Patient Protection and Affordable Care Act: Changes in Fraud, Abuse and Enforcement

AMGA Council of Attorneys
Savannah, Georgia
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"Health care fraud, waste, and abuse cost taxpayers billions of dollars every year and requires focused attention and commitment to solutions."

- Testimony of Daniel Levinson, Inspector General, to the United States Senate Committee on Finance, March 2, 2011

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Recent Headlines

Bad Medicine: Medicare Fraud Strike Force Teams Nab Doctors, Nurses
September 7, 2011 – Nearly 100 people across the country have been arrested for Medicare fraud, some of them doc... called Me... in eight U... announc... General ... Services

September – A Banner Month for Health Care Fraud Prosecution
September 8th, 2011, According to a USA Today article printed on September 2, 2011, government health care fraud prosecution, in the first eight months of 2011, was 85% higher than last year. This rise is attributed to increased funding and ...vestigative tools such as the creation of ...discussed in previous blogs.

OIG Cite Place-of-Service Coding Errors As Leading to Medicare Part B Overpayments
By James Swann, In a two-year period, Medicare overpaid physicians by an estimated $29 million for Part B claims that had an in... nonfacility place-of-service code, according to two audit rep... Department of Health and Human Services Office of Inspe... release Sept. 15. Physicians are required to correctly code... services are performed, as Medicare reimburses physician... rate for certain services that are performed in an office or o... nonfacility location, as opposed to at a hospital or ambulato...

IG Levinson Defends Legal Guidance On Physician-Owned Distributorships
By Daniel J. Roy, The Department of Health and Human Services Inspector General Daniel R. Levinson defended the quality of OIG's legal guidance on physician owned distributorships (PODs) in a Sept. 13 letter which he replied to criticism by key Senate overseers.

DOJ REACHES $3.8 Million Stark Settlement With Ohio Valley Hospitals; Physicians Next
By Bebe Raupe, CINCINNATI – A West Virginia healt... care corporation has resolved alleged Stark Act violations by entering into a $3.8 million settlement with the federal government, the Department of Justic... announced Sept. 12. DOJ officials said they will now turn to the physicians for potential liability and are asking them to "self-report" Stark law violations.

Stanford Hospital Faces $20M Action Over Data Breach
Law360, New York (September 29, 2011) – Stanford University's hospital was hit Wednesday with $20 million proposed class action over the recently revealed data breach that allowed the names, diagnoses and account numbers of 20,000 emergency room patients to be posted on a public website for nearly a year.

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2011 Federal Enforcement

- For the **first half of fiscal year 2011**, the OIG reported expected recoveries of **$3.2 billion**:
  - $22.4 million in audit receivables
  - $3.2 billion in investigative receivables
- For the same period, OIG also reported:
  - **Exclusions of 883** individuals and entities for fraud or abuse involving Federal health care programs and/or their beneficiaries
  - **349 criminal actions** against individuals or entities that engaged in crimes against departmental programs
  - **197 civil actions** which included false claims, civil monetary penalties settlements, and administrative recoveries related to self-disclosures

Source: Office of Inspector General, Semiannual Report to Congress, March 2011

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2011 Federal Enforcement

- On February 3, 2011, the OIG launched its "**Most Wanted Fugitives List**"
  - the first-ever list of individuals sought by authorities on charges of health care fraud and abuse
  - includes photos and profiles of each featured fugitive
- 10 individuals on the Most Wanted Health Care Fugitives List have allegedly cost taxpayers more than **$124 million** in fraud
- In all, OIG is seeking more than **170 fugitives** on charges related to health care fraud and abuse

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Paying for Health Reform?

- 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 the first five years to fund fraud and abuse enforcement
  - Additional $95 million for FY 2011
- FY 2011 HHS Budget includes a record $1.7 billion to fight waste, fraud and other improper payment*

*Source: April 19, 2011 Statement of HHS Deputy Secretary before House Committee Appropriations

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PPACA Changes Cheat Sheet

- False Claims Act
- Anti-Kickback Statute
- Overpayments
- Provider/Supplier Enrollment Protections
- Mandatory Compliance Plans
- Stark Law
- CMS Stark SDRP
- CMP Law
- MD Payment Sunshine
- 501(c)(3) Hospital Rules
- RAC Expansion
- Claims Submission, Suspension and Cross-Provider Recovery

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False Claims Act Changes

- Multiple phases at chipping away at defenses
- Fraud Enforcement and Recovery Act ("FERA") – Eliminates requirement that claim be presented to the United States (as had been read into 31 U.S.C. § 3729(a)(1))
- PPACA weakens public disclosure bar
  - *only* if disclosed in a *federal* criminal, civil, or administrative hearing, or a *federal* report, hearing, audit, or investigation
  - Expansion of the definition of an original source (eliminates the direct knowledge requirement)

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Anti-Kickback Statute Change

- 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.

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Overpayments – "60 Day Rule"

- Background:
  - Historically, no express statutory duty to refund innocent overpayments
  - OIG/CMS interpreted 42 U.S.C. § 1320a-7b(a)(3) as imposing a duty on providers to disclose receipt of overpayment whether innocently or result of impropriety
  - FERA expressly provided that the retention of any overpayment is an "obligation"

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Overpayment – "60 Day Rule"

- PPACA § 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

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Overpayment – "60 Day Rule"

- 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?

