



# Preparing Your Team for PBM Audits in 2025

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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
	Opioid Epidemic
	Contractual Requirements
术	Fraud, Waste & Abuse
<u> </u>	Common Billing Errors
	Data Analytics/Outliers
000	PBM Revenue Source = \$\$\$

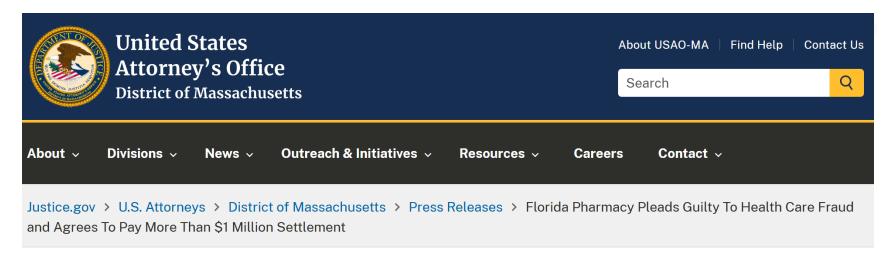




000	Financial Recovery
	Corrective Action Plans
<b>-</b>	Network Termination
S	Reputation
	License
	OIG Exclusion
	Fines
	Prison







#### **PRESS RELEASE**

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

Thursday, April 10, 2025

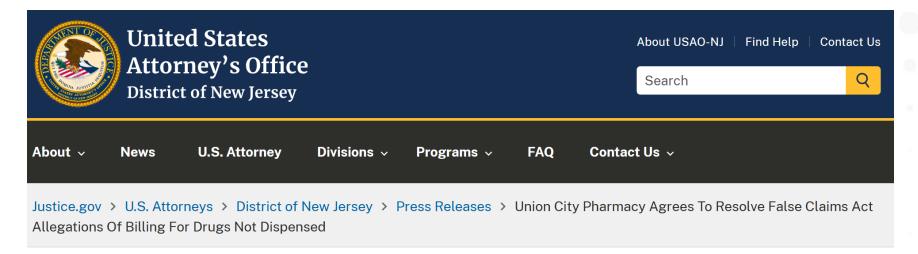


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U.S. Attorney's Office, District of Massachusetts







#### **PRESS RELEASE**

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



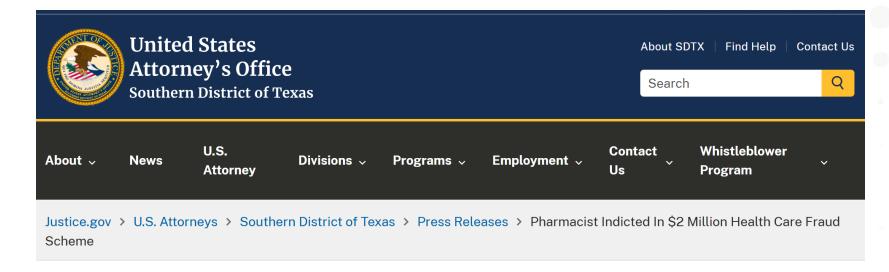




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U.S. Attorney's Office, District of New Jersey





#### **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





#### **PRESS RELEASE**

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







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%





### **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
    - Generally, 1-unit increments
    - Exceptions:
      - Humalog® Junior KwikPen (0.5 unit)
      - Toujeo<sup>®</sup> MAX SoloStar<sup>®</sup> (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 <u>June Jones (DOB 9/27/62)</u> Date <u>01/05/2025</u>

Address 123 Main St, Pharmtown, WI 55221



Lantus Solostar U-100

15 mL

Take 10 units SubQ at bedtime

Refills: 12

Dr. Dia Betes (NPI: 1234567)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221



#### 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



Lantus Solostar U-100

30 mL

Inject 30 units SubQ nightly at bedtime

Refills: \_11\_

Dr. Sue Gar (NPI: 1256891)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221





#### Insulin Example

- Toujeo<sup>®</sup> 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!

