THE NEWSLETTER OF PAAS NATIONAL®
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**Monthly Edition**

# Newsline

HELPING COMMUNITY PHARMACIES GAIN CONFIDENCE AND PEACE OF MIND

**Additional *eNewsline* Content available on the PAAS Member Portal:**

- Can Pharmacists Continue to Fill Controlled Substance Prescriptions That Are NOT Sent Electronically for Medicare Patients?
- The NEW Inventory Transfer Log and Why it Could Save You Big!
- Mailing Prescriptions? How to Ensure Audit Success
- Keeping the Diagnoses Straight for GLP-1 Products
- Billing Ozempic® 0.25 mg Weekly as Maintenance – What PBMs Say
- Combo Shop Pharmacy Inventory Considerations
- Oral Inhalers – What You Need to Know About Institutional Pack Sizes

## Proof of Patient Consent for a Refill Request: What You Need to Know

If you are a DMEPOS supplier billing Medicare Part B claims, then you should be familiar with the proof of refill request requirement. All DMEPOS items and supplies billed to Medicare Part B that are delivered or mailed require proof of refill request and an affirmative response to occur and be documented prior to shipment. PAAS National®'s Proof of Refill Request and Affirmative Response for DMEPOS Items form can be downloaded from the Portal.

For non-Part B claims, many PBM provider manuals include language requiring pharmacies to obtain (and retain) proof of member consent prior to delivery. However, enforcement of this requirement is often at the PBM's discretion (i.e., variable). These policies, at least in part, originate from the 2020 CMS Call letter revisions concerning Part D Mail Order Auto-Ship Modifications. While PBM requests are uncommon, they may ask pharmacies to provide "proof of patient consent to refill" during audits– often catching pharmacies off guard. When PAAS National® sees this request, there is typically an underlying reason and it is a seemingly effortless way for the PBMs to recoup claims if the pharmacy does not have the proof. PBM audit algorithms are looking for Fraud, Waste and Abuse conducted by bad actors and will use data analysis as a reason to audit suspicious claims. See the PAAS Tips for potential reasons why a PBM may ask for proof of refill request upon an audit, and how to ensure compliance of an automatic refill or medication synchronization program.

*See our eNewsline for PAAS Tips*

## From Headache to Hassle Free: Best Practices in Migraine Medication Billing

Migraine medications continue to be targeted for audit by all PBMs. With new products on the market, rising costs, and frequency of refills, PBMs are looking for billing errors to claw back payments on audit.

OptumRx's latest tactic is flagging migraine medications as *1N-Incorrect Days Supply: Submitted Days' Supply on Claim is Incorrect. Prior Authorization Required for Correct Days' Supply*. The auditor has calculated the days' supply strictly based on the prescription instructions, without accounting for the fact that the medication is prescribed to be taken as needed. Consider the following example:

Prescription is written for Ubrelvy® 100 mg, #16 tablets. Instructions are to take 1 tablet at onset and repeat in 2 hours if needed. Pharmacy billed this claim as a 30-day supply based on a plan limit rejection (when the pharmacy billed #16 for a 8 days' supply); however, the auditor also calculated the days' supply to be 8, and stated this prescription, as written, would require a PA.

PBMs simply don't allow pharmacists to use their professional judgement to determine the days' supply. Prescribers should be contacted to obtain the specific number of headaches per week/month they anticipate the patient to treat, or the maximum number of tablets the patient may use per week/month. This information should be obtained prior to dispensing, documented on the prescription, and included on the patient label.

Injectable, maintenance migraine medications have their own set of audit risks. Pharmacies must bill the days' supply according to the exact instructions. If the patient is to inject "monthly", the claim should be billed as a 30-day supply. When the patient is injecting "every 4 weeks," the claim should be billed as a 28-day supply. While you may not think two days can make a difference, understating the days' supply can create an opportunity for the PBM to argue a refill was too early.

**PAAS Tips:**

- Obtain utilization (headache frequency or maximum dosing over time) information directly from prescribers - patient notes are often not accepted by PBMs
  - ◊ Update the patient label accordingly
- A complete clinical note should include:
  - ◊ Date and time
  - ◊ Name and title of individual providing information
  - ◊ Specific information clarified
  - ◊ Pharmacy staff initials
- As needed migraine medications should only be refilled upon patient request

## The Next Big Wave: Anticipating a Surge in HIPAA Compliance Audits

Desk audits, onsite audits, invoice audits…and HIPAA compliance audits?! Unfortunately every community pharmacy has some familiarity with third party payor audits, and PAAS National® audit analysts bring their expertise to guide members through the entire audit process, ensuring everything goes as smoothly as possible.

But what about HIPAA compliance audits? With a potential surge in these audits on the horizon, it is important for covered entities (i.e., pharmacies) to evaluate their HIPAA compliance policies and procedures to fortify their program.

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You may ask, "*Why are these audits being performed*?". The Health Information Technology for Economic and Clinical Health (HITECH) Act requires that the Department of Health and Human Services (HHS) conduct periodic HIPAA audits, submit an annual report to Congress on HIPAA compliance, and provide annual guidance on the most effective technical safeguards for meeting Security Rule requirements. The Office for Civil Rights (OCR), within HHS, is tasked with overseeing these responsibilities. To verify OCR was performing their respective duties, the Office of Inspector General (OIG) performed a review of OCR's HIPAA compliance audit process.

