Audits on My Mind: Protecting the Bottom Line

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Disclosure

Trenton Thiede is Vice-President, PAAS National. The conflict of interest was resolved by peer review of the slide content.

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Learning Objectives

- Discuss audit triggers.
- Discuss workflow processes to catch mistakes.
- List top 11 audit discrepancies.

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

FOR IMMEDIATE RELEASE — Thursday, May 31, 2018

Pharmacy owners agree to pay $3.2 million to resolve False Claims case

PHILADELPHIA – The owners of I&L Express Pharmacy in Philadelphia have agreed to pay millions to resolve a False Claims Act case against them, U.S. Attorney William M. McSwain announced today.

FOR IMMEDIATE RELEASE — Thursday, April 26, 2018

Owner of Florida Pharmacy Sentenced to 15 Years in Prison for $100 Million Compounding Pharmacy Fraud Scheme

https://oig.hhs.gov/fraud/enforcement/criminal/

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Audit Trends from 2014 - 2018

	Desk %	Onsite %	Invoice* %
2014	72	27	1
2015	73	26	1
2016	78	20	2
2017	82	16	2
2018	86	12	1

- *Many invoice audits are in addition to desk/onsite audit
- 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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Big Picture

Prescription
- Do you have a prescription?
- Is prescription legal/valid per state and federal laws?

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

Data Entry & Filling
- Did you fill and bill accurately (including calculable directions?

Dispensing
- Do you have proof of dispensing?
- Do you have proof of copay collection?

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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

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Learning Assessment Question #1

Which of the following could trigger an audit?

a. Missing prescription
b. Refill too soon
c. No proof of dispensing
d. All of the above

b. Refill too soon

Audit Algorithms ≠ Random

- Historical billing/documentation errors
  - Days' supply
  - DAW
- Historical fraud targets
  - Controlled substances – "Pill Mills"
  - Compounds
- **Telemedicine & delivery - zip code analysis**
  - Patient
  - Prescriber
  - Pharmacy

Telemedicine

- Items to consider when reviewing prescriptions for Telemedicine:
  - 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…

Workflow Prevention Strategies – Practical Tips

Rx Drop Off

- Verify apparent alterations
- Clarify "use as directed" for insulin or topicals with patient or prescriber
- Implement Rx scanning if possible
- **Suggested *Clinical Note* Format:**
  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)
  - Be cautious with syringes and "kits"
- Quantity "1" = smallest package size unless confirmed otherwise
- Some products must be dispensed in original container – see NLM DailyMed for product labeling
- **Days' supply – estimate as per quantity and SIG, must submit accurately, call PBM helpdesk for override if smallest unbreakable package**
  - Document calculations on prescription
- DAW codes – only submit if supported by documentation

Source: NLM DailyMed (https://dailymed.nlm.nih.gov/dailymed/index.cfm)

Filling

- **Match NDC on stock bottle against billing label (including package size) using barcode technology if possible**
- Confirm quantity prepared matches billing label
- If time allows spot check DAW, Day Supply, 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, topicals, eye drops, inhalers**
- Verify Data Entry elements such as DAW, Day Supply, Origin Code
  - Suggest adding to "backslap" if doing paper verification

Cashier (Dispensing)

- Conduct Return to Stock at least twice a week using pharmacy management software "workflow" if possible
  - Document any unique exceptions where Rx was dispensed > 10 days
  - **<u>If patient promises to come "next week", then reverse/rebill/relabel to give more time to maintain compliance</u>**
- Obtain patient signature and date, implement electronic capture 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 good accounting practices

Learning Assessment Question #2

Which of the following is an audit prevention strategy that a *pharmacist* may do on a daily basis?

a. Compare day supply submitted with the prescription documentation during prescription verification

b. Analyze all DAW claims billed over last 30 days to ensure supporting documentation exists

c. Work with software vendor to build alerts for drugs that must be dispensed in original container

a. Compare day supply submitted with the prescription documentation during prescription verification

"Top Eleven" Audit Discrepancies

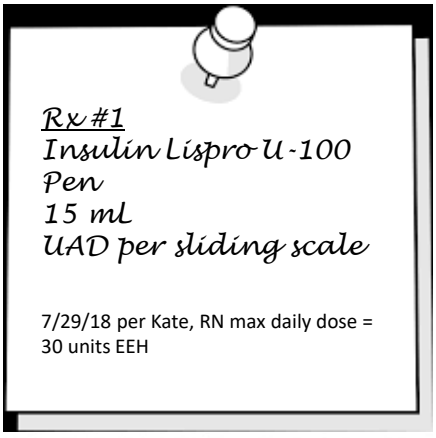
1. Day supply – Insulin
2. Day supply – Topicals
3. Day supply – Inhalers
4. Day supply – Eye drops

} "Unbreakable Packages"

5. DAW
6. Controlled substance prescriptions
7. E-prescriptions
8. Transfer prescriptions
9. Compound prescriptions
10. Proof of dispensing/copay collection
11. Non-FDA approved products or FDA approved devices

1. Day 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!!**



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!

D1 Note: The quantity billed exceeds the quantity authorized by the prescriber or plan.
Comments: As a result of recent DOJ decision, Humana will require pharmacies to break boxes of insulin depending on the directions and quantity prescribed. Submitted 30 for 90 days' supply (= 100 days' supply) Plan maximum 90 days' supply.

