Preventing and Preparing for PBM Audits

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Disclosure and Conflict of Interest

Trent is the COO of PAAS National®, a pharmacy audit assistance service. The conflict of interest has been resolved by peer review.

Richard is the Owner of Philadelphia Pharmacy

We will not discuss off-label and/or investigational use in my presentation

Pharmacist and Pharmacy Technician Learning Objectives

Identify practices in your pharmacy that are most likely to trigger an audit

Discuss how pharmacy employees can incorporate audit prevention strategies into pharmacy workflow

Identify and describe the current industry audit trends

Explain and evaluate Medicare Part D audit challenges

Identify how to create a proactive post-bill audit program
THIS SESSION WILL BE UTILIZING AUDIENCE POLLING SOFTWARE

Please go to MEET.PS/PBMAUDIT to answer poll questions

Why so many audits?

- Escalating Healthcare costs
- Opioid Epidemic
- **Contractual Requirement**
- Fraud, Waste & Abuse
- Common Billing Errors
- Data Analytics/Outliers
- **PBM Revenue Source = $$$**
Audit Penalties

Financial Recovery
Network Termination
Reputation
License
OIG Exclusion
Fines
Prison

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Audit Trends from 2014-2018

- 5-year trend is a 60.3% increase in audits overall
- 2018 started tracking ‘72-hour prescription validation’ requests
  - Extrapolated to 10.7% of annual total

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<thead>
<tr>
<th>Year</th>
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<th>Onsite %</th>
<th>Invoice* %</th>
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</table>

*Many invoice audits are in addition to desk/on site audit

FOR IMMEDIATE RELEASE: Friday, June 14, 2019
United States Files False Claims Act Complaint Against Two Compounding Pharmacies and Their Owner For Submitting Inflated Claims and Improperly Waiving Patient Copayments

FOR IMMEDIATE RELEASE: Wednesday, August 21, 2019
Two Los Angeles Pharmacy Owners Found Guilty in Multimillion-Dollar Health Care Fraud and Money Laundering Scheme
# Big Picture

<table>
<thead>
<tr>
<th>Category</th>
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<tr>
<td>Prescription</td>
<td>Do you have a prescription?</td>
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<tr>
<td></td>
<td>Is prescription legal/valid per state and federal laws?</td>
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<tr>
<td>Data Entry &amp; Filling</td>
<td>Did you fill and bill accurately (including calculable directions?)</td>
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<tr>
<td>Dispensing</td>
<td>Do you have proof of dispensing?</td>
</tr>
<tr>
<td></td>
<td>Do you have proof of copay collection?</td>
</tr>
<tr>
<td>Other</td>
<td>Did you purchase enough inventory from an appropriate source?</td>
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</table>

# Common Audit Discrepancies

## Prescription
- Missing/Invalid Rx
- Altered Rx

## Data Entry
- Overbilled Quantity
- Refill Too Soon
- Incorrect DAW Code

## Dispensing
- Missing/Invalid Signature Log
- Dispensed > 14 Days
- Copay Collection
Please go to MEET.PS/PBMAUDIT to answer poll questions!
Audit Algorithms ≠ Random

Historical Billing/Documentation Errors
1. Days’ Supply
2. DAW

Historical Fraud Targets
1. Controlled Substances – “Pill Mills”
2. Compounds

Telemedicine & Delivery – Zip code analysis
1. Patient
2. Prescriber
3. Pharmacy

Telemedicine Questions to Consider

Is the prescription valid?
Valid patient/provider relationship?
Is the prescriber licensed in the state the patient resides in?

Prescriber’s scope of practice?
Why are the prescriptions coming to your pharmacy?
Are you mailing the prescription?

And many more...
"Top Eleven" Audit Discrepancies

Day Supply – Insulin
Day Supply – Topicals
Day Supply – Inhalers
Day Supply – Eye drops
DAW
Controlled Substance Prescriptions
E-Prescriptions
Transfer Prescriptions
Compound Prescriptions
Proof of Dispensing/Copay Collection
Non-FDA approved products or FDA approved devices

1. Days Supply - Insulin

1 box of pens (15 mL)
• Obtain Max Daily Dose and add a Clinical Note
• Submit accurate DS
• Must break boxes if plan limits exceeded!!

