HCCA 13th ANNUAL COMPLIANCE INSTITUTE
P3:THE NEXT CHAPTER IN MEDICARE AND MEDICAID REGULATION AND ENFORCEMENT

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- GOOD IDEAS FROM MANY SOURCES
- ADOPTION IS COMPLIMENT, NOT PLAGIARISM
- FEEL FREE TO USE THESE SLIDES WITHOUT ATTRIBUTION
- WHISTLEBLOWER CALLS CHEERFULLY ACCEPTED-518 473-3782, ask for Jim

FREE STUFF FROM New York-OMIG website-WWW.OMIG.State.ny.us

- Model compliance programs-hospitals, managed care (coming soon)
- Over 100 provider audit reports, detailing findings in specific industry
- 66 page work plan issued 4/24/09-shared with other states and CMS, OIG
- Listserv
- New York excluded provider list
- Disclosure protocol

WHY IS MEDICAID GETTING ATTENTION, MONEY, AND LAWYERS?

- "unsustainable growth" in health entitlement programs
- Medicaid as safety net in recession
- Buy a dollar for 35 cents?
- Complexity of program on state level
- OMB, CMS skepticism of states

MEDICAID-

- 2007 spending:$350 billion in US ($159 billion state and $191 billion federal),50 million enrollees. Source: *OIG 2008 Statement of Management Challenges in 2008 HHS Annual Financial Report,www.hhs.gov/afr/2008sectiii ("AFR Report")*
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- 2008 spending: $46 billion in New York
- 2009 and 2010 "enhanced federal share" for Medicaid as part of federal stimulus package

THE MEDICAID BACKGROUND: FEDERAL IMPROPER PAYMENTS INFORMATION ACT of 2002

- "any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under . . .legally applicable requirements "Source:
- *IMPROPER PAYMENTS: PROGRESS MADE BUT CHALLENGES REMAIN GAO-09-628T 4/22/09 ("GAO REPORT")*

THE MEDICAID BACKGROUND: IMPROPER PAYMENTS

- Ineligible recipients
- Ineligible service
- Duplicate payment
- Payment for services not received
- Failure to give credit for discounts or other payments

MEDICAID BACKGROUND: IMPROPER PAYMENT REPORTING REQUIREMENTS FOR FEDERAL AGENCIES

- Agency head, annually,
  - required to identify program susceptible to significant improper payments" (over 2.5% of program and $10 million)
  - Estimate amounts improperly paid
  - Report on amounts improperly paid
  - Report on actions to reduce improper payments
  - US HHS reports through Agency Financial Report (AFR report)

FOR FY 2008, THE WINNER (ONCE AGAIN) IS MEDICAID AT $18.6 BILLION IN IMPROPER PAYMENTS

- AND THIS IS ONLY THE FEDERAL SHARE
- "Although it was required by the Office of Management and Budget to report improper payment information beginning in 2003, CMS began reporting improper payments for this program in FY 2007." (GAO Report)
- Reported error rate of 10.5% combined fee for service, managed care, and eligibility
- Error rate calculation base DID NOT include New York- only 17 states
- Medicaid has been on GAO's High-Risk list since 2003. Source:, *High Risk Series:An Update GAO-09-271 (2009)*

CONCERNS RAISED BY GAO ABOUT MEDICAID IMPROPER PAYMENTS IN APRIL, 2009

- “Shared oversight and enforcement activities between multiple federal and state entities create significant challenges”
- Need for “culture of accountability for improper payments”
- “magnitude of the program’s payment errors”

MEDICAID 2006-CONGRESS-DEFICIT REDUCTION ACT

- Congress specifically required the use of contractors to review the actions of those seeking payment from Medicaid, conduct audits, identify overpayments and educate providers and others on payment integrity and quality of care. It further mandated that CMS employ 100 full-time equivalent employees to provide support to the States.
- Congress has appropriated funds to CMS for a total of $75 million annually in 2009.
- Primary role assigned to program agency, not oversight agency

WHAT CMS IS DOING ON MEDICAID PROGRAM INTEGRITY

- AUDITS/EVALUATIONS OF STATE INTEGRITY PROGRAMS
- “State Program Integrity Assessment (SPIA) – This strategic planning and development contract, awarded in August 2006, has assisted CMS in detailing State agencies’ efforts to combat fraud, waste, and abuse. SPIA deliverables include surveying the Medicaid integrity landscape, identifying State program integrity profiles, and recommending performance measures and standards by which State performance may be assessed in the future.”

