

**Physician Practice
Compliance Conference**
TOP TEN MEDICAID PROGRAM
INTEGRITY ISSUES FOR 2009-
2010

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- GOOD IDEAS FROM MANY SOURCES
- ADOPTION IS COMPLIMENT, NOT PLAGIARISM
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FREE STUFF

- OMIG website-WWW.OMIG.State.ny.us
- Mandatory compliance programs-hospitals, managed care, all providers over \$500,000/year
- Over 100 provider audit reports, detailing findings in specific industry
- 66 page work plan issued 4/20/09-shared with other states and CMS, OIG
- Listserv (put your name in)
- New York excluded provider list
- DEAR PROVIDER LETTER –no billing for dead patients, repay credit balances, no balance billing Medicaid patients

MEDICAID-AN IMPERFECT INSTRUMENT

- FEDERAL FUNDING REQUIRES FEDERAL OVERSIGHT
- HHS OFFICE OF INSPECTOR GENERAL
- CMS MEDICAID INTEGRITY GROUP
- CMS MEDICAID INTEGRITY CONTRACTORS
- FALSE CLAIMS ACT AND WHISTLEBLOWER PROVISIONS
- HEALTH REFORM PROPOSALS FUNDING

2010 MEDICAID TOP TEN

#10 KNEES AND HIPS-PAYMENTS TO PHYSICIANS-Manufacturer Settlements

- ZIMMER-\$169 million
- Howmet-\$26.9 million
- Smith & Nephew-\$29 million
- DePuy-\$84.7 million
- Stryker-\$0
- 18 months of independent monitor paid for by company (except Stryker)
- The public list of payment recipients on each company's website

#9-THE MANUFACTURERS SETTLED-BUT WHAT ABOUT THE PHYSICIANS THEY PAID?

- Civil Monetary Penalty cases
- Exclusion risk
- Qui tam cases: when a physician submits claims for payments (CMS-1500's), the physician impliedly certifies that the claim and the underlying transaction comply with the Anti-**Kickback** Statute. *United States of America ex rel. Thomas v. Bailey*, No. 4:06-CV-00465, **2008** U.S. Dist. LEXIS 91221, *39, **2008** WL 4853630, (E.D.Ark. November 6, 2008)

NOT JUST KNEES AND HIPS

- Medtronic Inc., a leading maker of heart defibrillators and other medical devices, says it will start keeping track of how much money and other perks it gives to physicians for consulting and other work then make the numbers public (October, 2009) Medtronic will begin tracking all payments to doctors in excess of \$5,000 in January 2010 and expects to release its first public report on the funding in March 2010.
- In 2006, Medtronic paid \$40 million to settle allegations it paid illegal kickbacks to doctors who used its products. The company admitted no wrongdoing in ending charges that it showered lavish luxury trips and maintained fraudulent consulting deals with doctors who used Medtronic devices.
- From www.attorneyatlaw.com

Medtronic, again

- Medical devicemaker Medtronic has announced that it has suspended its consulting arrangements with a former military physician who has been accused of falsifying research involving the use of a Medtronic product. The announcement came in the wake of a scolding by Sen. Chuck Grassley (R-IA), whose staff had found that the suspect physician was not on a list of consultants supplied by the company.
- When asked why Dr. Kuklo had not been on the previously disclosed list of consultants, a Medtronic spokesperson told a reporter that it was because he had a general consulting contract with the company, rather than one specific to Infuse.

Source <http://www.fiercehealthcare.com/story/medtronic-rebuked-grassley-failure-disclose-consulting-relationship/2009-05-21#ixzz0TUBYQWxm>

#8 PAYMENTS TO PHYSICIANS BY DEVICE AND DRUG MFRS.-WHAT'S NEXT?

