THE NEWSLETTER OF PAAS NATIONAL®
Editor: Trenton Thiede, PharmD, MBA

FULL VERSION ONLINE
PAASNATIONAL.COM

Monthly Edition

Newsline

HELPING COMMUNITY PHARMACIES GAIN CONFIDENCE AND PEACE OF MIND

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

- Bowel Prep Products – What Quantity and Days' Supply to Bill?
- Staying Compliant with House Charge Accounts
- Major PBMs Announce "Cost Plus" Pharmacy Networks
- 2024 Update: CMS Mandatory E-Prescribing Requirements for Controlled Substances – Final Rule
- Best Practices for DAW Billing in Pharmacies
- Tip to Federal Agents Leads to Jail Time for Pharmacy Owner
- Caremark Bulk Purchase Notification
- 2024 Fraud, Waste & Abuse and HIPAA Compliance Program Updates

Dosing Increments for Insulin Pens

While insulin pens allow ease and convenience for diabetic patients, they also come with increased audit risks, for a variety of reasons, including dosing.

Prescribers are often unaware of what each insulin pen is capable of dispensing. Pharmacies must be hypervigilant of possible instructions that the insulin pen would not be able to deliver. Clinically, the patient would not be able to receive the prescribed number of units, and an audit discrepancy could be flagged. Appealing these types of discrepancies can often be very difficult.

While most insulin pens can be dialed in 1-unit increments, this is not the case for all pens. There are strengths of insulin pens that can only be dialed in 0.5-unit, 2-unit and 5-unit increments. Prior to dispensing these exceptions, the pharmacy must ensure the instructions for use are administrable with the pen prescribed. If the directions don't coincide with the dosing increments (e.g., 57 units of Tuojeo® Max Solostar®), contact the prescriber for a correction.

Insulin	Dosing Increments
Humalog® Junior KwikPen®	0.5 units
Toujeo® Max Solostar®	2 units
Tresiba® Flextouch® 200units/mL	2 units
Humulin® R U-500 KwikPen®	5 units

See our eNewsline for PAAS Tips

Be Conscientious When Refusing to Dispense (or Bill Insurance)…

No pharmacy should be forced to dispense prescriptions below their acquisition cost. With the effective date of the CMS Final Rule regarding DIR fees in 2024, we suspect that pharmacies will see an increased number of prescriptions paid below cost and PAAS National® wants to support you and help you steer clear of PBM scrutiny, where possible.

While there are many states that allow pharmacies to refuse dispensing below their acquisition cost, this typically only applies to commercial claims (including ERISA, thanks to Rutledge v. PCMA). The decision was made not to pursue Medicare Part D preemption in the Rutledge case, so state laws may be harder to enforce with PBMs on Part D (and Medicaid) claims underwater – but we still recommend pushing the issue with the PBMs. On generics, make sure you're filing MAC appeals, even it feels like it falls on deaf ears. PAAS also recommends complaining to your respective insurance commissioner or PBM oversight entity – if they're not hearing complaints from pharmacies, they think regulations are working.

In talking with pharmacy owners across the country, we know many pharmacies are refusing to dispense GLP-1 agonists. Not only is supply sporadic, but WAC discounts from wholesalers are lacking and pharmacies are seemingly losing money with every dispense (not to mention the potential audit risk– see December's Newsline *Zepbound Means Decreased Audit Risk…Right?*).

PBMs will not (knowingly) contract with a pharmacy who is refusing to dispense a medication (outside of state law allowances); however, there are a few provisions when a pharmacy can adhere to PBM Provider Manuals while refusing to dispense:

1. Prescription does not meet legal requirements.
2. Prescription is fraudulent.
3. Prescribed medication may cause a patient safety concern and pharmacist exercises their professional/clinical judgment (including when products are prescribed for off-label uses).
4. Medication is out of stock or unavailable

Ozempic® and Mounjaro® being prescribed for off-label use is an acceptable method for refusing to dispense - however difficult that conversation with the patient might be. Don't feel obligated to dispense the Type II Diabetes (T2DM) products if Wegovy® or Zepbound® are unavailable; it's an audit risk and likely not worth your trouble. Refusing to dispense GLP-1s for T2DM when supply is available is a slippery slope. Telling patients you can't dispense the medication because of reimbursement might turn them into your advocate – and work against you at the same time.

There are numerous situations that may alert a PBM to a network pharmacy's refusal to bill insurance; some bring more scrutiny than others.

- Loyal patients that leave the pharmacy without medication may call their PBM to advocate for the pharmacy to be paid more so they can receive their medication.
  Remember that certain PBM contract "gag clauses" are still in effect – while pharmacies are permitted to notify patients when your cash price is lower than the patient's copay, pharmacies are still generally prohibited from discussing PBM reimbursement.
- Patients that submit a receipt to their PBM for reimbursement as they paid cash at the pharmacy counter – particularly if the PBM can see a claim was paid and then reversed at the pharmacy.
- Patients may submit a receipt to their PBM because they were charged an additional amount beyond their copay (aka "balance billed") due to low reimbursement.

Consequences that may stem from a pharmacy's refusal to bill insurance may include a threatening PBM phone call, a "breach notification" letter requiring pharmacy to respond and attest that the violation will not be repeated, or potentially network termination (typically egregious situations).

