



Preparing Your Team for PBM Audits in 2025

Trenton Thiede PharmD, MBA

President, PAAS National®





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Pharmacist and Technician Learning Objectives

- 1. Discuss common audit discrepancies.
- 2. Identify which audit issues lead to the largest recoupments.
- 3. Summarize strategies for engaging pharmacy team members in preventing and responding to audit scenarios.





Speaker



Trenton Thiede PharmD, MBA

President PAAS National[®]



Why So Many Audits

<u>~~</u>	Escalating Healthcare Costs
Ę	Opioid Epidemic
	Contractual Requirements
- X •	Fraud, Waste & Abuse
	Common Billing Errors
<u>N</u>	Data Analytics/Outliers
000	PBM Revenue Source = \$\$\$





• • •	Financial Recovery
	Corrective Action Plans
} •	Network Termination
x	Reputation
	License
\bigcirc	OIG Exclusion
<u> </u>	Fines
	Prison





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Justice.gov > U.S. Attorneys > District of Massachusetts > Press Releases > Florida Pharmacy Pleads Guilty To Health Care Frau and Agrees To Pay More Than \$1 Million Settlement

PRESS RELEASE

Florida Pharmacy Pleads Guilty to Health Care Fraud and Agrees to Pay More than \$1 Million Settlement

Thursday, April 10, 2025





For Immediate Release

U.S. Attorney's Office, District of Massachusetts



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PRESS RELEASE

Union City Pharmacy Agrees To Resolve False Claims Act Allegations Of Billing For Drugs Not Dispensed

Friday, April 11, 2025





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PRESS RELEASE

Pharmacist indicted in \$2 million health care fraud scheme

Thursday, April 17, 2025





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U.S. Attorney's Office, Southern District of Texas



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PRESS RELEASE

Owner of Pharmaceutical Company Pleads Guilty to Unlawful Distribution of \$60 Million in Diverted HIV Drugs

Monday, April 21, 2025





For Immediate Release

U.S. Attorney's Office, Southern District of Florida



Audit Trends 2020 – 2024*

- 11% increase in audits first Quarter 2025 vs first Quarter 2024
- Many invoice audits are completed in tandem with desk/onsite audits

	Desk	Rx Validation Requests	Virtual	Onsite	Stand Along Invoice Audits
2020	62%	23%	7%	6%	2%
2021	67%	20%	11%	0%	2%
2022	67%	21%	5%	5%	2%
2023	51%	37%	1%	9%	2%
2024	49%	38%	1%	9%	3%



*Based on PAAS Audit Statistics

Top Ten Audit Discrepancies

Days'	Supply –	Insulin/GLP-1

Days' Supply – Topicals

Days' Supply – Inhalers

Days' Supply – Eye drops

DAW Codes

Controlled Substance Prescriptions

E-Prescriptions

Transfer Prescriptions

Migraine Medications

Proof of Dispensing/Copay Collection





<u>Insulin</u>

- Submit accurate days' supply, when possible
- Mathematically calculable directions
 - Max daily dose
 - Deliverable dose
 - o Generally, 1-unit increments
 - \circ Exceptions:
 - Humalog[®] Junior KwikPen (0.5 unit)
 - Toujeo[®] MAX SoloStar[®] (2 unit)
 - Tresiba[®] U-200 FlexTouch[®] (2 unit)
 - Humulin[®] R U-500 KwikPen (5 unit)





<u>Insulin – Priming Units</u>

- Not all third-party payors will use priming units in their days' supply (DS) calculations
- Document if priming units are used
- Not all insulin pens use a 2-unit prime

Insulin	Priming Units
Toujeo [®] SoloStar [®] (Insulin glargine)	3 units
Toujeo [®] Max SoloStar [®] (Insulin glargine)	4 units
Humulin [®] R U-500 KwikPen (insulin human injection)	5 units





