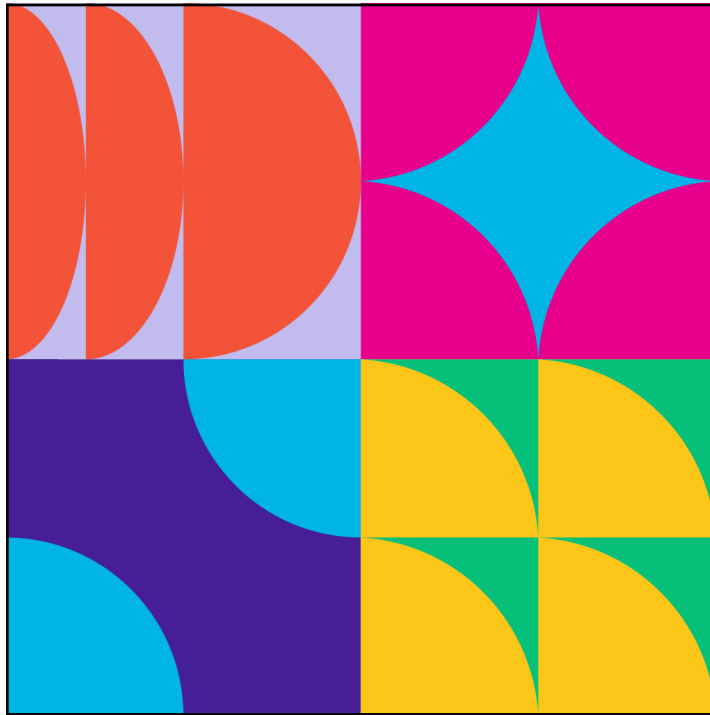




Staying Ahead of Compliance and Audit Hot Spots

Trenton Thiede, PharmD, MBA

ThoughtSpot | CEimpact 1

Description

Compliance missteps can quickly lead to costly audits. Step into an auditor's shoes to identify high-risk areas, documentation gaps, and key vulnerabilities. Apply practical safeguards to strengthen audit readiness and maintain consistent compliance in day-to-day operations.

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Meet the Faculty



Trenton Thiede, PharmD, MBA

President
PAAS National

Trent Thiede

Trent serves as President of PAAS National® (Pharmacy Audit Assistance Service), an organization dedicated to supporting the sustainability of community pharmacies nationwide through comprehensive audit guidance and active audit support. PAAS partners with over 8,000 community pharmacies across the United States and has reviewed more than 115K audits, helping these pharmacies avoid more than \$1.4 billion in PBM recoupments since 1993.

Disclosures

- Trenton Thiede has no relevant financial relationships with ineligible companies to disclose.
- Trenton Thiede discloses that AI tools were not utilized for this presentation.
- Brand names may be used as examples for educational purposes only. Their inclusion does not constitute endorsement, recommendation, or promotion of any specific product.

Funding for this course was provided by Cencora.

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Learning Objectives

Upon completion of this activity, learners should be able to:

- Recognize high-risk compliance and audit exposure areas affecting independent pharmacy practice, including LTC-at-home models of care.
- Differentiate documentation practices that strengthen audit defensibility from those that create risk.
- Analyze audit findings, reimbursement scenarios, and LTC-at-home documentation requirements to identify documentation gaps and appeal opportunities.
- Evaluate monitoring and documentation safeguards that strengthen compliance and audit preparedness.
- Prioritize two to three strategies to improve audit readiness and compliance without disrupting operations.

Why Are There So Many Audits?



Escalating Healthcare Costs



Opioid Epidemic



Contractual Requirements



Fraud, Waste, and Abuse



Common Billing Errors



Data Analytics/Outliers



PBM Revenue Source = \$\$\$

Why Are There So Many Audits?

THE AI JOURNAL

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Healthcare

America Spends \$5.6 Trillion on Healthcare and Wastes \$1.6 Trillion of It. AI Is Changing That.

