



**GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE**

**Healthcare Practice**

Our Healthcare Practice represents participants in all facets of the healthcare industry, including pharmaceutical, biotech and device companies, DME suppliers, hospitals, skilled nursing facilities, physician-owned companies, professional associations and research institutions. Our lawyers combine a strong background in the complexities of healthcare financing and delivery, including coding, reimbursement, and coverage issues, privacy and security, trade regulation, and competition. We have extensive experience representing clients on enforcement and regulatory matters before federal and state enforcement agencies.

**For further information on the Healthcare Practice, please contact:**

Paul E. Kalb, M.D.  
 +1.202.736.8050  
 pkalb@sidley.com

**Sidley Global Life Sciences Practice**

On three continents, Sidley’s Global Life Sciences Practice team offers coordinated cross-border and national advice on Food, Drug and Medical Device laws, Healthcare, Intellectual Property, Products Liability, International Trade and Arbitration, FCPA Enforcement, Environmental/Nanotechnology, Antitrust/Competition, Corporate M&A, Licensing and Joint Ventures.

Globally rated as one of the top life sciences practices, our team includes former government officials, medical doctors, and leaders in various life sciences fields.

**For further information on the Global Life Sciences Practice, please contact:**

Scott Bass  
 +1.202.736.8684 | +1.212.839.5613  
 sbass@sidley.com

**Health Care Reform Legislation Would Significantly Expand Fraud and Abuse Enforcement**

As the House and Senate work to reconcile their respective health care reform bills<sup>1</sup>, much attention has been paid to how the legislation would affect the scope of coverage and how expanded coverage would be funded. Significantly, the bills also contain a variety of provisions that, if enacted into law, would substantially expand the government’s enforcement authority concerning and the penalties for fraud and abuse in the health care sector. This alert provides an overview of key fraud and abuse provisions in the pending House-passed and Senate-passed bills.

**Provisions Contained in Both the House and Senate Bills**

Although the final form of any health care reform legislation remains unclear, the following provisions are contained in both bills, with some variation, making it highly likely that a version of these items will be included in any final legislation that is passed.

**Expansion of the False Claims Act (FCA):** Both bills provide for expanded application of the FCA. The Senate bill would apply the FCA to claims “submitted by, through, or in connection with” the newly-created health insurance exchanges, and the House bill would apply the FCA to the public health insurance option established in that bill. Notably, the Senate bill also would increase the damage multiplier for FCA claims involving payments through or in connection with an exchange to 3 to 6 times actual damages.

**New HHS-OIG Civil Monetary Penalties (CMPs):** The bills would create new CMPs covering the following:

- Conduct that also is actionable under the FCA, with a \$50,000 penalty for each false record or statement made to the government.
- Failure to grant timely access to the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) “for the purposes of audits,

<sup>1</sup> On November 7, 2009, the House approved the Affordable Health Care for America Act (H.R. 3962) by a vote of 220–215. On December 24, 2009, the Senate approved the Patient Protection and Affordable Care Act (H.R. 3590) by a vote of 60–39.

investigations, evaluations, or other statutory functions of” the OIG, with a \$15,000 penalty for each day of delayed access.

- Any false statement, misrepresentation or omission in applications, bids, or contracts to participate as a provider or supplier under any federal health care program. The penalty for such a violation would be \$50,000 for each false statement or misrepresentation of material fact, plus up to three times the damages for such claims.
- Submission of claims by excluded providers.

**Exclusions:** Both bills would amend section 1128(b)(2) of the Social Security Act (SSA) to authorize permissive exclusion for, among other things, obstructing an investigation or audit. Under current law, this provision permits exclusion only for obstructing certain criminal investigations.

**Overpayments:** The House and Senate bills require a “person” (including providers, suppliers and plan sponsors) affirmatively to report overpayments within 60 days.

**Physician Payments “Sunshine” provisions:** Both bills include robust requirements for drug, device, biological and medical supply manufacturers to report to HHS “any transfer of value” to physicians and other health care providers/entities. New CMPs, in addition to those noted above, would be associated with failures to report.

**Increased transparency requirements for Pharmacy Benefit Managers (PBMs):** The bills would impose new reporting and transparency requirements on PBMs or health benefits plans that provide PBM services.