MEDICAID 2008-CMS

- **Comprehensive Medicaid Integrity Plan of the Medicaid Integrity Program FY 2008 – 2012 (June 2008)- no identified Priority Areas**
- **Differs from 2006 MIP Plan**

THE MEDICAID INTEGRITY CONTRACTORS

- PROVIDER MICS
  - Develop and apply algorithms, analyze Medicaid data to select auditees, target audit issues
- AUDIT MICS
  - Do the audits, turn over results to states
- EDUCATION MICS
- First auditors in Regions III (Pa-Va.) and IV(NC –Fla.) are now doing audits
- REGIONS I (New England) and II (NY, NJ) expected by end of year
- How many will they do?

WHAT WILL MICS FOCUS ON?

- Desk Issues
  - Dead or alive
  - Inpatient at time of ambulatory service
  - Hysterectomy on male
- Field audit issues
  - Debridement (requires actual cutting) (Coding Clinic)
  - Heart failure and shock-failure to meet criteria for inpatient care (Interqual)
  - Ambulatory surgery-no complications to justify inpatient stay (APC list of procedures)
  - DRG assignment
  - Observation beds
- Provider failed to submit documents in response to RAC's request

Medicaid Integrity Contractors

- MEDICAID INTEGRITY CONTRACTORS WILL RELY ON MEDICAID STATISTICAL INFORMATION SYSTEM (MSIS) DATA for DATA MINING EFFORTS
- NATIONAL SYSTEM MAINTAINED BY CMS FROM QUARTERLY DATA SUBMISSIONS BY STATES IN STANDARD FORMAT

OIG CONCERNS ABOUT MSIS DATA TO BE USED IN MIC REVIEWS

- "National Medicaid claims data are limited in their capacity to support program integrity and oversight activities. Limitations include the following: some essential data elements, such as provider identification information, are not captured; data are updated quarterly, limiting the ability to analyze national data in real time; and CMS's process for collecting and validating the MSIS files can take as long as 2 years, making
- the final data too old for certain program integrity activities. These limitations can increase the time and costs for CMS to conduct certain Medicaid oversight and program integrity activities, such as analyzing claims across States to detect aberrant billing patterns." SOURCE: 2008 HHS Annual Financial Review

STATE MEDICAID PROGRAM INTEGRITY EFFORTS

- ADDED STAFF, DATA TOOLS
- NEW INSPECTORS GENERAL
- ASSESSMENTS OF ROI, BUDGET IMPACT BY LEGISLATURE, EXECUTIVE
- NATIONAL MEDICAID INTEGRITY INSTITUTE
- NEW QUI TAM/FALSE CLAIMS STATUTES

STATE INITIATIVES

- See SFY 2009-10 New York Work Plan (we borrowed good ideas from others, and share our ideas with CMS and other states)
- 70 pages of audit, investigative, data mining initiatives
- Medicaid Fraud Control Unit Reports at oig.hhs.gov (2007 most recent available): "In FY 2007, MFCUs recovered more than $1.1 billion in court-ordered restitution, fines, civilsettlements, and penalties. They also obtained 1,205 convictions. MFCUs reported a total of 607 instances in which civil actions were undertaken that resulted in successful outcomes."
- The National Association of Medicaid Fraud Control Units publishes a bimonthly newsletter, "the Medicaid Fraud Report" listing case narratives, available on NAMFCU.net
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NEW YORK OMIG HIGHLIGHTS

- QUALITY ISSUES-NEVER EVENTS, PRESENT ON ADMISSION CONDITIONS, PRESCRIPTION DRUG USE AND EVENTS
- BUREAU OF ALLEGATIONS AND COMPLAINTS
- COMPLIANCE MANDATE AND GUIDANCE
- CONSIDERATION OF CENSURE, OR EXCLUSION FOR GOVERNING BOARD MEMBERS "FOR SIGNIFICANT FAILURES" OF OVERSIGHT
- CORPORATE INTEGRITY AGREEMENTS
- FOCUS ON ORDERING PHYSICIANS

BUREAU OF ALLEGATIONS AND COMPLAINTS

- Review available hotline resources and returns
- Review audits for enforcement potential
- Review enforcement cases for audit potential
- External sources of information
- Evaluate sources for major cases

COMPLIANCE MANDATE AND GUIDANCE

- Regulation to be issued in final in May mandates an "effective compliance program" with eight elements
- Guidance for hospitals, managed care soon
- Nursing homes in 2009

INVESTIGATION AND CONSIDERATION OF SANCTIONS FOR BOARD MEMBERS

- SIGNIFICANT PROGRAM INTEGRITY FAILURES
- FAILURE OF OVERSIGHT/MONITORING
- POSITION OF RESPONSIBILITY
- WHAT DID YOU DO TO ASSURE THAT THERE WERE SYSTEMS IN PLACE REASONABLY CALCULATED TO DETECT VIOLATIONS OF LAW AND FAILURES OF QUALITY?

