GETTING SERIOUS ABOUT MEDICAID INTEGRITY: DATA, PPACA, HCERA, AND FERA
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THE MARCH 2010 PPACA, HCERA, AND THE MAY 2009 FERA

- PPACA =Patient Protection and Affordable Care Act (H.R. 3590) – Senate bill approved by House
- HCERA=Health Care and Education Reconciliation Act (H.R. 4872) – changes passed by the House to eliminate certain Senate provisions favoring specific states, approved by Senate
- -On March 23,2010 President Obama signed into law H.R. 3590, PPACA. On March 30, 2010 the president signed into law H.R. 4872, HCERA, which made modifications to H.R. 3590
- FERA= Fraud Enforcement and Recovery Act, signed by the President in May, 2009.

THE THREE MOST IMPORTANT MEDICAID INTEGRITY PROVISIONS OF PPACA

- MANDATORY REPORTING, REPAYMENT, AND EXPLANATION OF OVERPAYMENTS BY "PERSONS"
- RETENTION OF OVERPAYMENT IS A FALSE CLAIM (invokes penalties and whistleblower provisions)
- MANDATORY COMPLIANCE PLANS (first in nursing homes, later in other providers)

THE CURRENT STATE OF MANDATED COMPLIANCE

- CORPORATE INTEGRITY AGREEMENTS (US HHS-OIG)-early 1990s
- MANDATED COMPLIANCE DISCLOSURES FOR NON-PROFITS ON IRS 990 (2008) (not required to have compliance standards on conflicts, disclosure, etc. only to report whether you do)
- MANDATED COMPLIANCE PROGRAMS FOR MEDICARE ADVANTAGE AND PART D (CMS-2009) (72 FR 68700 and program memos)
- MANDATED COMPLIANCE PROGRAMS FOR FEDERAL CONTRACTORS (2009) (FAR 52.203-13) (reporting of "significant overpayment(s) on the contract)
- MANDATED "EFFECTIVE" COMPLIANCE PROGRAMS FOR NY MEDICAID PROVIDERS-(New York OMIG 2009) (18 NYCRR 521)
- MANDATED REPAYMENT OF MEDICARE AND MEDICAID OVERPAYMENTS (PPACA Section 6402 (2010)
- MANDATED COMPLIANCE PROGRAMS FOR NURSING HOMES AND SOME OTHER HEALTH PROVIDERS-Patient Protection and Affordable Care Act Sections 6102, 6401 (2013 for nursing homes)

PPACA SECTION 6402 MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

- *"(d) REPORTING AND RETURNING OF 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,* **State**, *intermediary, carrier, or contractor* **to whom the overpayment was returned in writing of the reason for the overpayment**.

RETURNING OVERPAYMENTS IN NEW YORK TO THE MEDICAID PROGRAM

- **report and return the overpayment** *to the State* **at the correct address**
- **OMIG's correct address:**
- **Office of the Medicaid Inspector General,800 North Pearl Street,Albany, New York 12204**
- **Providers may use void process for smaller or routine claims**

PROVIDER MUST STATE THE REASON FOR OVERPAYMENT

- **notify the State to whom the overpayment was returned in writing of the reason for the overpayment**
- **Use OMIG's Disclosure Protocol, available on the OMIG website, www.OMIG.state.ny.us**
- **Texas has similar protocol** https://oig.hhsc.state.tx.us/ProviderSelfReporting/Self_Reporting.aspx
- Pennsylvania 2001 self-audit protocol: http://www.dpw.state.pa.us/omap/omapfab.asp
- COMPARE WITH OIG self-disclosure protocol http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.

SEC. 6402 (d) MEDICARE AND MEDICAID PROGRAM INTEG-RITY PROVISIONS.

- *"(4) DEFINITIONS.—In this subsection:*
- *'(A) KNOWING AND KNOWINGLY.—The terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of title 31, United States Code.*
- *"(B) OVERPAYMENT.—The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.*

GOVERNMENT IS USING DATA TO DETECT OVERPAYMENTS

- EXCLUDED PERSONS
- DECEASED ENROLLEES
- DECEASED PROVIDERS
- CREDIT BALANCES
- WHAT IS GO-BACK OBLIGATION WHEN PROVIDER IS PUT ON NOTICE THAT SYSTEMS ARE DEFICIENT?

