The Patient Protection and Affordable Care Act of 2010: Fraud and Abuse Update

Presented by

John R. Washlick
jwashlick@cozen.com

Melanie K. Martin
mmartin@cozen.com

The confidence to proceed.
Amendments to health care program integrity and transparency-related provisions of various federal laws by Patient Protection and Affordable Care Act of 2010 (PPACA) (P.L. 111-148; Mar. 23, 2010), as amended by Health Care and Education Reconciliation Act of 2010 (P.L. 11-152; Mar 30, 2010)
Increased Funding of Health Care Fraud Initiatives

- Additional $10 million per year for FY 2011-2020 (PPACA Sec. 6402)
- Additional $250 million over FY 2011-2016 (Sec. 1303 of Reconciliation Act)
- Expect significant increases in False Claims Act enforcement and Stark-related FCA cases!
New and Enhanced Civil Monetary Penalties

- Sections 6402 and 6408 of PPACA add and enhance CMP penalties for:
  - Knowingly making, using or causing to be made, a false record or statement material to a claim for payment for items or services furnished under a Federal health care program
  - Failing to promptly report and return a known overpayment
  - Knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (including Medicare Advantage plan, Part D drug plan sponsor, or Medicaid MCO)
  - Failing to grant timely access, upon reasonable request, to the OIG for audits, investigations, evaluations or other statutory functions
  - Ordering or prescribing an item or service that a person knows will be paid by a federal health care program while the person is excluded
  - $50,000 for each false record or statement, and $15,000 for each day of delay
• Under Sec. 6402(h) of PPACA, Secretary may suspend **Medicare and Medicaid** payments to a Medicare provider or supplier “pending investigation” of a “credible allegation of fraud,” absent good cause not to do so

• Secretary must consult with the OIG in determining whether a credible allegation of fraud exists

• Regulations required

• Parallel provisions for Medicaid
Suspension of Payments

- Proposes to revise 42 C.F.R. § 405.370 to define “credible allegation of fraud” to include an allegation derived from “any source,” including:
  - “hotline” sources
  - claims data mining
  - patterns identified through audits
  - civil FCA claims and law enforcement investigation
- Allegations are considered “credible” when there is an “indicia of reliability;” determinations will be made on a case-by-case basis
Suspension of Payments

- Defines “resolution of investigation” as end-date for suspension
  - “Resolution” = legal action terminated by settlement, judgment, or dismissal or when case is dropped or closed; CMS seeks comments on alternative definition of “resolution” (e.g., when a legal action is initiated)
  - CMS must evaluate suspensions every 180 days to assess whether good cause still exists for suspension and request certification from the OIG or other law enforcement agency that the matter is still under investigation
  - Considering conclusion after 2-3 years of unresolved investigations

- CMS retains discretion regarding whether to impose or continue a suspension

- Includes “good cause” exceptions to full suspensions (e.g., impairment of beneficiary access to services or items; requests by law enforcement; alternative means to protect program)

- Parallel Medicaid provisions (modifying existing 42 C.F.R. 455.23(a))
Program Exclusions Enhanced

- Permissive exclusion of a person or entity for obstructing an investigation or audit (was previously limited to obstructing a criminal investigation) (PPACA § 6402)

- Permissive exclusion of a person or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any “application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program” (PPACA § 6402)

- Mandatory exclusion from Medicaid program by state of any person or entity if such person or entity was terminated by Medicare or another state’s Medicaid program (PPACA § 6501)
PPACA establishes conclusively that claims arising out of a violation of the AKS are false claims for purposes of the FCA.

