HCCA ANNUAL MEETING 2010 NEW YORK MEDICAID PROGRAM LESSONS FROM MANDATORY COMPLIANCE:INTEGRITY THROUGH COMPLIANCE MEASUREMENT

JAMES G. SHEEHAN
NEW YORK MEDICAID INSPECTOR GENERAL
JGS05@OMIG.STATE.NY.US
518 473-3782

DISCLOSURES

- New York state employee
- Not permitted to work on case against Johnson & Johnson (mentioned in this presentation) because of potential conflict
- Information on filed cases from public sources

MANDATORY COMPLIANCE

- New York 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
- Statute November 2006;regulation 7/1/09
- Effective compliance program-10/1/09
- Certification-12/31/09
- Evaluation-ongoing

Patient Protection and Affordable Care Act (PPACA) Section 6102

- *REQUIREMENT.—"On or after the date (March 22, 2013). . . a (snf or nursing)facility shall . . . have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care . . .*
- *Regs by March 2012, evaluation by March 2015*

PPACA

- *"(C) EVALUATION.—Not later than 3 years after the date of the promulgation of regulations under this paragraph, the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subsection. Such evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of patient quality of care."*

"compliance and ethics program" means, with respect to a facility, a program of the operating organization that

- *"has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and*

"(B) includes at least the required components specified in paragraph (4).

Section 6401 of PPACA

- *"(7) COMPLIANCE PROGRAMS.—*
- *"(A) IN GENERAL.—On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B)*

NO BIG DEAL?-MOST PROVIDERS HAVE HAD A COMPLIANCE PROGRAM FOR YEARS

- VERY BIG NEW DEAL-
  - HEALTH COMPLIANCE NEVER REQUIRED BY GOVT
  - HEALTH COMPLIANCE PROGRAMS NEVER FORMALLY EVALUATED BY GOVT
  - HEALTH COMPLIANCE NEVER MEASURED BY GOVT
  - HEALTH COMPLIANCE SELDOM TESTED BY GOVT
  - CONSEQUENCES OF INEFFECTIVE COMPLIANCE NEVER ARTICULATED EXCEPT IN SENTENCING GUIDELINES
  - THINK OF AN ORGANIZATION'S FIRST JCAHO REVIEW, OR FIRST MAJOR MALPRACTICE CASE, OR FIRST RAC AUDIT-
  - OR FIRST MAJOR DISASTER

“Effective in Preventing and Detecting. . . Violations and promoting quality of care”

- “effective”-law, accounting, psychology
- “effective”-communication
- “effective”-metrics
- “effective”-prevention
- “effective”-detection

CORE NY OMIG PRINCIPLES-EFFECTIVE COMPLIANCE PROGRAM

- MANDATORY COMPLIANCE PROGRAMS FOR ALL MEDICAID PROVIDERS OVER $500,000/ YEAR
- MEASURING COMPLIANCE OUTCOMES, NOT JUST STRUCTURE OR PROCESS
- USING COMPLIANCE OUTCOMES MEASURES TO FOCUS, LIMIT AUDITS AND INVESTIGATIONS
- USING TARGETED OUTREACH, MEASUREMENTS OF BEHAVIOR CHANGE, AND CORPORATE INTEGRITY AGREEMENTS TO CHANGE OUTCOMES

CORE NY OMIG PRINCIPLE: DEVELOP AND USE DATA MINING CAPABILITIES FOR COMPLIANCE

$200 Billion in claims in data warehouse

- End-to-end integration of all recipient services
- Using new databases and analytic tools
  - Salient
  - Integrated national exclusion databases
  - Demographic and financial data from multiple sources-death data, tax data, Accurint
  - Entity Analytics
  - HMS insurance coverage data
  - Mandatory cardswipe for certain providers
  - Edits, overrides, reject and resubmit

CORE NY OMIG PRINCIPLE: BEGIN PROCESS OF SUPPORTING COMPLIANCE EFFORTS BY PROVIDERS

- Identify and communicate compliance data analysis processes which will identify problem at source
- Identify and communicate issues discovered through data mining
- Train and equip employees and organizations in data analysis techniques
- Support compliance officers and organizations which demonstrate good outcomes
- Audit focus on non-compliant

A SYSTEMS APPROACH TO HEALTH CARE FRAUD, ABUSE, AND IMPROPER PAYMENTS

- Mistakes, improper claims, improper behavior influenced by financial incentives, conflict of interest
- Health care fraud and abuse in organizations-why does it happen?
- Data driven, systems approach to medical errors works-how about a data driven, systems approach to improper billing?
- Less fault-finding, more fixing

WHAT DOES CURRENT RESEARCH SUGGEST ABOUT SUPPORTING AND MANAGING EFFECTIVE COMPLIANCE PROGRAMS?

