

PPACA and Healthcare Reform Statutes Fraud and Abuse Provisions: Impact On Providers



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The Latest in a Long Series of Increasingly Rigorous Enforcement Legislation

- Patient Protection and Affordable Care Act of 2010 (PPACA)
 - Enacted March 23, 2010
- Health Care and Education Reconciliation Act of 2010
 - Enacted March 30, 2010

Key Provisions Affecting Providers

- Provides for Increased Funding over the Next 10 Years
- Tightens Language of the Anti-Kickback Statute
- Expands Reach of False Claims Act to include Anti-Kickback Statute Violation
- Imposes Mandatory Repayment of Overpayment
- Expands Recovery Audit Contractor Program

Key Provisions Affecting Providers (con't)

- Authorizes Secretary of HHS to Suspend Payments for Credible Evidence of Fraud
- Amends Stark Law Provisions Relating to in Office Ancillary Services Exception and Whole Hospital Exception
- Provides for a Voluntary Disclosure Program for Stark Law Violation
- Requires Providers to Have a Compliance Plan to Enroll in Medicare
- Enacts Physician Payment Sunshine Provisions, Requiring Disclosure of Payments to Physicians by Manufacturers of Drugs, Devices, Biologicals, and Medical Supplies

Increased Funding over the Next Ten Years

- PPACA increased Healthcare Fraud and Abuse Control Account for FY 2011 to 2020 by \$10 million per year
- Reconciliation Act added an additional \$250 million between 2011 and 2016
- Total increase of \$350 million dedicated to enforcement

Tightens Language of the Anti-Kickback Statute

- Reduces burden for prosecutors
- Eliminates the requirement that an individual have actual knowledge of the statute
- Eliminates the requirement to demonstrate that an individual had intent to violate this statute
- Responds to 9th Circuit Decision in Hanlester, which had imposed a specific knowledge requirement and effectively precluded aggressive government prosecution.

False Claims Act Expansion

- Anti-Kickback Statute violation constitutes a violation of the False Claims Act
- Eliminates historical litigation on this question, further easing the path for prosecutors

False Claims Act Expansion (con't)

- Provides that failure to refund identified overpayment within 60 days triggers a violation of the False Claims Act
- Critical question of how to define “identified” overpayments
 - Clear cases: Stark Law violation, credit balances, services rendered by excluded persons
 - Not so clear: questions of medical necessity; lack of documentation

Recovery Audit Contractor Expansion

- Expands RAC Program to include Medicare Part C and Medicare Part D
 - Parts A and B already included in RAC Program
 - Also expands RAC Program to Medicaid

Suspension of Payments for Credible Evidence of Fraud

- Provides for suspension of Medicare/Medicaid payments pending investigation of a credible allegation of fraud
- Legislation appears to presume that payments will be suspended in such cases, as it provides an exception if HHS determines there is a good cause not to suspend payments
- Regulatory provision for suspension of payments has existed for many years, but rarely used.
- Ratification of regulation suggests that this tool may be used more aggressively in the future

Stark Law Provisions

- Further limitation on in-office ancillary services exception
 - Physician is required to inform a patient in writing that the patient may obtain a designated health service from another supplier and provide a list of such suppliers in the area.
 - Applies to radiology and other services, as well as any other designated health services the Secretary determines appropriate.
- Prohibits new physician ownership in hospitals
 - Effectively eliminates the “full hospital” exception on a prospective basis.
 - Existing hospitals with provider agreements effective as of December 31, 2010 are grandfathered, although significant restrictions exist on expansion, and significant reporting requirements are imposed.

Stark Law Self-Disclosure Program

- Legislation directs HHS to establish a self-referral disclosure protocol for Stark Law violations
- In 2009, the OIG announced that it would no longer accept voluntary disclosures relating to Stark Law violations
- Significant provision in that HHS has discretion to resolve violations and to reduce the amount due as a result of those violations
- Protocol must be in place by September 23, 2010

Mandatory Compliance Plan

- Legislation mandates compliance programs for enrollment in Medicaid and Medicare for all providers and suppliers
- Secretary of HHS will establish core elements of the mandatory compliance program for providers and suppliers within a particular industry
- The Secretary of HHS is directed to establish standards in timing for implementation

Physician Payment Sunshine Provision

- Manufacturers of drugs, devices, biologicals, and medical supplies are required to submit information on an annual basis to HHS regarding the value, nature, purpose, and name of the individual who received anything of value.
- Language in this statute is “payment or other transfer of value” designed to capture not only payments made, but also gifts, meals, payment for travel, as well as investment interests, royalties, and licenses.
- Initial disclosures cover expenditures made in 2012, with first disclosure due March 31, 2013.
- All payments in excess of \$10, with an aggregate of \$100 per year, are covered.

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