Before PPACA:

Some courts held that the fact that program claims resulted from AKS violations did not render claims for payment false or fraudulent under AKS. See, e.g., U.S. ex rel. Westmoreland v. Amgen, Inc., 2010 U.S. Dist. LEXIS 40001 (D. Mass. April 23, 2010) (rejecting false implied certification theory) (e.g., even if there was prohibited remuneration, the claim itself was not false).
PPACA Change (Sec. 6402(f)(1)): any claims for items or services “resulting from” a violation of the AKS constitute “false or fraudulent claims” under the FCA

Amendments to Anti-Kickback Statute (AKS)

Expansion of “Knowingly and Willfully” (Mens Rea) Standard of § 1128B

- **Before PPACA**, some courts construed “knowingly and willfully” to require:
  - knowledge that AKS prohibits remuneration for referrals; and
  - specific intent to violate AKS

- **After PPACA** “a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS].” (Sec. 6402(f)(2), amending 42 U.S.C. § 1320a-7b)
  - Reverses “heightened mens rea” requirements of *U.S. v. Jain*, 93 F.3d 436 (8th Cir. 1996), cert. denied, and *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)
False Claims Act (FCA): Expanded Protections For Qui Tam Relator’s Actions

- Fraud Enforcement and Recovery Act of 2009 (FERA) expanded protection of employee whistle blowers to include contractors and agents
- PPACA limits public disclosure defenses to FCA suits
FCA: “Original Source” Expanded

Expands the definition of “original source” by eliminating the

- Before PPACA:
  - Original Source
    - has “direct and independent knowledge” and
    - voluntarily provided the information to the government before filing an action

- After PPACA:
  - Expands the definition of “original source” by eliminating the direct knowledge requirement
  - Original source:
    - voluntarily discloses information to the government prior to a public disclosure; or
    - has knowledge that is independent of and materially adds to the publicly disclosed allegations, and voluntary provided information to Government before filing suit
Public Disclosure Bar to FCA Qui Tam Suits Narrowed

- **Before PPACA:**
  - jurisdictional issue
  - federal, state and local reports, investigations or administrative hearings all are possible sources of public disclosure. *Graham County Soil & Water Conservation Dist. V. U.S. ex rel. Wilson* (U.S. Mar. 30, 2010)

- **After PPACA:**
  - no longer jurisdictional; government decides whether case may proceed
  - sources of public disclosure limited to *federal* criminal, civil, and administrative proceedings in which the government or its agent is a party and *federal* reports, hearings, audits, or investigations
  - State proceedings and private litigation are not qualifying public disclosures
Reverse False Claims

- Before FERA, “false record” or statement was required under the FCA as predicate for “reverse false claim”

- FERA amended the “reverse false claim” provisions of the FCA (U.S.C. § 3729(a)(1)(G)) to impose liability for:

  “Any person who ... knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government (emphasis added)”

- FERA reduced intent requirements (material element versus intent to cause payment) and applies FCA to claims against government contractors (i.e., Medicaid MCOs and MA Plans)
Reverse False Claims cont’d

- An “obligation” under 31 U.S.C. § 3729(b)(3), as amended by FERA, is:

  “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment (emphasis added).”
Reverse False Claims cont’d

Before PPACA, sources of repayment obligations included . . .

- Social Security Act (“SSA”) § 1877(g)(2), 42 U.S.C. § 1395nn(g)(2):
  Timely refunds “to individuals” for amounts billed in violation of Stark self-referral restrictions

  [whoever] having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized

After PPACA . . .

- Innocent overpayments can become false claims upon failure to satisfy PPACA refund “obligation”
Effective March 23, 2010, PPACA § 6402(a) adds SSA § 1128J(d), providing:

“(d) REPORTING AND RETURNING OVERPAYMENTS –

(1) IN GENERAL – If a person has received an overpayment, the person shall –

• (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and

• (B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayments

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS – An overpayment must be reported and returned under paragraph (1) by the later of -

• (A) The date which is 60 days after the date on which the overpayment was identified; or

• (B) The date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT – “Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31 of the United States Code) for purposes of section 3729 of such title. . .” (emphasis added)
Reverse False Claims cont’d

- “Person” includes providers, suppliers, Medicare Advantage plans, and Medicaid MCOs

- When is an overpayment deemed “identified”?

- “Overpayment” means any fund that a person receives or retains under Medicare or Medicaid to which the person, after “applicable reconciliation,” is not entitled retention. Requires “finally determined funds.” (House Rep. No. 111-443 on H.R. 4872 at 500)

  ➢ At what point and to what degree is an overpayment identified by self-audits?
  ➢ What is the applicable reconciliation?
  ➢ What about netting of underpayments? What about credit balances?

