NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

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.

PBM-2017-15 **SEPTEMBER 18, 2017**

ITEM: **Medtronic Recall of MiniMed Infusion Sets Due to Potential Over-Delivery of Insulin**

SPECIFIC INCIDENT(S): Medtronic is voluntarily recalling specific lots of infusion sets used with all models of Medtronic insulin pumps.

GENERAL INFORMATION:

- Field reports from patients and root cause analyses show that a component, the vent membrane, in the recalled infusion sets may be susceptible to being blocked by fluid during the process of priming/fill-tubing.
- This blockage can lead to potential over-delivery of insulin shortly after an infusion set change, which may cause hypoglycemia.
- Hypoglycemia requiring medical intervention has been reported to the manufacturer.
- The recall concerns a certain discontinued component in these infusion sets and does not include insulin pumps or glucose sensors. Currently manufactured infusion sets, available to patients since April 2017, include a design update of this component which the company believes reduces the risk of insulin over-delivery after an infusion set change.
- This is an extension of the product sequestration actions in **Product Recall Office Log # 12322** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html). Affected product to remove from inventory can be located in aforementioned link.
- Providers should continue to report any adverse events with the use of Medtronic MiniMed Infusion Sets by entering the information into electronic patient event reports (ePERs) 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, 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).

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PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 10/02/2017):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - Every patient potentially affected should be notified urgently. 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://www.medtronicdiabetes.com/res/img/pdfs/MVB-Patient-Notification-Letter.pdf
      - This template can be altered according to site-specific needs.
      - If patient letters are returned, facility should use another method to contact patient (i.e., phone).
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to identify affected product.
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to take the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled 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.
  - Respond directly to PBM indicating:
    - All patients letters were sent out via a carrier that uses a chain of custody procedure that is trackable and traceable.
    - How many returned infusion sets were identified as being affected lots, and that they were all exchanged.

SOURCE: FDA, Manufacturer

REFERENCE(S):

1. FDA Safety Alerts for Human Medical Products. Diabetes Infusion Sets by Medtronic: Recall - Vent Membrane May be Susceptible to Being Blocked by Fluid. https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm575778.htm . Accessed September 12, 2017.
2. Medtronic MiniMed Infusion Sets: Urgent Medical Device Recall Information. https://www.medtronicdiabetes.com/customer-support/product-and-service-updates/notice7-letter . Accessed September 12, 2017.

ATTACHMENT(S): None.

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