Insulin Example

- 1500 units per Carton
 - 10 units/day = 150 days' supply
 - Each pen has 28-day Beyond Use Date (BUD) once in use
 - Actual days' supply would be 140 days
- If insurance rejects 140 days:
 - Call the helpdesk for an override
 - Document on the hard copy
 - Do NOT refill the prescription early
 - Recommend actual days' supply add to the end of the patient's instructions (i.e., SIG)



For_June Jones (DOB 9/27/62)_Date_01/05/2025	
Address <u>123 Main St, Pharmtown, WI 55221</u>	
P_X	
Lantus Solostar U-100	
15 mL	
Take 10 units SubQ at bedtime	
Refills: <u>12</u>	
DrDia Betes_(NPI: 1234567)	
Address: 12 Sugarcreek Road, Pharmtown, WI 55221	
Phone: <u>555-867-5309</u>	
	2

Insulin Example

- 1500 units per Carton; prescribed 2 cartons = 3000 units
 - 30 units/day = 100 days' supply
- If insurance rejects 100 days:
 - Call the help desk for an override
 - Reduce the number of cartons to 1
 - i.e., bill 15 mL = 50 days' supply

For James Smith (DOB 1/7/60) Date 01/05/2025	
Address 3 S. Fourth St, Pharmtown, WI 55221	
P _X	
Lantus Solostar U-100	
30 mL	
Inject 30 units SubQ nightly at bedtime	
Refills: <u>11</u>	
Dr. <u>Sue Gar (NPI: 1256891)</u>	
Address: 12 Sugarcreek Road, Pharmtown, WI 55221	
Phone: <u>555-867-5309</u>	
	·



Insulin Example

- Toujeo[®] Max U-300
 - 2 pens per box; each pen is 3 mL
 - 1800 units/box
 - 31.6 (31/32) days' supply without priming units
 - 29.5 (29/30) days' supply when 4-unit prime included
- Problem
 - This pen has a 2-unit dosing increment
 - 57 units is not possible!

Ear Court M/ (how (DOB 0/5 (C2)) Date 02 (05 (2005	
For Sam Walters (DOB 8/5/62) Date_02/05/2025	
Address <u>222 N. South St, Pharmtown, WI 55221</u>	
P _X	
Toujeo Max Solostar	
#1 box	
Inject 57 units SQ at bedtime	
Refills: <u>11</u>	
Dr. <u>Sue Gar (NPI: 1256891)</u>	
Address: <u>12 Sugarcreek Road, Pharmtown, WI 55221</u>	
Phone : <u>555-867-5309</u>	





<u>GLP-1s</u>

- Common pitfalls
 - Quantity

- Directions
- Unit of measure Days' supply
- Ozempic[®] standard dosing
 - 0.25 mg SQ weekly x 4 weeks, then increase to 0.5 mg weekly
 - May continue to increase dose in 0.5 mg increments after 4 weeks if additional glycemic control is need
 - Maximum recommended dosage is 2 mg once weekly
 - Ozempic[®] is available in three different concentrations
 - All pens have a volume of 3 mL regardless of the strength





Standard dosing

- Initial fill
 - Billed with a 42 days' supply initially
 - 2 mg per pen
 - 0.25 mg per dose x 4 doses = 1 mg used
 - 1 mg remaining ÷ 0.5 mg dose = 2 doses
 - 6 doses x 1 dose/week = 6 weeks (42 DS)
- First refill
 - Billed as a 28 days' supply
 - Still using a 2 mg/3 mL pen
 - 2 mg ÷ 0.5 mg dose = 4 doses
 - 4 doses x 1 dose/week = 4 weeks (28 DS)

For Bru Sun (DOB)	11/5/70)	Data 0	1/05/202
For_ <i>Ray Sun (DOB</i> 1			
Address <u>356 N. Fou</u>	rth St, Pha	irmtown,	WI 5522
R ₂			
$-\boldsymbol{\lambda}$			
Ozem	bic Z n	ng 3 d	mL
3 mL			
Inject 0.25 mg	SubQ or	ice wee	kly x 4
then increase to	o 0.5 mg	, weekly	, there
Refills: <u>11</u>			
Dr. Sue Gar (NPI: 12	.56891 <u>)</u>		
Address: <u>12 Sugarcr</u>	eek Road,	. Pharmto	wn, WI S
Phone: 555-867-530)9		
	-		





What about 0.25 mg SQ weekly, <u>without</u> the increase?