By Jude Odu, Author, Model Optimal Care: End U.S. Healthcare Waste, One Health Plan at a Time | Founder, Health Cost IQ

A.I.J. AIJ Thought Leader 4 weeks ago 8 minutes read

Audit Penalties

	Financial Recovery
	Corrective Action Plans
	Network Termination
	Reputation
	License
	OIG Exclusion
	Fines
	Prison

Audit Penalties

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PRESS RELEASE

Pharmacy Technician Pleads Guilty to \$5.6M Health Care Fraud Scheme and Illegal Distribution of Oxycodone

Thursday, April 30, 2026

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Office of Public Affairs

Audit Penalties

The screenshot shows the official website of the U.S. Department of Justice Office of Public Affairs. The header includes the DOJ seal, the office name, and navigation links for 'Our Offices', 'Find Help', and 'Contact Us'. A search bar is located in the top right. Below the header is a dark navigation bar with links for 'About', 'News', 'Documents', 'Internships', 'FOIA', 'Contact', and 'Information for Journalists'. The main content area features a breadcrumb trail: 'Justice.gov > Office of Public Affairs > News > Press Releases > Queens Pharmacy Owner Sentenced To Over Five Years In Prison For Money Laundering Scheme'. On the left, a 'News' sidebar lists 'All News', 'Blogs', 'Photo Galleries', 'Podcasts', and 'Press Releases' (which is highlighted). The main headline reads 'Queens Pharmacy Owner Sentenced to Over Five Years in Prison for Money Laundering Scheme'. Below the headline, it says 'Friday, April 24, 2026' and 'For Immediate Release' from the 'Office of Public Affairs'. A 'Share' button is visible.

www.justice.gov/opa/pr/queens-pharmacy-owner-sentenced-over-five-years-prison-money-laundering-scheme

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The screenshot shows the official website of the United States Attorney's Office for the Western District of Kentucky. The header includes the DOJ seal, the office name, and navigation links for 'About WDKY', 'Find Help', and 'Contact Us'. A search bar is located in the top right. Below the header is a dark navigation bar with links for 'About', 'News', 'Meet the U.S. Attorney', 'Divisions', 'Programs', 'Jobs', and 'Contact'. The main content area features a breadcrumb trail: 'Justice.gov > U.S. Attorneys > Western District of Kentucky > Press Releases > Pharmacist Sentenced To 30 Months In Prison For Role In \$2M Health Care Fraud Scheme'. On the left, a 'PRESS RELEASE' label is visible. The main headline reads 'Pharmacist Sentenced to 30 months in Prison for Role in \$2M Health Care Fraud Scheme'. Below the headline, it says 'Friday, April 24, 2026' and 'For Immediate Release' from the 'U.S. Attorney's Office, Western District of Kentucky'. A 'Share' button is visible.

www.justice.gov/usao-wdky/pr/pharmacist-sentenced-30-months-prison-role-2m-health-care-fraud-scheme

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The screenshot shows the website of the United States Attorney's Office, District of New Jersey. The header includes the office's name and a search bar. The navigation menu has links for About, News, U.S. Attorney, Divisions, Programs, FAQ, and Contact Us. The breadcrumb trail reads: Justice.gov > U.S. Attorneys > District of New Jersey > Press Releases > Former Pharmacy President Sentenced To 24 Months In Prison For Health Care Fraud and Kickback Scheme Involving Compounded Medications. The main heading is "Former Pharmacy President Sentenced to 24 Months in Prison for Health Care Fraud and Kickback Scheme Involving Compounded Medications". The date is "Monday, April 20, 2026". A "Share" button is present. A box on the right says "For Immediate Release" and "U.S. Attorney's Office, District of New Jersey".

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District of New Jersey

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Justice.gov > U.S. Attorneys > District of New Jersey > Press Releases > Former Pharmacy President Sentenced To 24 Months In Prison For Health Care Fraud and Kickback Scheme Involving Compounded Medications

PRESS RELEASE

Former Pharmacy President Sentenced to 24 Months in Prison for Health Care Fraud and Kickback Scheme Involving Compounded Medications

Monday, April 20, 2026

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www.justice.gov/usao-nj/pr/former-pharmacy-president-sentenced-24-months-prison-health-care-fraud-and-kickback

Audit Penalties

The screenshot shows the website of the Office of Public Affairs, U.S. Department of Justice. The header includes the office's name and a search bar. The navigation menu has links for About, News, Documents, Internships, FOIA, Contact, and Information for Journalists. The breadcrumb trail reads: Justice.gov > Office of Public Affairs > News > Press Releases > California Man Pleads Guilty To Orchestrating \$270M Medication Reimbursement Fraud Scheme. The main heading is "California Man Pleads Guilty to Orchestrating \$270M Medication Reimbursement Fraud Scheme". The date is "Tuesday, April 7, 2026". A "Share" button is present. A box on the right says "For Immediate Release" and "Office of Public Affairs".

