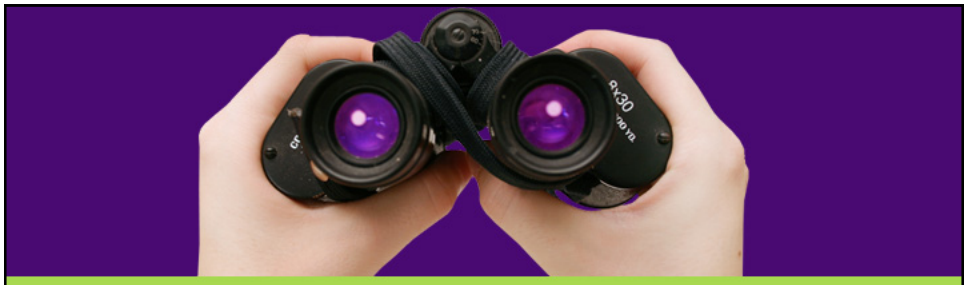

Paying for Health Care Reform: Government Enforcers Vigorously Seek Out Fraud, Abuse, and Waste

FOLEY

FOLEY & LARDNER LLP

Friday, April 16, 2010

11:30 a.m. – 12:30 p.m. CT

Today's Presenters

Robert D. Sevell

Los Angeles

Lawrence C. Conn

Los Angeles

Lawrence W. Vernaglia

Boston

Housekeeping

- We will take questions throughout the program via the Q & A tab located on your menu bar at the top of your screen and live questions at the end of the program
- Foley will apply for CLE credit after the Web conference. If you did not supply your CLE information upon registration, please e-mail it to mroth@foley.com
- Today's program is being recorded and will be available on our Web site
- For audio assistance please press *0
- For full screen mode, go to "View" on your toolbar and select "Full Screen" or press F5 on your keyboard

Roadmap for Today's Discussion

- Part 1: Background
  Enrollment-Related Changes
- Part 2: Anti-Kickback, Stark and CMPs
  New Requirements for Tax-Exempt Hospitals
- Part 3: Stark Self-Disclosure
  "Sunshine" Provisions
  RAC Expansion
  Overpayment Recovery
  Other Payment Changes

Part 1

- Background

  Enrollment-Related Changes

Reducing Fraud, Abuse and Waste: Why it matters

- Thompson Reuters White Paper (10/16/09)
  - $700 billion wasted in US health care system each year
    - Fraud: 19% ($133 billion)
      - Intentionally unnecessary services; services not provided; misrepresentation of cost of care; kickbacks; misbranding of drugs
    - Other Causes: 81%
      - Provider errors; preventable conditions; lack of coordination; administrative inefficiencies

Reducing Fraud, Abuse and Waste: Why it matters

- OMB estimate (2009): $98 billion in improper federal government payments
- White House estimate (2009): $54 billion in improper health care payments
- FCA Settlements and Judgments
  - Total 1986 - 2008: $21.6 billion (including $2.2 from whistleblowers)
  - Total health care 1986 - 2008: $14.3 billion (including $1.6 billion from whistleblowers)

Reducing Fraud, Abuse and Waste: Why it matters

- Pres. Obama: "We've estimated that most of this [health care reform] plan can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse."
- PPACA includes additional $250 million over six years to fund fraud and abuse enforcement
  - Additional $95 million for FY 2011
- FY 2010 all agency enforcement budget of over $311 million

Reducing Fraud, Abuse and Waste: Recent Initiatives

- Presidential Memorandum (March 10, 2010)
  - Expands payment recovery audits to executive departments and agencies
- Executive Order (November 23, 2009)
  - Sets roadmap for reducing improper payments
- CMS Restructuring - Creates Center for Program Integrity
- HEAT (Healthcare Fraud Prevention & Enforcement Action Team)
- MIP (Medicaid Integrity Program) and MICs (Medicaid Integrity Contractors)