- Medical exclusion provision of PPACA (§ 6502) presumes that “unpaid overpayments” will be defined by the Secretary
60-Day Repayment and Reporting Considerations

- Review your compliance program
- Review monitoring of overpayments and credit balances
- What is your process for repayment?
  - Who is responsible?
  - Are issues run through counsel (privilege)?
  - Is it time sensitive?
  - Are your CFO and board on board?
Hospital Overpayment “Tick List”

Derived from “risk areas” identified in OIG model compliance plans. These include:

- Billing for services not provided/covered
- Duplicate claims
- MSP refunds
- Improper observation service billing
- Same day discharges/readmits
- Billing transfers as discharges
- Providing medically unnecessary services
- Improper claims for “clinical trials”
- Claims for “never events”
- Upcoding
  - Incorrect coding
  - Multiple procedure codes
  - E&M coding
Hospital Overpayment “Tick List” cont’d

- Unbundling of codes (routine costs; three-day window)
- APC miscoding
- Prohibited/problematic cost report claims
  - Not “under protest”
  - Misallocations
  - Unallowable costs
  - Related party identification
  - Bad debts
- Accurate/timely credit balance reporting
- Record Retention
- Improper “provider-based payments”
  - Outpatient site for physician office
  - Physicians billing o’pt as office-based
Hospital Overpayment “Tick List” cont’d

- Teaching physician services lacking requisite supervision/documentation
- Discounts/waivers not based on financial need
- Payments resulting from AKS violations
- Contracts/financial relations with physicians that violate Stark (see below)
- Waivers of co-pays, free transportation, and other “patient inducements”
- Payments to reduce or limit services to patients under physicians direct care (CMP)
Stark Law Compliance as a Condition of Payment

- “No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (2)(1) of this section [i.e., “pursuant to a prohibited referral”]. 42 U.S.C. § 1395nn(g)(1)
- Potential overpayment liability, including for purely “technical” violations, is enormous
- Implied certification (FCA) theory applies to each claim arising out of unprotected referrals
• OIG “open letter” of Mar. 24, 2009 discontinued self-reporting of “pure” Stark (i.e., no colorable AKS) violations. Sets floor of $50,000 for self-reporting

• Sec. 6409 of PPACA requires Secretary, in cooperation with OIG, to establish a SRDP for disclosure of actual or potential Stark violations

• CMS published SRDP on September 23, 2010
Stark: Self Reporting Disclosure Protocol

- **Who:** Available to all health care providers and suppliers ("disclosing parties")
  - A government inquiry of disclosing party will not automatically preclude disclosure (but disclosing parties must identify pending investigations and audits)
- **What:** Self-disclosure protocol for actual or potential Stark violations only
  - Not an “Advisory Opinion” process but intended to facilitate resolution of actual or potential Stark violations and overpayment liability; issue is amount due, not liability
  - OIG’s Self-Disclosure Protocol available for addressing potential liabilities under other laws
Stark: Self Reporting Disclosure Protocol

- When: Section 6402 of the PPACA requires the reporting and returning of overpayments by the later of (1) 60 days after which the overpayment was identified or (2) the due date of the “corresponding” cost report
  - Disclosure under the SRDP suspends section 6402 reporting and refund obligation
- Why:
  - PPACA requires reporting and refunding of overpayments; potential FCA liability and CMPs for failure to do so
  - Potential reduction of overpayment liability
    - Section 6409 of the PPACA grants the Secretary the authority to reduce the amount owed for Stark violations (the disclosing party’s cooperation and timeliness in disclosing are factors for consideration in establishing and potentially reducing the overpayment)
Stark: Self Reporting Disclosure Protocol

How:

- Disclosure must be submitted electronically and via mail
- Submission must include:
  - Provider info (name, address, NPI, TIN, corporate structure, etc.)
  - Description of potential or actual violation, including time period and DHS claims at issue
  - Legal analysis of Stark and exceptions as applied to the conduct and potential causes of the violation
  - Circumstances under which the violation was discovered and measures taken to address the issue and prevent future violations
  - Financial analysis, including projected amount of the potential overpayment and methodology used to compute the overpayment
  - Related pending audits and investigations
  - Use SROP with copies of self disclosures related “solely” to Stark violations, to “monitors” for CIAs and CCAs
Resolution:

