Addressing Prescription Drug Fraud

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Discussion Topics

- Defining pharmacy fraud
- Detecting fraud in claims data
- Prevention measures for funds
Defining Pharmacy Fraud

- Pharmacy fraud is a complex white collar crime involving a single player to complex organizations:
  - A single member, pharmacy, physician or PBM
  - Combinations of all four “actors”
- Any act which is unlawful involving a prescription drug and which is performed for financial gain
- Can include drug diversion (theft) by employees (nurses, physicians, pharmacists, techs, PBM personnel)
  - Estimated 37,000 hospital personnel are impaired on any given day according to the International Health Diversion Association

Federal Laws

• False Claims Act
  – Any healthcare provider who presents a false or fictitious claim or demand to the government seeking reimbursement for medical goods or services can be liable
    • Health care reform added return of overpayments requirements

• False Statements Act
  – Imposes liability on a healthcare provider that in a communication submitted to the government, makes false or fraudulent statements or representations, false writings or documents, or that falsifies or covers up a material fact
    • Health care reform added specific monetary penalties for FS
Federal Laws (continued)

- **Social Security Act**
  - Concerns false statements in connection with services which are paid for in whole or in part by a state health care program receiving some federal funds
  - Prohibits anyone from knowingly and willfully soliciting or receiving any remuneration such as kickbacks, bribes or rebates, directly or indirectly in return for referring an individual under the Medicaid Act or a state health care program, or in return for purchasing, leasing, ordering, or arranging for or recommending any good, facility, service or item for which payment may be made

- **Federal Mail and Wire Fraud**
  - Proscribe the use of the mail, interstate television, radio and wire communications in furtherance of fraudulent schemes
• Health Care Fraud
  – Anyone knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program or to obtain by fraudulent pretenses, representations or promises any money or property owned by or under the control of, any health care benefit program faces a fine or imprisonment for not more than 10 years, or both

• Theft or Embezzlement in Connection With Health Care
  – Anyone knowingly and willfully converting or intentionally misapplying the assets of a health care benefit program is liable for a fine or imprisonment of not more than 10 years, or both
• Civil False Claims Act
  – Provides that anyone who presents to a government employee a false or fraudulent claim is liable for a civil penalty of not less than $5,000.00 and not more than $10,000.00 plus three times the amount of damages that the government sustains because of the action

• Civil Monetary Penalties Law
  – The law provides that any person presenting or causing the presentation of, a claim for Medicaid or Medicare benefits for medical items or services that the provider knows or should know is false is subject to a penalty of $10,000.00 per item or service
Federal Laws (continued)

• Health Care Reform requires PBMs to report price concessions confidentially to CMS
• Laws aimed at Corporate Fraud: Securities Fraud, Commercial RICO
Sec. 17-6. State Benefits Fraud
(720 ILCS 5/17-6)

(a) Any person who obtains or attempts to obtain money or benefits from the State of Illinois, from any political subdivision thereof, or from any program funded or administered in whole or in part by the State of Illinois or any political subdivision thereof through the knowing use of false identification documents or through the knowing misrepresentation of his age, place of residence, number of dependents, marital or family status, employment status, financial status, or any other material fact upon which his eligibility for or degree of participation in any benefit program might be based, is guilty of State benefits fraud.
Pharmacy Board Regulations

- **Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (2010)**
  - NABP Section 6. Unprofessional Conduct
    - Publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy
    - **Selling, giving away**, or otherwise disposing of accessories, chemicals, or **Drugs** or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities
Pharmacy Board Regulations

(continued)

• Engaging in conduct likely to **deceive**, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established

• Selling a Drug for which a Prescription Drug Order from a Practitioner is required, **without having received a Prescription Drug Order** for the Drug

• Obtaining any **remuneration** by fraud, **misrepresentation**, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient’s Pharmacist Care, absent a clear benefit to the patient, solely in response to promotion or marketing activities
Benitez Brothers

- Benitez Brothers stole $110 million from Medicare and Medicaid from 2006 to 2009
- Had a complex organization of over 30 HIV pharmacies and physician practices
- Included 20 co-conspirators
- Now presumed to be in Cuba

https://oig.hhs.gov/fraud/fugitives/profiles.asp#other-fugitives,
Why Florida and New York?