NEW YORK OMIG HIGHLIGHTS

- REVIEW OF IRS FORM 990 AND SCHEDULES
- REVIEW OF PHYSICIAN RELATIONSHIPS
- AUDIT ASSESSMENT SURVEY
- MARKETING AND ORDERING OF PRESCRIPTION DRUGS AND DEVICES
- MONITORING FEDERAL STIMULUS FUNDS
- REVIEW OF OFF-LINE MEDICAID EXPENDITURES

IRS 990 AND SUPPORTING SCHEDULES

- BOARD REVIEW PRIOR TO FILING
- CONFLICTS OF INTEREST PROCESS
- DISCLOSURES
- PAYMENTS TO CONTRACTORS AND EXECUTIVES
- TIE-IN TO PHYSICIAN RELATIONSHIPS
- TIE-IN TO COST REPORTS

2009 MODEL AUDITS, INVESTIGATIONS/QUI TAMS

- ATYPICAL ANTIPSYCHOTICS

2009 LIKELY INVESTIGATIONS/ QUI TAMS

- WHERE ARE THEY NOW? PROBLEM DOCTORS 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)

SOURCES:

- 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

SOURCES

- www.deadiversion.usdoj.gov/fed_regs/actions-
- Useful materials-denial of registration; restricted registration; suspension of registration
- Cross-walk to state licensing, state and federal prosecutions
- What about impaired physicians? See Washington Post series April 10-17, 2005

Dr. Jayam Krishna-Iyer, M.D.

- Respondent had issued prescriptions for controlled substances to three separate undercover operatives notwithstanding that each of the operatives had indicated that he was not in pain, and had told Respondent that he was obtaining controlled substances from non-legitimate sources such as friends. Respondent had failed to conduct a physical exam on each of the undercover operatives and had falsified each operative's medical record to indicate that she had done an exam. Respondent had made statements during each operative's visit indicating that she knew that the operative was seeking the drugs to abuse them and not to treat pain. Respondent had pre-signed prescriptions and given them to a registered nurse in her employ, and that she allowed the nurse to issue prescriptions to one of the operatives even though she did not attend to the operative during the visit and the nurse lacked authority under both Federal law and Florida law to prescribe controlled substances.
- Jayam Krishna-Iyer, M.D., 71 FR 52148, 52159 (2006). (Opinion of DEA Deputy Director)

Dr. Jayam Krishna-Iyer, M.D.

- 11th Circuit unpublished opinion
- "In considering Petitioner's experience in dispensing controlled substances . . . the DEA identified only four visits by three undercover 'patients,' who were all attempting to make a case against her. In short, the DEA did not consider any of Petitioner's positive experience. . . With thousands of other patients . . . in dispensing controlled substances." 11th Circuit Court of Appeals unpublished opinion, Case 06-15034

2009 LIKELY INVESTIGATIONS/ QUI TAMS 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

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)

WHAT ABOUT THE PHYSICIANS THEY PAID?

- compliance with the Anti-**Kickback** Statute is a condition of payment by the **Medicaid** program. 42 U.S.C. § 1320a-7b(b), *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.* 251 F.Supp.2d 28, 32 (D.D.C.2003).

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.

ZIMMER WEBSITE DISCLOSURES(www.zimmer.com)-PAYMENTS TO CONSULTANTS

- Click on " Zimmer corporate"
- Click on "enter"
- Click on "corporate compliance program"
- Click on "Company Consultants-identification and payments"
- Click on "View Company Consultants-identification and payments"
- Look for over $3 million payment to one Houston consultant

THE PHYSICIAN RECIPIENTS OF PAYMENTS FROM DRUG/DEVICE FIRMS

- Do the payments affect physician clinical or fiduciary behavior?
- How does it look to patients and public when disclosed?
- Do the payments violate the law?
- Is more information better, for physician, institution, patient?

SMITH & NEPHEW

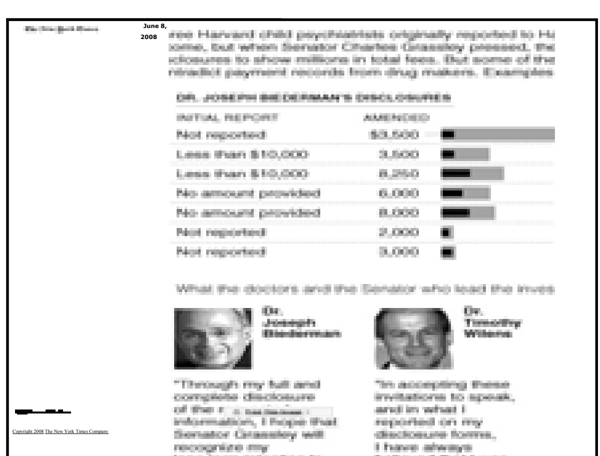
- "The Smith & Nephew minimally invasive techniques allow you to make the incision smaller at a pace with which you feel comfortable." Dr. H., quoted in S&N marketing flyer
- No disclosure of relationship on flyer
- 2007--$1.65 million in 2007 from Smith and Nephew
- Expert on specially designed knees for women