- Compliant behavior of individuals in large organizations can be significantly influenced by factors that those individuals do not consciously recognize
- Factors which influence compliant behavior can be affected by compliance program design and operation
- Factors which influence compliant behavior can be affected by governmental program design

COMPLIANCE

- Problem definition
- Goals
- Metrics
- Process Improvement
- Outcomes

A CULTURE OF NON-COMPLIANCE

- How do behaviors inconsistent with established rules become acceptable or tolerated?
- What mixture of compliance, communication, and enforcement are most efficient and effective in changing the extent of non-compliance?
- Next-the example of how not to do it

Atlantic City Press: Toll cheats beware February 2007

- Motorists cheated the Florida Turnpike out of $20 million in tolls in fiscal year 2006.
- About 250,000 motorists skip paying tolls on the Pennsylvania Turnpike every year.
- New Jersey Turnpike and parkway motorists skipped on paying more than $10 million in tolls from January 2003 through December 2006. Brenda Pierce, superintendent of toll operations, wouldn't disclose how much the Atlantic City expressway lost to toll cheats.
- **Five-that's how many people were ticketed for toll evasion by State Police on Tuesday as part of the SJTA's crackdown on toll cheats. Ten other motorists were ticketed for running toll booths at Exit 9 when the SJTA and State Police earlier this year ran the first of what will be a series of efforts to convince expressway motorists that they really, really have to pay tolls on the roadway.**

- The Massachusetts Turnpike, the main highway leading through Boston, is a toll road. . . .Commuting into the city from the suburbs costs $2.00, or more, *each way*. All those tolls really add up -- the average commuter spends $1000.00 per year on tolls -- but it's either that or keep our massive highway construction projects under budget.

  Recently, while giving away yet another $1.00 of my hard-earned money for the privilege of *driving into town*, I wondered: *how flexible are they about the tolls?* So I decided to undertake a series of experiments.

If you have exact change, you can use the "baskets," which are big scoop-shaped buckets into which you throw your money.

- You can see that the money goes to keeping the baskets clean and well-manicured.

Experiment #1.

- First, I went through one of the $1.00 toll gates, *but I only threw in 97 cents*. Believe it or not, I was nervous as I drove away -- would the Turnpike Police pull me over and make me fill potholes with gravel and hot tar until I paid off my debt? Would angry Dobermans chase me down the highway, chomping at my tires?
- Nothing happened.

Experiment #2

- . Emboldened, the next time I went through the toll booth, I decided to try throwing in just *seven* cents.
  Nothing happened.

Experiment #3

- . The next time I went through, I decided to just write them an I.O.U., and tape it to the toll booth. I signed it "Mariah Carey," because I figured she can afford the extra dollar.
  Nothing happened.
- *This is great!* I thought. *All these years, I've been paying tolls, and it turns out they're optional!* What other creative payment options could I use to pay my tolls on the Massachusetts Turnpike?

Experiment #4

- **.** This time, instead of throwing in $1.00, I decided to tape two pictures of rap superstar 50 Cent, because that *adds up* to a dollar
- As I drove away, I kept nervously glancing in my rear view mirror for the Toll Booth Police, or 50 Cent's posse, but the sad truth is that *nothing happened*.

Experiment #5

Experiment #5 (continued)

- Fortunately, the sign makes no mention of *other* foreign coins, which is the loophole I used for my next experiment. I consulted an online currency calculator to get up-to-the-minute exchange rates, then tossed in the following coins:

  1 Indian Rupee ($0.02 U.S.)
  15 Thai Baht ($0.36 U.S.)
  11 Singapore cents ($0.06 U.S.)
  1 Finnish Marka and 200 Italian Lira (no longer used, since the Euro came to town)

  That only added up to 44 cents, so I threw in a couple of Chuck E. Cheese tokens as well.

  When I went through this time, I heard the toll booth operator shout something that sounded like, "WALP!" I had been trying my little experiments at the same toll booth, so maybe he recognized my car, or maybe he was choking on a thick slice of ham. I didn't stick around to find out -- I got the WALP out of there

Experiment #6

- . In olden days, one could directly barter goods and services without the aid of money. So I bought a couple of oranges from a local convenience store, which cost me about a dollar.