- Florida is the perfect storm:
  - Pharmacy technicians can own pharmacies for $105 and a two week course
  - South Florida has the highest density of Medicare and Medicaid recipients

- New York is the largest state that does not regulate pharmacy technicians:
  - No license also for Pennsylvania, Wisconsin, Delaware, Colorado and Hawaii
Pharmacy Fraud or Pharmacy Benefit Fraud?

- **Pharmacy fraud** involves pharmacists or technicians performing illegal or inappropriate acts
  - Diversion of drugs, accepting/buying drugs from illegal sources, filling without a prescription
- **Pharmacy benefits fraud** involves illegal or inappropriate acts against benefit plans
  - ERISA laws, many Federal and State laws aimed at defrauding CMS, contract law
    - Inappropriate copays, submitting fraudulent claims, “adjusting” quantities, no signature logs
How Big Is It?

“Between $70 billion and $234 billion is essentially stolen from the American public through health care fraud schemes annually.”

– National Health Care Anti-Fraud Association, June 2009

https://www.nhcaa.org/docs/nhcaa/PDFs/Member%20Services/Fighting%20Health%20Care%20Fraud_NHCAAJune2009.pdf
DOJ AG Loretta Lynch announced the largest arrest of health care fraud practitioners to date on June 23, 2016 – 300+ physicians, nurses, pharmacists and other practitioners arrested in 36 judicial districts for over $900 million in fraud.
• Pharmacy fraud is a white collar crime
  – Responsibility of FBI, OIG, prosecuted through the ADA
White collar criminals believe they are entitled to “additional earnings”

- Within criminology, it was first defined by sociologist Edwin Sutherland in 1939 as “a crime committed by a person of respectability and high social status in the course of his occupation.”

- FBI has adopted the narrow approach, defining white-collar crime as “those illegal acts which are characterized by deceit, concealment, or violation of trust and which are not dependent upon the application or threat of physical force or violence.”

- Several strains or stressors are said to be especially relevant to the explanation of such crimes, including the blockage of economic goals, the experience of a range of other economic problems, the inability of achieve status goals, and a variety of work-related stressors.
According to think-tank Poneman Institute, medical identity theft costs members $22,000 and affects 1.85 million Americans.

http://www.ponemon.org/local/upload/file/Third_Annual_Survey_on_Medical_Identity_Theft_FINAL.pdf
The case that keeps on giving:

- Valeant allegedly hid its relationship with Philidor
- Philidor was a network of mail order pharmacies that solicited physicians and overrode plan design
- Accounting rules bended to “channel stuff” revenue
- Coupons used to increase sales, forgive copays

Michael Pearson left on May 16 for health reasons

Valeant Timeline

- All heck breaks loose in September 2015
- PBMs knew about Valeant at least as early as August of 2015, probably/should have known earlier
- Estimated $455 million paid by the PBM industry by CVS, ESI and Optum to Philidor pharmacies
- Network contracts terminated in October 2015
  - What happened to the checks already sent and cashed?

Did PBMs Know?

