Updated Dispense in Original Container Chart

Medications that are required to be dispensed in their original containers continue to appear in audits. Billing for a quantity that is not divisible by the full bottle size is a red flag to the PBM and, unfortunately, easily recoupable. Many of these products are sensitive to light/moisture or have only been studied under storage in their original container, thus, removing them from the original package may cause stability and potency issues. Product labeling can be obtained from the FDA’s DailyMed website, which was referenced by PAAS National to update the Dispense in Original Container chart under the Tools & Axis section of the PAAS member portal.

For example, PAAS analysts have seen an increase in questions regarding Truvada® for HIV post-exposure prophylaxis (PEP). Prescribers are issuing scripts for 28 days to follow the PEP treatment guidelines by the CDC, but one of the drugs included in the CDC 28-day PEP treatment regimen is Truvada®, which comes in 30-count bottles with labeling to “dispense only in original container.” PAAS cannot recommend dispensing outside of FDA guidelines and advises the pharmacy to obtain authorization from the prescriber to dispense the full bottle.

Additionally, pharmacies dispensing to nursing homes or providing medication packaging to patients in the retail pharmacy setting must also follow the FDA guidelines to dispense in the original container.

PAAS Tips:
- Print and display a copy of the PAAS National Dispense in Original Container chart near the billing station.
- Place labels on the shelf by products required to be dispensed in their original container.
- Only bill these products for quantities divisible by the full bottle size to decrease audit risk.
- If necessary, contact the prescriber for authorization to change the prescribed quantity to facilitate dispensing in the original container and document the change with a clinical note.
- Contact PAAS with concerns or for further clarifications.

Pitfalls of Transferred Prescriptions

Transferred prescriptions are at high risk for audit recoupments. Every element required by state regulations is one additional pitfall that PBMs utilize to try and recoup on claims. These prescriptions are easily identified due to their origin code. The NCPDP Telecommunication Version D section 3.1.4 explains that an origin code of S is utilized for any pharmacy-created prescription, which includes when pharmacists have authority to prescribe, when dispensing off a protocol and for prescriptions transferred in.

PAAS National analysts frequently see audit results with recoupments for:
- Missing transfer elements – always double check your transferred prescriptions against your state’s transfer requirements to avoid these recoupments. Contact PAAS (608) 873-1342 or info@paasnational.com if you need assistance obtaining a copy.
- Original written date – claims may be flagged as invalid when the written date is input incorrectly as the transfer date. Additionally, entering an incorrect written date could cause the pharmacy to accidentally dispense the medication after the legal expiration date.
- Central file – pharmacies that share a central file appear to be the newest pitfall with transferred scripts. Prescription data is maintained on one system for pharmacies under common ownership and the software allows for seamless sharing of information. This makes prescription transfers more efficient as the data is visible by all pharmacies on the shared system and a prescription can be pulled to a new location with a few keystrokes. However, pharmacies have seen hefty recoupments during audits for missing transfer information by not providing sufficient data to show all transferred elements or common ownership and proof of a central file. PAAS has successfully assisted pharmacies facing recoupment for this issue and have already saved these members over $230,000.

(Continued on back)
Pitfalls of Transferred Prescriptions (cont.)

**PAAS Tips:**
- Review state transfer regulations
  - Ensure staff involved in taking, giving, and billing transferred prescriptions are familiar with the required elements of a valid transfer in your state
  - Create transfer Rx blanks with all required elements
- Routinely perform a self-audit for prescriptions with an origin code of 5 and check hardcopies for accuracy

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**FWA and HIPAA Compliance with Job Shadows and Interns**

Students performing a job shadow or internship in the pharmacy need proper FWA/HIPAA training and preparation to be behind the pharmacy counter or you are inviting headaches into your operations (and potential legal complications).

Ensure all students entering the professional area of the pharmacy have received proper HIPAA training. They will undoubtedly be exposed to Protected Health Information (PHI) and must know the proper policies and procedures to prevent a breach. Private information about friends, classmates, relatives, or other community members may be learned and this information could be tempting to share with others. By completing HIPAA training prior to exposure to PHI, the students will have a better understanding of the problem with disclosing PHI, including the civil monetary penalties and criminal consequences.