CONCLUSION:

- Since none of my experiments had any effect on the automated change buckets, which cheerfully allowed me to pass, I concluded that the Massachusetts Turnpike Authority was the most laid-back government agency ever -- even more than the Department of Motor Vehicles, where most employees spend 92% of their workday in a deep, restful slumber.

NON-COMPLIANT BEHAVIOR

- 1) LARGE, ANONYMOUS BUREACRACY
- 2) SENSE OF GRIEVANCE- $2 IN TOLLS, LARGE BUCKET, "THROW YOUR MONEY"
- 4) TEST SYSTEM WITH MINOR NON-COMPLIANCE-WHAT HAPPENS?
- 5) INCREASE LEVEL OF NON-COMPLIANCE-WHAT HAPPENS?
- 6) SEARCH FOR "LOOPHOLES"
- 7) IT IS MASSPIKE'S FAULT FOR BEING LAID-BACK
- SO HOW DO WE CHANGE THE BEHAVIOR

The Scientific Basis of Influence and Reciprocity: A Symposium

- June 12, 2007,Washington, D.C.
- Sponsored by: Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit
- PDF version of this publication available for free download at www.aamc.org/publications
- Copyright AAMC
- Focus of symposium: influences on prescriber and patient behavior

Research: not bad intent, but unconscious psychological mechanisms-AAMC SYMPOSIUM

- **"The Scientific Basis of Influence and Reciprocity: A Symposium" American Association of Medical Colleges 6/12/ 2007**
- THE PSYCHOLOGICAL PERSPECTIVE-Dan Ariely, Ph.D. Sloan School, MIT(now at Duke) author of *Predictably Irrational (2009) and The Upside of Irrationality (2010)*
  -
  - CHANGING THE PROBABILITY OF "GETTING CAUGHT"
  - CHANGING BELIEFS ABOUT AVERAGE PERFORMANCE
  - INCREASING AWARENESS OF MORAL STANDARDS
  - IMPLICATIONS OF THE USE OF TOKENS
  -
- THE BEHAVIORAL ECONOMICS PERSPECTIVE –George Lowenstein, Ph.D.-Carnegie Mellon
  - UNCONSCIOUS INFLUENCES ON ADVICE-GIVERS
  - THE MOTIVES AND BEHAVIOR OF ADVICE RECIPIENTS
  -
- DOES DISCLOSURE WORK?
  - CONFLICTS OF INTEREST WILL INEVITABLY BIAS BEHAVIOR

DR. DAN ARIELY ON CHEATING

- 1.People do cheat when they have a chance to do so.
- 2. People cheat by only a "little bit."
- 3. People's magnitude of dishonesty is not strictly monotonic in its relation to the magnitude of external rewards.
- 4. People seem to know that they are overclaiming.
- 5. Cheating by "just a bit" does not cause people to think of themselves as dishonest.

CHEATING ON EXAMS

- *"control"* version of the experiment, students received a test with a series of general knowledge multiple-choice questions (e.g., "How deep is a fathom?") and a "bubble sheet" for answers. They were told they would be paid 10 cents for each correct answer.
- *"no-recycle"* condition, students received a bubble sheet with the correct answers premarked in grey. When the answer they had chosen was incorrect, the students could be honest and mark the circle they had actually chosen or be dishonest and mark the circle that showed the correct answer. They summed up the correct answers and wrote that number at the top of the sheet, handing both the test and the answer sheet to the researcher.
- "*recycle*" condition increased the odds that cheating students would not be caught by allowing the students to shred their original test sheet and take only the answer sheet to the experimenter.

CHEATING ON EXAMS? WHAT HAPPENED?

- The top 15% in both recycle and no-recycle all cheated (no one in the control group got a score of 42 or better)
- The modal group cheated by about 3 questions out of 48, to achieve a modal score of 36

DR. DAN ARIELY CHEATING STUDY

- The first group of participants was asked to write down ten books they read in high school before they did a series of math problems and checked their answers against the correct answers. The second group was asked to list as many of the 10 Commandments as they could recall.
- Participants were paid for the number of correct answers on the math problems.

DR. DAN ARIELY ON CHEATING

- Prediction?

ANSWERING TO A HIGHER AUTHORITY

- The group of people who simply recalled books read in high school cheated by just one question, on average. But there was no cheating when the Ten Commandments were recalled. The number of commandments students were able to remember made no difference.

DR. DAN ARIELY CHEATING STUDY

- participants were asked to sign a simple statement, "I understand that this short survey falls under [the University's]honor system." Variables included changes in the likelihood of "getting away with" deception and, in this experiment, the amount of payment, which was either 50 cents per correct answer or $2 per correct answer.