New Enforcement Tools under PPACA

- Mandatory Compliance Programs (§ 6401)
  - Applies to all providers and suppliers
  - As a condition of enrollment in Medicare, Medicaid, and/or CHIP
  - Industry sectors, standards and timing set by Secretary of HHS
    - Extent of industry compliance
    - DME companies and home health agencies
    - OIG Compliance Guidance
  - Question: Application to existing enrollees
    - Revalidation process

New Enforcement Tools under PPACA

- New Enrollment Protections (§ 6401)
  - PPACA grants Secretary new authority to combat fraud, waste, or abuse through the enrollment or revalidation process
  - New tools are likely to be targeted at certain "high risk" categories of providers and suppliers
  - Applies to enrollment in Medicare, Medicaid, and CHIP

New Enforcement Tools under PPACA

- Enhanced Screening (§ 6401)
  - The Secretary (in consultation with the OIG) will establish new enrollment screening procedures within 180 days of enactment
  - Level of screening will vary among categories of providers and suppliers
  - All levels will include license checks
  - May also include: fingerprinting, criminal background checks, multi-state database inquiries, random or unannounced site visits, or other appropriate screening
  - Fees

New Enforcement Tools under PPACA

- Enhanced Enrollment Screening (cont'd)
  - May apply as soon as:
    - For new enrollees: 1 year from enactment
    - For currently enrolled providers & suppliers: 2 years from enactment
    - Providers subject to revalidation: 180 days after enactment
  - Expedited Rulemaking

New Enforcement Tools under PPACA

- Secretary has new authority to: (§ 6401)
  - Subject certain providers/suppliers to temporary "provisional period" (30 days to one year)
    - During "provisional period" subject to enhanced oversight, prepayment review, prepayment caps
  - Grant enrollment moratoria on enrollment of certain providers or suppliers

New Enforcement Tools under PPACA

- Enrollment applications will require disclosures of affiliation with providers that have uncollected debt, or who have been suspended or excluded from participation (§ 6401)
  - Beginning 1 year from date of enactment
  - Applies to enrollment or revalidation applications
- Enhanced CMPs for false statements in enrollment process (§ 6402(d), discussed later).

New Enforcement Tools under PPACA

- DME and Home Health Services (§ 6406)
  - Secretary has new authority to revoke Medicare enrollment for physicians and suppliers who fail to maintain and, upon request, provide access to, documentation related to:
    - Written orders or claims for DME
    - Certifications for home health service
    - Other "high-risk" items as designated by the Secretary

New Enforcement Tools under PPACA

- DME and Home Health Services (§§ 6407, 10605)
  - Physicians must have face-to-face encounter with a patient prior to certification for home health services or DME
    - Telehealth encounters permitted
    - Documentation of encounter is a condition of payment for DME supplier or home health agency
  - Physicians who order DME or certify home heath services now must be enrolled in Medicare

- Part 2:

  Anti-Kickback, Stark and CMPs

  New Requirements for Tax-Exempt Hospitals

New Enforcement Tools under PPACA

- Anti-Kickback Statute (§ 6402(f))
  - Amended to state that a person "need not have actual knowledge of this section or specific intent to commit a violation of this section."
    - Likely to eliminate the *Hanlester* defense (*Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995))
  - New language states that claims that include items or services resulting from a violation of the Anti-Kickback Statute constitute false claims under the False Claims Act

New Enforcement Tools under PPACA

- Stark – Physician-Owned Hospitals (§§ 6001, 10601; Reconciliation Act § 1106)
  - Rural and "whole-hospital" exceptions severely limited
  - Available only for hospitals with Medicare provider agreement as of Dec. 31, 2010
  - Hospitals using the exception will not be able to increase capacity or percentage of physician ownership or investment after March 23, 2010
    - May cause confusion for hospitals that take advantage of the 12/31/10 date
    - Exceptions for hospitals that treat the highest percentage of Medicaid patients in the County, or that have a high Medicaid percentage and are located in high-growth, underserved areas