- Upon receipt, CMS will begin verifying disclosure information and may request additional information.
- CMS will not accept payments of presumed overpayments prior to completion of inquiry.
- As a condition of disclosure, disclosing party agrees to waive appeal rights for claims related to disclosed conduct.
- CMS cautions disclosing parties to make disclosure decisions carefully, as CMS reserves its right to refer matter to OIG and DOJ for further investigation/prosecution.
- Matters uncovered during the verification process, which are outside the scope of the disclosed matter, may be treated as new matters for which liability may attach.
- Payment under the SRDP will not relieve disclosing party of criminal, civil, or CMP liability.
CMS did not issue any agency guidance for reducing “draconian” Stark liability under PPACA § 6409(b), rejecting recommendations of American Hospital Association

Instead, will apply on a case-by-case basis statutory criteria including:

- Nature and extent of unlawful practice
- Timeliness of self-disclosure
- Cooperation of disclosing party
- Litigation risks
- Financial position of disclosing party
Stark Compliance Check List

- Identify “referrals”
- Does an “exception” apply?
- Is a Designated Health Service provided?
- Maintain lists of financial arrangements (compensation; leases; contracts; direct/indirect investments) of referring physicians (and immediate family members) with “a financial relationship.”
- Review contracts with referring physicians for “technical” compliance
  - Signed and dated
  - Expiration date / “evergreen”
  - Describes all services – Review “evergreen” contracts for modified services
Stark Compliance Check List cont’d

- Ensure contractual payments are FMV and without regard to value or volume of referrals
  - Document independent appraisals of salaries/fees
  - Independent appraisals or market research for leases
  - Service agreements with physicians include documented work product
- Equipment leases
  - Per click issues
- Recruitment fees
- Limits on professional courtesies
Sec. 6401(a)(8) of PPACA modifies the conditions of participation under Medicare, Medicaid and Title XXI

- Requires each provider or supplier to adopt a compliance program containing “core elements” established by Secretary in consultation with OIG for particular industry or category
- Secretary shall determine implementation date
- CMS published a notice soliciting comments on September 23, 2010 on “ethics and compliance programs” for skilled nursing facilities under Section 6401 of the ACA.
Seven Core Elements:

- Written policies and procedures (code of conduct)
- Compliance Officer
- “Hot lines” and other appropriate “open lines of communications” and reporting
- Appropriate training and education
- Enforcement and disciplinary actions
- Internal monitoring and auditing
- Response to overpayments/deficiencies (reporting/refunding/CAPs)
Sec. 6003 of PPACA amends Stark in-office ancillary services exception to require group practitioners to give written notice at the time of referral that patient may obtain from alternative suppliers PET, CT or MRI or “any other designated health service” determined appropriate by the Secretary.

Referrers must provide a “written list of suppliers” who furnish such services “in the area in which such individual resides”

Effective January 10, 2010

Questions: Is this retroactive? What is the relevant geographic “area”? 
Transparency: Alternative DHS Suppliers


- Limited to MRI, CT, PET
- Must list ten alternative suppliers
- 25 mile radius of physician practice location (not where patient resides)
- Signed record of patient disclosure
- Proposed effective date: Jan. 1, 2011
Transparency: Physician Ownership and Investments in Hospitals

- Sec. 6001 of PPACA (as amended by Sec. 10601 of PPACA AND Sec. 1106 of Reconciliation Act) amends SSA § 1877 to restrict referrals to physician-owned hospitals under Stark “whole hospital” exception

- Among other requirements:
  - Physician ownership must be disclosed in hospital advertising and on hospital’s website
  - Referring physicians must furnish advance written notice of ownership interest/investment to patients to facilitate “meaningful decision on receipt of care”
  - No new physician-owned hospitals after Dec. 31, 2010
  - Limits service expansions (e.g., no new operating rooms and “procedure rooms”)
  - Freezes physician investors as of Mar. 23, 2010

For more information, please contact us:

John Washlick  
215-665-2134  
jwashlick@cozen.com

Melanie Martin  
215-665-2724  
mmartin@cozen.com