

Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted

April 12, 2010

President Obama recently signed into law the much-anticipated health care reform legislation.¹ This legislation includes significant fraud-fighting and program integrity initiatives, including transparency requirements for pharmaceutical and medical device manufacturers, and amendments to federal enforcement tools, such as the federal anti-kickback statute (AKS), federal False Claims Act (FCA) and the federal physician self-referral law (Stark Law). A brief summary of the impact of the transparency and physician payment sunshine provisions as well as the changes to key enforcement statutes, such as the AKS, FCA and Stark Law, are set forth here. This summary is followed by a table highlighting select fraud and abuse provisions enacted in the health care reform legislation.²

Vendor-Provider Relationships in the Sunshine

The health care reform legislation incorporates the highly publicized “sunshine law” that was introduced and vigorously promoted by Senator Charles Grassley over the last several years, and requires extensive reporting and public disclosure of financial arrangements between manufacturers of drugs, medical devices, medical supplies and biologics and certain provider customers. Under the law, manufacturers must report such financial relationships to the U.S. Department of Health and Human Services (HHS), and HHS must disclose the information on a publicly available website and to the states. This transparency is intended to promote voluntary avoidance of conflicts of interest that can both compromise the quality, integrity and safety of clinical care, biomedical research and medical education, and lead to violations of the federal prohibitions against health care fraud and promotion of unapproved uses of medical products.

These federal sunshine provisions come at a time when health care product manufacturers are still struggling to develop a response to the myriad existing state reporting laws and codes of conduct relating to industry-provider financial relationships³. Moreover, this component of the health care reform legislation does not completely preempt the existing state sunshine requirements. Manufacturers are thus left to reconcile differences between federal and state laws so as to adjust their tracking systems to achieve compliance with both federal and state reporting and disclosure requirements.

In addition, this federal law differs from corresponding state sunshine laws in several notable respects. First, it addresses only the reporting and public disclosure of industry-provider relationships. It does not establish parameters for, or prohibitions against, the existence of such relationships. In that regard, it does not supplant the codes of conduct that have been established under state sunshine laws or by pharmaceutical and medical device manufacturer trade associations, most notably the Pharmaceutical Research and Manufacturers of America (PhRMA) and AdvaMed. Second, it requires disclosure of financial relationships with “teaching hospitals” as well as physicians, which introduces an element of institutional conflicts that is not present in corresponding state sunshine laws but is prominently addressed by conflict of interest standards and guidelines that have recently been adopted by university and academic medical center trade associations.

Widespread investigations of vendor-provider financial relationships by the federal government, state governments and leading media publications over the last several years have produced significant adverse consequences for manufacturers and providers—most notably, record-setting financial settlements (some exceeding \$1 billion), suspension or debarment from eligibility to participate in leading-edge federally funded research, loss of key clinical leadership positions at major academic institutions and loss of reputation. The ready and regular supply of reliable information concerning such relationships is likely not only to trigger, fuel and expedite similar investigations in the years ahead, but also to further heighten the responsibility and accountability of all key stakeholders for implementing and enforcing conflict of interest, fraud and abuse, and off-label promotion compliance best practices.

¹ The health care reform legislation consists of H.R. 3590, the Patient Protection and Affordable Care Act, and H.R. 4872, the Health Care and Education Reconciliation Act of 2010.

² There are numerous additional provisions that are not addressed here, including, among others, limits on physician ownership of hospitals, patient centered outcomes research, comparative effectiveness research, data bank revisions, MEWA provisions, the Elder Justice Act and evaluation of alternatives to current medical tort litigation.

³ To date, California, the District of Columbia, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia have enacted state sunshine laws.

Other Transparency Requirements

In addition to the vendor-provider payment sunshine provisions, the health care reform legislation includes transparency requirements for pharmacy benefit managers, nursing homes and physicians that provide in-office ancillary services, such as MRI, CT and PET scans. Information regarding these provisions is set forth in the table that follows.

Amendments to Enforcement Authority

The health care reform legislation requires overpayments to be reported within 60 days after the date the overpayment was identified (or date a cost report is due, if applicable), and further provides that failure to make a timely repayment gives rise to FCA liability. This provision represents a significant expansion of potential liability for health care providers.