Sources: DOJ https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civil-healthcare

FDA https://www.fda.gov/Drugs/DrugSafety/ucm435271.htm

2. Day Supply – Topicals

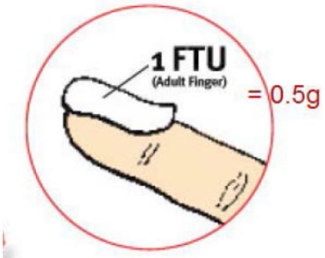
- **Submit accurate DS if possible**
- **Mathematical instructions for use**
  - Grams per application (if one area only)
  - Max daily dose per MD or expected day supply
  - List of affected areas + Finger Tip Unit (FTU) Method

Rx #2
Calcipotriene
0.005% cream
360 GM
AAA BID

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

Finger Tip Unit (FTU) Method

- 1 FTU ≈ 0.5 gram (adult)
- 1 FTU covers one hand (front/back)



Body Surface	# of FTUs
Hand	1
Foot	1
Arm + Hand	4 (3+1)
Leg + Foot	8 (7+1)
Buttocks	4
Trunk (front or back)	8 each
Face & Neck	2.5

3. Day Supply – Inhalers

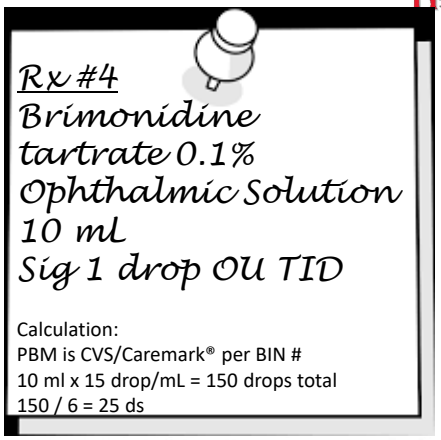
- **Submit accurate DS if possible**
- **Do not refill early**
- Strategies
  - Call for DS override
  - Add note to sig field (e.g. 60 ds)
  - Train staff to watch for refill intervals
- If patient requests early assess circumstances and document

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

4. Day 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)



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**

6. Controlled Substances

Federal Law

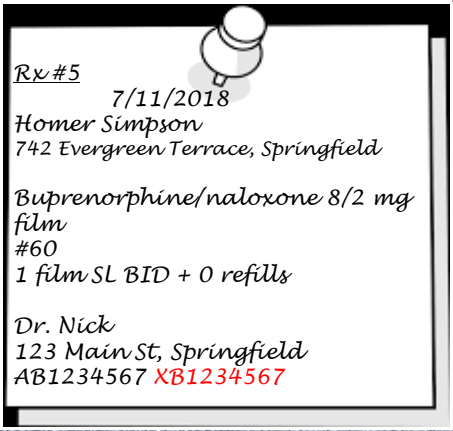
3 elements as per 21 CFR 1306.05(a)

- 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*



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 eRxs
  - Failover to fax (not a valid eRx)
  - eClinicalWorks
  - Downloading prescriptions (HITECH Act vs. NCPDP SCRIPT Standard)

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**

TRANSFER PRESCRIPTION

NAME _____ TRANSFER DATE _____

ADDRESS _____

ORIGINAL RX # _____

DATE OF ISSUE _____

DATE FIRST FILLED _____

ORIGINAL REFILLS _____

REFILLS REMAINING _____

DATE LAST REFILL _____

PHARMACY _____

ADDRESS _____

DEA # _____

PHARMACIST OF RECORD:

TRANSFERRING _____

RECEIVING _____

Rx

MAY SUBSTITUTE

DISPENSE AS WRITTEN

ADDRESS _____

DEA NO. _____

Reorder Item #6107 Total Pharmacy Supply, Inc. 1-800-878-2822

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

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**

Source: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf

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.

Source: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf

Learning Assessment Question #3

Which of the following is a data field that a *pharmacist* may review when performing a self-audit with a software report?

a. DAW
b. Origin code
c. Controlled substances
d. All of the above

d. All of the above

Learning Assessment Question #4

Which of the following prescriptions are payable under Medicare Part D?

a. Gentamicin foot soak (800 mg in one gallon of water BID x 30 days)
b. Doxepin 5% cream (Apply 1 gm TID x 10 days)
c. Loratadine 10 mg QD
d. Diclofenac Gel 5% (compounded from crushed tablets – not bulk powder) Apply 1 gm to both knees BID
e. None of the above

Long Term Care Challenges

- Humana is the only PBM that offers specific guidance on LTC orders
  - Prescription hard-copy requirements
    - May accept combination of chart orders, Physician Orders, refill stickers, MARs, discharge orders with a clear duration of therapy
  - Signature log requirements
    - Patient name, date of service, Rx number, facility name, date of delivery, signature of person who accepted
  - Cycle fill
    - May be done at the beginning or end of the month, must be consistent
    - If submitting SCC for short-cycle dispensing, must be able to produce two delivery document

Long Term Care Challenges

- Medicare A days' supply
  - Do not 'fudge' days supply on Med A bulk items (e.g. Insulin with 1 days' supply)
- Short cycle
  - Short cycle based on NDA/ANDA (versus Brand/Generic)
- Delivery Sheets
  - Detail from prior slide, careful with dates (e.g. manifest, billing, delivery, start)
- Physician Order Sheets
  - Ideal to have refills or valid time frame (e.g. All non-controlled prescriptions are good for one year from written date)

Long Term Care Challenges

- Agent of the Prescriber
  - Physician assents manifest to nurse for communicating controlled substances (pharmacy must have on file)
- Charge Accounts
  - Policies and Procedures for collecting, careful with provisions for bad debt, writing off indigent claims, tic and tie accounting
- Residence Codes
  - Use appropriate codes based on patients' residence

Learning Assessment Question #5

Which of the following is true?

a. You only have to short-cycle brand drugs
b. Any LTC nurse in a SNF can call in a prescription for a CIII-V
c. Collecting patient copays is optional
d. Discharge orders can be used as admitting orders
e. A, B and D
f. All of the Above

d. Discharge Orders - for Humana, if they are signed with a clear duration of therapy

Questions?

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