New Enforcement Tools under PPACA

- Stark – Physician-Owned Hospitals (cont'd)
  - Hospitals utilizing exception must submit annual report to HHS containing detailed descriptions of ownership
  - Additional standards for determining whether physician ownership or interest is "bona fide"
  - Regulations will be published by January 1, 2012

New Enforcement Tools under PPACA

- Stark – In-Office Ancillary Services (§ 6003)
  - New requirement: Physician ordering certain DHS (MRI, CT, PET, others per CMS) must inform patients that they may obtain service from alternate provider
  - Must be in writing
  - Must include list of alternate suppliers furnishing same service in area where individual resides

New Enforcement Tools under PPACA

- Civil Monetary Penalties Law
  - New violations (§§ 6402(d), 6408):
    - Knowingly making false statements in an application, bid, or contract to participate or enroll in a federal health care program (up to $50,000 per violation)
    - Knowingly making or using a false record or statement material to a false or fraudulent claim for payment by a federal health care program (up to $50,000 per violation)
      - Increases penalty per existing prohibition

New Enforcement Tools under PPACA

- Civil Monetary Penalties Law (new violations, cont.)
  - Failing to grant OIG timely access for audits, investigations, evaluations, etc. upon reasonable request (up to $15,000 per day)
  - Ordering or prescribing items or services when person ordering or prescribing is excluded from federal health care program
  - Failing to report and return known overpayment within 60 days/or when cost report due (such failure is also subject to potential FCA liability)

New Enforcement Tools under PPACA

- Further penalty increases on the horizon?
  - Members of the House plan to introduce a bill to double penalties for Medicare fraud
    - Proposed by Reps. Ileana Ros-Lehtinen (R – FL) and Ron Klein (D- FL)
    - Would double the penalties for violations of the Anti-Kickback Statute, False Claims Act, and Civil Monetary Penalty statute
    - Would double the length of prison sentences

New Enforcement Tools under PPACA

- Civil Monetary Penalties Law
  - Clarifies that certain "charitable" activities will not violate the law (§ 6402(d)):
    - Remuneration that promotes access to care and poses low risk of harm to patients and federal health care programs
    - The offer or transfer of coupons, rebates, or rewards from a retailer for free or less than fair market value
      - Must be offered on equal terms to public regardless of health insurance status
      - May not be tied to the provision of other items or services reimbursed by Medicare or state health care program

New Enforcement Tools under PPACA

- Civil Monetary Penalties Law (charitable activities, cont.)
  - The offer or transfer of items or services for free or less than fair market value to individuals determined to be in financial need
    - Must have reasonable connection with individual's medical care
    - May not be offered as part of advertisement or solicitation
    - May not be tied to provision of any other health care service reimbursed by government health care program
  - A prescription drug plan waiver of co-payments for the first fill of a covered Part D generic drug by a prescription drug plan under Medicare Part C or D

New Enforcement Tools under PPACA

- Requirements for 501(c)(3) hospital (§ 9007):
  - Conduct community needs assessment at least every 3 years and adopt implementation strategy
  - Adopt, implement, and publicize financial assistance policy, including eligibility criteria for free and discounted care
  - Amount billed to individuals who qualify for financial assistance must not exceed amounts billed to individuals with insurance
  - Hospitals (or affiliates) may not undertake "extraordinary collection actions" without making reasonable efforts to determine if individual qualifies for financial assistance
  - Must provide emergency care without regard for ability to pay
  - Effective on date of enactment, except community needs assessments not required for 2 years

Roadmap for Today's Discussion

- Part 3:
  - Stark Self-Disclosure
  - "Sunshine" Provisions
  - RAC Expansion
  - Overpayment Recovery
  - Other Payment Changes