The health care reform legislation also changes the AKS by revising the intent standard and explicitly linking AKS violations to the FCA. Specifically, the AKS has been amended to state that “a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]” for the government to prove a kickback violation. This amendment effectively overturns the intent standard articulated by the U.S. Court of Appeals for the Ninth Circuit, which was a minority view among the circuits that have taken up the intent issue. Moreover, these amendments provide that “a claim that includes items or services resulting from a violation [of the AKS] constitutes a false or fraudulent claim for purposes” of the FCA. This provision codifies court decisions holding that a violation of the AKS is sufficient to state a claim under the FCA.

Similarly, the health care reform legislation changes the intent requirement for health care fraud under 18 U.S.C. § 1347, such that “a person need not have actual knowledge or specific intent to commit a violation.” Another significant change for U.S. Food and Drug Administration (FDA) regulated companies, such as pharmaceutical and medical device manufacturers, is the inclusion of section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 331) in the definition of a “Federal health care offense” at 18 U.S.C. § 24(a). Accordingly, an FDA offense, such as off-label promotion, is a predicate for a health care fraud case.

In addition, the health care reform legislation significantly changes the FCA by removing the jurisdictional bar for allegations based on publicly disclosed information and by loosening the requirements for a *qui tam* relator to qualify as an “original source.” These changes will effectively increase FCA exposure by enabling a greater number of whistleblowers to bring a claim. For more information, see McDermott’s *On the Subject* “Health Care Reform: Legislation Expands False Claims Act, Whistleblower Cases Expected to Increase,” available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/a3520977-8f8a-4b5b-a83d-26ada4315a1d.cfm.

Finally, in a development that potentially will provide significant relief for certain health care providers, the health care reform legislation requires the Secretary of HHS to establish a Stark Law self-referral disclosure protocol, and permits HHS to accept payment of less than the full Stark Law measure of damages in appropriate circumstances.

Highlights of Key Fraud and Abuse and Program Integrity Amendments

Bill Provision	Patient Protection and Affordable Care Act (H.R. 3590) Health Care and Education Reconciliation Act of 2010 (H.R. 4872)
<p>Physician Payment Transparency/Sunshine Provisions</p>	<p>Annual reporting of payments or transfers of value to “covered recipients.” Covered recipients include <i>only</i> physicians or teaching hospitals. The term “physician” has the meaning given that term in section 1861(r) of the Social Security Act. It does not include physician employees of manufacturers.</p> <p>First annual report due March 31, 2013 (and on the 90th day of each calendar year thereafter) for activity during the prior calendar year (<i>e.g.</i>, beginning January 1, 2012).</p> <p>Annual reporting of physician ownership or investment interest in a manufacturer or GPOs (other than certain ownership or investment interests in publicly traded security and mutual funds).</p> <p>Requires reporting by manufacturers of drugs, devices, biologicals or medical supplies covered under Title XVIII or a state plan under Title XIX or XXI (or a waiver of such plan).</p> <p>Generally preempts state laws, except those that require reporting of different payments, information excluded from reporting, or by persons or entities other than applicable manufacturers or covered recipients.</p> <p>Permits delayed reporting for product research or development agreements and clinical investigations.</p> <p>Excludes reporting of the following:</p> <ul style="list-style-type: none"> ▪ Anything of value less than \$10 (unless the aggregate amount during the calendar year exceeds \$100) ▪ Educational materials that directly benefit patients or are intended for patient use ▪ Patient samples ▪ Loan of a covered device not to exceed 90 days ▪ Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device ▪ Discounts and rebates ▪ In-kind items for charity care ▪ Dividends or profit distributions from, or ownership or investment interest in, certain publicly traded securities or mutual funds ▪ Any transfer of value to a covered recipient not acting in his or her professional capacity ▪ Self insurance payments from a manufacturer for employees ▪ Transfers of value to licensed non-medical professionals for services ▪ Transfers of value to a covered recipient if the payment is solely for services with respect to a civil or criminal action or administrative proceeding ▪ Any transfer of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient <p>Reported information to be made publicly available.</p>

