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Health Care Reform Law Amends Many Existing Anti-Fraud Statutes, Increasing Need for Effective Compliance Programs

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Health Care Alert

This is the third in a series of health care alerts that Hinshaw & Culbertson LLP will publish on the topic of health care reform.

The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended, significantly changes many existing anti-fraud laws by expanding exposure to civil and criminal liability. PPACA also increases both funding for enforcement activities and penalties for violations. Health care providers should consider developing enhanced compliance programs to effectively respond to these new requirements. This alert discusses the major fraud and abuse provisions found in the new law, most of which became effective March 23, 2010.

The Anti-Kickback Statute
The Anti-Kickback Statute prohibits the knowing and willful payment or receipt of remuneration in exchange for the referral of business payable by a federal health care program. The PPACA adds a provision to the Anti-Kickback Statute that codifies the interpretation of the "knowing and willful" standard used by the majority of federal courts. Under this standard, the government can establish a violation of the Anti-Kickback Statute without showing that an individual knew about the statute's specific prohibitions or intended to violate the statute. This amendment does not eliminate the requirement that the government show that an individual knew his or her conduct was unlawful. Rather, it means that the government need not prove that a person had the intent to specifically violate the Anti-Kickback Statute.

In addition, the PPACA amends the Anti-Kickback Statute to provide that a violation of the Anti-Kickback Statute constitutes a false and fraudulent claim under the False Claims Act. Previously, prosecutors and whistleblowers were required to prove that a kickback was connected to the submission of a false claim, such as through a certification of compliance. This burden is now lightened, as the prosecutor or whistleblower need only prove a violation of the Anti-Kickback Statute in order to establish the submission of a false claim. This amendment may result in increased activity by whistleblowers, who may find it easier to prove their cases.

The False Claims Act
The False Claims Act provides that anyone who knowingly submits false claims to the government is liable for damages up to three times the amount of the erroneous payment plus mandatory penalties for each false claim submitted. Whistleblowers, or "relators," can bring False Claims Act actions of behalf of the interests of the government. Those claims are commonly referred to as "*qui tam*" lawsuits. Depending upon a variety of factors, relators may be entitled to a portion of the damages recovered.

The PPACA amends the False Claims Act in several ways. First, it abolishes the "public disclosure" bar, and it narrows the definition of "public disclosure," such that a relator can now bring a qui tam action that is based on allegations previously disclosed through state proceedings or private litigation. It also broadens the exception for whistleblowers claiming to be the "original source" of the publicly disclosed allegations. Previously, if there had been a public disclosure of the information upon which the *qui tam* suit was based, a relator had to be the original source of the information, meaning that he or she had to have direct and independent knowledge of the allegations. Now, the relator need not have direct

knowledge, but instead must provide information to the government prior to the public disclosure, and the information must be independent of and materially add to the publicly disclosed allegations. These amendments to the False Claims Act will likely serve to increase the number of *qui tam* lawsuits that involve public disclosure issues.

Overpayments
The PPACA requires health care providers to report and return any overpayment within 60 days of either the date the overpayment is identified or the date a corresponding cost report is due, whichever is later. An overpayment that is retained after this date becomes an "obligation" under the False Claims Act. In 2009, the False Claims Act was amended to prohibit, among other things, concealing, improperly avoiding, or decreasing an obligation to pay money to the government. The definition of "obligation" includes "retention of overpayments," which, under the PPACA amendment, means the failure to repay an overpayment within 60 days of the date on which the overpayment is identified. Retaining a known overpayment clearly creates potential False Claims Act liability, but what constitutes an "identified" overpayment is currently unclear. To mitigate the risk of substantial damages under the False Claims Act, health care providers are advised to have robust auditing and refund processing procedures in place.

Physician Self-Referral Law
The "Stark Law" prohibits a physician from referring a patient for certain designated health services to an entity with which he or she has a financial relationship, unless an exception applies. A violation of the Stark Law results in an overpayment, even if a party does not intend to engage in unlawful conduct. As substantial penalties may arise for technical violations, a fair process was needed to disclose and resolve actual or potential Stark Law violations. Under the PPACA, the U.S. Department of Health and Human Services has the discretion to reduce amounts due and owing, taking into consideration factors such as the nature and extent of the illegal practice, the timeliness of the self-disclosure, and cooperation in providing additional information. The self-referral disclosure protocol will be established within six months of enactment of the PPACA. It will likely take on increased importance because health care providers may discover previously undetected technical violations through improved compliance reviews undertaken in light of the other anti-fraud provisions in the law. It is important to note that the obligation to return identified overpayments, including overpayments that result from Stark Law violations, became effective on March 23, 2010, whereas the self-referral disclosure protocol will not be in effect for several months. Thus, for now, overpayments due to Stark Law violations must be reported and returned without the benefit of a self-referral disclosure protocol.

Civil Monetary Penalties Law
The PPACA expands liability under the Civil Monetary Penalties Law. These changes demonstrate the government's anti-fraud priorities, subjecting health care providers to civil monetary penalties, in addition to damages under the False Claims Act, for submitting false claims or retaining overpayments.

Also, the Civil Monetary Penalties Law imposes liability on a person who offers or pays to a Medicare or Medicaid beneficiary remuneration that the person knows or should know is likely to influence the beneficiary to order an item or service payable by a federal health care program. The PPACA amends the definition of "remuneration" under these circumstances to exclude, among other things, (a) a payment of remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs, and (b) the offer or transfer of items or services for free or less than fair market value to a person in financial need if certain conditions are met. This change to the definition of "remuneration" could allow activities that many not-for-profit health care providers would consider consistent with their charitable missions. However, such activities must be carefully analyzed to ensure that they would not violate the Civil Monetary Penalties Law, even as amended by the PPACA.

Criminal Health Care Fraud Statute
The exposure to criminal liability that results from the amendments to the Anti-Kickback Statute, as discussed above, is increased in light of the PPACA's amendment to the criminal health care fraud statute, a separate law. As with the Anti-Kickback Statute, the PPACA provides that actual knowledge of the criminal health care fraud statute, or specific intent to violate the statute, is not required. Furthermore, violations of the Anti-Kickback Statute, along with violations of the Food, Drug, and Cosmetic Act and certain provisions of the Employee Retirement Income Security Act (ERISA), are now considered criminal health care fraud violations.

Enforcement and Penalties
The health care reform law will result in increased anti-fraud enforcement activities. The PPACA appropriates $100 million for fiscal years 2011 through 2020, and the Health Care and Education Reconciliation Act of 2010 appropriates $250 million for fiscal years 2011 through 2016, to cover administrative and operational costs of health care fraud and abuse control programs. Further, audits by Recovery Audit Contractors will be expanded to include Medicaid and Medicare Parts C and D. In addition, the PPACA increases penalties for certain violations. It provides for suspension of Medicare and Medicaid payments during the investigation of a credible allegation of fraud, unless the U.S. Department of Health and Human Services determines that there is good cause not to suspend payments. Also, it amends the Federal Sentencing Guidelines to increase offense levels from 20 to 50 percent where the loss to the government exceeds $1 million.

Taken together, the anti-fraud provisions in the PPACA may increase health care providers' exposure to administrative, civil and criminal liability. Specifically, liability under the False Claims Act and various criminal statutes has been significantly expanded. Health care providers are advised to carefully structure transactions so as to avoid violations of the Anti-Kickback Statute, which now expressly constitute false claims. Also, health care providers should institute robust auditing procedures in order to discover and return overpayments to the government.

For more information, please contact your regular Hinshaw attorney.

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