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California Man Pleads Guilty to Orchestrating \$270M Medication Reimbursement Fraud Scheme

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www.justice.gov/opa/pr/california-man-pleads-guilty-orchestrating-270m-medication-reimbursement-fraud-scheme

Audit Penalties

The screenshot shows the website of the United States Attorney's Office, Eastern District of Michigan. The header includes the office's name and a search bar. The main navigation menu lists various sections like About, News, Meet the U.S. Attorney, Divisions, Programs, Jobs, Contact Us, and DOJ Grant Information. The breadcrumb trail indicates the path: Justice.gov > U.S. Attorneys > Eastern District of Michigan > Press Releases > Business Owner Convicted of \$1.9M Medicare, Medicaid, and Private Insurer Fraud Scheme. The press release title is "Business Owner Convicted of \$1.9M Medicare, Medicaid, and Private Insurer Fraud Scheme". It is dated Tuesday, April 7, 2026. A "Share" button is visible. A box on the right states "For Immediate Release" and "U.S. Attorney's Office, Eastern District of Michigan".

www.justice.gov/usao-edmi/pr/business-owner-convicted-19m-medicare-medicaid-and-private-insurer-fraud-scheme

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The screenshot shows the website of the United States Attorney's Office, Middle District of Pennsylvania. The header includes the office's name and a search bar. The main navigation menu lists various sections like About, News, U.S. Attorney, Divisions, Programs, Jobs, and Contact Us. The breadcrumb trail indicates the path: Justice.gov > U.S. Attorneys > Middle District of Pennsylvania > Press Releases > Florida Man Pleads Guilty In Health Care Fraud And Kickback Scheme Involving "Foot Baths". The press release title is "Florida Man Pleads Guilty In Health Care Fraud And Kickback Scheme Involving 'Foot Baths'". It is dated Friday, April 3, 2026. A "Share" button is visible. A box on the right states "For Immediate Release" and "U.S. Attorney's Office, Middle District of Pennsylvania".

www.justice.gov/usao-mdpa/pr/florida-man-pleads-guilty-health-care-fraud-and-kickback-scheme-involving-foot-baths

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Audit Enforcement

NEWS

DOJ and HHS Form Working Group to Intensify Health Care Fraud Enforcement

Juliet Gallagher

07/02/2025



The US Department of Health and Human Services (HHS) and the US Department of Justice (DOJ) announced the formation of the DOJ-HHS False Claims Act (FCA) Working Group, a joint initiative designed to strengthen enforcement efforts against health care fraud. The False Claims Act has long been one of the most effective legal tools for addressing fraud, and this new working group formalizes a coordinated strategy to pursue high-priority violations.

www.hmpgloballearningnetwork.com/site/fmc/news/doj-and-hhs-form-working-group-intensify-health-care-fraud-enforcement

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Audit Enforcement



www.whitehouse.gov/presidential-actions/2026/03/establishing-the-task-force-to-eliminate-fraud/

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Audit Trends 2021 – 2025*

- 19% year-over-year increase in on-site audits
- Many invoice audits are completed in tandem with desk/on-site audits

	Desk	PVR	Virtual	On-site	Invoice
2021	67%	20%	11%	0%	2%
2022	67%	21%	5%	5%	2%
2023	51%	37%	1%	9%	2%
2024	49%	38%	1%	9%	3%
2025	45%	42%	1%	10%	2%

*Based on PAAS National® Audit Statistics
PVR: Prescription Validation Requests

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Top Audit Hot Spots

Days' Supply – Insulin/GLP-1s

Days' Supply – Topicals

Days' Supply – Eye Drops

Migraine Medications

LTC Pharmacy at Home

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Days' Supply

Insulin/GLP-1s

Topicals

Eye Drops

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Days' Supply – Insulin/GLP-1s