For Sam Walters (DOB 8/5/62) Date 02/05/2025

Address 222 N. South St, Pharmtown, WI 55221



7oujeo Max Solostar

#1 box

Inject 57 units SQ at bedtime

Refills: 11

Dr. Sue Gar (NPI: 1256891)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221





#### GLP-1s

- Common pitfalls
  - Quantity

- Directions
- Unit of measure
- Days' supply
- Ozempic<sup>®</sup> 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<sup>®</sup> 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
    - $2 \text{ mg} \div 0.5 \text{ mg dose} = 4 \text{ doses}$
    - 4 doses x 1 dose/week = 4 weeks (28 DS)

For <u>Ray Sun (DOB 11/5/70)</u> Date <u>01/05/2025</u> Address 356 N. Fourth St, Pharmtown, WI 55221

 $P_X$ 

Ozempic 2 mg/3 mL

3 mL

Inject 0.25 mg SubQ once weekly x 4 weeks, then increase to 0.5 mg weekly thereafter

Refills: 11

Dr. Sue Gar (NPI: 1256891)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221





What about 0.25 mg SQ weekly, without the increase?

- Confirm dose with prescriber and document
- Use the 2 mg/3 mL pen which can deliver the 0.25 mg dose
- $2 \text{ mg} \div 0.25 \text{ mg per dose} = 8 \text{ doses}$
- 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 <u>Ray Sun (DOB 11/5/70)</u> Date <u>01/05/2025</u> Address <u>356 N. Fourth St, Pharmtown, WI 55221</u>

P<sub>X</sub>

Ozempic 2 mg/3 mL

3 mL

Inject 0.25 mg SubQ once weekly

Refills: 11\_

Dr. Sue Gar (NPI: 1256891)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221



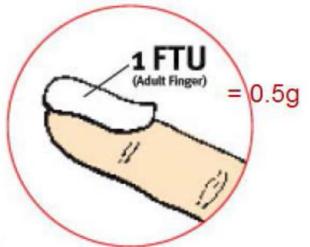
- Submit accurate days' supply (DS) if possible
- Mathematical instructions for use
  - Grams per application (if one area only)
  - Max Daily Dose per MD or expected day supply
  - List of affected areas + Finger Tip Unit (FTU) Method
- Collagenase use manufacturer dosing calculator





Finger Tip Unit (FTU) Method

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



<b>Body Surface</b>	# 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



#### Vaginal Creams

- Submit accurate days' supply, when possible
- Directions must include grams/application and frequency
  - 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
  - ½ 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 <u>Sue Zee (DOB 3/7/33)</u>

Date 07/05/2024

Address 523 James Way, Pharmtown, WI 55221



Premarin Vaginal cream

30 grams

AAA twice weekly

7/5/24 - Jay RN states insert half

applicatorful vaginally twice

Refills: 4

weekly. SH

Dr. Jean Jones (NPI: 1556363)

Address: 74 Park Place, Pharmtown, WI 55221

Phone: 555-863-5439



### 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"
  - CVS/Caremark® 15 drops/mL
  - Express Scripts<sup>®</sup> 16 drops/mL
  - OptumRx® 15-20 drops/mL
- Manufacturer guidance Miebo®, Vevye® and Vyzulta®





### 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







### 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 a 30-day period	8 each
	Preventative treatment	75 mg every other day		200 mg/24 hours and no	
Ubrelvy tablets	Acute treatment	50 mg or 100 mg	Yes, at least 2 hours after initial dose	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?

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#### **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



NABP Accredited Drug Distributor



Licensed as a Wholesaler



Authorized Distributor of the Manufacturer (diabetic testing supplies)



Pharmacy to Pharmacy Marketplace Transactions





# 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



Friday, February 16, 2024

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#### 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
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# **Engaging Your Team**







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	1. Verify correct NCPDP billing unit (EA, GM, ML)
	2. Quantity unit of measure is present/appropriate for eRx
	3. Some products must be dispensed in original container
Day's Supply	<ol> <li>Must be calculable based on quantity and SIG</li> <li>Call PBM help desk for override if the smallest option is an</li> </ol>
	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



Conduct
Return to
Stock on a
regular basis



Obtain patient signature for Proof of Delivery



For mail, make sure Rx # is "tied to" carrier tracking ID #



Collect copays at dispensing, maintain proof



In-house charge accounts must have good accounting practices





# **Purchasing Manager**



NABP Accredited Drug Distributor



Licensed as a wholesaler



Authorized
Distributor of the
Manufacturer
(diabetic testing supplies)





# 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
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#### Questions?



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