DR. DAN ARIELY ON CHEATING

- Prediction?

HONOR CODE

- The reminder of the honor code eliminated cheating completely, regardless of the amount of the reward.
- It had exactly the same effect at the Massachusetts Institute of Technology, which has no honor code!

EFFECTS OF TOKENS VS. CASH

- Dr. Ariely's experiment tested the impact of the use of tokens on dishonesty,using three conditions.
- The control condition in which experimenters could check their answers; (payment in cash)
- the "recycle" condition in which they could cheat without being caught; (payment in cash)
- the third condition in which after recycling the test sheet, participants received *tokens* from the experimenter that they then exchanged for money from a second experimenter.
- .

DR. DAN ARIELY ON CHEATING

- Prediction?

EFFECT OF TOKENS VS. CASH

- the use of tokens *doubled the amount of cheating*. The use of these transitional items, meaningless in themselves, apparently made it much easier for participants to deceive themselves about what they were doing without interference from their sense of morality.

The Scientific Basis of Influence and Reciprocity-Symposium Conclusions

- 1.There are systematic and predictable ways in which people act unethically that are beyond their own awareness.
- 2. The more leeway people have, the more likely they are, given the opportunity, to behave unethically, but only up to a point that appears to vary among individuals.
- 3. Increasing awareness of moral standards, or mindfulness, at the time of decision making diminishes the tendency to behave unethically.
- 4. Self-interest unconsciously biases well-intended people, who give themselves bounded "moral wiggle room" to engage in unethical behavior with an easy conscience.
- 5. The more detached from direct financial awareness of money impact, the more likely the cheating

My Suggested lessons from Ariely on effective compliance programs

- When no one is checking, people more inclined to cheat
- When an issue is framed in moral terms, people less inclined to cheat
- When an issue is framed in community standards terms, people less inclined to cheat
- The amount of the reward does not appear to change the likelihood of cheating
- Separating decisions from financial impacts increases the amount of cheating

USING ARIELY RESEARCH

- Need for individuals to perceive that checking will occur of their actions
- Need to emphasize moral element of daily actions
- Need to emphasize community standards
- Need to emphasize financial impact of cheating

HOW DO WE USE THESE LESSONS IN AN EFFECTIVE COMPLIANCE PROGRAM?ROBERT CIALDINI *INFLUENCE: THE PSYCHOLOGY OF PERSUASION*

- Reciprocity-gifts, recognition, symbols
- Commitment and consistency-certification
- Social proof-Jonestown
- Authority-titles, credentials, age
- Liking-Tupperware

DON'T FORGET-THEY DESERVE A BREAK!

- HCCA to Sunday speakers
- 15 minutes-back at

AN EFFECTIVE COMPLIANCE PROGRAM-BILLING FOR DEAD PATIENTS

- EVERY MONTH, THREE HUNDRED CLAIMS ARE SUBMITTED TO NY MEDICAID FOR DECEASED PATIENTS.
- NOT ALL ARE PAID (IF MORE THAN 30 DAYS LATE, EDIT SHOULD STOP PAYMENT) BUT-
- WHY DO HOSPITALS, NURSING HOMES,PHARMACIES, AMBULETTES BILL FOR DEAD PATIENTS?
- WHAT DO DEAD PATIENT CLAIMS TELL US ABOUT SYSTEM WEAKNESSES?
- KEY-INFORMATION ABOUT CAUSATION, NOT JUST COLLECTION OR PROSECUTION
- WHEN AN IMPROPER PAYMENT IS IDENTIFIED, ROOT CAUSE AND RESPONSIBLE INDIVIDUAL ARE IDENTIFIED

Professor Ariely's Theories About Influencing Behavior Applied to Billing for Deceased Patients

- Changing the personal probability of getting caught billing for dead patients-from minimal to high
- Changing beliefs about community standards-300 providers out of 60000
- Increasing awareness about moral standards-news coverage, letters, calls, outreach, posting on website
- Reducing tokens-actual dollar loss to program (how many employees know what revenue their actions generate?)

