Preparing and Preventing for PBM Audits in 2020

PREVENTING AND PREPARING FOR PBM AUDITS IN 2021

Eric Hartkopf, PharmD PAAS National

Disclosures And Conflict Of Interest

- I am an employee of PAAS National®, a pharmacy audit assistance company
- I will not discuss off-label and/or investigational use in my presentation

Pharmacist Objectives

At the conclusion of this program, the pharmacist will be able to:

1. Identify and describe prescription claims that are high risk for PBM audit
2. Identify practices in your pharmacy that are most likely to trigger an audit and learn how to avoid them
3. Recognize how to incorporate audit prevention strategies into pharmacy workflow
4. Explain new audit targets for 2021

Technician Objectives

At the conclusion of this program, the technician will be able to:

1. Identify and describe prescription claims that are high risk for PBM audit
2. Identify practices in your pharmacy that are most likely to trigger an audit and learn how to avoid them
3. Recognize how to incorporate audit prevention strategies into pharmacy workflow
4. Explain new audit targets for 2021

REASON FOR AUDITS

- Escalating Healthcare Costs
- Contractual Requirement
- Fraud, Waste & Abuse
- Common Billing Errors
- Data Analytics
- PBM Revenue Source

AUDIT TRENDS

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<thead>
<tr>
<th>Year</th>
<th>Desk</th>
<th>Desk Pre-Pay</th>
<th>Invoice</th>
<th>Pre-Pay</th>
<th>Virtual</th>
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<td>78</td>
<td>21</td>
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<td>83</td>
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<td>2019</td>
<td>64</td>
<td>13</td>
<td>2</td>
<td>22</td>
<td>-</td>
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<tr>
<td>2020</td>
<td>63</td>
<td>6</td>
<td>2</td>
<td>23</td>
<td>7</td>
</tr>
</tbody>
</table>

- Many invoice audits are “add-on” to desk or onsite audit
- *October 2018 started tracking pre-pay audits
- Shift from “pay and chase” to “pre-pay” when claim metrics warrant
- 2020 introduced VIRTUAL in place of onsite
SURVEY QUESTION #1

COVID-19 AUDIT ISSUES

- Most PBMs issued concessions in early March 2020 to relax billing & documentation requirements with end dates tied to HHS Public Health Emergency Declaration (90-day increments)
  - Patient signatures
  - Mail/Delivery
  - Early refill overrides
  - Audit postponements

- Pharmacies must have some proof of delivery in place of patient signature
  - “Impacted by COVID-19” notation by pharmacy staff
  - Date/time of delivery
  - Link to carrier tracking ID
  - Subject to audit oversight!

COVID-19 VACCINE

- **Billing**
  - Quantity
  - Day Supply
  - SCC02 vs SCC06

- **Documentation**
  - Suggest “placebo holder Rx” for your files
  - Vaccine Administration Record (VAR)
  - EUA Fact Sheet
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6/17/2021

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PBM “VIRTUAL” ONSITE AUDITS

- Began July 2020 in place of in-person audits at your pharmacy
- Hybrid of traditional desk and onsite
- Document submission via fax, email, mail, or web portal
  - Up to 125 prescriptions and 100+ signature logs
  - Copies of licensure, liability insurance
  - Phone interview to ask compliance questions (10-15 minutes)
  - Photos of pharmacy including consult area, sink, refrigerator, compound lab

BIG PICTURE

Prescription
- Do you have a prescription?
- In prescription valid per state and federal laws?

Data Entry & Filling
- Did you fill and bill accurately?

Dispensing
- Did you have proof of dispensing?

Other
- Did you purchase enough inventory from an appropriate source?

SURVEY QUESTION #2

COMMON AUDIT DISCREPANCIES

Prescription
- Missing or Invalid Rx
- Altered Rx

Data Entry
- Unauthorized Refill
- Overbilled Quantity
- Refill too Soon
- Unsupported DAW Code

Dispensing
- Missing or Invalid Signature Log
- Dispensed > 10 days

Other
- Did you purchase enough inventory from an appropriate source?