Bill Provision	Patient Protection and Affordable Care Act (H.R. 3590) Health Care and Education Reconciliation Act of 2010 (H.R. 4872)
	<p>Penalties include the following:</p> <ul style="list-style-type: none"> ▪ Civil money penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of penalties shall not exceed \$150,000. ▪ Civil money penalty of not less than \$10,000, but not more than \$100,000, for each payment or transfer of value or ownership or investment interest a manufacturer or group purchasing organization knowingly fails to report. The total amount shall not exceed \$1 million. ▪ All penalties will be imposed and collected in the same manner as civil money penalties under 42 U.S.C. § 1320a–7a. <p>(H.R. 3590, Sec. 6002)</p>
<p>Disclosure of Ownership for In-Office Ancillary Services</p>	<p>Physicians that provide in-office MRI, CT, PET or other services as the Secretary deems appropriate must, at the time of referral, inform patients in writing of alternative suppliers of the services. Applies to services furnished after January 1, 2010, but enforcement with respect to services provided prior to March 23, 2010, or the effective date of final regulations is unlikely. (H.R. 3590, Sec. 6003)</p>
<p>Prescription Drug Sample Transparency</p>	<p>No later than April 1 of each year (beginning in 2012) manufacturers and authorized distributors must annually report samples distributed to practitioners. (H.R. 3590, Sec. 6004)</p>
<p>Pharmacy Benefit Manager (PBM) Transparency</p>	<p>PBMs for health benefit plans that provide pharmacy benefits, Medicare Advantage drug plans or plans offered through exchanges must report information about pharmacy types used, generics, rebates and other price concessions.</p> <p>Secretary must specify the times, form and manner of reporting. (H.R. 3590, Sec. 6005)</p>
<p>Nursing Home Transparency and Improvement</p>	<p>Numerous provisions relating to nursing homes, including (i) disclosure of governing body, officers and directors; (ii) required adoption of a compliance program and quality assurance and performance improvement program (QAPI); (iii) website information; (iv) reporting of direct care expenditures; (v) development of a standardized resident complaint form and resolution process; (vi) civil money penalties; (vii) staff training; and (viii) employee background checks. (H.R. 3590, Secs. 6101, 6102, 6103, 6104, 6105, 6111, 6121, 6201)</p>
<p>Provider Screening and Enrollment Fees</p>	<p>Enhanced screening, such as licensure checks and/or criminal background checks of providers for enrollment and re-enrollment in Medicare, Medicaid and CHIP.</p> <p>Providers may be charged an application fee for screening, except physicians.</p> <p>Screening provisions to be implemented no later than 180 days after enactment.</p> <p>New Providers: Screening requirements apply to providers not enrolled as of the date of enactment on or after the date that is one year after the date of enactment.</p> <p>Current Providers: Screening requirements will apply to providers enrolled on the date of enactment or after the date that is two years after the date of enactment.</p>

Bill Provision	Patient Protection and Affordable Care Act (H.R. 3590) Health Care and Education Reconciliation Act of 2010 (H.R. 4872)
	<p>Screening procedures must be developed no later than 180 days after date of enactment. (H.R. 3590, Secs. 6401, 10603)</p> <p>Beginning January 1, 2011, the Secretary may withhold payment for the 90-day period beginning on the date of first claim submission for newly enrolled durable medical equipment (DME) suppliers if the Secretary determines there is a significant risk of fraudulent activity among suppliers of DME equipment within an identified category or geographic area. (H.R. 4872, Sec. 1304)</p>
Compliance Programs	<p>Establishment of a compliance program for providers or suppliers within a particular industry or category as a condition of enrollment. Secretary to determine timeline and required compliance program elements for specific types of providers and suppliers.</p> <p>Implementation date to be determined by the Secretary. (H.R. 3590, Sec. 6401)</p>
Reporting and Return of Overpayments	<p>Overpayments must be reported and returned by the later of 60 days after the date the overpayment was identified, or the date any corresponding cost report is due, if applicable. Overpayments retained after the deadline for reporting and returning is an “obligation” for purposes of the False Claims Act and is a basis for civil monetary penalties. (H.R. 3590, Sec. 6402)</p>
Exception from Civil Monetary Penalties for Certain Programs	<p>Definition of “remuneration” for civil monetary penalties purposes does not include remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs; coupons, rebates or other rewards from a retailer (e.g., pharmacy chain) that are offered to the general public and not tied to other items reimbursed under Medicare or a state health care program; unadvertised provision of items or services for free or less than fair market value based on financial need (e.g., transportation); or Part D plan waiver of first fill copayment for a generic Part D drug. (H.R. 3590, Sec. 6402)</p>
Sentencing Guidelines	<p>Requires amendments to the Federal Sentencing Guidelines to provide for enhanced penalties. (H.R. 3590, Sec. 10606)</p>
Intent Requirement for Fraud Under the Anti-Kickback Statute and Related Amendments	<p>Amendments to 42 U.S.C. § 1320a-7b (criminal penalties, including anti-kickback provisions):</p> <ul style="list-style-type: none"> ▪ Link to Federal False Claims Act. Claims resulting from violations of the anti-kickback statute constitute false or fraudulent claims for purposes of the False Claims Act. ▪ Revises intent standard. A person need not have actual knowledge of the anti-kickback statute or specific intent to violate the anti-kickback statute. ▪ Parallel amendment (“need not have actual knowledge of this section or specific intent to violate this section”) for 18 U.S.C. § 1347 (health benefit fraud). ▪ Adds violation of 42 U.S.C. § 1320a-7b, 18 U.S.C. § 1349, Section 301 of the FDCA (21 U.S.C. § 331) or Section 501 of ERISA (29 U.S.C. § 1131) as “federal health care offenses” as defined in 18 U.S.C. § 24(a). (H.R. 3590, Secs. 6402, 10606)
False Claims Act Amendments	<p>Narrows the False Claims Act public disclosure bar to <i>qui tam</i> actions whistleblowers file under the civil False Claims Act. (H.R. 3590, Sec. 1303)</p>