NEW YORK DECEASED PATIENTS PROJECT

- AUGUST, 2009-WARNING LETTER TO PROVIDERS-NO BILLING FOR DEAD PATIENTS
- OCTOBER 1, 2009-MANDATORY COMPLIANCE PROGRAMS
- NOVEMBER, 2009-develop, scrub list of deceased beneficiaries-death data from Social Security, Vital Statistics, data warehouse reports
- NOVEMBER 2009-CAPTURE ALL DEAD PATIENT BILLING FOR OCTOBER

NEW YORK DECEASED PATIENT PROJECT

- DECEMBER 2009-300+/- certified letters, return receipt requested
- Tell us: person who performed service, person who prepared bill for service, documents supporting claim, and-
- Tell us if the person is not actually dead (based on prior rates, about 3%)
- Please get back to us in two weeks.
- Send us a check if you got paid for an improper claim.

NEW YORK DECEASED PATIENT PROJECT

- By December 23, less than 2/3 of providers responded
- About 65 send checks-most with no other documentation
- Some providers explain that they are allowed to bill for a month, as long as the patient is alive for one day (in some cases, they are correct)
- I join my staff in calling non-responders

NEW YORK DECEASED PATIENT PROJECT

- SOME NON-RESPONDERS INCLUDE MAJOR HOSPITALS AND OTHER HEALTHCARE INSTITUTIONS
- SYSTEMS ISSUES-BILLERS WHO GET LETTER AFRAID TO TELL PHYSICIAN
- COMPLIANCE OFFICERS WHO GET LETTER DO NOT KNOW WHAT TO DO
- WHO OWNS THE PROBLEM? WRONG QUESTION

NEW YORK DECEASED PATIENT PROJECT

- RESULTS BY MARCH 1
- 11 Non-responders, despite letter and multiple calls
- Non-Responders posted on website, receive congratulations from New York Post
- Providers report: 152 patients still alive
  - So we are matching death certificates (4 month lag)
  - Bad idea if not true (false statement plus dead bill)

NEW YORK DECEASED PATIENT PROJECT

- Pharmacy-patient’s partner showed up two days after the death to pick up controlled substance prescription
- Physician directed that dead patient’s scripts be delivered to his office
- Dead patient’s number visits three dentists
- Bellevue-waits six weeks to advise
  - Deceased patient’s body transferred to Bellevue from community hospital for organ “harvesting” –”clerical error” resulted in coding as an admission

EFFECTIVE COMPLIANCE PROGRAM? READ ABOUT IT IN THE NEW YORK POST

- **The patient was transferred to Bellevue in a "clinically dead state" last April but was connected to life-supporting equipment "awaiting the removal of organs/tissue for donation," a Bellevue spokesman said.**
- **"The Medicaid program was mistakenly billed for the admission. When this was discovered (by the audit), the reimbursement was voided and returned to Medicaid."**
- **Following the investigation, Bellevue issued a new policy prohibiting staffers from billing Medicaid for harvesting organs from brain-dead patients.**
- **What was the old policy?**
- **Walgreen’s and CVS failed to respond-names posted on website**

NEW YORK DECEASED PATIENT PROJECT-NOT JUST PROVIDER COMPLIANCE

- Public System weaknesses-why doesn’t Social Security death dates match Vital Statistics?
- Public System weaknesses-shown on enrollment system as dead on December 1, alive again in January and eligible until 2011
- Data mining-who re-enrolled this patient

NEW YORK DECEASED PATIENT PROJECT

- FOCUS ON POOR COMPLIANCE SYSTEMS
- We will do runs and letters every month
- Did you bill for deads?
- Did you respond to letter?
- Was your response accurate?
- How often do you show up on the list?
- Is it a service involving face-to-face?
- How does your compliance system address issues?
- Are individuals accountable for their actions?

NEW YORK DECEASED PATIENT PROJECT

- Data mining aimed at predictive characteristics of frequent billers of dead patients-what is predictive?
- Dates of claims, amount of claims, other providers, credits and returns, auto-refill evidence, nursing home status-we don't know yet-run a regression analysis and see what pops up
- Key-focus audit, enforcement efforts on those who need them
- Key-individual responsibility going forward-not for punishment but for identified weaknesses
- Key-root cause analysis

NEW YORK DECEASED PATIENT PROJECT

- Can be run by any state or oversight agency with claims data and reliable death data.
- Will be run by GAO, OIG, Auditor General, bounty hunters, whistleblowers

PROJECTS IN DEVELOPMENT

- Similar projects
  - Dead providers
  - Excluded providers
  - Dead or excluded ordering providers
  - No valid NPI or DEA number
  - Inpatient ambulance trips or clinic visits
  - Pregnant males
  - Incompatible prescriptions

PROJECTS IN DEVELOPMENT

  - DUR overrides
  - Provider is also recipient
  - Claims submitted and rejected or modified
  - Match of 990, conflicts statements, and financial disclosures vs. pharmaceutical and device company disclosures

