⁵ Health care fraud legislation is not likely to face opposition by either party; in fact, it may constitute one of the few areas of common ground in the current debate on health care reform.

Particularly poised for passage is Senate Bill 1959, the Health Care Fraud Enforcement Act of 2009,⁶ which was introduced by Sen. Ted Kaufman (D-Del.) following an Oct. 28, 2009, Senate Judiciary Committee hearing titled "Effective Strategies for Preventing Health Care Fraud." S. 1959 was described as being aimed at ensuring that those who "steal" from the federal government's investment in health care will face swift prosecution and substantial punishment.⁷

¹ Press release, Department of Health & Human Services, "HHS Budget Makes Smart Investments, Protects the Health and Safety of America's Families" (Feb. 1, 2010), <http://www.hhs.gov/news/press/2010pres/02/20100201a.html>.

² Kathleen Sebelius, secretary, Department of Health & Human Services, Remarks to the National Health Care Fraud Summit (Jan. 28, 2010), www.hhs.gov/secretary/speeches/sp20100128.html.

³ U.S. Department of Justice, FY 2011 Budget Request Fact Sheet: "Restore Confidence in Our Markets, Protect the Federal Fisc, and Defend the Interest of the United States," www.justice.gov/jmd/2011factsheets/pdf/defend-interests-unitedstates.pdf.

⁴ Press release, Department of Health & Human Services, "Health & Human Services Secretary Kathleen Sebelius, Attorney General Eric Holder Convene National Summit on Health Care Fraud, Unveil Historic Commitment to Fighting Fraud in President's FY 2011 Budget" (Jan. 28, 2010), www.hhs.gov/news/press/2010pres/01/20100128a.html (hereinafter "Health Care Fraud Summit Press Release"). The HEAT initiative has been promoted as an effort to strengthen existing programs to combat fraud and invest new resources and technology. HEAT initiative efforts include the expansion of joint DOJ-HHS Medicare Fraud Strike Force teams to Detroit and Houston, Brooklyn, N.Y., and Baton Rouge, La. (other teams are operating in South Florida and Los Angeles). These teams use a data-driven approach to identify unexplainable billing patterns and investigate these providers for possible fraudulent activity. See www.hhs.gov/news/press/2009pres/05/20090520a.html.

⁵ Press release, "Department of Justice, Justice Department Recovers \$2.4 Billion in False Claims Cases in Fiscal Year 2009; More Than \$24 Billion Since 1986" (Nov. 19, 2009), www.justice.gov/opa/pr/2009/November/09-civ-1253.html.

⁶ S. 1959, 111th Cong. (2009).

⁷ Health Care Fraud Enforcement Act of 2009, Section-by-Section Justification, available at: http://kaufman.senate.gov/press/press_releases/release/?id=5e8767a9-e711-4f7a-8a52-27ad23e8fb53.

In the senator's words, S. 1959 is designed to "strengthen the government's capacity to investigate and prosecute waste, fraud, and abuse in both government and private health insurance."⁸ Sen. Kaufman's description is lockstep with the current administration's statements, particularly those of AG Holder, that the FY 2011 budget requests and the fraud initiatives, including HEAT, are key in combating crime and recovering stolen resources.⁹

S. 1959 has strong provisions that would assist AG Holder, who has already charged 200 defendants,¹⁰ in his efforts to prosecute health care fraud. Indeed, S. 1959 would increase the offense level in the federal sentencing guidelines for "federal health care offenses," redefine "federal health care offense," reduce the bar necessary to prove intent under the health care fraud statute, declare all kickbacks as "false" for purposes of the federal False Claims Act, and increase funding for health care fraud prevention and enforcement efforts.

Although, S. 1959 authorizes only the "modest" annual appropriation of an additional \$20 million for 2011 through 2016 to be used in investigating and prosecuting health care fraud, S. 1959 specifically allocates an additional \$10 million per year to the U.S. attorneys' offices and \$5 million each to the civil and criminal divisions of the Department of Justice.

S.1959 Proposes Significant Changes

In addition to expanded annual appropriations, S. 1959's substantive provisions increase the potential sanctions, including criminal sanctions, that can be imposed upon health care entities while at the same time lowering the scienter (intent) requirement necessary to successfully prosecute health care fraud. The specific provisions include the following.

