Healthcare reform ushers in a broad array of new enforcement tools

New law opens the door to more whistleblower suits, warn Arnold & Porter attorneys

By Jeffrey Handwerker, Keith Korenchuk and Kirk Ogrosky

Healthcare reform is now a reality. The new law includes numerous provisions that will profoundly affect the compliance burdens imposed on pharmaceutical and device manufacturers and make it easier for law enforcement officials to prosecute these companies under the False Claims Act (FCA) and the Anti-Kickback Act.

While there are many changes that will occur as the nation's healthcare system begins to implement these significant changes, it is clear that government enforcement efforts will continue to focus heavy scrutiny on the interactions that pharmaceutical and medical device companies have with healthcare professionals. Armed with the changes in the fraud statutes described below, the government will undoubtedly use those enhanced tools to continue to challenge conduct engaged in by the industry.

Below are nine of the most significant "compliance-related" changes imposed in the healthcare reform.

I. Opening the door for more *qui tam* suits under the False Claims Act

In a number of respects, healthcare reform opens the door to additional whistleblower suits under the FCA. First, it narrows the types of information that can trigger the public disclosure bar. Under the legislation, a whistleblower suit cannot be barred unless "substantially the same allegations or transactions [alleged in the suit] were publicly disclosed" in: (1) "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party"; (2) "a congressional, [GAO], or other Federal report, hearing, audit, or investigation"; or (3) from the news media. Previously, the public disclosure bar had applied to information disclosed "in a criminal, civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit, or investigation, or from the news media."

Second, it expands the definition of "original source" to include any individual who has knowledge that is "independent of and materially adds to the public disclosed allegations or transactions, and who has voluntarily provided the information to the government" before filing the suit. Previously, an original source was required to have direct and independent knowledge of the information on which the FCA allegations were based.

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Third, and potentially most significant, the legislation provides that, if the whistleblower suit is based on publicly disclosed information and the whistleblower is not an "original source," then "the court shall dismiss [the suit], unless opposed by the Government." Previously, the FCA mandated that "no court shall have jurisdiction over" a whistleblower suit based on publicly disclosed information unless the whistleblower is an original source. Healthcare reform thus appears to authorize the government to override the original source bar. How this provision will apply in practice will be subject to judicial interpretation.

NOTE: SUPREME COURT WEIGHS IN

The Supreme Court held yesterday in *Graham County Soil and Water Conservation District v. United States ex rel. Wilson*, that the word "administration" in the pre-health reform FCA included disclosures made to state and local authorities. In so doing, the Court acknowledged the health reform law's changes to the public disclosure bar and noted in a footnote that those changes do not apply retroactively to pending cases.

II. Removing the requirement for actual knowledge under the Anti Kickback Statute

The legislation removes the requirement that the defendant must have actual knowledge of the Anti Kickback Act or a specific intent to violate the statute to establish liability under the Act. This dilution of the intent requirement resolves a prior conflict in the circuits. In *Hanlester Network v. Shalala*, the Ninth Circuit had interpreted the Anti-Kickback Act's "knowingly and willfully" scienter standard to require the government to show that the defendant knew that the Anti-Kickback Act prohibited the conduct at issue and specifically intended to violate the Act. Conversely, the Fifth, Eighth, and Eleventh Circuits had held that the Anti-Kickback Act does not contain a specific intent requirement. The healthcare reform resolves this conflict in favor of the latter formulation, and could allow prosecutors to base anti-kickback charges on practices by individuals or companies acting without any intent to violate the Anti-Kickback Act or knowledge that they were doing so.

III. Codifying the "implied certification" theory under the Anti Kickback statute

The legislation amends the Anti-Kickback Act to provide that "a claim that includes items or services resulting from a violation [of the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]." In so doing, the legislation codifies the "implied certification" theory where items or services included in a claim "result[] from" anti-kickback violations. This theory had previously been adopted in a handful of court decisions.

IV. Diluting the intent requirement in the Health Care Fraud Statute

The legislation dilutes the intent requirement in the Health Care Fraud Statute (18 U.S.C. § 1347), which makes it unlawful to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses,representations, or promises, any of the money or property of a health care benefit program in connection with the delivery of or payment for healthcare benefits, items, or services. As with the Anti-Kickback Act, the legislation makes clear that the intent standard does not require proof that the defendant had actual knowledge of the Health Care Fraud Statute or specific intent to violate the Statute.