THINKING ABOUT HEALTH CARE COMPLIANCE AND ENFORCEMENT

- 2005-David Kammerer, the former director of Medicaid reimbursement at Omnicare's headquarters in Kentucky files qui tam suit under seal alleging kickbacks by Johnson & Johnson to Omnicare to induce consulting pharmacists to recommend Risperdal (an atypical antipsychotic) among other drugs for nursing home patients
- November, 2009-USA intervenes and files consolidated complaint, alleging false claims between 1999-2004

OMNICARE-DR. ARIELY'S RESEARCH

- Likelihood of individual detection
- Communicated moral standards
- Communicated community standards
- Cash vs. tokens

The Quality of Antipsychotic Drug Prescribing in Nursing Homes-Briesacher et al. *Arch Intern Med.* 2005;165:1280-1285.

- almost one-third of residents in nursing homes were prescribed antipsychotics; one-third of that number did not have dementia or psychosis. Newly arrived residents were more likely to receive this type of drug if they were in a nursing home that routinely prescribed such drugs, suggesting that organizational culture and not patients are driving the trend.(2001 data)
- Less than half (41.8%) of treated residents received antipsychotic therapy in accordance with NH prescribing guidelines. One (23.4%) in 4 patients had no appropriate indication, 17.2% had daily doses exceeding recommended levels, and 17.6% had both inappropriate indications and high dosing.
- **Conclusions** This study detected the highest level of antipsychotic use in NHs in over a decade. Most atypicals were prescribed outside the prescribing guidelines and for doses and indications without strong clinical evidence.

Unexplained Variation Across US Nursing Homes in Antipsychotic Prescribing Rates Chen, et al.*Arch Intern Med.* 2010;170(1):89-95.

- More than 29% (n = 4818) of study residents received at least 1 antipsychotic medication in 2006. Of the antipsychotic medication users, 32% (n = 1545) had no identified clinical indication for this therapy. Residents entering NHs with the highest facility-level antipsychotic rates were 1.37 times more likely to receive antipsychotics relative to those entering the lowest prescribing rate NHs (2005 data projected to 2006 patients)
- **Conclusions** The NH antipsychotic prescribing rate was independently associated with the use of antipsychotics

CHANGE IN ATYPICAL PRESCRIPTIONS-A POLICY FAILURE

- IN FIVE YEARS
- AFTER FDA WARNINGS AND DEAR DOCTORS
- AFTER CHANGE IN REGULATIONS
- AFTER CHANGE IN NURSING HOME SURVEY STANDARDS
- AFTER LITERATURE CONSENSUS
- AFTER MR. KAMMERER FILES HIS COMPLAINT
- Reduction From 31% to 29% of nursing home patients receiving atypicals off-label

NURSING HOME REFORM ACT REGS-42 CFR 483.60

- (c) *Drug regimen review.*
- (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
- (2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

42 CFR 483.30(l) NURSING HOME REGS (2002)

- (2) *Antipsychotic Drugs.* Based on a
- comprehensive assessment of a resident, the facility must ensure that—
- (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
- (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

OMNICARE NOTICE TO PHYSICIANS-ATYPICAL ANTIPSYCHOTIC INTERCHANGE

- Dear Physician (6/1/00 template-Omni 127541 from production)
- By checking the options below and signing this document you will authorize Omnicare pharmacists to modify existing orders and dispense the following alternative medications based on interchange protocols. This process promotes medication management which is therapeutically beneficial or equal and forwards cost effectiveness to the payer whenever possible. It will also reduce the number of individual drug regimen review comments. Conversion protocols will be implemented as noted below.
- YES NO
- (If interchange occurs prospectively, antipsychotic Interchange may be done *only* for new orders on existing residents defined as those in the facility for five days or longer. If retrospective, the consultant pharmacist may use their clinical judgment based upon the availability of resident specific data.)
- RIsperdal® (risperidone) will be dispensed in lieu of Zyprexa® and Seroquel® for a diagnosis of Dementia (Alzheimer's/ OMS) only, with a starting dose of Risperdal® O.5mg QD.

