



**PBM
REGULATION, INVESTIGATION, PROSECUTION,
AND COMPLIANCE**


**PHARMA AUDIOCONFERENCE
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DISCLAIMERS

- OUR OWN OPINIONS - NOT OFFICIAL GOVERNMENT POSITION
 - LIMITED IN WHAT WE CAN SAY ABOUT PENDING LITIGATION
 - GOVERNMENT COMPLAINT AGAINST MEDCO-MEDCO HAS RIGHT TO JURY TRIAL, AND TO PUT GOVERNMENT TO ITS PROOF AT THAT TRIAL
 - YOU SHOULD READ THE MEDCO COMPLAINT (AVAILABLE BY EMAIL)
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WHY DOES TRANSPARENCY MATTER?


“... WHEN SOMEONE CREATES A SYSTEM IN WHICH YOU CAN'T TELL WHETHER OR NOT YOU'RE BEING FOOLED, YOU'RE BEING FOOLED.”

(P.J. O'Rourke, How to Stuff a Wild Enron, Atlantic Monthly, April 2002.)






DOES TRANSPARENCY MATTER?

- WHOSE HEALTH IS IT?
 - WHOSE COST IS IT?
 - SHOULD PROFESSIONALS PROVIDE ADVICE WITHOUT KNOWLEDGE OF COST IMPLICATIONS?
 - DO PLAN FIDUCIARIES HAVE A DUTY TO INVESTIGATE COST IMPLICATIONS BEFORE SELECTING A PBM?
 - GOOD FAITH AND FAIR DEALING / BREACH OF TRUST / FIDUCIARY RELATIONSHIP
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Pharmacy Benefit Issues

- 10-15% increase in prescription drug costs per beneficiary each year
 - Costs driven by:
 - More drugs per patient
 - More expensive new drugs
 - Growth of long-term drug use
 - Aging population(older people use more drugs)
 - PBM role: promoting expensive drugs, capturing spreads
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CORE PBM CONCERNS

- PBMs generally do not get paid for managing the drug benefit, or taking risk
 - PBMs get paid for filling prescriptions
 - PBMs get paid by drug manufacturers for switching prescriptions
 - PBMs get paid for processing prescription claims
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CORE PBM CONCERNS

- Health Plans Have Turned over 15% of their business to PBMs with little incentive for cost or fraud control.
 - PBM contracts are negotiated by plan managers and consultants with limited expertise in fraud and cost control.
 - PBMs limit access to their information, and to data systems and software, which could allow cost and fraud control.
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Roles of Pharmacy Benefit Manager

- 1) ADMINISTRATOR OF RETAIL PHARMACY NETWORK
 - 2) DATA WAREHOUSE/FRAUD DETECTOR
 - 3) MAIL ORDER PHARMACY
 - 4) PLAN DESIGNER/BENEFITS ADMINISTRATOR
 - 5) NEGOTIATOR/AGENT FOR DRUG DISCOUNTS FROM MANUFACTURERS
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Administering Retail Pharmacy Network

- Qualifying pharmacies for network participation
 - Auditing, investigating pharmacies
 - Negotiating price/service w/pharmacies
 - Excluding pharmacies
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Qualifying Pharmacies

- State licenses –
pharmacy, pharmacists, technicians
 - DEA licenses - controlled substances
 - State inspections, DEA inspections,
violation notices, prosecutions
 - Criminal / civil prosecutions
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Auditing, Investigating Pharmacies

- What are incentives?
 - PBM is paid for each prescription processed, even fraudulent ones
 - PBM is not paid for investigative services, law enforcement referrals
 - Sample coupons / account charges
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- PBM which finds fraud may be liable to clients for losses resulting from fraud
 - How do you know *your* patient got this prescription?
 - unlicensed / unauthorized physicians
 - Shorting prescriptions
 - No pickup-return to stock
 - Controlled substances records issues
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Excluding Pharmacies

