# Amendments to Stark Law and Anti-Kickback Statute and New Compliance and Enforcement Authorities

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The Patient Protection and Affordable Care Act made important changes to the Medicare and Medicaid fraud and abuse laws. Many of these changes have been somewhat overlooked in the debate over the public option, abortion restrictions, the individual mandate and other contentious issues. However, the Act contains changes to the Stark Law, changes to the Anti-Kickback statute, new compliance mandates, and powerful new remedies in the event of overpayments and allegations of health fraud.

**Limitation on Stark Law Exceptions for Rural Hospitals and Physician-Owned Hospitals.**

The Stark Law and regulations currently contain exceptions allowing physicians who have ownership interests in hospitals to continue to make referrals of Medicare patients to those hospitals, either through the "rural provider" exception or through the exception that applies to an ownership interest in an entire hospital. Under the Act, the continued use of these exceptions is subject to stringent new requirements, including a freeze on increases in surgical capacity and beds for such facilities, patient disclosure requirements, and a freeze on issuing new investment interests to referring physicians. The freeze on expansion of capacity is subject to an exceptions process that will be administered by the Secretary of Health and Human Services.

This change takes effect 18 months after the date of enactment.

Clearly, the Administration is seeking to limit both the competitive and fiscal impact of physician-owned hospitals. The freeze will make it very difficult for these hospitals to expand their services or bring in new physician investors. This is a continuing pattern in amendments of the Stark regulations generally, which is to limit existing exceptions without expressly repealing them.

**Disclosure Requirements for In-Office Ancillary Services**

The Act amends the Stark Law as it applies to physician practices that provide MRI, CT and PET imaging services, requiring that any physician group practice that provides such services must notify its patients that they may obtain such services from other providers, and requiring the group practice to provide a list of other imaging suppliers at the time of the referral. The Secretary is also empowered to expand the disclosure requirement to other services through rule making.

This change takes effect for services furnished on and after January 1, 2010. There is already some dispute as to whether this requirement can be effective before the Secretary promulgates regulations.

The Medicare program has repeatedly raised concerns relating to high utilization of diagnostic imaging when ordering physicians have the opportunity to share in technical component revenue. This disclosure requirement is simply the latest in a series of regulatory requirements that seeks to narrow or modify Stark exceptions for self-referral in this area.

**Stark Law Violation Self-Disclosure Protocol**

The Act requires the Secretary of Health and Human Services and the Office of the Inspector General to jointly develop a self-disclosure protocol allowing provider and suppliers to disclose "actual or potential" violations of the Stark Law. The Act allows the Secretary to reduce the amount due and owing for "all violations" of the Stark Law to an amount less than otherwise required by the statute, and sets forth the factors that the Secretary may consider in making such reductions, including the nature and extent of an improper or illegal practice, the timeliness of self-disclosure, and the degree of cooperation in providing additional information related to the disclosure.

The Act directs the Secretary to establish the self-disclosure protocol no later than six months after the effective date of the Act. The Act requires the Secretary to report on the effectiveness of the self-disclosure protocol no later than 18 months after the creation of the protocol.

This provision of the Act may be a reaction to the Office of the Inspector General's March 24, 2009 Open Letter that excluded Stark violations from the OIG's self-disclosure protocol unless the underlying conduct also amounted to "colorable anti-kickback violation." In theory, the self-disclosure protocol should be good news for organizations that

want to resolve possible Stark violations by taking the initiative to approach the government first.

**Changes to the Anti-kickback Statute**

The Act amends the anti-kickback statute by classifying claims for items or services "resulting from" a violation of the anti-kickback statute as "false or fraudulent claims." In other words, if the government can demonstrate a nexus between a kickback and a referral, then that referral becomes a false claim subject to recoupment and the imposition of financial penalties.
The Act also revises the intent requirement for the anti-kickback statute, stating that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the anti-kickback statute in order to be found guilty of a "willful violation." This overrules the 1994 Circuit Court opinion in the *Hanlester Network* case, but does not change the law in the federal circuits that did not follow this opinion. In essence, this means that the government need not prove that a criminal defendant knew of and specifically intended to violate the anti-kickback statute, only that the defendant intended to perform the actions that violated the anti-kickback statute.