Bill Provision	Patient Protection and Affordable Care Act (H.R. 3590) Health Care and Education Reconciliation Act of 2010 (H.R. 4872)
Increased Funding to Fight Fraud and Abuse	Additional \$10 million/year for FY 2011–2020. (H.R. 3590, Sec. 6402) Additional \$200 million over FY 2011–2016. (H.R. 3590, Sec. 1304)
Requirement for Physicians to Provide Documentation on Referrals to Programs at High Risk for Fraud and Abuse	Physician’s enrollment may be revoked for failure to maintain and provide access to documentation regarding orders or requests for payment for DME, certifications for home health services, or referrals for other items or services as specified by the Secretary. Applies to orders, certifications and referrals made on or after January 1, 2010. (H.R. 3590, Sec. 6406)
Requirement of Face-to-Face Encounter Prior to Certification for DME and Home Health Services	Face-to-face encounter must be performed by a physician, physician assistant, nurse practitioner or clinical nurse specialist, or certified nurse-midwife within a reasonable timeframe as determined by the Secretary. (H.R. 3590, Secs. 6407, 10605)
Requirement for Establishment of Self-Referral Disclosure Protocol	Secretary must establish a Stark Law self-disclosure protocol no later than six months after enactment; Secretary may settle for less than the full Stark Law penalties (<i>i.e.</i> , Medicare collections relating to prohibited referrals) if warranted by the circumstances. (H.R. 3590, Sec. 6409)

Conclusion

According to a November 2009 press release from the U.S. Department of Justice (DOJ), in fiscal year 2009, health care fraud recoveries reached \$1.6 billion. The largest health care recoveries came from the pharmaceutical and medical device industries, which accounted for \$866.7 million in settlements. In a recent *Wall Street Journal* article, U.S. Assistant Attorney General Tony West, head of the DOJ's civil division, indicated that the DOJ has approximately 985 pending health care fraud cases, and that the significant number of cases reflects the DOJ's increased focus on health care fraud.

The fraud and abuse amendments in the health care reform legislation bring a number of changes to health care compliance and transparency requirements in an already daunting compliance landscape. Further, the government now has increased enforcement tools to aggressively pursue the various health care reform initiatives. Providers and industry will need to consider increased rigor in their compliance programs in order to fully integrate and account for the many complex and interrelated health care fraud and abuse reform initiatives.

For more information, please contact your regular McDermott lawyer, or:

Bernadette M. Broccolo: +1 312 984 6911 bbroccolo@mwe.com

Ankur J. Goel: +1 202 756 8234 agoel@mwe.com

Daniel H. Melvin: +1 312 984 6935 dmelvin@mwe.com

Joan Polacheck: +1 312 984 7556 jpolacheck@mwe.com

T. Reed Stephens: +1 202 756 8129 trstephens@mwe.com

Kate W. Feola: +1 202 756 8388 kfeola@mwe.com

For more information about McDermott Will & Emery visit www.mwe.com

The material in this publication may not be reproduced, in whole or part without acknowledgement of its source and copyright. "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" is intended to provide information of general interest in a summary manner and should not be construed as individual legal advice. Readers should consult with their McDermott Will & Emery lawyer or other professional counsel before acting on the information contained in this publication.

© 2010 McDermott Will & Emery. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery/Stamford LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, MWE Steuerberatungsgesellschaft mbH, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. McDermott Will & Emery has a strategic alliance with MWE China Law Offices, a separate law firm. These entities coordinate their activities through service agreements. This communication may be considered attorney advertising. Previous results are not a guarantee of future outcome.