

NATIONAL PBM BULLETIN

November 15, 2017

DEPARTMENT OF VETERANS AFFAIRS PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP), VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICATION SAFETY (VA MedSAFE)

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

AFLURIA® PRE-FILLED SYRINGE LABEL CREATES THE POTENTIAL FOR CONFUSION

I. ISSUE

Labeling of Afluria® quadrivalent influenza vaccine pre-filled syringes may lead to product confusion and creates the potential for vaccine administration errors.

II. BACKGROUND

One VISN's medication safety committee and pharmacy and therapeutics (P&T) committee reviewed a safety concern regarding visibility of product information on the label of Afluria® quadrivalent influenza vaccine. Each pre-filled syringe is labeled with the product name, volume, expiration date, lot number, and barcode identifier. The barcode design predominates in the label over the product name (*Figure 1*). However, vaccinations are often times administered in the outpatient setting where barcode administration verification is not widely used. The name of the product, volume, and national drug code (NDC) on the Afluria® quadrivalent influenza vaccine are small and not highly visible (*Figure 1*). After the lot number / expiration date stickers are peeled off, the label becomes clearer (*Figure 2*), although removal of the label to make it more readable cannot occur in pharmacy prior to dispensing due to their display of the lot number and expiration date. The tray that contains the vaccines contains no printed identifier, and even though the product name is apparent through the clear plastic cover, the staggered positioning of the syringes may make some of the labels less visible through the crease of the plastic (*Figure 3*). Additionally, the reporting facility observed that the drug name in their Pyxis® machine is "influenza vaccine (quad)" but the only visible name is "Afluria® Quadrivalent." These labeling issues may lead to product confusion.

Figure 1: Outer layer of product label. Identifying information appears small and not highly visible.



Figure 2: Outer and inner layers of product label. Peeling away the outer label layer containing lot number and expiration date reveals more noticeable identifying information. Both lot number stickers have to be removed; however, the second one (closer to the lock tip) is not easily unwrapped, which may leave half of the drug name covered.



Figure 3: The tray that holds the pre-filled syringes has no markings, but the clear plastic material of the container allows product information to show through the casing depending on the orientation of the syringe.



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III. DISCUSSION

There are multiple versions of seasonal influenza vaccination now available for use (trivalent, quadrivalent, high dose, etc.). Product labels of seasonal influenza vaccines that do not display important product identifying information in a clear manner may lead to errors in vaccine selection and wrong product administration. Seasonal influenza vaccine administration errors may lead to suboptimal protection against influenza, making at-risk patients vulnerable to contracting this virus.

IV. PROVIDER CONSIDERATIONS/RECOMMENDATIONS

- Pharmacy staff must be informed of poorly visible product information on the labeling of Afluria® quadrivalent influenza vaccine that may lead to product confusion.
- Pharmacy must create a warning system for staff to notify of potential product confusion due to labeling issues (i.e., warning stickers on packaging, additional auxiliary stickers, high alert bins, a product label created in pharmacy for each tray in the box).
 - CDC provides guidance on how to organize influenza vaccines within the storage unit to reduce product confusion, including:
 - i. Label the area where vaccines are stored. Depending on how the vaccines are organized within the storage unit, labels can be placed on the containers, bins, or directly attached to the shelves where the vaccines are placed. Labels may be color coded and provide additional information unique to each vaccine.
 - ii. Store vaccines within their original packaging. The box is fully labeled to help prevent medication errors, and storage within the box protects the vaccine from light while also keeping the vaccine within its recommended temperature range.
 - One site uses the following measures to ensure that the product is easily identifiable and errors do not occur:
 - i. When refilling the refrigerator, pharmacy technicians place the entire box intact (which is fully labeled), leaving the trays inside.
 - ii. Nursing is instructed to store the trays inside the original box and not to discard the box when opening for the first time.
- Providers should always verify the name of the vaccine on the syringe with the name of the product on the prescription prior to administration. Barcode verification prior to administration should occur when possible.
- Use documentation templates with prepopulated lot number selections and verify prior to drug administration as a secondary product check. One site does this as a clinical reminder tool, where clinical application coordinators (CACs) add new lots as they are received.
- Limit product selection options and/or floor stock at the facility level to avoid vaccine mix ups.

V. REFERENCES

1. Center for Disease Control and Prevention. National Center for Immunization and Respiratory Diseases. Immunization Services Division. 2017-2018 Influenza Season Vaccine Label Examples. September 12, 2017.
2. Internal VISN 8 Data.

ACTIONS

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers and health care staff (e.g., **primary care providers, infectious disease providers, nursing staff, pharmacy staff, and employee health services, including contract providers, etc.**). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).