These changes take effect on upon enactment of the Act.

**Exemption from Civil Penalties for Certain "Charitable and Other Innocuous Programs"**

The Act also creates an exception to the civil monetary penalty statute for charitable programs that increase access to care, by protecting remuneration that increases access to care and poses a low risk of program harm, as determined by the Secretary. The Act also protects rebates offered to consumers, and for free products or services that are offered only on the basis of financial need and are not otherwise linked to or used to promote reimbursable services or items.

This change takes effect upon enactment of the Act.

**Compliance Plans to be Required for Nursing Homes and May be Required for Other Providers and Suppliers**

The Act requires that every skilled nursing facility and long term care facility adopt a compliance and ethics program for the prevention and detection of criminal, civil, and administrative violations and promoting quality of care. The compliance plan must meet standards set forth in regulations promulgated by the Secretary in consultation with the OIG. The regulations are intended to be scalable, such that larger organizations will be subject to more formal and detailed compliance requirements.

Significantly, the Act also permits the Secretary to require all other types of providers or suppliers to establish compliance programs as a condition of enrollment. The compliance programs must contain "core elements" determined by the Secretary in consultation with the OIG. The Secretary can impose these requirements by industry sector or category. State Medicaid programs will require compliance plans in a similar matter, based on criteria adopted by the Secretary.

This requirement for nursing homes to have a compliance plan take effect 36 months after enactment of the Act. If the requirements are extended to other providers and suppliers, those requirements shall apply when and if determined by the Secretary of Health and Human Services.

Compliance guidance has, until now, been "voluntary." For nursing homes, it soon will be mandatory. It seems probable that it will eventually become mandated for all providers and many kinds of suppliers, as well.

**Enhanced Enforcement Remedies for Overpayments and False Claims**

The Act's new program integrity provisions require any provider, supplier, Medicaid managed care organization, Medicare Advantage organization or Medicare Prescription Drug Plan Sponsor to report and return any overpayments made under the Medicare or Medicaid programs within 60 days after the date that the overpayment is identified, or 60 days after any corresponding cost report is due, whichever is later. Failure to return an overpayment is now also grounds for the imposition of false claims liability against the entity who received the overpayment, without regard to whether the overpayment was received as a result of a false claim.

This change takes effect upon enactment of the Act.

The 60-day reporting requirement will put additional stress on compliance programs, and could make full investigation of possible overpayments challenging. This is a significant expansion of the government's false claims authority.

**Enhanced Civil Monetary Penalties for False Statements or Delaying Inspections**

The Act allows the imposition of civil monetary penalties for the creation or use of false records or statements material to a false claim. The Act also imposes penalties on providers and suppliers that fail to grant the OIG timely access to records for the purpose of audits, investigations, evaluations, or other statutory functions performed by the OIG. The Act allows a $50,000 penalty for each false record or statement, and a $15,000 penalty for each day that an entity does not provide required records to the OIG.

These provisions apply to acts committed on or after January 2, 2010.

**Suspension of Medicare and Medicaid Payments Pending Investigations of Credible Allegations of Fraud**

Significantly, the Act allows the Secretary to suspend Medicare payments otherwise owed to a provider of services or a supplier "pending an allegation of a credible investigation of fraud" against the provider or supplier, unless the Secretary determines that there is good cause not to suspend payments. The Act requires the Secretary to consult with the OIG in determining whether a "credible allegation" of fraud exists, and requires the Secretary to promulgate regulations governing the use of payment suspensions.

This new enforcement power will become effective on a date to be specified in final regulations.

These new responsibilities and authorities represent a significant expansion of the government's power to recover overpayments from providers, and further tilt the playing field in favor of the government in the event of a payment dispute. The 60-day window for refunding overpayments is quite short, given the complexity of determining whether an overpayment even exists. The ability to suspend payment in the event of a "credible allegation" raises serious due process concerns.