

NATIONAL PBM COMMUNICATION • June 17, 2011

Recall of Churchill Medical (Vygon) Skin Prep Wipes Due to Bacterial Contamination

INFORMATION FOR PROVIDERS

- Due to the potential for bacterial contamination, which may lead to patient infection (especially in at risk populations, including immune suppressed and surgical patients), Churchill Medical Systems, a Vygon Company, is issuing a product recall for skin-prep wipes used in convenience kits.
- The affected skin-prep wipes can be found in many commercially available procedure kits, such as:
 - **Dressing Change Kits**, for central line catheter dressing changes;
 - **Central Line Dressing Kits**, for dressings associated with central line catheter placement;
 - **PICC Insertion Trays**, for dressings involved with peripheral placement of a central catheter line.

FOR PHARMACY SERVICE

- Following the action due dates in Product Recall Office Log # 1335 (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 affected lot number(s) per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- Affected lot number(s) are listed below:

Product Name	Product Code	Lot Number
Dressing Change Kit	AMS-7080CP	10J29, 10J55, 11A18, 11A47, 11B06
Central Line Dressing Kit	AMS-8316CP-1	10I60, 10K42, 10F87
PICC Insertion Tray	AMS-8431CP	10H30
Dressing Change Kit	AMS-9189CP-1	1006150, 1006149, 1008143
Dressing Change Kit	AMS-9189CP	1003527

- Since a complete list of commercially available procedure kits affected by this recall is not available, inspect all commercial procedure kits in facility inventory for the recalled item(s). Perform the following actions if the affected skin-prep wipes are found:
 - Remove the affected skin-prep wipes 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 lot number(s) (refer to lot number[s] provided above) were dispensed to any patient(s) for home administration. These products were distributed from September 3, 2010 through March 11, 2011. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot(s) 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.

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 other surgical service**, 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 07/01/2011), 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.