See our eNewsline for PAAS Tips

160 Business Park Circle | Stoughton, WI 53589 | p: 608.873.1342 | info@paasnational.com

Insulin Substitution Review: Understanding Purple Book Terminology

PAAS National® frequently gets questions about whether pharmacies may substitute various medications and if such substitutions require the approval of the prescriber. For biological products, pharmacies can refer to the FDA Purple Book to identify biosimilarity and interchangeability.

Pharmacy level substitution of a reference product is only allowed if biologic drugs are either identified as (i) an *interchangeable biosimilar* OR (ii) an *unbranded biologic* with the same BLA number of a reference product. Importantly, unbranded biologics are NOT separately listed in the Purple Book as explained by FDA here (see FAQ #11). For biologic drugs that don't fall into these two categories, you must obtain prescriber approval prior to substituting.

Additionally, pharmacy level substitution is regulated at the state level. If you're unsure of your requirements, Cardinal Health has a great website to find biosimilar interchangeability laws for each state.

It is also important to understand the terminology used in the Purple Book as biologic products are not described in familiar terms like "brand", "generic" or "AB-rated" that most pharmacy staff have been trained on. Here is a short summary of the different terms:

1. **Reference product** is a single biological product approved under a *351(a) BLA*.
2. **Biosimilar** products are approved through an abbreviated BLA pathway under a *351(k) biosimilar* BLA.
3. **Interchangeable** biological products are biosimilar products that have been deemed interchangeable with a reference product after going through additional switching studies and are approved under a *351(k) interchangeable* BLA.
4. **Unbranded biologic** products are NOT listed in the Purple Book but are approved under the reference product's *351(a)* BLA.

Our eNewsline provides a translation from Orange Book terms to Purple Book terms to help staff recognize the nuances.

Below is an example of Insulin Lispo to better understand the relationship between various products that have a similar proper name and when pharmacies can (or cannot) substitute without prescriber approval (where allowed by state law). Our eNewsline also includes Insulin Glargine and Aspart examples and PAAS Tips.

Insulin Lispro

Proprietary Name	BLA Number	BLA Type	RPh Substitute*
Humalog®	020563	351(a) Reference product	Yes
Insulin lispro	020563	Unbranded biologic	Yes
Admelog®	209196	351(a) Reference product	No
Lyumjev™	761109	351(a) Reference product	No

**Where allowed by state law*

Cybersecurity Incident at Change Healthcare – Documentation is Key to Reducing Audit Risk!

Pharmacies are feeling the impact of the cyber-attack at Change Healthcare resulting in workflow nightmares. PAAS issued an email alert to members about audit risk on 2/23 (details contained herein). It is not clear, how many partners of Change Healthcare were affected and to what degree. Pharmacies are continuing to fill prescriptions, so it is important to be conscious of audit risk.

The following areas represent the greatest audit risk:

1. **Validity of faxed 'electronic' prescriptions**
   - If an e-Rx fails over to fax, that changes the origin of the prescription to fax. In many states, a physical, or digital, prescriber signature is required for faxed prescriptions. If required, be sure to document a call was made to the prescriber's office for validation.
2. **Refilling claims too soon**
   - Since pharmacies can't rely on real-time claim rejects, be careful not to refill prescriptions too early.
3. **Proof of delivery in relation to date of service**
   - When rebilling claims, backdate the date of service to the actual date the patient received the medication.
4. **Proof of copay collection**
   - If the copay estimated/billed during the outage is incorrect:
     i. Refund any overpayments to the patient via a trackable method
     ii. PAAS recommends the balance of any underpayments be put on a house charge account to document the rationale and potential attempts to collect, as appropriate.

PAAS has shared these concerns with NCPA, who is working diligently with CMS and PCMA to advocate against repercussions and recognize pharmacy sacrifices during this time.

PBM Prescription Validation Requests Rose 123% in 2023 – What You Need to Know

PAAS National® saw the number of validation requests/concurrent claim reviews more than double in 2023! OptumRx®, who conducts the majority of these reviews, discusses the Prescription Validation Request (PVR) in their pharmacy manual as follows:

Administrator conducts limited scope prescription validation reviews for quality assurance purposes ("PVRs"), which are distinct from and are not considered audits. PVRs are utilized to verify the accuracy and validity of prescription claim submissions. Claims are monitored daily for appropriateness and potential billing errors and selected for review prior to payment. Network Pharmacy Providers are typically contacted via fax or email and asked to provide photocopies of specific documents and records related to its claims submitted to Administrator.

While they want to skirt audit laws by not calling them an audit, make no mistake – they are audits, and payment is at stake! Besides OptumRx®, we also see claim reviews from Caremark®, Express Scripts®, Humana®, MagellanRx, MedImpact and Prime Therapeutics. Below you can see the top 5 drugs reviewed in 2023 and the top 5 concerns after reviewing each claim.

Top 5 drugs reviewed in 2023:

- Lantus®
- Humalog®
- Creon®
- Levemir®
- Invega®

The top 5 concerns:

1. Black out acquisition cost and/or profit margin values on the pharmacy backtag
2. Document the reason for the cut quantity – auditor will want to know why the pharmacy dispensed less than what was prescribed
3. A clinical notation is needed and requires 4 elements: Date, who you spoke with and their title, what they confirmed and the pharmacy employee initials
4. No backtag/sticker attached, typically requested by the PBM and also helpful for PAAS in order to review the billing elements
5. Verify the quantity prescribed and make a clinical notation on the hard copy – Unit of Measure (UOM) is not specified or doesn't make sense for the medication ordered

See our eNewsline for PAAS Tips