Insulin

- 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® Max SoloStar® (2 unit)
 - Tresiba® U-200 FlexTouch® (2 unit)
 - Humulin® R U-500 KwikPen® (5 unit)

Priming Units

Insulin: Priming Units

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

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

www.dailymed.nlm.nih.gov/dailymed

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Days' Supply – Insulin/GLP-1s

Insulin

- 1,500 units per carton
- Prescribed 2 cartons = 3,000 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

www.dailymed.nlm.nih.gov/dailymed

For James Smith (DOB 1/7/60) Date 01/05/2025

Address 3 S. Fourth St, Pharmtown, WI 55221

R_x

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

Phone: 555-867-5309

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Days' Supply – Insulin/GLP-1s

Insulin

- Toujeo® Max U-300
 - 2 pens per box; each pen is 3 mL
 - 1,800 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!

www.dailymed.nlm.nih.gov/dailymed

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

Address 222 N. South St, Pharmtown, WI 55221

R_x

Toujeo Max Solostar

#1 box

Inject 57 units SQ at bedtime

Refills: 11

Dr. Sue Gar (NPI: 1256891)

Address: 12 Sugarcreek Road, Pharmtown, WI 55221

Phone: 555-867-5309

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Days' Supply – Insulin/GLP-1s

GLP-1s: Common Pitfalls

Quantity

Unit of measure

Directions

Days' supply

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Days' Supply – Insulin/GLP-1s

GLP-1: Standard Dosing

- Initial fill
 - Billed as a 42 days' supply
 - 2 mg per pen
 - $0.25 \text{ mg per dose} \times 4 \text{ doses} = 1 \text{ mg used}$
 - $1 \text{ mg remaining} \div 0.5 \text{ mg dose} = 2 \text{ doses}$
 - $6 \text{ doses} \times 1 \text{ dose/week} = 6 \text{ weeks (42 days' supply)}$
- First refill
 - Billed as a 28 days' supply
 - Still using a 2 mg/3 mL pen
 - $2 \text{ mg} \div 0.5 \text{ mg dose} = 4 \text{ doses}$
 - $4 \text{ doses} \times 1 \text{ dose/week} = 4 \text{ weeks (28 days' supply)}$

www.dailymed.nlm.nih.gov/dailymed

For Ray Sun (DOB 11/5/70) Date 01/05/2025

Address 356 N. Fourth St, Pharmtown, WI 55221

R_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

Phone: 555-867-5309

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Days' Supply – Insulin/GLP-1s

GLP-1: What about 0.25 mg subcutaneously 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
- $2 \text{ mg} \div 0.25 \text{ mg per dose} = 8 \text{ doses}$
- $8 \text{ doses} \times 1 \text{ dose/week} = 8 \text{ weeks or } 56 \text{ days' supply}$
- Guidance:
 - Most PBMs require 56 days
 - Don't forget the pen needles!

www.dailymed.nlm.nih.gov/dailymed

For Ray Sun (DOB 11/5/70) Date 01/05/2025

Address 356 N. Fourth St, Pharmtown, WI 55221

R_x

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

Phone: 555-867-5309

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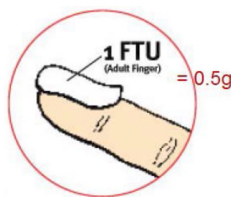
Days' Supply – Topicals

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

Days' Supply – Topicals

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

Days' Supply – Topicals

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
Estradiol (Estrace®) 0.01% vaginal cream	42.5 grams	1 to 4 grams (1-gram increments)
Conjugated estrogens (Premarin®) 0.625 mg/g vaginal cream	30 grams	0.5 to 2 grams (0.5-gram increments)

www.dailymed.nlm.nih.gov/dailymed

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Days' Supply – Topicals

- As is, this prescription does not have sufficient directions to mathematically calculate the days' supply
- Clarify + clinical note + update label
 - Sample script: 30 grams
 - $\frac{1}{2}$ applicatorful of Premarin® = 1 gram
 - $30 \text{ grams} \div 2 \text{ grams/week} = 15 \text{ weeks}$
 - $15 \text{ weeks} \times 7 \text{ days/week} = 105 \text{ days' supply}$
 - Plan limit? Watch refill interval!

