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 · December 28, 2010

Recall of Abbott Glucose Test Strips - False Low Blood Glucose Results

INFORMATION FOR PROVIDERS WHO USE, OR HAVE PATIENTS WHO USE, ABBOTT GLUCOMETERS/STRIPS

- FDA and Abbott Diabetes Care are issuing a recall of 359 different lots of glucose test strips marketed under the following brand names:
  - Precision Xceed Pro,
  - Precision Xtra,
  - Medisense Optium,
  - Optium,
  - OptiumEZ, and
  - ReliOn Ultima.
- The defect is associated with test strips exposed to warm weather or prolonged storage and involves insufficient absorption of blood into the test strip.
- Affected test strips may provide falsely low blood glucose results, resulting in the possible outcomes:
  - Patients raising their blood glucose when it is unnecessary; or
  - Patients failing to treat elevated blood glucose due to a falsely low reading.

- The following products listed in the *Urgent Product Recall* in this link carry the affected lot numbers:
  - http://www.precisionoptiuminfo.com/img/Lot-Numbers.pdf
- No other lots of this product are affected by this recall.

FOR PHARMACY SERVICE

- Return all remaining product at the facility/CMOP level with the affected lot numbers. Please inform your Facility Recall Coordinator when completed.
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s) for home administration. It is recommended to use a 12-month time frame for this determination. NDCs and McKesson Item numbers will be sent to Pharmacy Chiefs as a follow-up to this Communication. CMOP data 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.
    - To continue using the product with the affected lot number until they receive a new supply. 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.
- Refer to http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm237910.htm , http://www.precisionoptiuminfo.com/EN/ , and http://www.precisionoptiuminfo.com/img/Lot-Numbers.pdf for further details regarding this urgent drug recall.

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, endocrinologists, and diabetes specialists,*** *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 receipt (due 1/12/2011), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx*