DEPARTMENT OF VETERANS AFFAIRS VETERAN HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM) & MEDICAL ADVISORY PANEL (MAP)
VA CENTER FOR MEDICATION SAFETY (VAMedSAFE)

NATIONAL PBM COMMUNICATION · March 29, 2011

Recall of Povidine® Iodine Prep Pads Due to Potential Microbial Contamination

- H&P Industries, Inc., is issuing a product recall for ALL LOTS of POVIDINE® PREP PADS due to:
  - FDA concerns regarding product contamination (specifically with *Elizabethkingia meningoseptica)*, which may lead to patient infection (especially in at risk populations, including immune suppressed and surgical patients); and
  - The same raw material as the recalled Alcohol Prep pads being present in the Povidine® Prep Pads.
- Private labeled Povidine® Iodine Prep Pads are:
  - distributed nationwide;
  - enclosed in individual packets;
  - sold as single boxes, each containing 100 packets;
  - packaged using the names listed below:
    - Cardinal Health
    - Medical Specialties
    - VHA
    - Triad
    - Triad Plus
    - North Safety
    - Total Resources
- To date, FDA has not received any reports of adverse events associated with Povidine® Iodine Prep Pads.

SEQUESTERING ACTIONS

- Following the action due dates in Product Recall Office Log # 1053 (available at http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining product at the CMOP/facility level with the affected lot numbers per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Since a complete list of commercially available drug kits affected by this recall is not available, inspect all commercial drug and procedure kits in facility inventory for the recalled items. Perform the following actions if the affected Povidine® Iodine Prep Pads are found:
  - Remove the affected Povidine® Iodine prep pads from the kit.
  - Provide a separately packaged alternative when dispensing to patients.
  - Include a notice to the patient explaining the action.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product was dispensed to any patient(s) for home administration. It is recommended to use a 12-month time frame for this determination. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product for home administration by any appropriate method.
    - A sample letter can be found at:
    http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc
    - This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of product.
    - How to return the product being recalled to the pharmacy.
    - Not to continue using the product with the affected lot number. When the correct product is received, patient should begin using the new product and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this product to the VA ADERS program.

REFERENCES:

FDA Firm Press Release. http://www.fda.gov/Safety/Recalls/ucm247658.htm. (Accessed March 24, 2011).

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, and any relevant surgical service physicians or other medical specialties who may use Povidine® Iodine Prep Pads,*** *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 4/12/2011), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*