"OVERPAYMENT" INCLUDES:

- PAYMENT "RECEIVED OR RETAINED" IN VIOLATION OF STARK LAW
- PAYMENT "RECEIVED OR RETAINED" FOR SERVICES WHERE ORDER FOR SERVICES INDUCED BY KICKBACK
- PAYMENT RECEIVED OR RETAINED FOR SERVICES ORDERED OR PROVIDED BY EXCLUDED PERSON "no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished by an excluded individual or entity or at the medical direction or on the prescription of a physician or other authorized individual who is excluded . . ." 42 CFR 1001.1901
- DRUG REBATES? ("*after applicable reconciliation")*
- PAYMENT INDUCED BY OFF-LABEL MARKETING INVOLVING FALSE STATEMENT OR OMISSION OF KNOWN SAFETY RISKS (SYNTHES THEORY)?
- OFF-LABEL SALES IN SOME STATES WHICH HAVE ON-LABEL OR COMPENDIUM REQUIREMENTS? "*not entitled "*

“OVERPAYMENTS” INCLUDE:

- INACCURATE COST REPORTS
- NEVER EVENTS NOT REPORTED
- TRANSFER/DISCHARGE
- PRESENT ON ADMISSION INACCURATE REPORTING
- DISCHARGE/READMIT WITHIN 30 DAYS
- DRUGS BILLED FOR INPATIENTS AS IF OUTPATIENTS
- MISCHARGED 340B DRUGS

SEC. 6402 (d)MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

- *"(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.*

PPACA SECTION 6402 (d) MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

- *"(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, United States Code) for purposes of section 3729 of such title. (False Claims Act)*

SEC. 6402 (d)MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS

- *"(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section (i.e., a kickback)constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code." (False Claims Act)*

SEC. 6402 (d)MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS

- *WHERE:*
- *the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments; ".*
- *CMS may recover payments from state*

SEC. 6508. GENERAL EFFECTIVE DATE.

- *Except as otherwise provided in this subtitle, this subtitle and the amendments made by this subtitle take effect on January 1, 2011, without regard to whether final regulations to carry out such amendments and subtitle have been promulgated by that date. (this "subtitle" appears to be only section 65, not Section 64, so that the 6402 repayment statute has been in effect since March 2010.)*

THE MAY, 2009 FERA Amendments to the False Claims Act (FCA)

1. Expand FCA liability to indirect recipients of federal funds
2. Expand FCA liability for the retention of overpayments, even where there is no false claim
3. Add a materiality requirement to the FCA, defining it broadly
4. Expand protections for whistleblowers
5. Expand the statute of limitations
6. Provide relators with access to documents obtained by government

Defendant violates FCA if it:

- "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" **new** 31 U.S.C. 3729(a)(1) (G)

FERA + OMIG + PPACA = ?

- “knowingly and improperly avoids or decreases an obligation to pay or transmit money”
- Plus
- New York mandatory compliance and repayment obligation
- Or Plus-the duty to repay overpayments w/i 60 days under PPACA
- Equals
- Improper avoidance of an obligation to pay money

knowingly conceals or knowingly and improperly avoids or decreases an “obligation” to pay or transmit money

- “’obligation' means 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 **new** 31 U.S.C. 3729(b)(3)

Expands “reverse false claims” to liabilities that are not “fixed”

- A duty to repay the government need not be fixed for FCA liability to attach
  - Nursing home penalties? Environmental violations?
- Accelerates the point at which recipients of federal funds must decide if a repayment is due
  - For example, interim payments under Medicare
- Combined with “reckless disregard” standard, this amendment could spawn numerous suits
  - Will turn on meaning of “improperly” retaining overpayments