New Enforcement Tools under PPACA

- Stark – Self-Disclosure Protocol (SDRP)
  - In 2009, OIG announced no longer accept "Stark-only" disclosures (i.e., without "colorable" AKS violation)
  - Perception that CMS lacked authority to accept settlement of < 100%
  - § 6409: HHS "in cooperation with" OIG to create a Self-Referral Disclosure Protocol (SDRP) within 6 months
  - HHS may accept lower repayments through SDRP

New Enforcement Tools under PPACA

- Stark – Self-Disclosure Protocol (SDRP)
  - Factors to be considered:
    - Nature and extent of "illegal or improper practice"
    - Timeliness of disclosure
    - Cooperation in providing additional information
    - "Other Factors"
  - See OIG's Voluntary Disclosure Protocol
  - Separate from Stark AO process

New Enforcement Tools under PPACA

- Physician Payment "Sunshine"
  - Background:
    - Various State laws passed (CA, DC, ME, MA, MN, NV, VT & WV); another 7 or 8 rejected
    - State initiatives include "gift ban" and disclosure
    - Sensitive issues:
      - (1) protection of trade secrets
      - (2) what entities covered
    - Sen. Charles Grassley's "Physician Payment Sunshine Act"

New Enforcement Tools under PPACA

- § 6002 – Transparency Reports - Payment
- No "Gift Ban"
- "Applicable manufacturers" of drug, device, biological, and medical supply
  - Includes entities that provide "assistance and support", including distributors if under common ownership with manufacturer
- Annual reports (beginning March 31, 2013) to HHS of payments or other transfers of value to a:
  - physician or
  - "teaching hospital"
- Public availability

New Enforcement Tools under PPACA

- Transparency Reports (cont.)
  - Reports include:
    - Recipient's name;
    - Date of payment
    - Business address, specialty, NPI;
    - Amount and form of payment; and
    - Description of nature of payment:
      - Consulting, comp, honoraria, gift, entertainment, food, travel, ed, research, charitable contribution, royalty/license, "current or prospective ownership interest," faculty fee, grant, other.

New Enforcement Tools under PPACA

- Transparency Reports (cont.)
  - Delayed reporting for payments pursuant to:
    - Product research or development agreement
    - Clinical investigation
  - Delay for lesser of:
    - (1) FDA approval/clearance or
    - (2) 4 years
  - Still must report, but will not be public

New Enforcement Tools under PPACA

- Transparency Reports (cont.)
  - Exempts from reporting:
    - *De minimus*: < $10 each, up to $100 aggregate
    - Ed materials
    - Evaluation units (90 days)
    - Items under contractual warranty
    - Discounts and rebates
    - In-kind for charity care
    - Expert witness fees
    - Samples (not for sale)
      - *N.B.: § 6005 drug sample reports

New Enforcement Tools under PPACA

- Transparency Reports – MD ownership
- § 6002 also requires disclosure of physician ownership of "applicable manufacturers" *and GPOs*.
  - Disclosures of dollar amt invested
  - Value of that investment
  - Any payment/transfer of value to the physician
- Not publicly-traded securities
- Includes "immediate family members" of physicians (Stark def.)

New Enforcement Tools under PPACA

- Transparency Reports (cont.)
  - Preemption of State Laws:
    - If they require manufacturers to report the same "type of information"
    - Not for other types of disclosures or other entities
    - Doesn't address "gift bans."

New Enforcement Tools under PPACA

- Transparency Reports (cont.)
  - Penalties:
    - If not "knowing" - $1k to $10k *for each payment* (max of $150k)
    - If "knowing" - $10k to $100k *for each payment* (max of $1MM)

New Enforcement Tools under PPACA

- Expansion of RAC program (§ 6411)
  - Contingency Fee "bounty hunter" contractors
    - § 306 of the MMA 3-year demo project (CA, FL, NY – later MA and SC)
      - MSP RAC
      - Claim RAC
  - Permanent RAC roll-out started 2009
  - Currently limited to Medicare parts A and B