V. Amending current law regarding exclusion of entities from participation in federal healthcare programs

Healthcare reform amends current law regarding exclusion of entities from participation in federal healthcare programs for violations of healthcare fraud statutes. For example, it requires states to terminate individuals or entities from their State Medicaid programs if they have been terminated from Medicare or another state's Medicaid program. State Medicaid programs must also exclude an individual or entity that owns, controls, or manages another entity that has failed to repay overpayments, has been suspended, terminated, or excluded from Medicaid participation, or is affiliated with any such entity. Healthcare reform also expands HHS OIG's permissive exclusion authority under section 1128 of the Social Security Act to apply in instances of obstruction of program audits and investigations.

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VI. Amending the Sentencing Guidelines

The legislation amends the sentencing guidelines applicable to persons convicted of federal healthcare offenses involving federal healthcare programs. The U.S. Sentencing Commission will be required to review the federal sentencing guidelines and policy statements in this area and, where appropriate, provide increased penalties. In addition, the legislation specifically directs the Commission to increase the offense levels for defendants convicted of a federal healthcare offense related to a government healthcare program by 20 to 50 percent for crimes that involve more than $1 million in losses. It also provides that, in applying the sentencing guidelines, the aggregate dollar amount of fraudulent bills submitted to a government healthcare program shall constitute prima facie evidence of the amount of the "intended loss" by the defendant.

VII. Updating the definition of "health care fraud offense" to enable increased enforcement

The legislation updates the definition of "health care fraud offense" in the federal criminal code (18 U.S.C. § 24(a)) to include violations of the Anti-Kickback Act, the Food, Drug and Cosmetic Act, and certain provisions of the Employee Retirement Income Security Act (ERISA). These changes may enable increased enforcement by: (1) making the proceeds of these offenses subject to criminal forfeiture; (2) rendering obstruction of an investigation of these offenses a crime; (3) including these offenses as specified unlawful activity for purposes of money laundering; and (4) authorizing the use of administrative subpoenas for the production of documents.

VIII. Expanding HHS' civil monetary penalty authorities

The legislation empowers HHS to impose civil monetary penalties of $15,000 per day on any person who fails to grant timely access to the OIG for purposes of audits, evaluations, investigations, or other statutory functions. It also authorizes civil monetary penalties of up to $50,000 for any false claims or false statements submitted to or made to any federal healthcare program. Other provisions imposing new or enhanced sanctions apply specifically to Medicare Advantage and Part D plans that engage in "prohibited conduct" with respect to individuals' enrollment in or transfer between plans, employment and contracting practices, marketing violations, or the misrepresentation or falsification of information.

IX. Imposing new obligations on manufacturers with regard to the Section 340B drug pricing program,

Healthcare reform imposes new obligations on manufacturers with regard to the Section 340B drug pricing program, which requires manufacturers to charge a specified ceiling price to eligible safety net providers. Specifically, the legislation requires the Health Resources Services Agency (HRSA) to make a number of "improvements" designed to enforce manufacturer compliance with 340B program requirements, including (a) amending the Pharmaceutical Pricing Agreement (PPA) to require drug manufacturers to provide HRSA with quarterly reports of the ceiling price for each covered outpatient drug subject to the agreement; (b) requiring that manufacturers offer each covered entity covered drugs for purchase at or below the ceiling price if such drug is made available to any other purchaser at any price; (c) establishing a process to verify the accuracy of 340B ceiling prices calculated by manufacturers and charged to covered entities; (d) creating a process for evaluating any discrepancies between ceiling prices and manufacturer pricing data and taking corrective action in response to such discrepancies; (e) adopting mechanisms for manufacturers to report rebates and other lagged discounts provided by manufacturers to purchasers subsequent to the sale of drugs to 340B entities and to issue credits and refunds to covered entities if the rebates would lower the ceiling price for the relevant quarter; and (f) developing a process for manufacturers to issue refunds in the event there is an overcharge to 340B covered entities.The legislation authorizes civil monetary penalties if a manufacturer "knowingly and intentionally" charges a covered entity a price that exceeds the 340B ceiling price, not to exceed $5,000 for each instance of overcharging a covered entity that may have occurred.

Expect more enforcement

The impact of health care reform on the industry is clear. Expect more enforcement, more aggressive claims of fines and penalties, and heightened and visible criminal charges being brought against industry executives. Maintenance of robust and effective compliance programs has never been more important.

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