- Web-based disclosure-voluntary in some cases, statutory in others, part of settlement in others
- Minnesota, Vermont, Massachusetts
- "GlaxoSmithKline (GSK) announced that starting in 2010, they will be disclosing payments to researchers, in addition to payments for grants, consulting, and promotional talks." Merck and Pfizer in 2009.
- U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) : The Physician Payment Sunshine Act to require manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities.
- If passed, beginning in 2010, the government will require yearly reporting of all physician payments over a cumulative value of \$100 dollars - with the first report being due by March 31, 2011 - and made available to the public by September 30, 2011.

June 9, 2008 WALL STREET JOURNAL

- Senator Grassley asked Harvard and Mass General for the conflict-of-interest forms from Dr. Joseph Biederman and two colleagues as part of his look into financial ties between drugmakers and doctors. The forms were a "mess," he said, and made it look as if the doctors had only taken a few hundred thousand dollars sums from industry over a seven-year period. After the doctors took another whack at disclosures, the amounts involved soared to more than \$1 million per doctor.

#7 USING "PRESENT ON ADMISSION," "NEVER EVENTS," AND READMISSION DATA TO IDENTIFY PROVIDER QUALITY ISSUES

- Practice patterns and issues
- Where did this patient come from before admission? Where did they go after discharge?
- Track records of individual physicians-both for ambulatory and for in-patient care
- HHS/OIG 2010 WORK PLAN-Office of Evaluation and Inspections-"State Medicaid Agency Policies to Deny Payment for Hospital-Acquired Conditions" (p. 42)

CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- **2005 Deficit Reduction Act Requires Development of Value-Based Payment Plan for hospitals and physicians**
- **REPORT TO CONGRESS:Plan to Implement a Medicare Hospital Value-Based Purchasing Program (November 21, 2007)**

CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- “CMS recommends replacing the current quality reporting program with a new program that would include both public reporting and financial incentives for better performance as tools to drive improvements in clinical quality, patient-centeredness, and efficiency. A Medicare Hospital VBP Program should be implemented in a manner that does not increase Medicare spending.”

CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- CMS Value Based Purchasing components:
- (1) a potential Performance Assessment Model that incorporates measures from different quality “domains” (clinical process of care, patient perspective of care, outcomes, etc.) to calculate a hospital’s Total Performance Score;
- (2) options to translate of that score into an incentive payment that makes a portion of the base DRG payment contingent on performance;
- (3) options for criteria to select performance measures for the financial incentive and candidate measures for FY 2009 and beyond;
- (4) a potential phased approach to transitioning from RHQDAPU to VBP;
- (5) a redesign of current data transmission and validation infrastructure to support VBP Program requirements;
- (6) potential enhancements to the Hospital Compare website to support expanded public reporting; and
- (7) an approach to monitoring VBP impacts.

THE NEXT PAYMENT REFORM WILL BE QUALITY AND OUTCOMES BASED

- PREDICTION: THE SHIFT TO QUALITY BASED REPORTING AND PAYMENT WILL HAVE INDUSTRY EFFECTS GREATER THAN THE SHIFT FROM COST REIMBURSEMENT TO DRGs.
- HOSPITALS WILL PASS REPORTING AND CHARTING OBLIGATIONS TO PHYSICIANS

#6 USING PRESCRIPTION DRUG DATA TO IDENTIFY QUALITY AND CARE ISSUES

- NURSING HOMES-What patients get atypical antipsychotics without schizophrenia diagnosis?
- What physicians write for atypicals for children and nursing home patients?
- How do individual physicians respond to "dear doctor", "black box," and medical literature warnings
- Hospital, nursing home, outpatient adverse events
- How many physicians write for controlled substances for this patient? How do you manage controlled substances patients (chart instruments, questionnaires)

#5 CREDENTIALING AND EXCLUSION

- WHERE ARE THEY NOW? PROBLEM DOCTORS , NURSES, PHARMACISTS, THERAPISTS, AND PROVIDERS-STRAIGHTFORWARD FALSE CLAIM ACTION-CMS, OIG CITE 1999 STANDARD
- KEEPING BAD AND EXCLUDED PROVIDERS OUT OF HEALTH CARE- USING AUTOMATED BACKGROUND CHECKS, PRIOR LICENSE ACTIONS, PRIOR EXCLUSIONS(state and federal)

