NATIONAL PBM COMMUNICATION · November 1, 2012

Ameridose Recall of All Product Line

- As of October 31, 2012, Ameridose has issued a voluntary recall of ANY unexpired products remaining in circulation in cooperation with the Food and Drug Administration (FDA) and the Massachusetts Board of Registration in Pharmacy as part of their ongoing investigations into the fungal meningitis outbreak associated with New England Compounding Center (NECC) injectable steroid products. Both Ameridose and NECC have linked management.
    - Neither FDA nor Ameridose has identified impurities in any Ameridose products, but questions of sterility assurance have come about during their investigations.
    - To date, this recall is not associated with any adverse reports related to the affected Ameridose product(s).
- No patient notification actions are needed at this time.

PRODUCT SEQUESTERING ACTIONS

- This recall requires that facilities remove all Ameridose products from use and return to the company. The recall allows up to **10 business days** for completion to allow VA pharmacies to safely transition to alternatives without negatively impacting patient care. This is a reasonable and prudent recall process. However, products should be removed as quickly as possible. The due date for completion is November 16, 2012.
- **Sequestration process:**
    1. The recall should be processed with patient safety in mind, both in timely replacement, and selection of alternative products.
    2. Facilities should pull low use products and medications that can quickly be replaced with alternative products immediately.
    3. Any facilities with Ameridose products that are medications in short supply from alternative sources may continue to use the Ameridose medication until a safe alternative is available.
    4. However, all Ameridose products must be removed, replaced and reported to the Facility Recall Coordinator (FRC) by November 16, 2012.
- Following the action due dates in **Product Recall Office Log # 3164** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining Ameridose product at the CMOP/facility per manufacturer's instructions. Please inform your FRC when completed.
- A complete list of all products subject to this recall can be accessed on-line at: www.ameridose.com.

PATIENT NOTIFICATION ACTIONS

- At this time, the FDA is **NOT recommending** a need to follow up with patients who received Ameridose products.
- Healthcare professionals and facilities should discontinue use of Ameridose products and return them to the company.
- Facilities with Ameridose products in stock should contact Ameridose: **888-820-0622**.
- Providers should continue to report any adverse reactions with the use of any Ameridose 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).

REFERENCES

Recall – Firm Press Release: Ameridose Issues Recall of All Products. http://www.fda.gov/Safety/Recalls/ucm326349.htm?source=govdelivery . (Accessed 10/31/12).
Ameridose News: Ameridose Issues Recall of All Product. http://www.ameridose.com/news/ . (Accessed 11/01/12).

FEEDBACK NOTIFICATION ACTIONS:

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, surgery, anesthesiology staff, pain specialists, neurology, 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. Report completion of actions to the Facility Director.*
- ***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).*
- ***VISN Directors:*** *Within 10 business days of issue (due 11/16/2012), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx .*