





# POTENTIAL FRAUD ISSUES IN THE OPERATION OF PHARMACY BENEFIT MANAGEMENT ENTITIES

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# PBM ISSUES

- Transparency
  - Trust(breach of trust=mail fraud)
  - Recommend drugs and switches of drugs(kickback issue)
  - Cost management(fiduciary, intent to create false impression)
  - Professional Responsibility and Accountability(loyal and faithful service, fiduciary responsibility)
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# PBM ISSUES FOR MANUFACTURERS

- Conspiracy
  - Aiding and Abetting
  - “cause to be submitted” false claims
  - Kickbacks-Medicare, Public  
Contracts, Commercial Bribery
  - Best Price
  - Inducing breach of duty
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# FLAWED PREMISE OF SWITCHING PROGRAMS

- DIFFERENT CHEMICAL COMPOUNDS IN A THERAPEUTIC CATEGORY ARE “THERAPEUTIC EQUIVALENTS”
  - INCONSISTENT WITH MANUFACTURER’S MESSAGE
  - INCONSISTENT WITH CONSUMER EXPECTATIONS AND EXPERIENCE
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# PHARMACY BENEFIT MANAGEMENT ENTITIES

- Not just freestanding PBMs
  - Health plans
  - PBM subsidiaries of health plans
  - Pharmacy providers/consultants to skilled nursing facilities, hospitals, other residential facilities
  - Pharmacy providers to dialysis centers
  - Practice management firms with significant drug/device component
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# FRAUD RISKS(1)

- Kickbacks to induce Medicare referrals or to cause PBM to act against the interest of patient or client.
  - Interference with trust relationship between patient and physician, or pharmacist, or other professional
  - False statements to patients, or PBM clients, in order to obtain business
  - Secret payments to health plans to act against interest of their clients or members
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# FRAUD RISKS(2)

- Payments to PBM may set new best price or new Federal Supply Schedule ceiling price
  - Potential Responsibility for off-label marketing of product by PBM(withdrawn FDA draft guidance?)
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# PBM/MANUFACTURER INTERACTION

- 1) rebates, discounts
  - 2) administrative fees/formulary fees
  - 3) payment for services (marketing, disease management, letters)
  - 4) data purchases
  - 5) detailing activities
  - 6) "unrestricted grants"
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# Roles of Pharmacy Benefit Manager

- 1) ADMINISTRATOR OF RETAIL PHARMACY NETWORK
  - 2) MAIL ORDER PHARMACY
  - 3) PLAN DESIGNER/BENEFITS ADMINISTRATOR
  - 4) 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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# 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
  - PBM which finds fraud may be liable to clients for losses resulting from fraud, and to manufacturer for lower rebate payment
  - Unlicensed/unauthorized physicians
  - Shorting prescriptions
  - No pickup-return to stock
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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 Duties





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 container and contents prior to dispensing(back end checking) to determine:
    - Right drug
    - Right strength
    - Right patient
    - Right patient instructions
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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
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# 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
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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.**







## **C. GOOD BUSINESS, BEST PRICE VIOLATION, OR KICKBACK?**


### **PAYMENTS TO PBMs**

XYZ Drug Manufacturer offers PBM a rebate of \$1 per script for each GERD prescription written by plan physicians and filled by pharmacists. PBM formulary manager counters with a demand for a \$2 rebate per prescription.





**XYZ states that they cannot pay \$2 per prescription, because it will create a new Medicaid Best Price. However, they are prepared to offer value-added services which will equal a \$2 rebate per prescription, with \$1 going directly to PBM.**







# **MEDICAID BEST PRICE**

## **MEDICAID DRUG REBATE PROGRAM**

### **42 U.S.C. 1396r-8**


- Title XIX of the Social Security Act (“The Act”)
  - The Omnibus Reconciliation Act of 1990, Section 401, - amended Section 1927 of the Act setting forth the requirements.
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# **What is included in the Best Price Calculation?**


**Anything that is paid or given to a customer or a payor as part of pricing transaction.**

- 1. Rebates**
  - 2. Administrative fees**
  - 3. Access fees**
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# **WHAT FORM MIGHT PAYMENTS IN LIEU OF PRICE REDUCTIONS TAKE**

1. Newsletters to physicians
  2. Disease management programs
  3. Patient review programs
  4. Closed category fee
  5. Formulary fee
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- 4. Clinical pharmacists' fees**
  - 5. Free or nominally priced products**
  - 6. Payments to “play”, service payments**
  - 7. Program grants**
  - 8. Up front fee, or licensing fee**
  - 9. Closed category fee**
  - 10. Sale of data**
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# **WHO IS LIABLE FOR BEST PRICE FALSE STATEMENT?**


- 1. Manufacturer**
- 2. Any person who conspires with or aids and abets manufacturer in making false statement about best price**







**18 U.S.C. Section 1035(a)(2)**  
**(False statements –**  
**Health Care Matters)**

**(a) Whoever, in any matter involving a health care benefit program, knowingly and willfully . . .**





**(1) Makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.**





# PENDING CASES

USA ex rel. Hunt v. Medco Health  
Solutions et al

US complaint filed 9/29/03

Copy available on USAO website-






# MEDCO HEALTH

## Prior enforcement actions

1995 State Attorneys General settlement – issue: failure to disclose Merck ownership of Medco in advocating drug switches.








# MEDCO HEALTH ACTIONS

1998 FTC Consent Decree

FTC Claim Medco favored Merck drugs

Consent decree – Medco must “accept” all rebates, cannot share competitor price information, and must offer an “open formulary”





# ADVANCE PCS

Subpoenas served November, 1999


CIDs issued April, 2002



Pending CID enforcement actions and  
defense challenge to CIDs stayed





# FEDERAL ENFORCEMENT ISSUES

1. False Claims Act (31 U.S.C. Sec. 3729-3733)
  2. Public Contracts Anti-Kickback Act (41 U.s.C. 52)
  3. Intentional misrepresentation
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4. Common law theories of law
  5. Negligent misrepresentation
  6. Payment under mistake of fact
  7. Equitable claims of unjust enrichment
  8. Mail Fraud/Health Care Fraud Injunction Act (18 U.S.C. 1345)
  9. Restitution
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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

- WHAT ARE YOU PAYING TO PBM<sub>s</sub>
  - WHAT DO YOU EXPECT TO GET FROM PBM<sub>s</sub>
  - WHAT DISCLOSURE IS MADE BY PBM<sub>s</sub> OF FACT OF PAYMENT
  - WHAT TECHNIQUES DO PBM<sub>s</sub> USE TO OBTAIN RESULTS YOU WANT
  - IS TRANSACTION TRANSPARENT TO PHYSICIANS AND PATIENTS
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