OMNICARE REPORT CARDS FOR PHARMACY CONSULTANTS

- "Omnicare has developed a Patient Specific Therapeutic Interchange (P.S.T.I.) program forRisperdal®. The consultants are evaluated on their monthly report cards as to the success they are having with this P.S.T. I. Through June of 1999, national Risperdal Market Share for Omnicare was at 41 % … (1999)
- Source-www.pharmacyfraudsettlement.com

Payments by J &J to Omnicare to Recommend Risperdal

- Omnicare has over 800 consultant pharmacists who review patient charts monthly and make recommendations based on the formulary and Omnicare programs for physicians. Pharmacists'recommendations are accepted more than 80% of the time. Consultant pharmacists actively meet with physicians or correspond with them through the mail to obtain approval to make appropriate medication switches for all their applicable nursing home patients.

"RESISTANT PRESCRIBERS"

- "In June of 1999, Omnicare agreed to supply the LTC Group and Janssen ElderCare with the names of their most resistant prescribers. The Janssen ElderCare representatives have agreed to target these prescribers on a monthly basis. An opportunity now exists for both Omnicare and Janssen ElderCare;
- the ElderCare sales force can better target and direct their *efforts* to the prescribers that are adversely affecting Risperdal market share, and Omnicare has a "dedicated sales force" committed to driving the Risperdal market share.

MAYBE THOSE "RESISTANT PRESCRIBERS" KNEW SOMETHING

- April 2003, J&J sent out a "Dear Healthcare Provider letter"
- (1) Risperdal enhanced the risk of cerebrovascular events such as strokes, and
- (2) Risperdal was neither safe nor effective when prescribed for dementia-related psychosis.
- BUT USE CONTINUED AT SAME LEVEL UNTIL 2008

"INCONSISTENT WITH SOUND MEDICAL PRACTICE"- ATYPICAL ANTIPSYCHOTIC USE IN NURSING HOMES

- Phillip S. Wang et al. Risk of Death in Elderly Users of Conventional vs. Atypical Antipsychotic Medications 353 N. Eng. J. Med. 2335-41 (2005)

INCONSISTENT WITH SOUND MEDICAL PRACTICE-ATYPICAL ANTIPSYCHOTICS IN NURSING HOMES

- FDA Black box August 2008:
- "Elderly patients with dementia-related psychosis treated with anti-psychotic drugs are at an increased risk of death."

INCONSISTENT WITH SOUND MEDICAL PRACTICE-ATYPICAL ANTIPSYCHOTICS PAID BY MEDICAID

- 8879 New York Medicaid nursing home patients prescribed atypicals
- 3589 patients-no prior diagnosis of psychosis
- 330 patients had a reported diabetes diagnosis since being prescribed atypicals in 2007 or 2008
- What do physicians do in response to black box warnings? Very little. **Metabolic Testing Rates in 3 State Medicaid Programs After FDA Warnings and ADA/APA Recommendations for Second-Generation Antipsychotic Drugs, Morrato,E. et al. *Arch Gen Psychiatry.* 2010;67(1):17-24.**
- **Unexplained Variation Across US Nursing Homes in Antipsychotic Prescribing Rates Yong Chen et al.** *Arch Intern Med.* 2010;170(1):89-95.

INCONSISTENT WITH SOUND MEDICAL PRACTICE-ATYPICAL ANTIPSYCHOTICS PAID BY MEDICARE PART D

- PATIENT AND PRESCRIBER DATA NOT AVAILABLE UNTIL 15 MONTHS AFTER END OF CALENDAR YEAR IN WHICH DRUGS WERE PRESCRIBED
- STATE MUST MAKE SPECIAL, DETAILED REQUEST AND SPECIFY USES OF DATA TO OBTAIN INFORMATION ABOUT PART D PRESCRIPTIONS FOR DUAL ELIGIBLE PATIENTS

INCONSISTENT WITH SOUND MEDICAL PRACTICE

- What about the several hundred black box warnings on other FDA approved drugs?
- CMS?
- FDA?
- New York state Medicaid data integration allows us to integrate (at least for non-elderly patients) across spectrum of providers and services
- Need for clinical support and analysis, literature review

Suggested lessons from Ariely on effective compliance programs-the case of physician payments by mfrs.