STRYKER

- **Dr. K., h**as a significant relationship as a Consultant with **Stryker** Orthopedics and. may refer to it in his presentation –(AAOS 2004 program).
- "Significant relationship"=$1.5 million in 2007.
- Designer of Stryker knee navigation system.

CONFLICTS OF INTEREST 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.



The New York Times

June 8, 2008

ree Harvard child psychiatrists originally reported to H
ome, but when Senator Charles Grassley pressed, the
closures to show millions in total fees. But some of the
ntradict payment records from drug makers. Examples

DR. JOSEPH BIEDERMAN'S DISCLOSURES

INITIAL REPORT	AMENDED
Not reported	$3,500
Less than $10,000	3,500
Less than $10,000	8,250
No amount provided	6,000
No amount provided	8,000
Not reported	2,000
Not reported	3,000

What the doctors and the Senator who lead the inves

Dr. Joseph Biederman

"Through my full and complete disclosure of the r
information, I hope that Senator Grassley will recognize my

Dr. Timothy Wilens

"In accepting these invitations to speak, and in what I reported on my disclosure forms, I have always

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2009 LIKELY INVESTIGATIONS/ QUI TAMS ENHANCED KICKBACK THEORIES

- "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

- 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)

MANDATORY, “EFFECTIVE” COMPLIANCE PROGRAMS ARE COMING FOR LARGE PROVIDERS

- Medicare Part D-2006 (sort of)
- Federal Acquisition Regulations-November 2008, effective December 2008
- New York Medicaid-2009
- Includes mandatory disclosure of overpayments, false claims, and criminal conduct

USING “PRESENT ON ADMISSION,” “NEVER EVENTS,” AND READMISSION DATA TO IDENTIFY PROVIDER QUALITY ISSUES

- Not just hospitals
- 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

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

LIKELY INVESTIGATIONS/QUI TAMS USING PRESCRIPTION DRUG DATA TO IDENTIFY QUALITY AND CARE ISSUES

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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

PHARMA PROVIDES STRONG DATA MINING OPPORTUNITIES

- STANDARDIZED PRODUCTS/CODES
- STANDARDIZED INDICATIONS (FDA AND COMPENDIA)
- HIGHLY AUTOMATED REAL-TIME BILLING AND PAYMENT
- THREE PARTICIPANTS IN EVERY PRESCRIPTION TRANSACTION-PHYSICIAN, PHARMACIST, PATIENT

Data Mining for Patients

- Unanticipated deaths in hospital, snf and prescription history
- Off-label use and better outcomes
- Experimental use and consent-by facility, by ordering physician
- Third party liability for treating adverse events
- Capturing adverse events

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

DATA MINING FOR RELATIONSHIPS AND DISCLOSURE

- FIVE KINDS OF REPORTING
- IRS FORM 990 (2008 version) and reporting questions Does the organization have a written conflict of interest policy? *If "Yes",*, how many transactions did the organization review under this policy and related procedures during the year?" *If "Yes":* Are officers, directors or trustees, and key employees required to disclose annually interests that could giver rise to conflicts? Does the organization regularly and consistently monitor and enforce compliance with the policy?
- Company websites (voluntary or required by CIA)
- State law required disclosures
- patient consent disclosures
- IRB disclosures

THE FUTURE OF MEDICARE AND MEDICAID PROGRAM INTEGRITY THROUGH DATA MINING

- IDENTIFY AND COMMUNICATE BEST OUTCOMES FROM DATA MINING
- IDENTIFY AND COMMUNICATE COMPLIANCE DATA ANALYSIS PROCESSES WHICH WILL IDENTIFY PROBLEM AT SOURCE
- IDENTIFY AND COMMUNICATE ISSUES IDENTIFIED THROUGH DATA MINING
- TRAIN AND EQUIP EMPLOYEES AND ORGANIZATIONS IN DATA ANALYSIS TECHNIQUES
- EVERYONE'S A DATA MINER-THE SOUTH CAROLINA HHS MODEL
- EVERYONE'S A DATA MINER-RACs,MICs,CMS, ZPICs,Relators