- PBMs were aware that Philidor transactions were not valid and may have halted payment to Philidor pharmacies before October 2015.
- On the other hand, PBMs may have continued to charge clients for Philidor prescriptions.
- One health insurer informed my client that “there was no fraud associated with Philidor pharmacies” and refused to investigate in March of 2016.
RI CO Charges Against Valeant

- Suit filed in September 2016 by the Detectives Endowment Association of the City of New York and the New York Hotel Trades Council & Hotel Association Health Benefits Fund
  - Actively changing codes on prescriptions to ensure that the prescriptions would be filled with a Valeant drug rather than a generic equivalent
  - Using false pharmacy identification information to bill payors/PBMs for prescriptions in order to fraudulently bypass payors’ denials of claims for reimbursement
  - Submitting prescription renewals for reimbursement and falsely representing to payors/PBM that patients had requested renewals of their prescriptions when no such request had been made
  - Waiving patient co-pays through manufacturer coupons or otherwise to remove patients’ incentive to seek out cheaper drugs
  - Using affiliate pharmacies within the “Valeant Enterprise” to enable Philidor to indirectly operate in States where it had been denied a license

### What We Saw in October 2014...

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th># of Rxs</th>
<th>Plan Amount</th>
<th>Plan Coverage</th>
<th>Main Ingredients Billed</th>
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</thead>
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<tr>
<td><strong>PRECISE COMPOUNDING PHARMACY</strong></td>
<td>26</td>
<td>$211,979.46</td>
<td>No</td>
<td>FLUTICASONE PROPIONATE POWDER, 1ST BASE CREAM TERODERM CREAM</td>
</tr>
<tr>
<td><strong>TOTAL PHARMACY</strong></td>
<td>15</td>
<td>$126,022.34</td>
<td>No</td>
<td>RESVERATROL POWDER 98%</td>
</tr>
<tr>
<td><strong>R&amp;O PHARMACY</strong></td>
<td>34</td>
<td>$25,027.83</td>
<td>No</td>
<td>ACANYA GEL 1.2-2.5%, ATRALIN GEL 0.05%, CLINDAGEL GEL 1%, JUBLIA SOL 10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ONEXTON GEL 1.2-3.75, RETIN-A MICR GEL 0.08%, SOLODYNN TAB 105MG, SOLODYNN AB 55MG</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SOLODYNN TAB 80MG, ZYCLARA PUMP CRE 3.75%</td>
</tr>
<tr>
<td><strong>PHILIDOR RX SERVICES LLC</strong></td>
<td>32</td>
<td>$15,909.68</td>
<td>No</td>
<td>JUBLIA SOL 10%, LUZU CREAM 1%</td>
</tr>
<tr>
<td><strong>IRMAT PHARMACY</strong></td>
<td>36</td>
<td>$14,142.64</td>
<td>Yes</td>
<td>ACTICLATE TAB 150MG, ADAPALENE CRE 0.1%, BETAMETH VAL AER 0.12%, CLOBEX SPR 0.05%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CORDRAN, DESONATE GEL 0.05%, DIFFERIN GEL 0.3%, EPI DUO GEL 0.1-2.5%, FINACEA GEL 15%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>METRONIDAZOL GEL 1%, MIRVASO GEL 0.33%, SOOLANTRA CRE 1%, VERDESO AER 0.05%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>XOLEGEL GEL 2%, ZIANA GEL, ZYCLARA PUMP CRE 3.75%</td>
</tr>
</tbody>
</table>
Enter the Pharmacy America Trusts

- Walgreens and Valeant in December 2015 “get to do a partial end-run around payers.”
- Copay offsets, reduced prices at WAG, sold on consignment
- Help fill out “paperwork” around PA’s
- September 2016: WAG offers online dermatological care for $9
  - Who is serving who?

http://www.drugchannels.net/2015/12/walgreens-and-valeant-devise-new-twist.html,
“This is another example of Valeant attempting to circumvent what PBMs do for payers,” CEO Larry Merlo told Wall Street analysts at the CVS investor day in New York. “These actions ultimately drive up costs for payers when you think about the use of prescription co-payment programs.”
Why PBMs Are Not Concerned

• Traditional undisclosed spread pricing means spread is taken on fraudulently submitted claims
• Plans aren’t asking about it
• PBMs don’t do anything about it
• PBMs can’t make money off of fraud programs
• PBM’s lobbyists (PCMA) advocate the ability to audit pharmacies without the mandate to reimburse employers (spread pricing)

