KIRKLAND & ELLIS LLP

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The Health Reform Law Significantly Increases the Risk of Protracted Fraud and False Claims Act Investigations in the Health Care Industry

The media coverage surrounding passage of the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010) (the "Act") largely focused on the impact on the insurance industry. However, within the Act's more than 900 pages are more than 32 sections related to healthcare fraud and abuse and program integrity. These provisions make significant amendments to existing criminal, civil, and administrative anti-fraud statutes, including significant amendments to the Anti-Kickback Statute and False Claims Act. These amendments significantly increase companies' potential legal exposure under each statute as well as increase the risk of protracted fraud investigations or litigation.

Amendments to the Anti-Kickback Statute. The fraud and abuse amendments that may have the most significant impact on the health care industry are the amendments to the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b. Under the Act, Section 1128B of the Social Security Act is amended to expressly state specific intent is not an element of a violation of the statute. The Act thus repeals the judicially recognized specific intent element recognized by some courts, including the Ninth Circuit Court of Appeals in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). This new standard thus increases criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the statute.

The Act further amends the Anti-Kickback Statute to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act. Thus, prosecutors or *qui tam* relators no longer have to demonstrate a connection between an alleged kick back and the submission of a false claim. This amendment will have significant impact on downstream liability scenarios in which entities do not themselves submit claims directly to the government but allegedly "cause the submission of a false claim" by other entities. This amendment thus expands the reach of the "caused the submission of a false claim" liability provisions of the False Claims Act.

Amendments to the False Claims Act. The Act also includes a series of amendments designed to simplify civil False Claims Act prosecutions by the Government and private whistleblowers in *qui tam* actions and reduce, if not eliminate, the likelihood of earlier dismissals. In particular, the Act makes a significant change to the jurisdictional bar that has historically protected corporations from opportunistic *qui tam* suits. The Act amended the False Claims Act to eliminate the "public disclosure" jurisdictional element that required dismissal of a *qui tam* suit pursued by the private citizen (relator) where the allegations had been publicly disclosed in a criminal, civil, administrative or other proceedings or other public disclosure. The Act amended the False Claims Act to provide that the public disclosure bar is <u>not</u> jurisdictional and does not require dismissal *if* the government opposes dismissal. As a result the Government now has a veto that can be used to over-ride dismissal of a whistleblower suit who fails to qualify as an original source.

The Act also narrows the scope of what constitutes a public disclosure. The scope of the public disclosure bar had been judicially extended to include state proceedings and this expansion was affirmed by the U.S. Supreme Court in *Graham County Soil & Water Conservation District v. U.S. ex rel. Wilson, 130 S. Ct. 1396 (2010)*, issued March 30, 2010, after the enactment of the Act. However, the Act effectively overrides that decision. Public disclosure is now limited to federal criminal, civil, and administrative proceedings in which the government or its agent is a party; and federal reports, hearings, audits, or investigations, or disclosures "from the news media." State proceedings and private litigation are not qualifying public disclosures.

The Act also relaxes the requirements to be an original source. Where there has been a public disclosure, the relator may only proceed with the action if he or she is the original source of the information. Prior to the amendments contained in the Act, to qualify as an original source, the relator had to have direct and independent knowledge of the allegations. The original source exception has now been amended to eliminate the direct knowledge requirement. Rather, to qualify as an original source the relator must provide the information to the government prior to the public disclosure, and the information must be independent of and "materially add" to the publicly disclosed allegations.

Unlike the 2009 False Claims Act amendments, which contained express retroactivity provisions, the 2010 public disclosure amendments contain no retroactivity provision. However, while the 2010 False Claims Act amendments do not apply to cases pending on or before March 23, 2010, the new provisions do apply to conduct occurring prior to enactment.

Section 6402 of the Act also establishes independent False Claims Act liability for any "identified overpayment" that is not reported and repaid within 60 days to the applicable government contractor, intermediary, or other entity. Under the Act, the retention of any overpayment after the 60-day period constitutes an "obligation" under the False Claims Act. (Prior amendments to the False Claims Act expanded the definition of "obligation" to expressly include "retention of overpayments.") An "overpayment" is defined as any funds that a person receives or retains under title XVIII or XIX (the federal Medicare and Medicaid programs) to which the person, after applicable reconciliation, is not entitled under such title. 'Person' is broadly defined to include, among others, a "provider of services" or a "supplier." However, the concept of "identified" overpayments is not defined in the Act.

The Act contains a host of anti-fraud and abuse provisions that will impact business operations. These provisions will require new compliance procedures and policies in all corners of the health industry. However, the amendments to the Anti-Kickback Statute and False Claims Act contained within the Act are sure to increase potential legal exposure, including exposure arising from even inadvertent regulatory noncompliance. Careful planning is therefore a must. Compliance policies should be carefully reviewed and monitored.

If you have any questions about the matters addressed in this *Kirkland Alert*, including the potential impact of the Health Reform Law on your business, please contact the authors, Jay P. Lefkowitz or Patrick M. Bryan, or your regular Kirkland contact.

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