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 include 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](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](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...
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: 
      - 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: 

**SOURCE:** CDC
REFERENCE(S):


ATTACHMENT(S): None.

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