- Follow-up - law enforcement and insurance investigation
 - Attempts - Who is probing the system for weaknesses?
 - Bad physician DEA numbers, bad member numbers
 - Linkages to bad physicians, member fraud
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Data Warehouse/Fraud Detector

- Largest non-governmental computer system
 - Single biggest point of interaction between health plans and consumers-more transactions, more information
 - No connection between med / surg information and drug information - is this a treating physician? Is this drug for a diagnosis for which patient is being treated?
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MAIL ORDER PHARMACY

PBMs operate mail order pharmacies

PBMs operate mail order call centers, where patients and physicians call pharmacists for information


PBMs provide pharmacy counseling

These pharmacy activities are governed by OBRA 90 requirements and State Pharmacy Licensing Laws






Mail Order Pharmacy Duties

- Licensed Pharmacist must review prescription
 - Licensed Pharmacist must call prescribing physician if:
 - Prescription is unclear as to drug, strength, dosage, or instructions (“Doctor Call”)
 - Prescription history raises concerns about drug interaction, patient allergies, or other patient risks (Drug Utilization Review -“DUR”)
 - Plan or PBM wants to switch patient to different chemical compound
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Mail Order Pharmacy Duties

- Licensed Pharmacist must review prescription container and contents prior to dispensing (back end checking) to determine:
 - Right drug
 - Right strength
 - Right patient
 - Right patient instructions
 - Right Dosage
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Mail Order Pharmacy Duties

- Must not delegate pharmacist duties to non-pharmacists, except as specifically authorized by state law.
 - Pharmacy techs
 - Supervision requirements
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Mail Order Pharmacy Duties

- Must dispense the prescription written by the physician unless:
 - Physician authorizes change
 - Drug is not in stock
 - Pharmacist advises patient and physician that prescription will not be filled






Mail Order Pharmacy Duties

- Must provide number of pills ordered and paid for (no shorting)
 - Must ship product ordered (or, in some states, generic equivalent)
 - Must not put returned goods back in stock
 - Must provide accurate response to WHIZMO (Where's my order) calls
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Why would Mail Order Pharmacy Cheat?

- Pharmacist staffing shortages
 - Pharmacist services are expensive - need to reduce pharmacist labor
 - Pharmacy contracts require prompt turnaround time-calls delay turnaround
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How to Detect Mail Order Pharmacy Fraud

- Very Difficult-Data is in hands of perpetrator - intentionally difficult to compile and analyze
 - Employee complaints - to whom?
 - Customer complaints - but whom do they complain to? What records of complaints?
 - Pharmacy board, PBM, Employer, Health Plan, Congress, State Legislatures
 - 88% of plan beneficiaries do not know who their PBM is
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EMPLOYER OF LICENSED PHARMACISTS AND PHARMACY TECHNICIANS

As an employer of licensed professionals, a PBM has a legal duty not to interfere with the performance of a pharmacist's professional duties.






PBM AS NEGOTIATOR/AGENT

PBM negotiates price discounts, disease management programs, and rebates in return for formulary position with drug manufacturers “on behalf of plans”

PBM has duty to act on behalf of principal
18 U.S.C. 1346

PBM has duty not to solicit or accept improper payments from manufacturers to affect their judgment or advice to clients







PBM AS NEGOTIATOR/ AGENT

Most PBMs take payments from pharmaceutical companies to influence the ordering of prescription drugs by doctors, and the purchase of prescription drugs by patients.

Potential problems with these payments:







If they don't disclose to physicians their financial interest in advocating a switch from one drug to another for a patient.


“calling on behalf of your health plan”


“preferred formulary to keep benefit affordable”






If they advocate switches which result in actual physical or emotional harm or risk of harm to patients.







If they advocate switches which result in higher costs to patient or the plan, and don't disclose this fact to both the patient and the plan.






If they advocate switches which result in other additional costs to patients and plans - physician visits, lab costs, in-patient hospitalization, and they don't disclose these facts to both the patient and the plan.





If they make secret deals with manufacturers to “not disfavor” that company’s drugs, involving payments or stock arrangements, with no disclosure to patients, physicians, or payors.