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Rx #1
Insulin Lispro U-100
Pen
15 mL
UAD per sliding scale
7/29/18 per Kate, RN max daily dose = 30 units EEH

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1. Days Supply - Insulin
DOJ Settlement with WAGs

- January 22, 2019 - $209.2 million settlement
  - Regarding billing and dispensing of insulin pens (WAGs had Rx system set up to prevent breaking boxes)
  - Forced pharmacies to alter Days' Supply to plan limits
  - Then put patients on auto-refill program leading to early refills
    - DOJ cited examples of patients selling insulin on Craigslist
  - For Single Patient Use Only
    - FDA safety announcement from 2015: guidance regarding HCP utilizing the same pen on multiple patients and just swapping the pen needles
  - Remember to provide Patient Information Handouts
  - Seeing PBMs enforce (Humana, EnvisionRx, ESI, OptumRx, and Prime)!

2. Days Supply - Topicals

Finger Tip Unit (FTU) Method

- 1 FTU = 0.5 gram (adult)
- 1 FTU covers one hand (front/back)
2. Days Supply - Topicals

- Submit accurate DS if possible
- Mathematical instructions for use
  - Grams per application (if one area only)
  - Max Daily Dose per MD or expected day supply
  - List of affected areas + Finger Tip Unit (FTU) Method

Rx #2
Calcipotriene
0.005% cream
360 GM
AAA BID

7/29/18 per Josie, RN
affected area = both hands and feet EEH

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3. Days Supply - Inhalers

- Submit accurate DS if possible
- Do not refill early
- Strategies
  - Call for DS override
  - Add note to sig field (e.g. 60 ds)
  - Train staff to watch for refill intervals
- If patient requests early assess circumstances and document

Rx #3
Fluticasone Inhaler 110 mcg
#1
Sig 1 puff BID

Calculation:
120 puffs / 2 per day = 60 ds
EEH, max plan limit = 30 ds

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4. Days Supply – Eye Drops

- Submit accurate DS if possible
- In General
  - 20 drop/mL for solution
  - 15 drop/mL for suspension
- PBMs have their own “estimates”
  - CVS/Caremark® 15
  - Express Scripts® 16
  - OptumRx® 15
- Document any patient factors that may impact ability to dose accurately (e.g. Parkinson)

Rx #4
Brimonidine tartrate
0.1% Ophthalmic Solution
10 mL
Sig 1 drop OU TID

Calculation:
PBM is CVS/Caremark® per BIN #
10 ml x 15 drop/mL = 150 drops total
150 / 6 = 25 ds

5. DAW

- Values 0-9
  - 0 = Default for brand and generic
  - 1 = Brand per Prescriber
  - 2 = Brand per Patient
  - Generally avoid 3-8
  - 9 = Brand per Plan
- DOCUMENTATION must support

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6. Controlled Substances

**Federal Law**
3 elements as per 21 CFR 1306.05(a)
- Patient Address
- MD Address
- DEA number

**State Law(s)**
- Where applicable
- Part D Opioid Restrictions

_Buprenorphine/naloxone – DATA 2000 Waiver ID aka “X DEA number” in addition, not in replace of_

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7. Electronic Prescriptions

- Quantity “1” = smallest package size
- DAW – default? (false positives – furosemide, Lyrica®)
  - Sig field vs. free text
- Days’ Supply
  - Be cautious about DS field when conflict with quantity/Sig calculation
- Invalid eRx
  - Failover to Fax (not a valid eRx)
  - eClinicalWorks
  - Downloading prescriptions (HITECH Act vs. NCPDP SCRIPT Standard)

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8. Transfer Prescriptions

- General Requirements
  1. “Copy” or “Transfer”
  2. Transferring pharmacy info – RPh, pharmacy, address, phone, DEA #
  3. Rx info
  4. Rx history – Rx #, first/last fill, original/remaining refills
  5. Your info – date of transfer, RPh