AUDIT ALGORITHMS

DMEPOS STANDARD WRITTEN ORDER (SWO)

- SWO as of January 1, 2020
  - Requires for previously ordered items
  - Detailed Written Order (DWO)
  - Five Element Order for ACA items (5EO)
  - Seven Element Order for PMD (7EO)

- CMS Final Rule 171 November 8, 2019
  - When to have in your possession
    - Before billing = ALWAYS
    - Before delivery = SOME items require (WOPD)

- Elements include:
  1. Beneficiary name OR Medicare Beneficiary Identifier (MBI)
  2. The order date
  3. A description of the items ordered
  4. The quantity to be dispensed, if applicable
  5. Treating practitioner’s name OR NPI
  6. Treating practitioner’s signature*

- Signature and date stamps are not allowed

- NEW: Notably absent (i) instructions for use and (ii) refills

- NEW: Pharmacies may clarify and add Clinical Notes

  standard-written-order-for-items-requiring-a-written-order-676.html

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  standard-written-order-for-items-requiring-a-written-order-676.html
### DMEPOS TARGETED PROBE & EDUCATE (TPE)

**Targeted**
- Suppliers with high claim denials rates
- Product categories with high error rates
- Review of 20-40 claims in 3 “rounds”
- Opportunity to exit loop if successful

**Educate**
- 1-on-1 education offered by DME MAC to facilitate improvement
- 45 days between rounds to implement corrective measures

### WORKFLOW PREVENTION STRATEGIES

<table>
<thead>
<tr>
<th>Workflow</th>
<th>RX DROP OFF</th>
<th>DATA ENTRY</th>
<th>FILLING</th>
<th>VERIFICATION</th>
<th>CASHIER</th>
</tr>
</thead>
</table>

#### RX DROP OFF
- Verify apparent alterations
- Clarify “use as directed” for insulin or topicals with prescriber (or patient)
- Implement Rx scanning if possible
- Clinical Note Best Practice:
  1. Who you spoke with
  2. When you spoke with them
  3. What you spoke about
  4. Who is writing the note

#### DATA ENTRY
- Verify correct NCPDP billing unit (EA, GM, ML)
- Quantity “1” = smallest package size
- Must dispense in original container as per labeling or U.S. NLM DailyMed
- Always estimate as per quantity and instructions for use
- Call PBM Helpdesk for override if unbreakable package
- Document calculations
- Only submit if supported by documentation
- Don’t force to get paid claim

#### FILLING
- Match NDC on stock bottle against billing label (including package size) using barcode technology if possible
- Confirm quantity prepared matches billing label
- Spot check: SWC code, Day Supply and Origin Code

#### VERIFICATION
- Match NDC on stock bottle against billing label (including package size) using barcode technology if possible
- Double check Day Supply estimate as per documented calculations
- Pay close attention to insulin, inhalers, eye drops
- Verify data entry elements such as Day Supply, DAW and Origin Code
- Suggest adding “tracking” if doing paper verifications

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CASHIER (DISPENSING)

Conduct Return to Stock at least twice a week and use Pharmacy Technology to help you

- 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
- Turn on "hard stop" at Point-of-Sale (POS) register to prevent Rx from being sold after 10 days

Obtain patient signature and date, implement electronic capture if possible

- COVID-19 waivers have been in place since March 2020 – patient signatures NOT required as of June 11, 2021

If mailing, make sure that Rx # is "tied to" carrier tracking ID #

Collect Copay at dispensing, implement Point-of-Sale (POS) itemized system

In-house charge accounts must have good accounting practices

"TOP 10" AUDIT DISCREPANCIES

1. Day Supply – Insulin
2. Day Supply – Topicals
3. Day Supply – Inhaled
4. Day Supply – Eye Drops
5. DAW
6. Controlled Substance Rx
7. Electronic Rx
8. Transfer Rx
9. Compound Rx
10. Proof of Dispensing & Copay Collection

SURVEY QUESTION

#3

1. DAY SUPPLY – INSULIN

- Do NOT break boxes of insulin pens as of November 15, 2019
- FDA intervened June 2019
- "Dispense in this sealed carton" language on outside of package
- Industry "flip flop" from Walgreens–DOJ decision January 2019
- Must submit accurate day supply if possible
- Call helpdesk to request override
- Consider Beyond Use Dating (per pen)

Sample Rx #1

John Doe
06-01-2021
Insulin aspart U-100 Pen 15 mL
UAD per sliding scale
5 refills
Dr. Smith
06-01-2021
max daily dose = 60 units
Calculation: 1500 units/60 units daily = 25 days