For Sue Zee (DOB 3/7/33) Date 07/05/2024
Address 523 James Way, Pharmtown, WI 55221

Rx

Premarin Vaginal cream

30 grams

AAA twice weekly

7/5/24 - Jay RN states insert half applicatorful vaginally twice weekly. SH

Refills: 4

Dr. Jean Jones (NPI: 1556363)

Address: 74 Park Place, Pharmtown, WI 55221

Phone: 555-863-5439

www.dailymed.nlm.nih.gov/dailymed

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Days' Supply – Eye Drops

- Submit accurate days' supply 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® 16 drops/mL
 - OptumRx® 15-20 drops/mL
- Manufacturer guidance: brinzolamide/brimonidine tartrate (Simbrinza), cyclosporine (Vevye), latanoprostene (Vyzulta), loteprednol (Inveltys), netarsudil (Rhopressa), netarsudil/latanoprost (Rocklatan), and perfluorohexyloctane (Miebo)

Source: Respective PBM Provider Manuals.

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Migraine Medications

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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

Migraine Medications

Drug	FDA-approved indications	Recommended dose	Can patient repeat the dose?	Maximum daily dose	Billing unit per package
Dihydroergotamine mesylate (Migranal) nasal spray	Acute treatment	One spray in each nostril (must prime with 4 pumps prior to each use and discard 8 hours after priming)	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
Rimegepant (Nurtec) ODT tablets	Acute treatment	75 mg daily	No	No more than 18 doses in a 30-day period	8 each
	Preventive treatment	75 mg every other day			
Ubrogepant (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

LTC Pharmacy at Home

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LTC Pharmacy at Home

- CMS Requirements for pharmacies servicing LTC include:
 - Ability to provide IV medications
 - Compounding/alternative forms of drug composition
 - Pharmacist on-call service
 - Emergency boxes and logbook
 - Written LTC policies and procedures

LTC Pharmacy at Home

- Inventory transfers
 - Brands purchased under LTC group purchasing organization cannot be transferred/billed under retail NPI
 - Some exceptions exist for immunizations, long-acting injectables, and other physician-administered drugs

LTC Pharmacy at Home

- Billing multiple NPIs to the same payor
 - What is the pharmacy's rationale?
 - Recommend billing patient under one NPI
- Additional payers under a second NPI may be appropriate
 - OTCs under Medicaid
 - Medicare Part B

LTC Pharmacy at Home

- Residence Codes and Upcoding
 - Appropriate pharmacy service type and residence codes based on qualifications
 - Do not bill residence codes 03/04 when patient resides in their home
 - Make sure patients qualify for LTC Pharmacy at Home
 - Don't be overly aggressive

Active Learning Question #1

Which of the following is the best method for calculating days' supply on topicals?

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

Active Learning Question #1

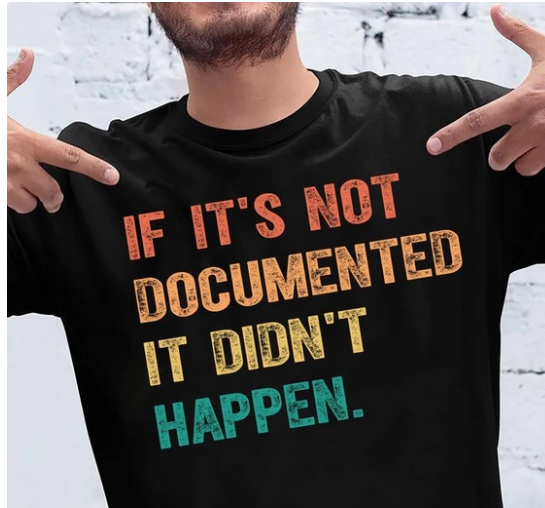
Which of the following is the best method for calculating days' supply on topicals?