- Confirm dose with prescriber and document
- Use the 2 mg/3 mL pen which can deliver the 0.25 mg dose
- 2 mg ÷ 0.25 mg per dose = 8 doses
- 8 doses x 1 dose/week = 8 weeks or 56 days' supply
- Guidance:
 - Conservative approach 56 days' supply
 - Some variance between PBMs 56 vs 42 days' supply
- Don't forget the pen needles!

For_ <i>Ray Sun (DOB 11/5/70)</i> Date <u>01/05/2025</u>
Address <u>356 N. Fourth St, Pharmtown, WI 55221</u>
P_X
Ozempic 2 mg/3 mL
3 mL
Inject 0.25 mg SubQ once weekly
Refills: <u>11</u>
Dr. <u>Sue Gar (NPI: 1256891)</u>
Address: <u>12 Sugarcreek Road, Pharmtown, WI 55221</u>
Phone: <u>555-867-5309</u>
RRCMENNE



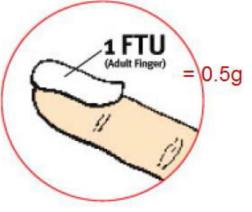
- Submit accurate days' supply (DS) if possible
- Mathematical instructions for use
 - Grams per application (if one area only)
 - Max Daily Dose per MD or expected day supply
 - List of affected areas + Finger Tip Unit (FTU) Method
- Collagenase use manufacturer dosing calculator

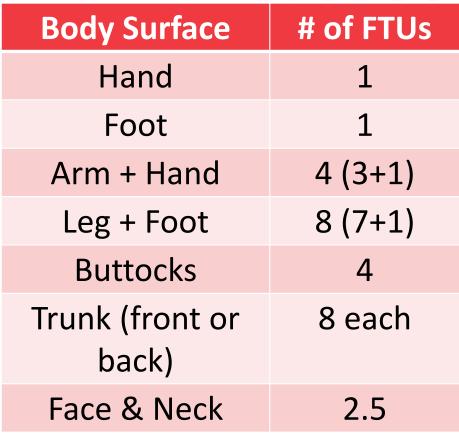




Finger Tip Unit (FTU) Method

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









Vaginal Creams

- Submit accurate days' supply, when possible
- Directions must include grams/application and frequency
 - $\ensuremath{\circ}$ Clarification required for the following:
 - Pea sized
 - 1 application three times weekly
 - Insert three times weekly as directed

Product	Package Size	Applicator Measurements
Estrace [®] (estradiol) 0.01% vaginal cream	42.5 grams	1 to 4 grams (1 gram increments)
Premarin [®] (conjugated estrogens) vaginal cream	30 grams	0.5 to 2 grams (0.5 gram increments)



- As is, prescription did not have sufficient directions to mathematically calculate the days' supply
- Clarify + clinical note + update label
- Sample script:
 - 30 grams
 - ¹/₂ applicatorful of Premarin[®] = 1 gram
 - 30 grams ÷ 2 grams/week = 15 weeks
 - 15 weeks x 7 days/week = 105 days' supply
 - Plan limit? Watch refill interval!