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Provider/Supplier Enrollment Changes

- New tools are likely to be targeted at certain "high risk" categories of providers and suppliers
- 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
- Subject certain providers/suppliers to temporary "provisional period" (30 days to one year)
  - During "provisional period" subject to enhanced oversight, prepayment review, prepayment caps

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Provider/Supplier Enrollment Changes

- DME and Home Health Services (§§ 6407, 6406 10605)
  - Physicians must have face-to-face encounter with patient prior to certification for HHA or DME
    - Telehealth encounters permitted
    - Documentation of encounter is a condition of payment for DME supplier or home health agency
  - Physicians who order DME/certify HHA now must be enrolled in Medicare
  - New authority to revoke enrollment for physicians and suppliers who fail to maintain documentation related to:
    - Written orders or claims for DME
    - Certifications for home health service
    - Other "high-risk" items as designated by the Secretary

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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

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Stark Law Changes

- 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

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Stark Law Changes

- In-Office Ancillary Services (§ 6003)
  - Physician ordering certain DHS (MRI, CT, PET, others per CMS – none yet) 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

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CMS Stark Self-Disclosure Protocol (SDRP)

- In 2009, OIG announced they will no longer accept "Stark-only" disclosures (i.e., without "colorable" AKS violation)
- Perception that CMS lacked authority to accept settlement of < 100%
- § 6409: Self-Referral Disclosure Protocol (SDRP) (Published 9/26/2010)
- CMS may accept lower repayments through SDRP

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CMS 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
  - “Litigation Risk”
  - “Other Factors”
- CMS gave little comfort that “technical” violations will be treated gently
- About 60 SRDP Submissions to date (as of late Spring 2011)
- One Settlement to date (2/10/2011) - $14.5MM potential exposure, settled for $579K

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Civil Monetary Penalties Law Changes

- Increased penalties ($50,000) for:
  - Knowing false statements in an application, bid, or contract to participate or enroll in a federal health care program
  - Knowing false record or statement material to a false or fraudulent claim for payment by a federal health care program
- 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 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)

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Civil Monetary Penalties Law Changes

- Clarifies that certain "charitable" activities will not violate the law (§ 6402(d)):
  - Remuneration 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

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Civil Monetary Penalties Law Changes

- 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

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Physician Payment "Sunshine"

- Background:
  - State Sunshine and Gift Ban laws: CA, DC, ME, MA, MN, NV, VT & WV); another 7 or 8 rejected
  - Sen. Charles Grassley's "Physician Payment Sunshine Act"
- § 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 <u>if under common ownership</u> with manufacturer

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Physician Payment "Sunshine"

- Annual reports (beginning March 31, 2013) to HHS of payments or other transfers of value to a:
  - physician or
  - "teaching hospital"
  - (also requires disclosure of physician ownership of "applicable manufacturers" and GPOs)
- Public availability:
  - Recipient's name;
  - Date of payment;
  - Business address, specialty, NPI;
  - Amount and form of payment; and
  - Description of nature of payment:
    - Consulting, services other than consulting, honoraria, gift, entertainment, food, travel, education, research, charitable contribution, royalty/license, current or prospective ownership interest, faculty fee, grant, other.

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Physician Payment “Sunshine”

- Exempts from reporting:
  - *De minimus*: < $10 each, up to $100 aggregate
  - Educational materials
  - Evaluation units (90 days)
  - Items under contractual warranty
  - Discounts and rebates
  - In-kind for charity care
  - Expert witness fees
  - Samples (not for sale)
    - § 6004 drug sample reports

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Physician Payment “Sunshine”

- 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

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Physician Payment “Sunshine”

- Preemption of State Laws:
  - If State law requires manufacturers to report the same “type of information”
  - Not for other types of disclosures or other entities
  - Doesn’t address “gift bans” (likely won’t preempt state gift ban laws
- Penalties:
  - If not “knowing” - $1k to $10k *for each payment* (max of $150k)
  - If “knowing” - $10k to $100k *for each payment* (max of $1M)

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Sunshine and Conflicts of Interest: Why the Focus?

- Trends in Disclosure Reporting
  - Cleveland Clinic (www.clevelandclinic.org)
  - 2nd consecutive year, named one of world’s most ethical companies*
- Financial Conflicts and Personal Conflicts
- Transparency on industry relationships of physicians and researchers
- Disclosure of physician consulting agreements:
  - DOJ and OIG continue to scrutinize physician consulting arrangements with pharmaceutical and medical device companies
- Media and public interest
- Continuing environment of transparency

*Source: Ethisphere Institute

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New Requirements for 501(c)(3) Hospitals (§ 9007)

- Conduct community needs assessment at least every 3 years; 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
  - New instructions to IRS Form 990 (Schd. H) make clear that bills may include uniform charge, and show discount/reduction off that charge (Feb. 2011)

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New Requirements for 501(c)(3) Hospitals (§ 9007)

- 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

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Expansion of RAC program

- Permanent RAC roll-out started 2009, limited to Medicare parts A and B
- PPACA expands to Medicaid (§ 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
- Roll-out to Medicare Parts C & D

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Claims/Payment Changes

- Submission of Claims (§ 6404)
  - Parts A and B claims must be submitted within 1 calendar year from date of service
  - Previously was (generally) three years from the year of service

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Claims/Payment Changes

- Suspension of Payments During Fraud 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
- Government can "disarm" parties fighting fraud case

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Claims/Payment Changes

- Cross-Provider Recoveries
  - Background: Medicare could not reach other providers – except through common law successor liability, "veil piercing," etc.
  - § 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

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Questions?

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