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

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Documentation Practices That Strengthen Audit Defensibility

Clinical Notes and Prescription Annotations



Clinical Notes and Prescription Annotations

Four elements to prescription clarifications:

1. Date/time
2. Who you spoke with and their title
3. What you spoke about
4. Your initials

Electronically time/date stamped notes are ideal

Submission Clarification Codes

- Plan Specific Allowances for:
 - 03 – Vacation Supply
 - 04 – Lost/Damaged Prescription
- Example Clinical Note:
 - 7/28/2026 0800 – Spoke with patient Ms. Jones; she's traveling to Italy from 8/1 – 8/21, requested vacation supply of medication. TGT



DUR Codes

- Drug Utilization Review overrides must have supporting documentation
 - Professional service code “M0” requires consultation with the prescriber and a supporting clinical note
 - Consider other professional service codes, like “MR” (Medication Review) or “R0” (Pharmacist consulted other source)
 - PBMs know if DUR codes were adjudicated within seconds of the rejection that it's unlikely the pharmacy called and/or documented
- Example Clinical Note:
 - 7/28/2026 0800 – Spoke with patient Dr. Jones; patient is discontinuing semaglutide and transitioning to tirzepatide. TGT

Professional Judgement

- Auditors love ambiguity on prescriptions
 - They cannot consider professional judgement
 - They'll mark issues as discrepant, forcing the pharmacy to pursue appeals options, when available
 - Consider clarifying *expensive* professional judgement calls

Changes to Quantity Prescribed

Changes to the quantity prescribed should be documented

- Example Discrepancy Code List:
 - 2V – *Quantity – Undocumented quantity changed or altered – Full Recoupment*
 - When states allow 'accelerated refills,' document with state regulation
 - When dispensing a reduced quantity, PBMs can insinuate pharmacy is trying to avoid Extended Days' Supply (EDS) contract rates and/or collect additional dispensing fees
 - Document rationale for reducing quantity (e.g., patient request, med sync)

Active Learning Question #2

Which of the following is true about DUR rejections?

- A. Documentation is recommended, but not required
- B. Documenting the codes utilized is sufficient for audit purposes
- C. Documentation is only required for professional service code M0
- D. A complete clinical note is required for DUR overrides

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Active Learning Question #2

Which of the following is true about DUR rejections?

- A. Documentation is recommended, but not required
- B. Documenting the codes utilized is sufficient for audit purposes
- C. Documentation is only required for professional service code M0
- D. A complete clinical note is required for DUR overrides

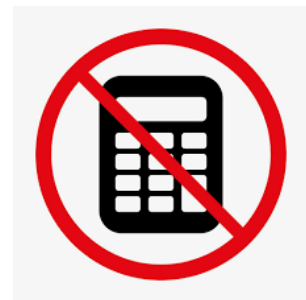
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Audit Findings, Reimbursement Scenarios, and LTC Pharmacy at Home Documentation

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Most Common Audit Hot Spots

- Days' supply discrepancies
- Refill too soon
- Non-calculable directions
 - Better to clarify on appeal –
mismatched SIG may be non-appealable



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Reimbursement Scenarios

- Billing for the appropriate NCPDP billing units
 - Enoxaparin
 - # of syringes versus mL
 - Zoster Vaccine Recombinant, Adjuvant
 - Vials (1 EA) versus syringes (0.5 mL)

LTC Pharmacy at Home

- Attestation qualifications and frequency
 - Barriers to activities of daily living (ADLs)
 - Three or more chronic diseases
 - Advise against 'overcategorization' of LTC Pharmacy at Home patients
 - Be sure to obtain patient qualification attestations, preferably from prescribers
 - Recommend 'renewals' at least every 6 months, based on patient circumstances

Active Learning Question #3

Best practice for renewing LTC Pharmacy at Home patient attestations is:

- A. Quarterly
- B. Every 6 months
- C. Only if there's a change in circumstances
- D. Whenever there's a change in circumstances, but at least every 6 months

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Active Learning Question #3

Best practice for renewing LTC Pharmacy at Home patient attestations is:

- A. Quarterly
- B. Every 6 months
- C. Only if there's a change in circumstances
- D. Whenever there's a change in circumstances, but at least every 6 months

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Mailing Compliance and Documentation