**Increased funding to combat fraud and abuse:** The Senate bill would add an extra \$10 million to the Healthcare Fraud and Abuse Control Fund (the Fund) in each fiscal year from 2011 through 2020—a total of \$100 million in additional funding. The House bill would do even more, as it provides for an

additional \$100 million to the Fund per fiscal year, beginning in 2011.

**Other key provisions in both bills would:**

- Require providers and suppliers to adopt compliance programs;
- Direct HHS to develop and issue a self-referral protocol for Stark Law violations, which would “enable health care providers of services and suppliers to disclose an actual or potential violation” of the Stark Law; and
- Require HHS to maintain a national fraud and abuse data collection program for final adverse actions and to provide the data collected to the National Practitioner Data Bank.

**Other Significant Fraud and Abuse Provisions**

There are several other significant fraud and abuse provisions contained in one bill or the other, including:

**Elimination of heightened specific intent requirement under the Anti-Kickback Statute:** The Senate bill would amend the Anti-Kickback Statute to overrule court decisions holding that an individual must have actual knowledge of and the specific intent to violate the Anti-Kickback Statute to be criminally liable. The Senate bill also specifies that any claim to the federal government that includes items or services “resulting from” a violation of the Anti-Kickback Statute would constitute a “false or fraudulent claim” under the FCA.

**Suspension of payments:** The Senate bill would permit the Secretary of HHS to “suspend payments to a [Medicare] provider of services or supplier . . . pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.” This provision requires the Secretary to consult with the OIG in determining whether there is a credible allegation of fraud against a provider of services or supplier.

**Sentencing guidelines:** The Senate bill would substantially enhance sentences for health care fraud by defining the loss amount as the aggregate dollar amount of fraudulent bills submitted to the Government health care program.

**Enhanced protections for whistleblowers:** The House bill would create enhanced protections for whistleblowers by prohibiting employer retaliation (including discharge or any other type of discrimination with respect to compensation or terms or privileges of employment) against employees who provide, cause to be provided, or “are about to provide” information to federal or state government authorities relating to any violation, or any act or omission that the employee “reasonably believes” to be a violation, of the health care legislation or any regulation promulgated under it. Testimony and assistance or participation in proceedings regarding such violations also are protected. This provision of the House bill also creates a private cause of action under the Consumer Product Safety Act (15 U.S.C. § 2087(b)) for employees covered by the provision who allege discrimination by an employer in connection with this section.

★ ★ ★

Sidley Austin is closely monitoring the health care reform legislation and would be pleased to answer any questions about the fraud and abuse provisions, or other aspects of the proposed legislation.

**If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work, or one of the following:**

Paul E. Kalb, M.D.  
+1.202.736.8050  
pkalb@sidley.com

Scott D. Stein  
+1.312.853.7520  
sstein@sidley.com

William A. Sarraille  
+1.202.736.8195  
wsarraille@sidley.com

Patrick Morrisey  
+1.202.736.8228  
pmorrisey@sidley.com

Stephanie P. Hales  
+1.202.736.8349  
shales@sidley.com

To receive future copies of this and other Sidley Updates via email,  
please sign up at [www.sidley.com/subscribe](http://www.sidley.com/subscribe)

This **Sidley Update** has been prepared by Sidley Austin LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.

[www.sidley.com](http://www.sidley.com)

*Sidley Austin LLP, a Delaware limited liability partnership which operates at the firm's offices other than Chicago, London, Hong Kong, Singapore and Sydney, is affiliated with other partnerships, including Sidley Austin LLP, an Illinois limited liability partnership (Chicago); Sidley Austin LLP, a separate Delaware limited liability partnership (London); Sidley Austin LLP, a separate Delaware limited liability partnership (Singapore); Sidley Austin, a New York general partnership (Hong Kong); Sidley Austin, a Delaware general partnership of registered foreign lawyers restricted to practicing foreign law (Sydney); and Sidley Austin Nishikawa Foreign Law Joint Enterprise (Tokyo). The affiliated partnerships are referred to herein collectively as Sidley Austin, Sidley, or the firm.*

SIDLEY AUSTIN LLP  
**SIDLEY**