Detecting Fraud Is Complex

• Use to be: auditors ran random “hunch” queries
• Use to be: auditors go into pharmacies and ask for prescription orders, signature logs and claims get reversed
• Bad guys said: “Here you go.”
• Today’s conversation: “Why are your patients statistically aberrant?”
• Mobile technology sends messages to patients to verify if fraud is committed on their behalf
• PBM industry is reluctant to adopt these changes
Today, highly sophisticated tools using multiple multivariate statistics detect aberrant behavior in a set of data or as new data is added . . .

- If a pharmacy/provider relationship yields drugs that are dispensed to an inappropriate age group (multivariate analysis)
- And the same pharmacy/provider relationship indicates more refills than other pharmacies (multivariate analysis)
- And the same pharmacy/provider relationship indicates more than average late night prescriptions (multivariate analysis)
- Then that pharmacy/provider relationship will be tagged with a high fraud score and each pharmacy/provider relationship has MANY multivariate analysis that comprises a “pharmacy signature”
Each field of “active” data is tagged.

A score is developed based on that data element’s distance from the mean for that data field and assigned an “actor.”

Certain data fields are weighted more heavily than others.

Every score is accumulated and a fraud score is developed for each “actor.”

Fraud is detected and investigated.
Detecting Bad Actors

- Pharmacy
- Prescriber
- Patient

- Claim volume
- Excess supply of drugs
- Maximum refills for patients
- Prescriber and Pharmacy location
- Quantity of dispensed drugs
- Distance between pharmacy and prescriber

- Univariate/
  Multivariate outlier Detection
- Correlation
- Clustering
- Association and sequence

- Interpret Results
- Flag anomalous activity

- Score Actors
  - Univariate/
    Multivariate outlier Detection
  - Correlation
  - Clustering
  - Association and sequence

- Flagged data ready for Supervised learning

Identify Probable Fraudulent Actors
What PBMs Are Doing

- Pharmacy technicians running queries and trying to detect FWA with no criminology, law enforcement or statistical backgrounds.
- Staffs at PBMs range from 5 to 10 “investigators”
- Some desk audits, 50 to 100 onsite audits to nothing.
- Most PBMs are implying that there is a FWA program, with little to show for results.
- Like to promote lock in programs and target members when the real issue is pharmacists/physicians.
Lock In Programs

Heroin-Linked Deaths Surge 39% CDC Finds
The number of overdose deaths overall increased to 43,982 (2014) from 41,340 (2013).

“‘Lock-in/out programs’ INCREASE drug abuse problems and may in fact be the cause of the heroin related deaths.”

– Dr. Paul Jeffrey, Pharmacy Director for the Massachusetts Medicaid program
What Funds Must Do

• Talk to your PBM about fraud
  – Tell them you want to know what they are doing to protect you and your members

• Audit your data
  – Hear a scheme, detect a scheme

• Contract special services
  – An auditor trained in fraud detection

• Move to a transparent relationship
Fighting Fraud Starts at Home

• Insist on EOBs to members
  – Phantom claims submitted by pharmacies can be caught by members

• Refer to a fraud hotline

• Educate members
  – Copay forgiveness is a crime
  – Selling your ID is a crime
Glossary of Terms

Pharmacy Outcomes Specialists

**Academic Detailing of Prescribers**
Fact-based information about prescription drugs provided by credentialed clinicians to physicians and other prescribers. Traditional “detailing” refers to the process pharmaceutical manufacturer sales representatives use to promote their brand-name drugs.

**Actual Rebate Amount per Mail Script**
Actual dollar amount of rebate for each mail-service prescription by drug manufacturers which may or may not be passed on to plan sponsors.

**Actual Rebate Amount per Retail Script**
Actual dollar amount of rebate for each retail prescription by drug manufacturers which may or may not be passed on to plan sponsors.