- Mailing prescriptions requires extra documentation:
 - Tracking # tied to Rx Number contemporaneously
 - Delivery confirmation obtained and retained
- Compliance Consideration:
 - Non-resident pharmacy license for out of state mailings
 - Some PBMs prohibit mailing under a retail agreement

Proof of Copay Collection

- PBM contracts require collection with **proof** (limited exceptions)
 - Credit card receipts need to include sufficient detail
 - Merchant reports may be required
 - Checks
 - Cash
 - Difficult to prove
 - Must be making regular deposits of cash into business account
 - Secondary payors



First-Party Charges / Accounts Receivable

- First-party charge accounts face additional audit or scrutiny
 - Insurers rely on copays/coinsurance for plan benefit design
 - Bad actors may use as an artifice to write-off copays
- Need detailed policies and procedures
 - How are accounts approved/established?
 - How often does the pharmacy send out invoices?
 - What happens after 60 days outstanding?
 - Are you documenting efforts to collect?
 - Financial Hardship requires documentation



Return to Stock Procedures

- PBMs want *accurate* Dates of Service
 - Prescriptions not picked up timely must be reversed
 - Utilize pick-up reminders (when available)
 - Some Point-of-Sale (POS) systems can prevent you from selling a prescription past the return to stock timeframes
 - Medicare Part B is an exception

Return to Stock Procedures

PBM	Return to Stock	Reference Source
Calendar Days		
TRICARE	10 calendar days	2024 ESI Network Provider Manual (revised 01/2024) Section 10.1.2 Page 91
Express Scripts®	13 calendar days	2024 ESI Network Provider Manual (revised 01/2024) Section 2.5 Page 8, Section 7.6 Page 55
Capital Rx	14 calendar days	Provider Manual December 2, 2024 v6 Section 12(b), Page 22
Caremark®		2024 Provider Manual Section 4.03 (12) Page 31
Livinit™		Pharmacy Services Manual Under "Pharmacy Provider Rights & Responsibilities" Page 9
MedImpact		Provider Manual 11014 Section 5.4 Page 18
MedOne		Pharmacy Provider Manual (revised 1/1/2026) page 10
Navitus		Pharmacy Provider Manual v20410 under "Claims – General" Page 39
OptumRx®		2025 Pharmacy Provider Manual First edition Version 1.1 Section V(R) Page 59
PDMI		Pharmacy Manual "Claim Submission Requirements" Page 15
Prime Therapeutics		January 2025 Provider Manual Section 4 Page 26
Serve You Rx		Follows OptumRx Provider Manual as of October 2023
WellDyne		WellDyne Pharmacy Provider Manual Version 21.1 Page 13, 21
Horizon NJ Health	15 calendar days	Horizon NJ Health/Conduent discrepancy code list "LSL" discrepancy June 2024
Script Care	30 calendar days	Pharmacy Agreement PPAIndVer20230209 Section 4(D) Page 3
Business Days		
MagellanRx	14 business days	Provider Manual Section 2.1.2.2 "Return to Stock" Page 14 (last viewed on 12-12-2024)
Humana®	15 business days	Humana Pharmacy Solutions Audit Guide Section 5.18 (last viewed 12-12-2024)

Source: PAAS National® and respective PBM Provider Manuals.

DAW 1

- Dispense as Written/Brand Medically Necessary prescriptions are frequently audited
 - State regulations typically dedicate requirements
 - Medicaid may have different requirements

447.512 (c) was updated years ago to allow for “an electronic alternative means approved by the Secretary”

(c) Certification of brand name drugs.

- (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under [§ 447.514](#) does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.*
- (2) The agency must decide what certification form and procedure are used.*
- (3) A check off box on a form is not acceptable but a notation like “brand necessary” is allowable.*

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www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.512

DAW 1

- When to use:
 - Multisource brand with available generics where the provider has expressly indicated
- Do not use for:
 - Single-source brands without a generic
 - Biologics without an interchangeable biosimilar
- Do not use in lieu of DAW 9
 - However, a DAW 1 *supersedes* a DAW 9 if both apply

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Active Learning Question #4

When mailing prescriptions,
best practice is to:

- A. Only mail in-state
- B. Use USPS
- C. Ensure the tracking # is tied to the Rx #
- D. Avoid high-cost prescriptions

