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FRAUD, ABUSE LAWS EXPANDED UNDER REFORM LEGISLATION

Health-care providers should take extra steps to ensure compliance

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The Patient Protection and Affordable Care Act (PPACA) of 2010 made sweeping changes to existing federal fraud and abuse laws in the health-care context. The program integrity provisions of the PPACA expand the scope and applicability of existing anti-fraud legislation in ways that will have a significant and immediate impact on all entities involved in the health services industry including health plans, providers, practitioners, suppliers, and manufacturers. This article discusses three changes to fraud and abuse laws that will have widespread effect on the business operations and compliance efforts in the health-care market.

Anti-Kickback Statute

Health-care arrangements and transactions funded by federal health-care programs (such as Medicare and Medicaid) are subject to the federal anti-kickback statute. Prior to passage of the PPACA, the statute prohibited individuals and entities from knowingly and willfully offering, soliciting, or accepting consideration of any kind in exchange for referring a person to receive or purchase items or services paid for by a federal health program.

A violation of the anti-kickback statute is a felony that is punishable with imprisonment of up to five years in prison and/or a fine of up to $25,000. Health-care providers who violate the statute can also be excluded from participation in Medicare and Medicaid.

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Prior to passage of the PPACA, courts held that the government must prove that an individual accused of a violation actually knew that his or her conduct violated the anti-kickback statute. The PPACA legislatively overturns this narrow construction of the specific intent requirement and provides that the government can now prove a violation without having to show that the individual intended to violate the statute. The government must still prove that the accused intended to induce the underlying purchase or referral, but specific intent to violate the anti-kickback statute is no longer required.

While the statute has been applied to prohibit a wide variety of transactions, its application is best illustrated by the example of a doctor who bribes a Medicare beneficiary to become a patient so that the doctor can bill Medicare for the cost of the beneficiary's health-care services. Prior to passage of the PPACA, the government had to prove that the doctor intentionally bribed the Medicare beneficiary and knew that payment of the bribe violated the statute. Today, the government need only show that the doctor intended to pay the bribe.

The PPACA also adopted a "fruit of the poisonous tree" approach to violations. The PPACA provides that any claim for services resulting from a violation of the anti-kickback statute now constitutes a false or fraudulent claim for purposes of the federal False Claims Act (FCA). Under the FCA, the government can recover treble damages, impose a $5,000 to $10,000 civil penalty per violation, and recover its litigation costs. So not only do offenders get prosecuted and penalized for the initial violation of the AKS, but the government can seek additional criminal and civil penalties for each claim arising out of the prohibited arrangement. So the doctor who bribed the Medicare beneficiary gets

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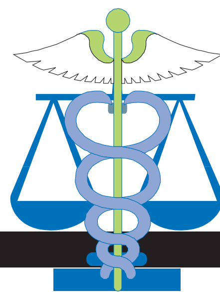
HEALTH  LAW

prosecuted for the bribe under the anti-kickback statute, and then prosecuted for submitting false claims to Medicare under the FCA.

A single violation can lead to significant criminal liability and financial exposure. Health-care entities should review their arrangements with referral sources to ensure that they comply with the requirements and safe harbors of the anti-kickback statute.

Overpayments

Another provision of the PPACA increases the exposure associated with failing to report government overpayments. Prior to health-care reform, the knowing concealment or avoidance of "an obligation to pay or transmit money or property to the Government" was enforceable under the False Claims Act. While most risk managers and compliance officers would agree that health-care entities had an obligation under existing law to refund government overpayments, there were no clear standards governing the time frame for returning such overpayments.

Health-care reform now requires health-care entities to return overpayments to the government within 60 days or face liability under the False Claims Act. The PPACA expressly provides that Medicare and Medicaid overpayments must now be reported and returned within 60 days of "identification." At first blush, the new amendment appears to be straightforward; however, an issue that is likely to be developed by regulation or litigation will be determining when an overpayment is "identified" in various contexts for purposes of triggering the 60 day repayment period.

Health-care reform amendments to the federal whistleblower law further increase the risk associated with retaining government overpayments. Under the False Claims Act, an insider is barred from bringing a *qui tam* case as a government relator when the information related to the case has been publicly disclosed. Prior to the PPACA, "public disclosure" was interpreted broadly, thereby limiting the number of claims that could be brought by relators. The PPACA narrows the definition of "public disclosure" which will make it easier for insiders to bring *qui tam* cases. By making clear that FCA penalties apply to overpayments, the PPACA also makes bringing a whistleblower claim potentially more lucrative for the relator, who typically retains a percentage of the amount recovered in the case.

Entities receiving payments from government programs should have policies and procedures for identifying and reporting overpayments. Entities that keep overpayments face significant risk not only from government fraud fighters, but from internal whistleblowers who could reap substantial bounties by bringing *qui tam* actions on the government's behalf.

Self-Disclosure Protocol

The federal physician self-referral law, otherwise known as the Stark Law, prohibits a physician from referring patients to an entity with which the physician has a financial relationship. There are statutory and regulatory exceptions to Stark, but such exceptions are fact specific and construed narrowly.

Technical compliance with the Stark Law can be challenging, and it is not uncommon for providers to find themselves out of compliance with Stark years after entering into a prohibited relationship with another entity. Under existing law, there was no practical way for a provider to remedy an existing Stark violation without incurring catastrophic financial consequences, because providers who self-disclose a Stark violation must repay all payments received from Medicare and Medicaid during the period of time while the prohibited relationship was in place. Providers in this situation are faced with choosing between willful non-compliance with Stark and the risks attendant thereto, or self-imposed financial ruin.

In a bit of good news for health-care providers, the PPACA requires the Department of Health and Human Services to establish a self-referral disclosure protocol on or before Sept. 23, 2010. The protocol will allow entities to disclose Stark violations to Health and Human Services, and the department will have the discretion to reduce the amount due for violations under the Stark Law based on several factors. It is unclear exactly how officials will apply the self-referral disclosure protocols, but it will at a minimum provide health-care entities with the possibility of avoiding a catastrophic penalty through self-disclosure of a Stark violation.

The administration of President Barack Obama is focusing its efforts on reducing the amount of fraud and waste in federal health-care programs. Health-care providers should take efforts now to ensure that their operations are compliant with the requirements of these programs in order to avoid significant liability.

If areas of operation are determined to be out of compliance, providers should make timely disclosure of these errors through appropriate channels and with the assistance of legal counsel. ■