NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2016-03 **June 29, 2016**

ITEM: **All oral liquid docusate products: Recall for contaminated product.**

SPECIFIC INCIDENT(S): CDC is recommending sequestration of all oral liquid docusate products due to contaminated product that might be related to cases of *Burkholderia cepacia* (*B.cepacia*) infections in one state.

GENERAL INFORMATION:

- The CDC is collaborating with the FDA, multiple state and local health departments, and numerous healthcare facilities to investigate a multi-state outbreak of *B.cepacia* infections**. These infections have occurred primarily in ventilated patients without cystic fibrosis and who are being treated in intensive care units.**
- Based on available information, usage of oral liquid docusate should be stopped in the meantime and any available oral liquid docusate products should be sequestered.
- Affected products includes **all oral liquid docusate products**
  - It is not clear which products are impacted at this time, facilities should not replenish oral liquid docusate products, and patients should be converted for alternate drugs.
- The CDC will be continuing to evaluate and provide an update as information become available.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10896** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Healthcare providers and laboratories should be on alert for *B.cepacia* cases occurring among non-cystic fibrosis patients and should inform infection prevention staff when these infections occur. Cases should be reported to state or local public health authorities.
- Providers should continue to report any adverse reactions with the use of liquid docusate product(s) 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, gastroenterology**

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providers, pulmonary-critical care providers, emergency care providers 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 07/13/2016):
  - Sequester all NDC numbers, brands, lots, and doses of oral liquid docusate products from all areas. Do not reorder supply while sequestration is under effect until further information is available.
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration within the last 90 days.
  - 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 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.
      - In the event patient feels ill (such as fevers and chills), then they should seek immediate medical care and inform their provider that they had taken oral liquid docusate.
  - 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: CDC

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REFERENCE(S):

1. CDC Outbreak and Patient Notifications – Mulit-state Outbreak of Burkholderia cepacia Infections. http://www.cdc.gov/hai/outbreaks/b-cepacia/index.html. (Accessed 06/27/2016)

ATTACHMENT(S): None.

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