FDA GUIDANCE – INSULIN PEN PACKAGING & DISPENSING

OCTOBER 13, 2020

- There is an increased risk of dispensing errors and patients using the wrong product of insulin because pens are stored or dispensed outside of their carton. Insulin pens dispensed individually outside of their carton may have contributed to medication errors by being confused with similar medications or hypoglycemic therapy. Complete or partial dispensing and dispensing without the instructions for use.
- Medicaid users are reimbursed for dispensing in their original sealed carton. Medicaid not approved the first single pen carton size for an insulin product on June 11, 2020. Insulin pens are generally marketed in cartons containing two to five pens. Insulin pens are not labeled for dispensing as individual units.
- FDA understands that there are situations where health care professionals may choose to dispense individual pens on an individual patient basis. However, in these situations, health care professionals should exercise the utmost care to avoid dispensing incorrect pens to individual patients. For example, if a health care professional determines that there is a situation in the hospital where the insulin pen is the only insulin available and the insulin pen is needed for a patient, the health care professional should consider this situation carefully. For more information, please visit the FDA website.

Sample Rx #2

John Doe
06-01-2021
Calcipotriene 0.005% cream 240 GM
AAA BID
5 refills
Dr. Smith
06-01-2021
max daily dose = 80 units
Calculation: 240 units/80 units daily = 3 days

2. DAY SUPPLY – TOPICALS

- Must submit accurate day supply if possible
- Mathematical instructions for use
  - Grams per application (if one concentration)
  - Max Daily Dose or expected daily supply
  - List of affected areas + Fingerlip Unit (FTU) Method

Sample Rx #5

John Doe
06-01-2021
Calcipotriene 0.005% cream 240 GM
AAA BID
5 refills
Dr. Smith
06-01-2021
max daily dose = 80 units
Calculation: 240 units/80 units daily = 3 days
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FINGERTIP UNIT METHOD

- **Fingertip Unit (FTU) Method**
  - 1 FTU = 0.5 gram (adult)
  - 1 FTU covers one hand (front/back)

<table>
<thead>
<tr>
<th>Body Surface</th>
<th># of FTUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand (both sides)</td>
<td>1</td>
</tr>
<tr>
<td>Arm + Hand</td>
<td>4 (3+1)</td>
</tr>
<tr>
<td>Leg + Foot</td>
<td>8 (7+1)</td>
</tr>
<tr>
<td>Buttocks</td>
<td>4</td>
</tr>
<tr>
<td>Trunk (front or back)</td>
<td>8 each</td>
</tr>
<tr>
<td>Face &amp; Neck</td>
<td>2.5</td>
</tr>
</tbody>
</table>

**EXAMPLE CALCULATION**

Calcipotriene 0.005% cream

- **Quantity**: 240 GM
- **sig**: AAA BID (both arms)

1. 1 arm = 3 FTU (per chart)
2. 3 FTU x 2 = 6 FTU/application
3. 6 FTU twice daily = 12 FTU/day
4. 12 FTU/day x 0.5 gm/FTU = 6 gm/day
5. 240 gm/(6 gm/day) = 40 ds  
   If plan limit = 30 ds, then reduce to 120 gm as 20 ds

3. DAY SUPPLY – INHALERS

- Must submit accurate day supply if possible
- Do not rely solely
- Strategies:
  - Call PBM helpdesk for day supply override
  - Add note to sig field after patient instructions for use
  - Train staff to watch for refill intervals
- Adjust inpatient/day refill, ask if circumstances have changed and document
- Close increase, lost medication, refills

**EXAMPLE**

**Sample Rx #3**

John Doe 06-01-2021  
Fluticasone propionate 110 mcg HFA inhaler  
12 GM  
1 puff/BID  
5 refills  
Dr. Smith  
Calculation: 120/2 puffs daily = 60 days  
Example sig on Patient dispensing label = “Inhale 1 puff two times daily (60 days)”

4. DAY SUPPLY – EYE DROPS

- Must submit accurate day supply if possible
- In General
  - 20 drops/mL for solution
  - 15 drops/mL for suspension
- PBMs have their own “estimates”
  - Caremark® 15
  - Express Scripts® 16
  - OptumRx® 15–20
- Document any patient factors that may impact ability to dose accurately (e.g., Parkinson’s)