PENDING CASES AGAINST PBMs

USA V. MEDCO HEALTH


AMENDED COMPLAINT FILED

DECEMBER 9, 2004






Medco Complaint Allegations

- False claims from pharmacy operation
 - Improper prescription cancellations/prescription destruction
 - Failure to perform legal pharmacy responsibilities—conflict with production pressures—doctor calls, DUR, Managed Care
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MEDCO COMPLAINT ALLEGATIONS

- Lack of effective compliance program as evidence of reckless disregard
 - Kickbacks to health plans to obtain PBM contracts
 - False statements, mail fraud on all beneficiaries (federal and private) as basis for mail fraud injunction
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FEDERAL ENFORCEMENT ISSUES

1. False Claims Act-civil and criminal (31 U.S.C. Sec. 3729-3733, 18 U.S.C. 267?)
 2. Public Contracts Anti-Kickback Act-civil and criminal (41 U.S.C. 52)
 3. False Records or Statements-criminal (18 U.S.C. 1001)
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4. Health Care Fraud-18 U.S.C. 1035
 5. Health Fraud Injunction 18 U.S.C. 1345
 6. DEA violations/controlled substances
 7. Restitution/Disgorgement
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State Enforcement Issues

1. Unfair Trade Practices
 2. Pharmacy Board Regulations
 3. Commercial Bribery/Kickback Statutes
 4. State Insurance Regulation
 5. False Claims Act (some states)
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CONCLUSION

- PBMs today are where health insurers were in 1992
 - Rapidly escalating costs passed through to customers
 - Increases in utilization of services result in increases in revenue
 - No incentives to detect, control cost increases, fraud losses
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FRAUD CONTROL MEASURES FOR PBMS

- Access to data, audit reports, software programs
 - Requirements of Fraud Control-audits, attempt detection, referral for prosecutions, education, regular reporting of internal irregularities
 - Effective internal and external compliance program
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FRAUD CONTROL MEASURES FOR PBMs

- Respecting legal, professional duties and commitments of pharmacists
 - Honoring responsibilities to patients-don't treat them like the cable company treats its customers
 - Capturing, reporting errors, false records, misconduct within mail order pharmacies
 - Capturing, responding to patient, physician complaints and concerns
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TEN COMPLIANCE ISSUES FOR PBMS

1. ADOPT TRANSPARENCY
STANDARDS USED BY EXPRESS
SCRIPTS?
 2. EXAMINE INVOICES FROM RETAIL
PHARMACIES FOR GENERICS AND
COMPARE THEM WITH INVOICES
TO CUSTOMERS
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TEN PBM QUESTIONS

3. ADMINISTRATIVE FEES FROM ANY DRUG MANUFACTURERS? WHICH ONES? HOW MUCH? WHAT FOR?
 4. YOU HAVE NOMINAL PRICE AGREEMENTS FOR ANY DRUGS? WHICH ONES? HOW DISCLOSE TO PLANS/PATIENTS?
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TEN PBM QUESTIONS

5. IS THE AVERAGE WHOLESAL PRICE YOU USE TO CALCULATE THE PRICE TO CLIENTS THE SAME AVERAGE WHOLESAL PRICE YOU USE TO CALCULATE PAYMENTS TO PHARMACIES?
 6. WHAT OTHER PAYMENTS DO YOU GET FROM DRUG MANUFACTURERS BESIDES REBATES? WHAT DO YOU DO FOR EACH PAYMENT?
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TEN PBM QUESTIONS

7. HOW DO YOU POLICE YOUR PHARMACY NETWORK-

- Audits
- Attempts
- DEA numbers
- Pay and chase?law enforcement referrals?

8. Do you report fraud to clients?





TEN QUESTIONS FOR PBMS

9. ARE YOUR REBATE
CALCULATIONS ACCURATE?
 10. DO YOU PAY HMOs, TPAs, or
AGENTS to OBTAIN PBM
CONTRACTS? HOW MUCH? WHAT
FOR?
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