Pharmacy students completing their internship typically spend more time in the pharmacy than someone job shadowing. Interns assisting with daily operations such as billing, filling, counseling, and other professional services, must also complete FWA training. Though their time with your pharmacy may be temporary, these students have access to many of the same pharmacy operations as regular employees. The potential to oversee or partake in wasteful practices, diversion, or other fraudulent activities exists and FWA training must be completed. PAAS National® also recommends completing exclusion checks for interns against both the Office of Inspector General (OIG) and General Services Administration (GSA) lists.

**PAAS Tips:**
- Before entering the professional service area of the pharmacy all students should complete HIPAA training
- All interns should also receive FWA training
- All interns should be checked against the OIG and GSA exclusion lists before entry into the pharmacy and at least monthly thereafter
- Students performing a job shadow should have direct supervision
- Check with your board of pharmacy for the required oversight of pharmacy student interns
- **PAAS FWA/HIPAA Compliance members should modify the student’s “termination date” when their rotation through your pharmacy ends to remove them from your list of active employees**

Contact PAAS National® at (608) 873-1342 or info@PAASnational.com for assistance regarding student access to the portal or to become an FWA/HIPAA Compliance member.

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**COVID-19 Vaccine Billing Guidance**

The light at the end of the tunnel is approaching as Operation Warp Speed delivered COVID-19 vaccines to healthcare workers and LTC residents in December 2020. There will certainly be bumps in the road, supply chain delays and allocations, which means that most patients will not be able to receive COVID-19 vaccines until mid- to late 2021.

The federal government has pre-paid for millions of vaccine doses and will be distributing them to health care providers at no cost, which means that when government-supplied vaccine becomes available at community pharmacies, you will not have to pay to acquire it. For vaccine doses supplied by the federal government, pharmacies may NOT charge patients for the vaccine itself, but may bill payers for the administration.

The federal government has mandated coverage under Medicare Part B, Medicaid and Commercial insurance with no out-of-pocket costs to patients. The CARES Act also provides for reimbursement for uninsured patients through the Health Resources & Services Administration (HRSA).

<table>
<thead>
<tr>
<th>Payer</th>
<th>Coverage and Billing Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Part B</td>
<td>- PHARMACY must enroll as Part B Provider (either as supplier type Pharmacy or Mass Immunizer)</td>
</tr>
<tr>
<td></td>
<td>- Two-dose vaccine administration reimbursement: 1st dose $16.94, 2nd dose $28.39</td>
</tr>
<tr>
<td></td>
<td>- Single-dose vaccine administration reimbursement = $28.39</td>
</tr>
<tr>
<td>Medicaid</td>
<td>- May be covered under pharmacy or medical</td>
</tr>
<tr>
<td></td>
<td>- All programs required to cover – FFS and Medicaid MCO</td>
</tr>
<tr>
<td></td>
<td>- Reimbursement will vary</td>
</tr>
<tr>
<td>Commercial</td>
<td>- May be covered under pharmacy or medical</td>
</tr>
<tr>
<td></td>
<td>- Providers MUST cover it for both in-network AND out-of-network providers</td>
</tr>
<tr>
<td></td>
<td>- Reimbursement will vary</td>
</tr>
<tr>
<td>Uninsured</td>
<td>- Pharmacies may bill HRSA – managed by “Optum Pay” (must be contracted) – not the same as Optum</td>
</tr>
</tbody>
</table>

The coverage for COVID-19 vaccine may be under the pharmacy benefit (via NCPDP standard) or the medical benefit (via CPT codes). Here is a summary of billing information known to PAAS National® as of December 23, 2020.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>NDC-11</th>
<th>Billing Quantity</th>
<th>Days’ Supply</th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>59267-1000-01</td>
<td>0.3 mL</td>
<td>1</td>
<td>SCC-02</td>
<td>SCC-06 to indicate “first dose”</td>
</tr>
<tr>
<td>BioNTech</td>
<td>80777-0273-10</td>
<td>0.5 mL</td>
<td>1</td>
<td>to indicate “final dose”</td>
<td></td>
</tr>
</tbody>
</table>

NCPDP also recommends that pharmacy claims will need to submit the following for ZERO-COST vaccines:

1. **Professional Service Code (440-E5) of “MA” (Medication Administered)**
2. **Ingredient Cost Submitted (409-D9) of $0.00 or $0.01**
3. **Incentive Amount Submitted (438-E3) to request payment for administration (e.g., $16.94 or $28.39)**
4. **Basis of Cost Determination (423-DN) of “15” (free product or no associated cost)**

*New guidance sent 3/15/2021 and updated article published 4/2/2021*