Effect of Exclusion From Participation in Medicaid

- September 1999 OIG bulletin
- No excluded person can receive any compensation from federal health care programs
- In effect, this bars even janitors if their compensation is derived in any part from Medicaid
- <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/effectof.htm>

Provider Exclusions – State Medicaid Directors Letter 08-003 (available on CMS website)

- Issued on June 12, 2008
- Clarifies CMS policy
- Reminds States of their duty to report to HHS-OIG about excluded persons
- Tells States where and when to look for exclusions
- Reminds States of the consequences of paying excluded providers

EXCLUSIONS

- section 1932(d)(1) of the Act prohibits organizations:
- from knowingly having a director, officer, partner, or person with a beneficial ownership of more than 5 percent of the entity's equity who is debarred, suspended, or excluded, or from having an employment, consulting, or other agreement
- from having an employment, consulting, or other agreement with an individual or entity for the provision of items and services that are significant and material to the entity's obligations under its contract with the State where the individual or entity is debarred, suspended, or excluded.

SOURCES FOR EXCLUSIONS:

- EXCLUSION LISTS
 - OMIG.STATE.NY.US
 - Exclusions.hhs.oig.gov
 - Healthgrades.com
 - Medical board records
 - Fsmb.org/docinfo (\$9.95 fee)
 - Address tracer Accurint or Westlaw
 - GSA list

#4-FALSE CLAIMS CASES AGAINST GOVERNMENT ENTITIES AND THEIR MEDICAID GRANTEES

- US DOJ PRESS RELEASE 7/21/09
- "The state of New York and New York City have agreed to pay \$540 million to settle allegations that they knowingly submitted, or caused to be submitted, false claims for reimbursement for school-based health care services, primarily speech therapy and transportation, provided to Medicaid eligible children from 1990 to 2001, the Justice Department announced today. The settlement is a record federal recovery by the Justice Department for the Medicaid Program."
- Whistleblower was a North Country special ed teacher

MEDICAID-FALSE CLAIMS ENFORCEMENT

- WHAT HAPPENED IN SCHOOL SUPPORTED SERVICES
- MULTIPLE OVERSIGHT SYSTEMS-NO OVERSIGHT
- CORPORATE INTEGRITY AGREEMENT REQUIRES ONGOING MONITORING

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

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NEW KICKBACK THEORIES UNDER THE FALSE CLAIMS ACT ADOPTED BY COURTS

- “Defendants The Christ Hospital (“TCH”) and The Health Alliance of Greater Cincinnati (“THA”) assigned time to cardiologists in the hospital's heart station in proportion to the volume of referral of cardiac procedures made by cardiologists to TCH”-CABG referrals and gross revenues-the assigned time is illegal remuneration.

NEW KICKBACK THEORIES UNDER THE FALSE CLAIMS ACT ADOPTED BY THE COURTS

- UNITED STATES of America, ex rel Dr. Harry F. Fry v. THE HEALTH ALLIANCE OF GREATER CINCINNATI
- 2008 Westlaw 5282139 (S.D.OHIO 12/18/2008)

#3-HHS OFFICE OF INSPECTOR GENERAL AUDITS OF MEDICAID PROVIDERS

- 2010 OIG WORKPLAN-20 pages of audits and evaluations focused on Medicaid
- HHS OIG REPORT 6/08/09 (A-02-07-01054)PERSONAL CARE SERVICES-"The State improperly claimed Federal Medicaid reimbursement for some personal care services claims submitted by providers in New York City during calendar years 2005 and 2006. Of the 100 claims in our random sample, 80 claims complied with Federal and State requirements, but 18 claims did not. Based on our sample results, we estimate that the State improperly claimed \$275.3 million in Federal Medicaid reimbursement during the audit period"

OIG-HHS-AUDIT-FOCUS ON RECOVERIES FROM PROVIDERS

- OIG REQUIRES RECOVERY OF FEDERAL SHARE FROM STATE FOR IMPROPERLY EXPENDED FUNDS
- BUT-AUDIT REPORTS WILL LOOK TO SPECIFIC PROVIDERS
- EXPECTATION-STATE WILL TAKE ACTION AGAINST SPECIFIC PROVIDERS