For Sue Zee (DOB 3/7/33) Date 07/05/2024
Address 523 James Way, Pharmtown, WI 55221
P _X
Premarin Vaginal cream
30 grams
AAA twice weekly
7/5/24 - Jay RN states insert half
applicatorful vaginally twice
Refills: <u>4</u> weekly. SH
Dr. Jean Jones (NPI: 1556363)
Addrosse 74 Park Place Pharmtown W/LEE221
Address: 74 Park Place, Pharmtown, WI 55221





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 Days' Supply)
 - Train staff to watch for refill intervals
- Be mindful of undocumented Albuterol HFA substitutions





4. Days' Supply Eye Drops

- Submit accurate DS if possible
- In General
 - 20 drops/mL for solution
 - 15 drops/mL for suspension
- PBMs have their own "estimates" ED1
 - CVS/Caremark[®] 15 drops/mL
 - Express Scripts[®] 16 drops/mL
 - OptumRx[®] 15-20 drops/mL
- Manufacturer guidance Miebo[®], Vevye[®] and Vyzulta[®]





- ED1 Is this public information? Citation? Elise Damman, 2025-06-03T19:18:00.363
- **GU1 0** Only OptumRx is public. I could just use that as an example and remove CRK/ESI if inappropriate. Guest User, 2025-06-04T18:27:34.976
- ED1 1 Okay to include from our end Elise Damman, 2025-07-02T20:47:30.177

5. DAW Codes

NCPDP Field 408-D8

- Values 0-9
- Documentation must support use

Code	Description
0	No Product Selection Indicated
1	Substitution Not Allowed by Prescriber
2	Substitution Allowed – Patient Requested Product Dispensed
8	Substitution Allowed – Generic Drug Not Available in Marketplace
9	Substitution Allowed By Prescriber but Plan Requests Brand





5. DAW Codes

Use DAW 1 appropriately

- Not for single source brands, biologics without an interchangeable biosimilar or OTC items
- Generics without rationale
- Careful with state/Medicaid requirements





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





7. Electronic Prescriptions

- Quantity
 - "1" smallest package size
 - Unit of Measure "unspecified"
- •Erroneous DAW
- Default Days' Supply
- Invalid eRxs





8. Transfer Requirements

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
 - State specific laws/variations thereof

NAME	TRANSFER DAT	'E
ADDRESS		
DRIGINAL RX #	P	
DATE OF ISSUE		
DATE FIRST FILLED	/ `	
ORIGINAL REFILLS		
REFILLS REMAINING		
DATE LAST REFILL		
PHARMACY		
ADDRESS		
DEA#		
PHARMACIST OF RECORD:		
TRANSFERRING		
RECEIVING		
MAY SUBSTITUTE	DISPENSE AS WR	RITTEN
ADDRESS		
DEA NO		
Reorder Item #6107	Total Pharmacy Supply, Inc.	1-800-878-2822

TRANSFER DRESCRIPTION





9. Migraine Medications

PRN Migraine Medications

- Specific directions for use and dosage form
- Estimated # of headaches per/week or month (particularly when > one package)
- FDA approved dosage range

Drug	FDA approved indications/usage	Recommend dose	Can patient repeat the dose?	Maximum daily dose	Billing Unit per package
Migranal Nasal Spray	Acute treatment	One spray in each nostril (must prime with 4 pumps prior to each use and discard 8 hours after it is primed)	Yes, 15 minutes later	No more than 4 sprays (2 mg) per 24 hours. No safety studies for doses > 3 mg/24 hours and 4 mg/7 days.	8 mL
Nurtec ODT tablets	Acute treatment	75 mg daily	No	No more than 18 doses in	8 each
	Preventative treatment	75 mg every other day		a 30-day period	
Ubrelvy tablets	Acute treatment	50 mg or 100 mg	Yes, at least 2 hours after initial dose	200 mg/24 hours and no more than 8 migraines in 30-day period	10 or 16 each

10. Proof of Dispensing and Copay Collection

Proof of Dispensing (in-person)

- Elements:
 - Rx #
 - Date of Service (or refill indicator)
 - Date of Receipt
 - Signature of Patient/Representative
- "Curbside" or "Drive Thru" notations by staff are not sufficient





10. Proof of Dispensing and Copay Collection

Proof of Dispensing (delivery)

- Elements:
 - Patient name/address
 - Rx #
 - Date of Service (or refill indicator)
 - Date of Delivery (handwritten or time-stamped)
 - Signature of Patient/Representative
- Driver signature and geotag pictures are insufficient





10. Proof of Dispensing and Copay Collection

Copay Collection

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





10. Proof of Dispensing and Copay Collection

Copay Collection

What does documented proof look like?

