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Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions

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The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), contains more than 32 sections related to healthcare fraud and abuse and program integrity and makes significant amendments to existing criminal, civil, and administrative anti-fraud statutes. The new program integrity provisions impose substantial requirements that will compel updates and enhancements to business operations, commercial transactions, and compliance policies in every sector of the health industry. These provisions establish fundamental expectations for regulatory compliance, disclosure, transparency, and quality of care and are matched by extraordinary enforcement provisions that could greatly increase potential legal exposure. Healthcare entities should reinforce their broad and sustained commitment to compliance to successfully implement these provisions.

This alert presents a brief summary of the major fraud and abuse provisions in the Healthcare Reform Law as well as an overview of the program integrity provisions. Morgan Lewis has also prepared a detailed chart[1] outlining the fraud and abuse and program integrity provisions in the Healthcare Reform Law, many of which we note became effective on the date of enactment, March 23, 2010, and will require prompt compliance attention.

These provisions will also significantly impact government audit, investigation, and litigation resources and the structure for intra-agency cooperation. To address the impact on key program integrity and law enforcement agencies, the Healthcare Reform Law provides for the HIPAA Fraud and Abuse Control Program and the Medicare Integrity Program to receive total funding of $100 million for FY 2011 through 2020 under the March 23, 2010 legislation and an additional $250 million for FY 2011 through 2016 under the Reconciliation legislation, for a total of $350 million.

Morgan Lewis will continue to monitor and report on developments in healthcare fraud and abuse and program integrity matters.

I. FRAUD AND ABUSE PROVISIONS

A. Anti-Kickback Statute. The fraud and abuse amendments that may have the greatest impact on the healthcare industry in a direct and daily fashion are the amendments to the federal Anti-Kickback

[1] This chart is also available at http://www.morganlewis.com/pubs/FraudAbusePrgmIntegrityProvisions.pdf.

Statute (AKS). Healthcare arrangements and transactions directly and indirectly related to federal healthcare programs are regulated by the criminal and administrative provisions of the AKS. Violations of the AKS have resulted in significant False Claims Act liability for many healthcare entities. The amendments to the AKS will impact fraud and abuse counseling and liability evaluations in criminal and civil government investigations and judicial proceedings.

Under the Healthcare Reform Law, the AKS is amended to relax the specific intent requirement judicially recognized in *U.S. v. Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). The amendment provides that an AKS violation may be established without showing that an individual knew of the statute's proscriptions and intended to violate the statute. This new standard will impact transaction and arrangements counseling and could potentially create significant criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the statute.

The AKS is further amended to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the False Claims Act. This amendment may have its most significant impact on downstream liability scenarios involving manufacturers and other entities that do not themselves submit claims to the government under the "caused the submission of a false claim" liability provisions of the False Claims Act.

Interestingly, in Section 6402 of the Healthcare Reform Law, the definition of remuneration, the touchstone for the general application of the statute, is amended for the beneficiary inducement provisions under the civil monetary provisions of the AKS's Section 1320a-7a, *to exclude from the definition*, among other things, any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs. The beneficiary inducement statute does not apply directly to manufacturers but does apply to providers, practitioners, suppliers, health plans and other healthcare services entities. This definitional change is potentially significant as many health industry activities may come within this broad exclusion and will require thoughtful assessment in fraud and abuse transaction counseling.

B. False Claims Act Qui Tam Public Disclosure Bar. The Healthcare Reform Law makes a significant change to the jurisdictional bar that has historically served as a strong protector of health and other industries from parasitic and opportunistic qui tam suits that do not advance the public interest in the context of Department of Justice declined whistleblower qui tams. The False Claims Act previously contained a "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, or administrative proceeding; a congressional, administrative, or GAO report, hearing, audit, or investigation; *or in the news media.* The scope of this 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 (No. 08-304)*, issued March 30, 2010, after the enactment of the Healthcare Reform Law.

The False Claims Act is now amended to provide that the public disclosure bar is not jurisdictional and does not require dismissal *if the government opposes dismissal*. Public disclosure is also 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. State proceedings and private litigation (for example, employment, shareholder suits) are not qualifying public disclosures. Importantly, news media reports, and by logical extension social media, remain a qualified public disclosure.

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 Healthcare Reform Law, to

qualify as an original source, the relator had to have direct and independent knowledge of the allegations.

The original source exception is now amended to eliminate the direct knowledge requirement and provides that to qualify as an original source (1) the relator must provide the information to the government prior to the public disclosure, and (2) 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. Courts generally have found that False Claims Act amendments, including the 2009 amendments, *are not* retroactive. In *Graham County*, the majority opinion, authored by Justice Stevens, noted that because the 2010 False Claims Act amendments contain no retroactivity provisions, the public disclosure amendments are not retroactive. This means that 2010 False Claims Act amendments do not apply to cases pending on or before March 23, 2010.