**Average Wholesale Price (AWP)**
The published or suggested cost of pharmaceuticals charged to a pharmacy by a large group of pharmaceutical wholesalers. The AWP is the basis for most third-party prescription reimbursement. It is analogous to a sticker price on a new automobile. Pharmacies do not pay for their drugs using the AWP. A markup of wholesale acquisition cost (WAC) is the current method.

**AWP Discount % – (AWP Minus X%)**
The negotiated amount a drug plan pays to pharmacies for the ingredient cost of a prescription and commonly expressed as a percentage off of Average Wholesale Price.

**Biotech Drugs (Specialty Drugs)**
Drugs manufactured through biologic processes to treat chronic, complex or life-threatening conditions. These drugs are also called specialty drugs.

**Brand Drug**
Prescription drug covered by patent exclusivity for only one manufacturer of the product and coded by Medispan by an M, N or O in the drug classification field.

**Carve-in**
Pharmacy benefit program administered by the same company as medical benefit.

**Carve-out**
Different companies administer drug and medical benefit programs.

**Copayment Relief or Waivers**
Reduced or zero-dollar copayments commonly used as incentives for plan members to use generic drugs and adhere to medication regimens.

**Diabetic Supplies**
Medical materials used for treatment of diabetes, specifically glucose meter strips, syringes, and needles.

**Dispensing Fee**
The contracted amount in a traditional third-party prescription plan that is paid to the pharmacy by the PBM in addition to the negotiated ingredient cost of the prescription.

**Dose Optimization**
Pharmacist-driven program to ensure patients are taking the best dosages and strengths of a given medication to manage costs of drug therapy.

**Drug Utilization Review (DUR)**
The process by the PBM of evaluating physicians’ prescribing patterns and/or patient drug utilization to determine the appropriateness of therapy. Three types are: prospective (before prescription dispensing), concurrent (at point of dispensing), and retrospective (after drug therapy is complete).
Experimental/Investigational Drugs
Prescription drugs being tested in clinical trials that may or may not be approved for sale by the U.S. Food and Drug Administration.

Generic Sampling
A program that provides samples of generic drugs to medical offices and clinics to encourage the prescribing of generic drugs when medically appropriate by drug manufacturers.

Gross Cost of Script
Total cost of a prescription = AWP - AWP Discount + Dispensing Fee - Member Cost.

Growth Hormones
Prescription hormone supplements used to treat patients with growth deficiencies.

Guarantee Rebate per Mail Script
Pharmacy benefit manager guarantees a flat-dollar amount of rebate for each mail-service prescription.

Guarantee Rebate per Retail Script
Pharmacy benefit manager guarantees a flat-dollar amount of rebate for each retail prescription.

Ingredient Cost
The discounted unit AWP times the quantity of units and before the copay or taxes are assessed for drug costs.

Injectable/Infused Products
A prescription drug product that is injected by patient or provider or infused by a provider (doctor or nurse). These drugs are often used as a synonym for high cost specialty or biotech drugs because most are administered via injection or infused in IV.

Lifestyle Drugs
Drugs that are not medically necessary but used to improve the quality of life.

Mail Cost Share (90-day Supply)
Cost share amount for 90 days of a prescription therapy typically dispensed at a mail-order pharmacy. Some plan designs may allow for this at a retail pharmacy.

Maintenance Prescriptions
Drugs used to treat chronic diseases or conditions.

Maximum Allowable Cost (MAC)
The unit price that has been established for a generic drug. The same MAC price applies to all versions of identical generic drugs. MAC prices were created because the cost of identical generic drugs may differ from distributor to distributor.

MAC Pricing Applied
MAC list used to price generic prescriptions.

Maximum Annual Benefit (MAB)
Total amount of expenses a plan will pay in a 12-month period.