According to the OIG November 2024 brief, *"OCR fulfilled its requirement under the HITECH Act to perform periodic HIPAA audits. However:*

- *OCR's HIPAA audit implementation was too narrowly scoped to effectively assess ePHI protections and demonstrate a reduction of risks within the health care sector. Specifically:*
  - ◊ *OCR's audits consisted of assessing only 8 of 180 HIPAA Rules requirements; and*
  - ◊ *Only 2 of those 8 requirements were related to Security Rule administrative safeguards and none were related to physical and technical security safeguards.*
- *OCR oversight of its HIPAA audit program was not effective at improving cybersecurity protections at covered entities and business associates."*

**OIG recommended OCR increase the volume and breadth of their audits to raise their assurance that covered entities (like pharmacies) and business associates have complied with the Security Rule.** OIG stated these audits will also help OCR provide covered entities with more opportunities to strengthen their security over ePHI.

Since HIPAA compliance audits may be in your future (along with Security Rule updates), now is a great time to evaluate your HIPAA compliance program to get a good handle on where your vulnerabilities are, what threats you have and the risk of those threats. If you're not sure where to start, check out the PAAS FWA/HIPAA Compliance Program!

**PAAS Tips:**

- Understand the components and importance of a HIPAA Security Risk Analysis
  - ◊ Perform an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the pharmacy's ePHI
  - ◊ Identify and implement reasonable and appropriate physical, technical, and administrative safeguards as required by the HIPAA Security Rule
- PAAS' FWA/HIPAA Compliance Program members have access to:
  - ◊ Update their HIPAA Risk Analysis
  - ◊ Complete annual Cybersecurity training on the Member Portal
  - ◊ Policies and procedures to comply with HIPAA Privacy, Security and Breach Notification rules
  - ◊ Contingency Planning and Preparedness

## USP 800 Compliance Program Updates: NIOSH 2024 List

USP 800 outlines the standards for healthcare providers that handle hazardous drugs, as defined by the National Institute for Occupational Safety and Health (NIOSH). Pharmacies that handle hazardous drugs (including carbamazepine, clonazepam, colchicine, and cyclosporine – these are just a few of the "C" drugs – there are over 400 unique drug/dosage forms in all that must be considered) should have a list of all hazardous drugs in their pharmacy, specific policies and procedures on how they will receive, store, and dispense these drugs, and provide staff training on specific policies and procedures. Pharmacies are also required to label the hazardous drugs to ensure staff are aware of occupational risks. Additionally, an "assessment of risk" must be performed and documented for each unique hazardous drug and dosage form to determine appropriate safety measures and minimize exposure.

## USP 800 Compliance Program Updates (cont.)

NIOSH recently released the updated *2024 List of Hazardous Drugs in Healthcare Settings* in December 2024. This list replaces the previously official 2016 list and must be incorporated into the USP 800 compliance programs for all healthcare entities as soon as possible.

PAAS National®'s USP 800 Compliance Program has been updated to incorporate these changes and pharmacies utilizing the PAAS program should perform the following steps to maintain compliance:

1. Review the drug inventory for currently defined hazardous drugs using the PAAS' Master Hazardous Drug formulary
2. Review and finalize your Assessments of Risk and ensure staff are using these updated versions
3. Review the updated Program Guide and print an updated Policy and Procedure Manual
4. Educate staff about the NIOSH 2024 List changes. PAAS' USP 800 Training module has been updated to reflect these changes, and quiz competency can be reset, if desired.

**PAAS Tips:**

- Numerous entities can have oversight/enforcement of USP 800 including state boards of pharmacy and OSHA
- Pharmacies may be prompted to provide USP 800 policies and procedures to NCPDP during annual re-credentialing
- Pharmacies interested in a turnkey USP 800 Compliance Program should view the PAAS National® website or call (608) 873-1342

## OptumRx® Continues to Pocket More Money from Days' Supply Issues

OptumRx® continues to maximize chargebacks on pharmacies due to days' supply errors. It's important to take the extra time to confirm billing elements are accurate prior to adjudicating – this could save you on the back end of an audit. The following is a common chain of events that happens when a pharmacy submits an incorrect days' supply on a claim under audit.

OptumRx® will flag the initial fill of the prescription with an invalid days' supply (1N) discrepancy and subsequently re-adjudicate the claim with the correct days' supply. If the correct days' supply increases the patient's copay, the pharmacy will see the copay difference as a recoupment. For example, an inhaler was billed with a 30-day supply and had a $20 copay, but it should have been billed as a 60-day supply (assuming no days' supply limitation) and would have had a $40 copay. The recoupment difference would be $20. However, OptumRx® does not stop here. Since they found a discrepancy on the claim under audit, they will continue to look at all associated refills over the life of that prescription. The interval of time between each fill will be scrutinized to see if the pharmacy has refilled the prescription too soon according to the accurate [60] days' supply. OptumRx® states in their provider manual on page 76 under Section H. Coverage Limitations,

> *"A Member may refill most Prescriptions when a minimum of seventy-five percent (75%) of the quantity is consumed based on the number of days supplied. This minimum quantity consumed amount is seventy percent (70%) for eye drops."*

In this example, let's say the prescription was refilled every 30 days with a total of 6 refills. OptumRx® will flag every other fill as a refill too soon (2Z) and charge back the full amount of the claim. Now the recoupment has gone from one incorrect days' supply to six incorrect days' supply (1N) and three refill too soon discrepancies, assuming the pharmacy never caught the error. This causes the recoupment to alternate between the patient's copay difference and the full claim, and this can add up very fast!

*See our eNewsline for PAAS Tips*

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