NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2015-05 **SEPTEMBER 15, 2015**

ITEM: **OmniPod® Insulin Management System: Recall for Higher Rate of Failure than Manufacturing Standards**

SPECIFIC INCIDENT(S):

Insulet Corporation initiated a lot-specific voluntary recall of over 40,000 boxes (10 Pods per box) of the OmniPod (Pod) Insulin Management System due to a higher rate of failure than Insulet's current manufacturing standards. This problem can result in interruption of insulin delivery due to either of the following malfunctions:

- The cannula may either completely retract or fail to fully deploy, which may result in the patient not receiving the expected insulin dose; or
- The Pod may trigger an audible alarm indicating it will no longer deliver insulin and will need to be replaced.

GENERAL INFORMATION:

- Interruption of insulin delivery can cause hyperglycemia, which, if left untreated, may in some patients lead to diabetic ketoacidosis (DKA) or other adverse clinical outcomes.
- 90 reports ensued from affected lots:
  - 13 required medical intervention.
  - No serious deaths or injuries were reported.
- Affected products and lots are included below:

Distribution	Catalogue Number	Description	Lot Number
United States	POD-ZXP420	OmniPod® Insulin Management System	L40806; L40811; L40895; L40976; L41014; L41025; L41067; L41162; L41171; L41197; L41198; L41250
International	14810	OmniPod® Insulin Management System	L40771; L40892;L40901; L40905; L40997; L41199; L41208

- Affected products were distributed to customers from December 2013 to March 2015.
- This recall does not affect the OmniPod Personal Diabetes Manager (PDM).
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 9993** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of OmniPod® (Pod) Insulin Management System by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or

by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **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 who prescribe this agent (e.g., **primary care providers, endocrinology staff, and pharmacy staff, 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).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 09/28/2015):
    - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Sites may not have lot number information available locally, so in the case that the lot number data is not available, sites will need to call all patients that received the product and ask them to check the lot numbers. For purchases made outside of Pharmacy Services, pharmacy staff should work with other hospital services (Prosthetics, surgery, etc.) to identify patients who may have received affected product(s) from other areas. CMOP did not dispense any prescriptions for this product from any CMOP location.
    - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
        - Identify the patient(s).
        - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
            - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
            - This template can be altered according to site-specific needs.
        - Provide patient(s) in possession of the recalled product with instructions on the following:
            - How to return the product being recalled to the pharmacy.
            - How to obtain a new supply of product.
            - Patients should not continue to use the product until they obtain replacement product.
            - When the correct product is received, patients should begin using the new product and return the recalled

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

supply as instructed.

- Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S):

1. FDA Recall – Firm Press Release: Insulet Corporation Issues Voluntary Recall of OmniPod® Insulin Management System. http://www.fda.gov/Safety/Recalls/ucm460169.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery . (Accessed 09/08/2015)

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.