#2 CMS MEDICAID INTEGRITY CONTRACTORS-BEGINNING 11/09

- PROVIDER MICS-data analysis and selection of audit subjects
- AUDIT MICS-estimate 200 audits in FFY 2010 (in addition to OMIG audits)
- EDUCATION MICS
- NOT OPTIONAL FOR STATES

#1- MANDATORY COMPLIANCE-PROGRAMS INTEGRITY ON FRONT END-the 4Rs

- PROVIDER-REQUIRE, RECOMMEND, REVIEW, REWARD EFFECTIVE COMPLIANCE PROGRAMS
- NY-mandatory "effective" compliance programs
- House and Senate bills contain similar provisions
- "effective" compliance program requires disclosure to state of overpayments received, when identified
- "effective" compliance program requires risk assessment, audit and data analysis, remedial measures
- "effective" compliance program requires response to issues raised through hotlines, employee issues

TESTING COMPLIANCE-DEAD PATIENTS PROJECT

- 1400 claims for services to dead patients in first six months in New York
- Beginning October 1:
 - Every provider who bills for dead patient will be required to:
 - Identify the employee who provided the service
 - Identify the employee who prepared the bill for the service
 - Produce the documents used to prepare the claim
 - Identify the compliance officer
 - Provide any exculpatory evidence

NEW RESPONSIBILITIES IN COMPLIANCE-NO LONGER JUST A GOOD IDEA

- MANDATORY COMPLIANCE PROGRAMS-here or coming
- New York Medicaid:18 NYCRR § 521. This rule is effective on July 1, 2009 and covered providers(Medicaid billings over \$500,000 p.a.) must have compliance programs in place satisfying the requirements of the rule by October 1, 2009, and must certify an "effective" compliance program by December 1, 2009
- WHO WILL CERTIFY YOUR PROGRAM?
- Federal contracting-December 2008
- HHS/OIG –testimony of OIG-considering mandatory compliance program-June 2009

8 Elements: Mandatory Compliance Programs in NY

1. Written policies and procedures, including code of conduct, how to report
2. Employee designated as chief compliance officer-must report periodically "directly to governing body" on compliance activities
3. Training of everyone on compliance, including orientation for new executives and governing body members about compliance expectations

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8 Elements: Mandatory Compliance Programs in NY

4. Communication lines from employees to chief compliance officer, including anonymous and confidential reporting
5. Discipline for failure to report suspected problems, permitting non-compliant behavior
6. Routine identification of compliance risk areas, including internal audit and appropriate external audit

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8 Elements: Mandatory Compliance Programs in NY

7. System for responding to compliance issues as they are raised; correcting such problems promptly and thoroughly, and identifying and reporting compliance issues to DOH or the OMIG; refunding overpayments
8. Non-intimidation and Non-retaliation

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AUDITING "EFFECTIVE" COMPLIANCE PROGRAMS

- Who is the compliance officer?
- To whom do they report?
- Do employees and vendors know about the compliance program?
- Who does billing? How accurate is it?
- Contingency fee contracting for coding and billing
- FMV reviews of physician payments
- Conflicts of interest
- Relationships with non-profits and the IRS form 990

THE FUTURE- Program Integrity and Data Mining Systems

- Data mining is a developing area – processing speed doubles every two years, software and analytic approaches move at same speed.
- Existing state data systems, at best, reflect reliable, tested systems and the state-of-the-art at the time of procurement. Existing New York systems procured five years ago, began operating three years ago.
- Significant opportunities for post-payment recoveries

Data Mining Quality Tools

Providers Not Meeting Minimum Standards

- Never events
- Unreported adverse events
- Unreported adverse outcomes/unanticipated deaths
- Ranking/rating facilities-audit focus
- Condition of participation failures (structure)
- Drug outcomes in populations and in facilities

THANK YOU

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