New Enforcement Tools under PPACA

- Expansion of RAC program (cont.)
  - § 6411: States must implement for Medicaid
    - Must use contingency-fee payment system
    - In addition to Medicaid Integrity Contractors (MICs)
  - No later than December 31, 2010
  - Secretary and OIG will review RAC activities

New Enforcement Tools under PPACA

- Expansion of RAC program (cont.)
  - Roll-out to Medicare Parts C & D
  - Also requires Part C & D RACs to:
    - Ensure each plan has an anti-fraud plan and
    - Review effectiveness of the anti-fraud
    - Examine reinsurance payments to see if claims excessive
    - Review enrollment of high-cost beneficiaries

New Enforcement Tools under PPACA

- Payment Changes – Overpayments
- Background:
  - Historically, no express duty to refund innocent overpayments (arguable on Part A)
  - DOJ/CMS disagreed
  - Language on “wrongful retention”
  - 2009 Fraud Enforcement and Recovery Act (FERA) expressly referenced improper retention of "obligations"

New Enforcement Tools under PPACA

- Payment Changes – Overpayments (cont.)
  - § 6402(a): Express duty to refund and report Medicare and Medicaid overpayments
  - By *the later of* 60 days after overpayment “identified” or the date cost report is due
  - Failure to report and return is an “obligation” for the purpose of FCA

New Enforcement Tools under PPACA

- Payment Changes – Overpayments
  - What is an "overpayment"?
    - "funds that a person receives or retains under title XVIII or XIX [Medicare or Medicaid] to which the person, *after applicable reconciliation*, is *not entitled under such title*"
    - Application to technical/documentation/COPs/other errors vs.
    - Application to services not rendered/paid higher than performed
  - When is it "identified"?
    - What level of confidence?
    - Ability to know actual amount?

New Enforcement Tools under PPACA

- Payment Changes– Submission of Claims
  - § 6404: Claims must be submitted to Medicare parts A and B within 1 calendar year from the date of service
    - Previously was (generally) three years from the year of service
    - For services furnished before January 1, 2010, claims must be filed by December 31, 2010.

New Enforcement Tools under PPACA

- Payment Changes – Suspension of Payments During Fraud Investigation
  - OIG and others believed it had right to suspend payment pending investigation
- § 6402(h):
  - HHS ***may*** suspend Medicare payments if there is "**pending investigation of a credible allegation of fraud**" against provider or supplier
  - HHS ***shall*** withhold FPP from State if State Medicaid program doesn't suspend payment
- CMS must consult with OIG to determine whether there is a credible allegation of fraud
- Government can "disarm" parties fighting fraud case

New Enforcement Tools under PPACA

- Payment Changes – Cross-Provider Recoveries
  - Background:
    - Medicare couldn't reach other providers – except through common law, "veil piercing," etc.
    - Some state Medicaid laws included express rights to set-off overpayments against payments to related providers

New Enforcement Tools under PPACA

- Payment Changes – Cross-Provider Recoveries
  - § 6401(a): Secretary has new authority to recover payments from providers and suppliers that share same TIN as an individual or entity with a past-due obligation to Medicare

Questions and Answers

FOLEY
FOLEY & LARDNER LLP

Contact Information

- Rob Sevell, Partner
  Foley & Lardner LLP
  555 South Flower Street
  Suite 3500
  Los Angeles, CA 90071
  213-972-4804
  rsevell@foley.com

- Larry Conn, Special Counsel
  Foley & Lardner LLP
  555 South Flower Street
  Suite 3500
  Los Angeles, CA 90071
  213-972-4781
  lconn@foley.com

- Larry Vernaglia, Partner
  Foley & Lardner LLP
  111 Huntington Avenue, 26th Floor
  Boston, MA 02199-7626
  617-342-4079
  lvernaglia@foley.com

- Anil Shankar, Associate
  Foley & Lardner LLP
  555 South Flower Street
  Suite 3500
  Los Angeles, CA 90071
  213-972-4584
  ashankar@foley.com