Required Components of Nursing Facility Compliance Program

- § 6102
  - Established compliance standards and procedures reasonably capable of reducing prospect of criminal, civil and administrative violations
  - Assign specific individuals within high-level personnel responsibility to oversee compliance- sufficient resources and authority to assure such compliance
  - Organization must use due care not to delegate substantial discretionary authority to individuals whom the organization knew (or should have known through due diligence) had a propensity to engage in criminal, civil and administrative violations
  - Must take steps to communicate effectively its standards and procedures to all employees and other agents (requiring participation in training programs or by disseminating publications that explain in practical terms)

Required Components of Nursing Home/SNFCompliance Program

- § 6102
  - Must have taken reasonable steps to achieve compliance with its standards (utilizing monitoring and auditing systems, establishing and publicizing reporting system whereby employees and other agents can report violations by others within organization without fear of retribution
  - Standards consistently enforced through appropriate disciplinary mechanisms (including as appropriate disciplining individuals responsible for failure to detect an offense)
  - After offense detected, must have taken all reasonable steps to respond appropriately and prevent further similar offenses (necessary modifications to program)
  - Must periodically undertake reassessment of its compliance program to identify changes (necessary to reflect changes

Additional Compliance Requirements

- § 6401 – Compliance Programs
  - Certain providers and suppliers will be required *as condition of enrollment* to establish a compliance program.
  - Requirements for the compliance program ("core elements") will be developed by the Secretary and HHS OIG.
  - Secretary shall determine timeline for the establishment of the core elements and the date of implementation for providers or suppliers within a particular industry or category.

§ 6401 – Provider Screening & Disclosure Requirements

- applicants/ providers reenrolling would be required to disclose current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a Federal health care program, or has had their billing privileges revoked.

Additional Medicaid Program Integrity Provisions

- § 6501 – Termination of Provider Participation
  - States are required to terminate individuals or entities from Medicaid programs if individuals/entities were terminated from Medicare or other State plan under same title.
- § 6502 – Exclusion Relating to Certain Ownership, Control and Management Affiliations
  - Exclude if entity/individual owns, controls or manages an entity that: (1) failed to repay overpayments, (2) is suspended, excluded or terminated from participation in any Medicaid program, or (3) is affiliated with an individual/entity that has been suspended, excluded or terminated from Medicaid.
- §6503 – Billing Agents, Clearinghouses, or other alternate payees that submits Medicaid claims on behalf of health care provider must register with State and Secretary in a form and manner specified by Secretary

NY Mandatory Compliance

- New York Mandatory Compliance Program
  - NY Medicaid law and regulation: every provider receiving more than $500,000 per year must have, and certify to, an effective compliance program with eight mandatory elements. 18 NYCRR 521
  - Statute – November 2006; Regulation – 7/1/09
  - Mandatory compliance includes
    - Audit program,
    - Disclosure to state of overpayments received, when identified (over 80 disclosures in 2009)
    - Risk assessment, audit and data analysis
    - Response to issues raised through hotlines, employee issues
  - Effective Program Required by 10/1/09
  - Certification of Effective Compliance program – 12/31/09
  - Evaluation - ongoing

OMIG SELF DISCLOSURE FORM FROM WWW.OMIG.STATE.NY.US

- You must provide written, detailed information about your self disclosure. This must include a description of the facts and circumstances surrounding the possible fraud, waste, abuse, or inappropriate payment(s), the period involved, the person(s) involved, the legal and program authorities implicated, and the estimated fiscal impact. (Please refer to the OMIG self disclosure Guidance for additional information)

OMIG DISCLOSURE GUIDANCE

- “OMIG is not interested in fundamentally altering the day-to-day business processes of organizations for minor or insignificant matters. Consequently, the repayment of simple, more routine occurrences of overpayment should continue through typical methods of resolution, which may include voiding or adjusting the amounts of claims.”

CONCLUSION: THE THREE MOST IMPORTANT MEDICAID INTEGRITY PROVISIONS OF PPACA

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FREE STUFF FROM OMIG

- OMIG website-WWW.OMIG.State.ny.us
- Mandatory compliance program-hospitals, managed care, all providers over $500,000/year
- Over 1500 provider audit reports, detailing findings in specific industry
- 66 page work plan issued 4/20/09-shared with other states and CMS, OIG (new one coming in April)
- Listserv (put your name in, get emailed updates)
- New York excluded provider list