While the public disclosure bar remains an important check on abusive qui tam suits, the amendments add significant litigation complexity and cost to declined qui tam actions and ensure that the Department of Justice has a prominent role in determining a relator's status to proceed with the declined qui tam action. To avoid abusive suits that do not advance the public interest, it will be critical that DOJ develop fair and balanced objective criteria to assess its now mandatory role in declined *qui tams* that involve pubic disclosure issues. It will be necessary for qui tam defense counsel to assess public disclosure issues well in advance of the government's intervention decision to positively impact both DOJ's and the trial court's consideration of this important legal defense.

C. Overpayments and False Claims Act Liability. Section 6402 of the Healthcare Reform Law provides that identified overpayments must be reported and returned (repaid) within 60 days to the applicable government contractor, intermediary, or carrier. The retention of any overpayment after the 60-day period constitutes an "obligation" under the False Claims Act. Under the 2009 amendments to the False Claims Act, the definition of "obligation" was expanded to expressly include "retention of overpayments."

The concept of "identified" overpayments in the Healthcare Reform Law is not defined. There are a host of duplicative and confusing statutory concepts between Section 6402 and the current version of the False Claims Act that it will be necessary to work through in providing compliance guidance. What is clear, however, is that the government's position will be that any delay in processing a *known* overpayment creates the potential for False Claims Act liability—a potential that has always existed in healthcare fraud enforcement and has been the basis for numerous False Claims Act settlements over the last 20 years.

Healthcare providers, suppliers, and health plans should ensure compliance with the new overpayment provision by putting in place robust auditing and refund processing structures. The overpayment obligation should be viewed in context with increased government audits under the Recovery Audit Contractor (RAC) program for federal healthcare programs, as well as with the new self-disclosure protocol for Stark Law physician self-referral violations, which *should* provide an opportunity for reasonable overpayment settlements under the identified criteria.

D. Stark Law Self-Disclosure Protocol. The Healthcare Reform Law creates a statutory disclosure protocol for violations of the physician self-referral prohibitions, known as the Stark Law. Under the Stark Law, a violation results in an overpayment liability to the government under a strict liability

standard without regard to intent. 42 U.S.C. § 1395nn(g)(2) and 42 C.F.R. § 411.353(d). Because the Stark Law imposes extraordinary financial liability for technical violations, there was an industry need for a fair and principled process to disclose and resolve Stark Law violations with CMS. Significantly, the new protocol will provide for agency discretion to resolve Stark violations and authorizes HHS to reduce the amount due and owing for all violations under the Stark Law, considering such factors as the nature and extent of the improper practice, timeliness of the disclosure, cooperation, and other factors in the agency's discretion. The Stark self-disclosure process will be critical to both the healthcare community and HHS in reasonably and fairly managing the expected discovery of technical Stark violations from enhanced compliance reviews.

The CMS protocol for self-disclosure will be developed in the next six months. Healthcare providers and suppliers need to assess disclosure efforts in context with the new overpayment provision in Section 6402, which is effective now. There will continue to be a significant potential for False Claims Act exposure for Stark Law violations through qui tam whistleblower suits.

E. Expanded Recovery Audit Contractor Activities (RAC). RAC audits of providers will increase and also expand to the Medicare Part D and Medicare Advantage healthcare programs. RAC auditors are compensated, in part, through a bounty process that includes a percentage of any amounts recovered through the audit. Healthcare providers and health plans will need to resource both internal audit activities as well as responses to RAC requests. Because RACs operate on behalf of the government, and may make program integrity and fraud referrals to law enforcement, it is necessary to structure audit responses to RACs with the same degree of diligence as a direct government request, including documenting interactions with RAC representatives.

F. Healthcare Fraud Criminal Statute. The Healthcare Reform Law amends the intent requirement contained in the healthcare fraud criminal statute, 18 U.S.C. § 1347. That statute now provides that proof of actual knowledge of the healthcare fraud statute or specific intent to violate the statute is not required. The definition of healthcare offense, 18 U.S.C. § 24(a), is also amended to include violations of the AKS, the Food Drug and Cosmetic Act, and certain ERISA provisions.

The U.S. Sentencing Guidelines are also amended with respect to individuals convicted of healthcare offenses related to any federal healthcare program. The offense level for such individuals is increased anywhere from 20 to 50 percent where the loss involves more than a million. In a highly regulated industry, with a myriad of complex regulations, these provisions effectively increase exposure for a broad array of business and regulatory activities where there is no specific intent to violate the provisions of the statute.

II. PROGRAM INTEGRITY PROVISIONS

The Healthcare Reform Law contains a host of program integrity provisions that will impact business operations and require enhanced procedures and policies in all health industry sectors. Some of these provisions, if violated, may comprise a basis for overpayment or fraud liability. These provisions include new employee and vendor screening requirements, new financial disclosure requirements, the requirement of face-to-face physician and patient encounters for DME and home health services, and new price reporting requirements in the 340B program. Of special note in the program integrity provisions is the requirement that Medicare and Medicaid providers and suppliers, effective January 1, 2011, include their national provider identifier on all program applications and *claims*.

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