- Suggest using a dedicated transfer Rx pad with all required elements

- Data Entry – original date vs. transfer date

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9. Compounds

- Rx must match compound log AND Claim
- NDCs
- Quantities

- Ingredient strengths assumed to be “final” unless specified
  E.g. in lidocaine 5% ointment

- Base QS amount – make sure software does not overbill

- LOE codes 11-15

Be careful with defaults

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10. Proof of Dispensing & Copay Collection

Proof of Dispensing

Elements
1. Rx #
2. Date of Service
3. Signature of Patient/Representative

• “Mail”, “Drive Thru” or “Delivery” will NOT be sufficient

Copay Collection

• Contracts require collection WITH PROOF (limited exceptions)
  • In-house charge accounts
  • Manufacturer Coupons
    – Medicaid/Medicare
    – Caremark: non-FDA approved

10. Copay Collection

• Copayments are used to sensitize patients to the cost of their medications
  • Documented proof of collection
    • Front/Back copies of canceled checks, bank deposits, and even Credit Card Merchant Account Reporting, including evidence of settlement and payment through bank records
    • How could you prove copay collection on a transaction from last year on a specific prescription?
  • House Charge Accounts (Red Flag)
    • Documented Policy and Procedures
    • Timely invoice and documented attempts at collection
    • How are payments applied
  • Bad Debt/Hardships
    • Documented Policy and Procedures
    • Tax return documentation, etc
11. Non-FDA approved products or FDA approved devices

• Medicare Part D definition of a covered drug:
  • A Part D covered drug is available only by prescription, approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, vaccines licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. The definition also includes medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug.
  • No dietary supplements or FDA approved devices
  • No off-label use


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11. Non-FDA approved products or FDA approved devices

• Medicare Part D definition of a covered drug:
  • Compounded prescription drug products can contain: (1) all Part D drug product components; (2) some Part D drug product components; or (3) no Part D drug product components. As defined in §423.120(d), only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredients covered under Part B as prescribed and dispensed or administered, may be covered under Part D. Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug. For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary. Bulk powders (i.e., Active Pharmaceutical Ingredients for compounding) do not satisfy the definition of a Part D drug and are not covered by Part D. For any non-Part D ingredient of the Part D compound, the Part D sponsor’s contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.


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Waiting for the meeting to start

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Practical Keys to Preventing Audit Recoupments

Staff Training and Follow up

Integrate Workflow Checks

Documentation - Tell the story

**Documentation Format:** WWW
- Who authorized the changes (time & date)
- What changes are being made
- What are you changing

Staff Training and Follow up

- You cannot do it all yourself
- Lead Technician - Trainer
- Problem Technician - Problem solver
- Post Audit Technician
Workflow Processes = Prevention Strategies

1. RX DROP OFF
2. DATA ENTRY
3. FILLING
4. PHARMACIST VERIFICATION
5. CASHIER

- Verify all controlled prescriptions
- Look for apparent alterations
- Confirm that the Patient’s Name is the same on all prescriptions
- Confirm Patient’s Address, Date of Birth, Insurance Information, and Allergies
- Separate patients and establish pick up priority using colored bins-One bin per patient

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Data Entry

**Quantity**
1. Verify correct NCPDP billing unit (EA, GM, ML)
   • Be cautious with syringes and “kits”
2. Quantity “1” = smallest package size unless confirmed otherwise
3. Some products must be dispensed in original container – see NLM [DailyMed](https://dailymed.nlm.nih.gov) for product labeling
   - Document quantity discrepancies

**Days’ Supply**
1. Estimate as per quantity and SIG, must submit accurately, call PBM helpdesk for override if smallest unbreakable package
2. Document calculations on prescription- Staff Training and Tools
3. Spot Check DAW