Multi-source Brand
A drug product manufactured by more than one company or source. Multi-source is commonly used to describe a brand drug where generic equivalents are available.

Net Cost (after copayments) of Script
Total amount paid for prescription less the cost sharing amounts.

Nonformulary Drugs
Drugs not included on plan’s drug list or formulary.

Nonpreferred Brands
Brand-name drugs not included on plan’s preferred drug list.
Non-sedating Antihistamines
Prescription allergy drugs that typically do not cause drowsiness.

Pill Splitting
Cutting prescription medications in half to double the number of days supply from one prescription. This practice, which decreases total cost of the drug therapy, is commonly used to manage the cost of cholesterol-reducing medications.

Preferred Drug List
A list of drugs available to plan members with a lower copayment than drugs not on list established by a PBM or in some cases, a managed health plan.

Prescriber Profiling
The assessment of prescribing patterns to identify areas to manage utilization and cost of prescription drugs performed by a health plan. Drug claim data is sorted by prescriber (physician, physician assistant or nurse practitioner) to identify outliers in prescribing patterns.

Retrospective DUR
Drug utilization review conducted after a prescription is adjudicated.

Single-source Brand
A drug product manufactured by one company or source.

Specialty Drugs (Biotech Drugs)
Drugs manufactured through biologic processes to treat chronic, complex or life-threatening conditions.

Specialty Pharmacy Benefit
Coverage of drugs manufactured through biologic processes to treat chronic, complex or life-threatening conditions.

Spread Pricing
A method used by PBMs to charge clients whereby the PBM retains an undisclosed amount of money on retail, mail order and specialty claims as well as rebates as its administrative fee instead of charging a client an upfront and disclosed administrative fee.

Step Therapy
Treatment guidelines used to recommend drug therapy beginning with the least expensive therapy. More expensive therapies are only used when the patient fails to respond to the first-line drug.

Therapeutic Substitution
A pharmacist-initiated change in a dispensed drug when a medically equivalent drug is available for the prescription presented. State prescribing laws address the required physician permission for substitutions.

Traditional Pricing/Programs
In a traditional program, the PBM does NOT charge a separate per member or per claim fee but instead charges clients by taking an undisclosed “spread” between the amount the PBM reimburses a pharmacy and what it charges the client for the same transaction, or retains an undisclosed amount of rebates from pharmaceutical manufacturers.

Transparent or Pass Through Pricing/Programs
In a transparent program, the PBM charges a per member or per claim fee for its services which is disclosed. There is no spread taken or monies retained by the PBM other than the administrative fee.

Wholesale Acquisition Cost (WAC)
The price used by a pharmaceutical manufacturer to sell prescription products to a wholesaler; can also be known as Wholesale List Price.
Session #H14

Addressing Prescription Drug Fraud

- Health care fraud is a booming business—$70 to $234 billion dollar business
- Scandals like Valeant and DOJ takedown reinforce that it is happening in your fund
- Your PBM isn’t paying attention
- You need to pay attention
  - Talk to your PBM
  - Contract away from traditional deals
  - Hire expertise in this area

Website
Resources
www.ifebp.org/resources/infoQuick/default/htm
Records
Retention
Requirements for Benefit Plans (members only)
2017 Educational Programs
Health and Welfare

63rd Annual Employee Benefits Conference
October 22-25, 2017
Las Vegas, Nevada
www.ifebp.org/usannual

Certificate Series
February 27-March 4, 2017
Lake Buena Vista (Orlando), Florida
July 24-29, 2017
Denver, Colorado
www.ifebp.org/certificateseries

Certificate of Achievement in Public Plan Policy (CAPPP®)
Part I and Part II, June 13-16, 2017
San Jose, California
Part II Only, October 21-22, 2017
Las Vegas, Nevada
www.ifebp.org/cappp

Health Care Management Conference
May 1-3, 2017
New Orleans, Louisiana
www.ifebp.org/healthcare

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