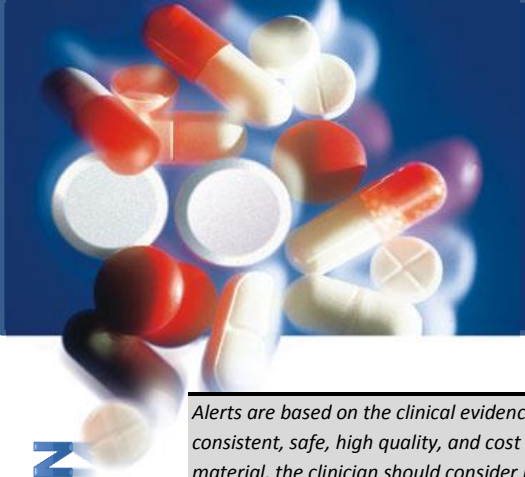

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

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-2017-07 **JUNE 15, 2017**

ITEM: SPECIFIC INCIDENT(S):

Becton Dickinson - #4406 – Insulin Syringes

GENERAL INFORMATION:

- Becton Dickinson is initiating a recall of one lot of insulin syringe with BD Ultra-Fine™ needle due to the product being potentially mislabeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Catalog # 328468.
- The shelf carton is correctly labeled as BD Insulin Syringes with the BD Ultra-Fine™ needle ½ mL 12.7mm 30G.
- Affected lot includes:

NDC	Description	Lot Number	Expiration
08290-8466-01	BD Insulin Syringes with the BD Ultra-FineTM needle ½ mL 12.7mm 30G	6291768	NA
08290-3284-66	SYR INS BD 0.5ML 30GX1/2 100	6291768	NA
08290-8468-01	.5 mL 8 mm 31G BD Insulin Syringe	6291768	NA

- Affected product started shipping March 3, 2017.
- This recall is an extension of the product sequestration actions in **Product Recall Office Log # 12042** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of insulin administered with the BD Insulin Syringes 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, 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 06/29/2017):
  - 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.
  - 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.
      - 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.

SOURCE: Manufacturer

REFERENCE(S): Becton Dickinson Recall Notification [Data on file, Date 06/14/17].

ATTACHMENT(S): None.

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

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