The Impact of the PPACA on Fraud and Abuse Issues

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The Patient Protection and Affordable Care Act

• The Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148
  – Enacted on March 23, 2010
  – Signed by President Obama on March 30, 2010
  – CBO estimate of $940M cost during first 10 years
    • Paid for, in part, by eliminating fraud, abuse and waste in Federal health care programs
Reconciliation Act

• The Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), Pub. L. 111-152, made changes to PPACA
  – Signed into law on March 30, 2010
Significant Fraud and Abuse Provisions

• Increased funding for enforcement
• Expansion of RAC program
• *Hanlester* overruled
• Public disclosure standard
• Stark law amendments
  – Notification to patients under IOAS exception
  – Physician investment in hospitals
• Stark self-disclosure protocol
• Mandatory return of overpayments within 60 days
• CMP changes
• Exclusions under Medicaid
• Mandatory compliance programs
Increased Funding for Enforcement

• Omnibus Appropriations Act of 2009 provided a one-time additional $198 million.
• 2010 Budget invests $311 million in 2-year funding (50-percent increase over FY09).
• 2011 Budget seeks $250 million to expand HEAT.
• PPACA increases Health Care Fraud and Abuse Control (HCFAC) Account for FY11-20 by $10 million a year.
• Reconciliation Act added an additional $250 million to the account between 2011 and 2016.
Expansion of RAC Program

• Expands the Recovery Audit Contractor program to cover Medicare Parts C and D
  – Existing program covers Parts A and B
• Expands coverage to Medicaid program
• Expansion takes place not later than December 31, 2010
Hanlester Overruled

- In *Hanlester Network v. Shalala*, the Ninth Circuit interpreted the Anti-Kickback Statute’s “willfully” intent requirement to mean that the government had to prove that a defendant knew that the AKS prohibited the conduct at issue. 51 F.3d 1390 (9th Cir. 1995).

- PPACA makes clear that the AKS does not require a heightened scienter standard resolving circuit split.

- Removing this burden in the Ninth Circuit allows prosecutors to charge and present cases based on a substantially reduced evidentiary foundation and may encourage increased utilization of the AKS.
Public Disclosure Standard

• PPACA narrows the FCA’s “public disclosure bar.”
• PPACA provides that a whistleblower suit cannot be barred unless “substantially the same allegations or transactions were publicly disclosed” in: (1) “a Federal criminal civil or administrative hearing in which the government or its agent was a party;” (2) “a congressional, [GAO], or other Federal report, hearing, audit, or investigation,” or (3) “from the news media.”
• No more bar based on prior state and local disclosure.
• PPACA expands “original source” to include any individual who has knowledge that is “independent of and materially adds to the publicly disclosed allegations or transactions, and who voluntarily provided the information to the government” before filing the suit.
Stark Law Amendments:
IOAS Exception

• Section 6003 amends the statutory exception for IOAS
  – Requires a physician to inform a patient in writing that the patient may obtain the DHS from another entity outside the physician’s group practice
  – Applies to MRI, CT and PET, and “any other DHS specified under (h)(6)(D) that the Secretary determines appropriate”
    • Section (h)(6)(D) reference is to radiology and other services
  – Requires a physician to provide a written list of suppliers in the area in which the patient resides
• Effective for services furnished on or after January 1, 2010
• CMS will promulgate regulations to implement this section
• Location of the new language in the statute is KEY.
Stark Law Amendments: Physician Investment in Hospitals

• Section 6001 limits rural provider and “whole hospital” exceptions
  – Prohibits physician ownership in any hospital that does not have a Medicare provider agreement as of December 31, 2010
  – May Grandfather existing hospitals with provider agreements as of December 31, 2010 (statute ambiguous), but
    • Restricts ability to expand capacity (except in limited cases)
    • Restricts ability to increase aggregate percentage of physician ownership
  – Requires written annual report to HHS regarding identify of owners and extent of ownership interests
    • Information will be published on an HHS web site
  – Tests regarding “bona fide” investment included in statute
  – Regulations must be promulgated by January 1, 2012
Stark Self-disclosure Protocol

- Section 6409 requires HHS and OIG to establish a self-referral disclosure protocol (“SRDP”) within 6 months of enactment of PPACA
  - Must be established by September 23, 2010
  - CMS taking informal self-disclosures prior to enactment
- CMS must publish on its web site instructions for how to access and use the SRDP
- Clear statement that the SRDP is not to be used as part of the advisory opinion process to determine whether there is a Stark violation
Mandatory Return of Overpayments within 60 Days

• Section 6402 (new 1128J of the SS Act) provides that, if an entity has received an overpayment, it is required to report and return the overpayment to the Secretary or the State Medicaid Agency or the appropriate contractor and notify it of the reason for the overpayment.

• The overpayment must be reported and returned within 60 days of the date on which the overpayment was identified, or the date any corresponding cost report is due (if applicable), whichever is later.

• Any overpayment retained past the deadline is an “obligation” (as defined in, and for purposes of, the reverse false claims provision of the False Claims Act)
  – In 2009 FERA made changes to the reverse false claims provision
  – Whether and under what circumstances FERA imposed a duty to disclose self-discovered overpayments has been the subject of much discussion.

• “Overpayment” is defined in section 6402 of the PPACA as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled.
CMP Changes

• Adds penalties for
  – Knowingly making false statements in an application, bid or contract to participate or enroll as a supplier or provider
  – Failing to report or return a known overpayment
  – Ordering or prescribing items or services during a period when the prescriber was excluded from a Federal health program and the person knows or should know that a claim will be made for the item or service
  – Failing to grant OIG timely access for audits, investigations, evaluations, etc.
  – False statements material to a false or fraudulent claim for payment for an item or service furnished under a Federal health care program
Exclusions under Medicaid

- PPACA requires States to terminate individuals or entities from their State Medicaid programs if they have been terminated from Medicare or another State’s Medicaid program.
- Medicaid programs must also exclude an individual or entity that owns, controls, or manages another entity that has failed to repay overpayments, been suspended, terminated, or excluded from Medicaid participation, or is affiliated with any such entity.
Mandatory Compliance Programs

- As a condition of enrollment in Medicare, Medicaid and/or CHIP, providers and suppliers must develop and implement a compliance program
- HHS will establish standards and timing through regulations
- Likely to have different standards for various provider/supplier categories