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.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2017-20 **DECEMBER 28, 2017**

ITEM: **Enoxaparin Sodium Injection: Recall Due to Incorrect Strength Syringe in Blister**

SPECIFIC INCIDENT(S): Sanofi is voluntarily recalling one lot of Enoxaparin Sodium Injection 120mg/0.8mL for containing a single syringe of 150mg/1.0mL product in the 120mg/0.8mL blister.

GENERAL INFORMATION:

- ISMP considers enoxaparin a high-alert medication due to the increased risk of causing devastating harm when used in error. Not taking the prescribed dose can cause serious injury. A lower dose than prescribed may result in signs and symptoms of a clot (i.e., chest pain; shortness of breath; numbness, tingling, pain or swelling in extremities; headache; vision changes; seizure; slurred speech; weakness on one side of body; dizziness); while a higher dose than prescribed may lead to signs and symptoms of bleeding/bruising.
- According to the manufacturer, although packaging contains the wrong product, the label on all syringes displays the correct concentration. In addition, the syringes display graduation marks to ensure correct dosing. Product label and dosing instructions should be verified to ensure appropriate and correct dose.
- Affected lot is listed below:

Description	Lot #	Exp Date	NDC	UPC
ENOXAP SOD SYR120/0.8MLWINT10@	7S572	04/30/2019	00955101210	30955101210

- Affected product started shipping September 14, 2017 and ended October 24, 2017.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log #12590** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of enoxaparin sodium injection 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).

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, anticoagulation 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 1/12/2018):
  - Determine whether the affected product(s) was administered to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was administered to patient(s) during home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home use 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) who have received the recalled product with instruction 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 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): Sanofi U.S. Urgent Voluntary Drug Recall [Data on file, Date 12/18/17]. Manufacturer Recall, written communication, Sr. Manager, Regulatory Compliance Recall Leader Sanofi US. September 14, 2017.

ATTACHMENT(S): None.

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