Proposed amendments to the federal sentencing guidelines would result in increased sentences for persons convicted of federal health care offenses in two ways:

- ❖ By increasing the offense level range by two to four levels for federal health care offenses according to the following tiers of monetary loss: a two-level increase for losses of \$1 million or more, a three-level increase for losses of \$7 million or more, and a four-level increase for losses of \$20 million or more;
- ❖ By "clarifying" that the definition of "intended loss includes the aggregate dollar amount of all claims submitted." This proposed "clarification" is significant because under Section 2B1.1 of the sentencing guidelines, monetary loss is determined as the greater of actual loss or intended loss. Since actual loss will rarely exceed intended loss, intended loss is a key driver of sentences for federal health care offenses, and some courts have limited intended loss to the amount actually paid by the government or payable under government fee schedules.¹¹ By allowing "intended losses" to include claims submitted (as opposed to actually paid) the sentences received for health care fraud are sure to be longer.

Proposed amendments to 18 U.S.C. § 24(a), the provision defining federal health care offense, would add violations of the anti-kickback statute as well as health care-related offenses under the federal Food, Drug and Cosmetic Act (FDCA) and Employee Retirement Income Security Act (ERISA) to the definition. Violations of the newly included sections would allow the proceeds of these offenses to be subject

⁸ *Id.* S. 1959 is co-sponsored by Judiciary Committee Chairman Leahy (D-Vt.) and Committee members Specter (D-Pa.), Kohl (D-Wis.), Schumer (D-N.Y.), and Klobuchar (D-Minn.).

⁹ *Health Care Fraud Summit Press Release (Jan 28, 2010).*

¹⁰ Eric H. Holder Jr., U.S. attorney general, Remarks to the National Health Care Fraud Summit (Jan. 28, 2010), www.justice.gov/ag/speeches/2010/ag-speech-100128.html.

¹¹ *Health Care Fraud Enforcement Act of 2009, Section-by-Section Justification.*

The possibility of more severe penalties under the FCA and federal sentencing guidelines combined with the potential lowering of the AKS intent requirement proposed in other legislation means that it will be imperative for providers to review their financial relationships with potential referral sources to try to align these relationships as closely as possible with a safe harbor or statutory exception.

to criminal forfeiture, render obstruction of an investigation a crime, include these offenses as “specified unlawful activity” for purposes of money laundering, and authorize the use of administrative subpoenas to investigate such violations.

Proposed amendments to 18 U.S.C. § 1347, the health care fraud statute, would add a definition of willful conduct which specifies that a defendant need not act with actual knowledge of the law in question or specific intent to violate that law. Rather, the willful intent requirement would be met if the defendant acted voluntarily and purposefully to do the act prohibited under the law.

Proposed amendments to 42 U.S.C. § 1320a-7b, the law that enumerates criminal penalties for acts involving federal health care programs, including the anti-kickback statute, would provide that all claims submitted in violation of this law constitute a false

or fraudulent claim under the False Claims Act, allowing the trebling of damages. Importantly, if the amendments are adopted, a tainted claim would constitute both a prohibited kickback and a false claim, even when the claims are submitted by someone other than the payer or recipient of the kickback.

Bill Would Augment Other Fraud Enforcement Initiatives

In addition to the increased criminal penalties and sanctions proposed above, passage of the Health Care Fraud Enforcement Act would augment earlier federal government efforts to intensify health care fraud enforcement, including the Fraud Enforcement and Recovery Act of 2009 (FERA),¹² which President Obama signed into law on May 20, 2009. Specifically, FERA already expanded the scope of the False Claims Act (FCA)¹³ in significant ways, including:

- ❖ Eliminating the presentment requirement and requiring only a nexus to the government. Under FERA, the definition of “claim” was revised to include any request or demand 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 the government provides or reimburses any portion of the money or property. Significantly, the act does not define either of the key phrases “used on the government’s behalf” or “to advance a government program or interest.”
- ❖ Incorporating a materiality requirement that adopts the weaker standard. With respect to FCA liability for submission of false records or statements, FERA now specifies that the false record or statement must be material to the government’s payment decision and defines “materiality” as having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.
- ❖ Expansion of the “reverse false claim” provision to expressly include retention of an overpayment. FERA imposes FCA liability for knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay the government. “Obligation” is defined broadly to include an established duty, whether or not fixed, arising from certain relationships, statutes, regulations, or the retention of an overpayment.
- ❖ Authorizing government intervention complaints to relate back to the date of the original complaint. FERA provides a statute of limitations extension in qui tam cases where the government intervenes or amends the relator’s complaint, so long as the government claim arises out of the conduct, transactions, or oc-

¹² Pub.L. No. 111-21, 123 Stat. 1616 (2009).

¹³ 31 USC § 3729-3733.

currences set forth, or attempted to be set forth, in the relator's complaint. Given the delay already inherent in government investigations, this amendment dramatically affects a defendant's ability to defend itself for business conduct dating back many years.

What Enactment Would Mean for Health Care Providers

If S. 1959, or the provisions thereof, become law, providers face greater potential exposure to the penalties imposed by the anti-kickback statute (AKS), the False Claims Act, and the health care fraud statute. The Health Care Fraud Enforcement Act would both authorize the "bootstrapping" of AKS violations into false claims and also make a violation or conspiracy to violate the AKS a federal health care offense, thereby subjecting those convicted of violating the AKS to sentencing under the federal sentencing guidelines, the trebling of damages together with \$5,500 to \$11,000 per claim fines, and possible exclusion from all federal health care programs.

The possibility of more severe penalties under the FCA and federal sentencing guidelines combined with the potential lowering of the AKS intent requirement proposed in other legislation¹⁴ means that it will be imperative for providers to review their financial relationships with potential referral sources to try to align these relationships as closely as possible with a safe harbor or statutory exception.

The HHS Office of Inspector General (OIG) has identified arrangements involving clinical laboratory services, such as waiver of charges to managed care patients in exchange for non-managed care business,¹⁵ certain arrangements for discounted pathology services provided to physicians,¹⁶ and certain discount arrangements between clinical laboratories and skilled nursing facilities as potentially suspect.¹⁷ Providers of clinical laboratory services should be especially cautious with respect to the practices flagged by OIG and should ensure that their compliance program adheres to the recommendations of the OIG in its Compliance Program Guidance for Clinical Laboratories.¹⁸

S. 1959 would also increase provider risk under the health care fraud statute. As outlined above, S. 1959 would lower the intent requirement necessary to establish a violation of the health care fraud statute and also increase the penalties for persons convicted under this statute. This administration has already increased the number of defendants charged with health care offenses, and with the health care fraud statute setting forth a broad prohibition against committing any scheme to defraud any state, federal, or private health plan, these amendments could have far-reaching implications for all health care providers.

In this heightened enforcement climate, health care providers are likely to face increased government scrutiny. Therefore, it is critical that providers continually review, adapt, and audit their compliance programs and their policies governing financial relationships and monitor their financial arrangements with referral sources to ensure they are compliant with the law if they want to adequately address the issues identified by these enforcement efforts.

Rebekah N. Plowman can be reached at Epstein, Becker & Green, Resurgens Plaza, 945 E. Paces Ferry Road Suite 2700, Atlanta, GA 30326. George B. Breen and Emily E. Bajcsi can be reached at Epstein, Becker & Green, 1225 25th St. N.W., Suite 700, Washington, DC 20037. E-mail: gbreen@ebglaw.com, rplowman@ebglaw.com, and ebajcsi@ebglaw.com. 🏛️

¹⁴ Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (as passed by the Senate, Dec. 24, 2009).

¹⁵ OIG Special Fraud Alert, Arrangements for the Provision of Clinical Laboratory Services, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

¹⁶ OIG Adv. Op. No. 99-13 (issued Nov. 30, 1999, posted Dec. 7, 1999).

¹⁷ OIG Letter, Discount Arrangements Between Clinical Laboratories and SNFs (Sept. 22, 1999).

¹⁸ 63 Fed. Reg. 45,076 (Aug. 24, 1998).