- When no one is checking, people more inclined to cheat
- When an issue is framed in moral terms, people less inclined to cheat
- When an issue is framed in community standards terms, people less inclined to cheat
- The amount of the reward does not appear to change the likelihood of cheating
- Separating decisions from financial impacts increases the amount of cheating

US ATTORNEY PLEA MEMORANDUM IN 2009 PHARMACIA/PFIZER CASE

- **"Payments and other Remuneration to Physicians and Purported Consultants**:
- Pharmacia used so-called advisory boards, consultant meetings and other forums and remuneration to promote Bextra for unapproved uses and dosages."
- ALLEGATION: Pharmacia/Pfizer promoted Bextra for off-label uses, including post-surgical use

US ATTORNEY PLEA MEMORANDUM IN 2009 PHARMACIA/PFIZER CASE

- **Control of Purportedly Independent Medical Education:** Pharmacia sponsored purportedly independent continuing medical education programs ("CME") to disseminate specific messages about unapproved uses of Bextra.
- **G. Use of a Publication Strategy to Disseminate Off-label Messages:** Pharmacia initiated, funded and sometimes drafted or paid vendors to draft articles about Bextra for unapproved uses without appropriately disclosing Pharmacia's role

PFIZER CIA-8/31/09

- **On or before March 31, 2010** Pfizer shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians, and Related Entities (as defined below) who or which received Payments directly or indirectly from Pfizer between July 1, 2009 and December 31, 2009 and the aggregate value of such Payments.
- For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician or Related Entity has provided to Pfizer for contact purposes; and (iv) the aggregate value of the payments to the physician
- www.pfizer.com (not up as of 1/21/10)

ELI LILLY CIA-1/4/09

- On or before August 1, 2009, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all US.-based physicians and Related Entities (as defined below in Section IILMA) who or which received Phase I Payments (as defined below in Section IILMA) directly or indirectly from Lily or Lily USA during the first three months of 2009 and the aggregate value of such Payments.
- www.lillyfacultyregistry.com

GLAXO SMITHKLINE POLICY

- December 15, 2009 publication
- http://gsk-us.com/docs-pdf/responsibility
- 121 pages of payments

DISCLOSURES OF PAYMENTS TO PHYSICIANS BY DEVICE AND DRUG MFRS.-WHAT'S NEXT?

- USING OUR DATA WAREHOUSE WITH PAYMENT DISCLOSURES
- RELATIONSHIPS OF PAYMENTS TO PRESCRIBING OF-
  - Dangerous drugs
  - Contraindicated drugs (black box)
  - Off-label drugs
  - Expensive drugs
  - Publicly employed physicians
  - Comparison of physician and company disclosures

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

- OMIG Research on Medicaid enrollees-IRB disclosure, cost and billing information
- Unexplained variation in utilization
- Doctors who received payments or gifts from PHARMA companies with large settlements
- Matching Medicaid and Medicare Part B and D data for dual eligible patients to look at physicians who receive payments
- Tracking drugs and outcomes-particularly for very vulnerable patients
- IMS information? "rabbits" and tortoises

"effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care . . ."

- Remember mandatory programs?
- What should we look for on front end?
- What data is available to compliance programs and govt. agencies for metrics?
- How should compliance programs be evaluated after significant adverse events? (patients, claims, money)
- What should corporate integrity programs require?

BINARY DATA ON COMPLIANCE- EXCLUSIONS

- Any excluded employee, contractor, service provider
- Cannot be billed
- Cannot perform a service
- Cannot order a service
- tracking

DATA MINING: 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)
- NEW JERSEY PROJECT X

Provider Exclusions – State Medicaid Directors Letter 08-003 and 09-001 (available on CMS website)

- Issued on June 12, 2008 and January 2009
- Reminds States of their duty to report to HHS-OIG about excluded persons
- Reminds States of the consequences of paying excluded providers
- Recommends that providers screen employees and contractors for excluded individuals both prior to hiring and contracting and periodically thereafter

REMEMBER PROF. ROBERT CIALDINI'S *INFLUENCE: THE PSYCHOLOGY OF PERSUASION*

- Reciprocity-gifts, recognition, symbols
- Commitment and consistency-certification
- Social proof-Jonestown
- Authority-titles, credentials, age
- Liking-Tupperware

FREE STUFF FROM OMIG

- OMIG website-WWW.OMIG.State.ny.us
- Mandatory compliance program-hospitals, managed care, all providers over $500,000/year
- Over 1300 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)
- Updates on Medicaid Integrity Contractors IPRO and Thomson-Reuters
- New York excluded provider list

DON'T FORGET NY OMIG FIRST DEPUTY ROBERT HUSSAR'S PRESENTATION TUESDAY MORNING

- Certified in compliance by HCCA (one of three in OMIG)
- Formerly employed as compliance officer in major Albany health care system
- Will talk about details of OMIG's efforts and findings in mandatory compliance

THANK YOU

- Contact:

- Jim Sheehan Medicaid Inspector General
  - JGS05@omig.state.ny.us
  - jamesgsheehan@aol.com
  - 518 473-3782