**Hard Copy**
1. Each RX should have a Hard Copy
2. Print Electronic RX’s

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Data Entry-Continued

**Changes, Clarifications, and Documentation**
All documentation should tell a story.
- Who authorized the changes (time & date)
- What changes are being made
- What are you changing

**Prescribers Information**
Verify NPI and License numbers
- DEA and “X” number where applicable

**Hard Copy Scan**
1. Scan Hard Copy RX at data entry only after any changes have been documented.

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Data Entry sample E-scripts documentation

Drug: INSULIN DETEMIR (U-100) 100 UNIT/ML (3 ML) QTY: 15 Milliliter
QTY: FIFTEEN SUBCUTANEOUS PEN
NDC: 00169-6438-10
Refills: 5
Sig: INJECT 10 UNITS INTO THE SKIN NIGHTLY.
DAW: 0

Drug: OZEMPIC 1 MG/DOSE (2 MG/1.5 ML) SUBCUTANEOUS PEN QTY: 45 Milliliter
QTY: FORTY FIVE INJECTOR
NDC: 00169-4136-02
Refills: 6
Sig: INJECT 1 MG INTO THE SKIN EVERY 7 DAYS.
DAW: 1

Drug: LEVEMIR FLEXTOUCH 100 UNIT/ML SUBCUTANEOUS SOLUTION QTY: 1 Package
QTY: ONE PEN-INJECTOR
NDC: 00169-6438-10
Refills: 5
Sig: 20-30 UNIT UNIT TWO TIMES DAILY
DAW: 0

Data Entry-Insulin Calculator

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<th>3 ML Insulin</th>
<th>BILL QTY</th>
<th>ML/Package</th>
<th>Units/MCG Package</th>
<th>Number of Pens dispensed (RX)</th>
<th>Total Units dispensed</th>
<th>Total Units/Day (RX)</th>
<th>Day Supply</th>
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<td>Admireag</td>
<td>3</td>
<td>3ml</td>
<td>1 pens</td>
<td>300</td>
<td>(A)</td>
<td>(B)</td>
<td>(C)</td>
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<td>3ml</td>
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<td>(A)</td>
<td>(B)</td>
<td>(C)</td>
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<td>(A)</td>
<td>(B)</td>
<td>(C)</td>
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<td>(A)</td>
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<td>(A)</td>
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<td>(C)</td>
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Other Pens

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**Filling-Quality Assurance Station**

- Match NDC on stock bottle against billing label (including package size) using barcode technology
- Confirm Patients Name and Quantity - Hardcopy Prescription matches the Billing Label
- Spot Check DAW, Day Supply and Origin Code
- Scan Hardcopy RX - Scanning at the QA station scans the final RX with all documentation written

**RPh Verification**

- **Match**
  - Match NDC on stock bottle against billing label (including package size) using barcode technology if possible if not done at QA

- **Check**
  - Double check day supply estimate as per documented calculations
    - Pay close attention to insulin, topicals, eye drops, inhalers

- **Verify**
  - Verify Data Entry elements such as DAW, Days’ Supply, Origin Code
Please go to MEET.PS/PBMAUDIT to answer poll questions!

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Cashier (Dispensing)

- Verify patients name and address - Obtain signature (electronic if possible)
- If mailing, make sure that Rx # is "tied to" carrier tracking ID #
- Collect Copay at dispensing, implement itemized POS system
- In-house charge accounts must have proper accounting practices
- Conduct Return to Stock at least twice a week
  - Document any unique exceptions where Rx was dispensed > 10 days
  - If patient promises to come "next week", then reverse/rebill/relabel to give more time to maintain compliance

Post Fill Audit

- Audit all RX's over $150
- Create a report using your Pharmacy Management System
- Implement into daily work of a specific employee
## Post Fill Audit Report

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Please go to [MEET.PS/PBMAUDIT](https://meet.ps/pbmaudit) to answer poll questions!
Waiting for the meeting to start
Key Takeaways

1. Identify Audit Flags
2. Methods to educate pharmacy staff on audit prevention
3. Procedures to reduce audit risk

Questions?

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www.ncpanet.org/convention