**EXAMPLE**

**Sample Rx #4**

John Doe 06-01-2021  
Brimonidine tartrate 0.1% solution 15 mL  
One drop QID  
5 refills  
Dr. Smith  
Calculation: (Assume patient has Caremark®)  
15 mL x 15 drop/mL = 225 drops/6 = 37 or 38 days  
*If plan limit = 30 days, then MUST reduce to 10 mL as 25 days

5. DAW

- NCPDP Field 408-DB
- Vol 0 = 0
- **Default** should be 0 (zero)
- Do not “force” to get paid claim
- Documentation must support use
  - On prescription itself
  - In pharmacy computer system

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No Product Selection/Indicated</td>
</tr>
<tr>
<td>1</td>
<td>Substitution Not Allowed by Prescriber</td>
</tr>
<tr>
<td>2</td>
<td>Substitution Allowed – Patient Requested Product Dispersed</td>
</tr>
<tr>
<td>3</td>
<td>Substitution Not Allowed – Generic Drug Not Available in Marketplace</td>
</tr>
<tr>
<td>4</td>
<td>Substitution Allowed by Prescriber/Doc Requires Brand</td>
</tr>
</tbody>
</table>

6. CONTROLLED SUBSTANCE RX

- Federal Law
  - 3 elements per part 21 CFR 1306.05(a)
  - Patient Address
  - NPI Address
  - DEA Number
- State Law
  - All CS Rx valid x 6 months
  - Part D Opioid Restrictions

**Sample Rx #5**

John Doe, Jr. (DOB 1/1/1973) 06-01-2021  
123 Main Street, St. Louis, MO  
Buprenorphine/naloxone 8/2 mg film #20  
1 film sublingual BID  
0 refills  
Dr. Smith  
555 Second Street, St. Louis, MO  
AB1234567  
XB1234567  
https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_05.htm  
http://164.64.110.134/parts/title16/16.019.0020.html
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7. ELECTRONIC RX

<table>
<thead>
<tr>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “1” = smallest package size</td>
</tr>
<tr>
<td>• Unit of Measure “unspecified”</td>
</tr>
</tbody>
</table>

**Day Supply**

- Does DS field conflict with quantity/sig calculation?
- Invalid eRxs
  - Follow to Fax (not a valid eRx)
  - Email

**DAW**

- DAW field vs. Sig field vs. free text field
- Erroneous – generic drug or brand with no generic approved

8. TRANSFER RX

**General Requirements**

1. “Copy” or “Transfer”
2. Transferring pharmacy info – RX#, pharmacy, address, phone, DEA
3. Rx info
4. Rx history – Rx #, for refill, original/remaining refills
5. Face info – date of transfer, APN

- State Specific:
  - New Mex “in 24 hrs”
  - Suggest using a dedicated transfer RX with all required elements
  - Barcode – original dose vs. transfer dose

9. COMPOUND RX

- Rx must match compound AND claim NDCs
- Ingredient strengths assumed to be “final” unless specified e.g., in label
- Base QS amount: make sure software does not overbill
- Level of Effort codes 11-15

- Be careful with defaults
- Each PBM has a different definition

10(A) PROOF OF DISPENSING

**Relai/PBM Elements**

1. Rx #
2. Date dispensed
3. Signature of Patient/Representative*

**Exceptions during COVID as previously noted**

**Outside of COVID pandemic, placeholders such as “mail” or “drive-thru” are NOT sufficient**

**DMEPOS Elements (in-person)**

1. Beneficiary’s name
2. Delivery address
3. Description of item
4. Quantity delivered
5. Beneficiary (or designee) signature

- Retail/PBM signature log is NOT SUFFICIENT!
- Date delivered must match billing date (cannot hold in will-call bins)

10(B) COPAY COLLECTION PEARLS

- Contracts require collection WITH PROOF (limited exceptions)
-Copayments are used to sensitize patients to the cost of their medications
- Documentation:
  - Copay checks (front & back)
  - Copay must be processed within 15 days, or a statement is required

- Hardship Waivers
  - Written Policy & Procedure
  - Objective evidence to qualify (tax returns)
  - Must NOT be advertised

- Manufacturer Coupons
  - Medicaid/Medicare/TRICARE prohibited
  - Caremark Provider Manual limits
  - Non-FDA approved
  - Dietary Supplements
  - Medical Devices

SPEAKER CONTACT INFORMATION

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