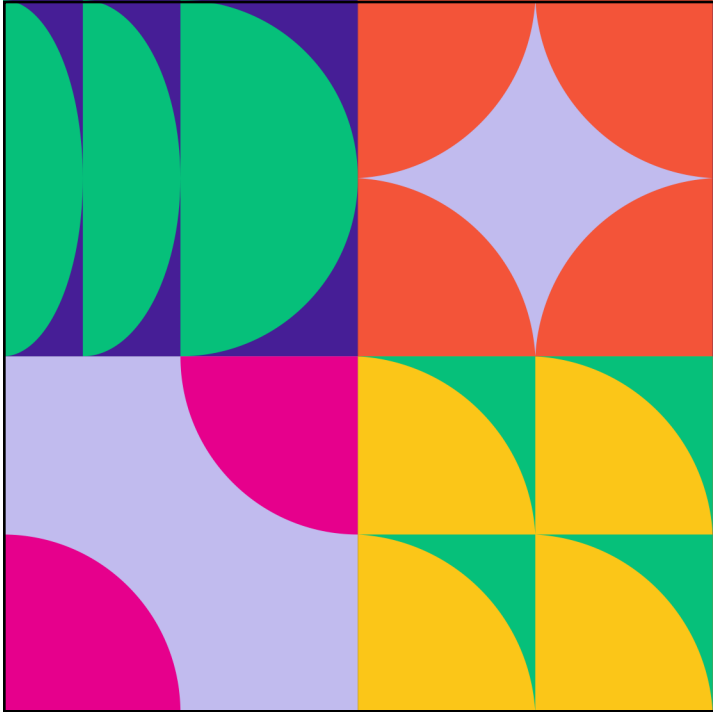
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Active Learning Question #4

When mailing prescriptions,
best practice is to:

- A. Only mail in-state
- B. Use USPS
- C. Ensure the tracking # is tied to the Rx #
- D. Avoid high-cost prescriptions

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Improve Audit Readiness and Compliance

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Drug Procurement



NABP Accredited Drug Distributor



Licensed as a Wholesaler



Authorized Distributor of the Manufacturer
(diabetic testing supplies)



Pharmacy to Pharmacy Marketplace Transactions

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Integrated POS System

- Proof of copay collection
- Signature capture for proof of delivery
- Ensure return to stock compliance

Barcode Scanning Technology

- Pharmacies are required to dispense the NDC billed
- Drug availability and consequential substitutions are rampant
- Helps prevent dispensing errors, maintains billing compliance
- Typically very cost effective

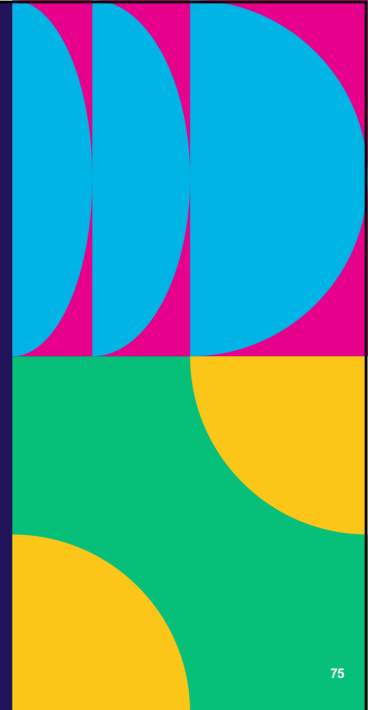
Key Takeaways

- Document clarifications, DUR overrides, and quantity changes consistently
- Strengthen audit preparedness through monitoring, tracking, and proof-of-service documentation
- Verify LTC-at-Home qualifications and maintain supporting attestations
- Ensure billing reflects what was dispensed and delivered
- Focus on systems and workflows that support compliance without disrupting operations

Top Audit Hot Spots to Monitor in Your Pharmacy

- ✓ Days' supply calculations
- ✓ DUR documentation
- ✓ Quantity changes
- ✓ LTC-at-Home qualification
- ✓ Mailing documentation
- ✓ DAW requirements
- ✓ Return-to-stock procedures

What will you do
differently tomorrow
as a result of this
session?



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Questions?