- Credit Cards POS receipt, may need cc merchant report
 - The last 4 digits of the credit card number
 - The transaction authorization
 - The merchant ID number
- Checks front/back copies of canceled check
- Cash bank deposits show cash going into the bank





10. Proof of Dispensing and Copay Collection

- 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.
- Secondary Payer Information
 - Insurance, MFR coupon, eVoucher





Which of the following is the <u>best</u> method for calculating days' supply on topicals?

- A. Finger-Tip Unit
- B. Grams/Application
- C. 1 tube = 30 days' supply
- D. A and B





Which of the following is the <u>best</u> method for calculating days' supply on topicals?

A. Finger-Tip Unit

B. Grams/Application

- C. 1 tube = 30 days' supply
- D. A and B





Audit Issues Leading to Largest Recoupments

Drug Procurement

Prior Authorization Integrity

Dispense in the Original Container

Telemedicine

Template Forms

Refill too Soon





1. Drug Procurement

LS1

NABP Accredited Drug Distributor

Licensed as a Wholesaler

Authorized Distributor of the Manufacturer (diabetic testing supplies)

Pharmacy to Pharmacy Marketplace Transactions





Slide 42

LS1 Please mention product verification as a failsafe / Step #1 in suspect product investigation. Every package has a serialized product identifier that the manufacturer must respond to dispenser verification requests in 48 hours. Pharmacies need to be able to do this electronically or have documentation that shows progress towards being able to do this by November 2026 https://www.fda.gov/media/179256/download?attachment Lisa Schwartz, 2025-05-27T17:11:13.869

GU1 0 I am happy to mention

Guest User, 2025-06-04T18:29:26.746

2. Prior Authorization Integrity

Most PBMs have language prohibiting the pharmacy from completing a prior authorization on behalf of a prescriber

- OptumRx will allow pharmacies to assist with prior authorizations if the pharmacy acquires an "appointment of representation"
- Express Scripts if the prescriber has authorized the Network Provider to assist in completing the PA on its behalf (must be in writing)





3. Dispense in Original Container

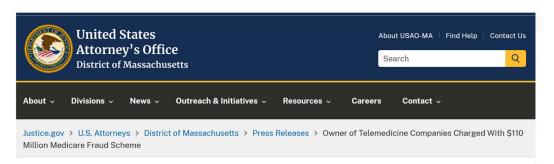
- Per the manufacturer's [FDA approved] labeling and package insert
- Approved language is not always clear
 - Store in the original container
 - Store and dispense in the original container
- Targeted Drugs include:
 - Linzess
 - Pancreatic Enzymes
 - Antiretroviral medications





4. Telemedicine

- Valid patient/prescriber relationship
- Prescriber licensed in state patient is located in
- Prescriber's scope of practice
- Proximity between patient, prescriber and pharmacy



PRESS RELEASE

Owner of Telemedicine Companies Charged with \$110 Million Medicare Fraud Scheme

Friday, February 16, 2024

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U.S. Attorney's Office. District of Massachusetts





5. Template Forms

- PBM Concern about pharmacy soliciting prescriptions and influencing prescriber
 - Small list of high AWP items, pain/scar compounds
 - Not individualized medicine identical quantities, sig and refills
- Cascading or overly broad substitution language
- 2025 OptumRx Provider Manual, Version 2.1:
 - Dispensing or distributing Prescription Drugs/Drug Products which are not based on valid prescriptions for individually identified Members or are otherwise on pre-populated or templated prescriptions is prohibited.





6. Refill Too Soon for Unbreakable Packages

- PBMs often force the pharmacy to submit a value less than the actual day's supply
 - For example, calculated DS is 80 days, but plan limit is 30 days
- Audit risk for refilling the prescription before the plan defined utilization threshold has been reached for the <u>actual</u> days' supply





6. Refill Too Soon for Unbreakable Packages

- PBMs know the first days' supply adjudicated (80) is likely the accurate DS (even though the plan limit required is different), so when looking for claims to audit, PBMs will take the 80 days and multiply it by the utilization threshold to identify claims that are potentially 'refill too soon'
 - This can lead to refills being fully recouped
- Targeted drugs include: Insulin/GLP-1, Topicals, Inhalers and Eye Drops





Which of the following is likely to lead to the largest audit recoupments?

- A. Procuring drugs from inappropriate sources
- B. Failing to have Proof of Copay Collection
- C. Mailing prescriptions out of state
- D. Invalid day's supply





Which of the following is likely to lead to the largest audit recoupments?

A. Procuring drugs from inappropriate sources

- B. Failing to have Proof of Copay Collection
- C. Mailing prescriptions out of state
- D. Invalid day's supply





Engaging Your Team



1. RX DROP OFF



4. VERIFICATION



2. DATA ENTRY



5. CASHIER



3. FILLING



6. OTHER SUPPORT STAFF/MANAGERS





Prescription Drop Off



Verify apparent alterations



Clarify "use as directed" for insulin or topicals with prescriber

Implement Rx scanning if possible



Suggested *Clinical Note* Format:

- 1. Who you spoke with
- 2. When you spoke
- 3. What was discussed
- 4. Who made the note





Data Entry

Quantity	 Verify correct NCPDP billing unit (EA, GM, ML) Quantity unit of measure is present/appropriate for eRx Some products must be dispensed in original container 	
Day's Supply	 Must be calculable based on quantity and SIG Call PBM help desk for override if the smallest option is an unbreakable packages 	
DAW Codes	1. Only submit if supported by documentation	





Filling



Match 11-digit NDC on stock bottle against billing label



Confirm quantity prepared matches billing label

If time allows spot check DAW, Day Supply, Origin Code





Verification

Match	Match the 11-digit NDC on the stock bottle against the billing label using barcode technology, if possible
Check	Double-check the days' supply estimate as per documented calculations • Pay close attention to insulin, GLP-1s, and vaginal creams
Verify	Verify additional Data Entry elements such as DAW, SIG, and Origin Code • Suggest adding elements to the "backtag" if doing paper verification





Cashier





Purchasing Manager







Other Support Staff/Manager



Create reports to audit high risk claims (e.g., DAW 1, days' supply for targeted products)



Review adherence to Return to Stock procedures Ensure Proof of Delivery and Copay Collection are available and retrievable, in accordance with PBM requirements



Incorporate audit training and prevention strategies for all staff





Which of the following audit prevention strategies helps engage your team for audit success?

- A. Data entry technicians ensuring there are calculable directions
- B. Filling technicians matching to an 11-digit NDC
- C. Purchasing manager assuring drugs are procured from appropriate sources
- D. Cashiers collecting signatures and copays
- E. All of the above





Which of the following audit prevention strategies helps engage your team for audit success?

- A. Data entry technicians ensuring there are calculable directions
- B. Filling technicians matching to an 11-digit NDC
- C. Purchasing manager assuring drugs are procured from appropriate sources
- D. Cashiers collecting signatures and copays
- E. All of the above





Questions?



NCPA® NATIONAL COMMUNITY PHARMACISTS ASSOCIATION Trenton Thiede PharmD, MBA President, PAAS National[®] trent@paasnational.com 608-873-1342

