NATIONAL PBM COMMUNICATION · December 4, 2013

ADDENDUM: Additional Lots Identified for Recall of Abbott FreeStyle® Glucose Test Strips

- In November 2013, PBM issued a National PBM Communication addressing the recall announced by Abbott Diabetes Care of certain lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips due to producing out of range control solution results and erroneously low blood glucose results when using FreeStyle® Blood Glucose Meters, FreeStyle Flash® Blood Glucose Meters, and the FreeStyle® meter built into the Omnipod® System.
- The manufacturer expanded their recall to include the additional lots listed below. The additional products hold expiration dates from between May 2014 and March 2015.
- A falsely low blood glucose level may lead to an insulin dosing error that could bring about a hyperglycemic episode requiring immediate medical attention.

PRODUCT SEQUESTERING ACTIONS

- Additional affected lot(s) include:

Lot Numbers		
1281732	**1363321**	**1367917**
1283345	**1365056**	**1373262**
1283603	**1365920**	**1374907**
1285007	**1365934**	**1366515**
1366111	**1366337**	**1366006**
1363015	**1366347**	**1350414**
1363109	**1365921**	

- Following the action due dates in **Product Recall Office Log # 7592** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Consult with diabetic clinics and diabetic educators because they are typically well aware of patients on non-contracted meters and strips. 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(s) for home administration by any appropriate method.
    - A sample letter can be found at:

https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc

- 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.
  - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Providers should continue to report any adverse reactions with the use of any glucose test strip(s) or glucose meter kit(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:

1. Recall-Firm Press Release: Abbott Issues Voluntary Recall of Certain FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips in the United States. http://www.fda.gov/Safety/Recalls/ucm376975.htm. (Accessed 12/02/2013)
2. National PBM Communication: Abbott FreeStyle Glucose Test Strips Recall. November 29, 2013. http://www.pbm.va.gov/PBM/vacenterformedicationsafety/nationalpbmcommunication/Abbott_Freestyle_Glucose_Test_Strips_Recall_NATIONAL_PBM_COMMUNICATION.pdf .

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, endocrinology, 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 12/18/2013), 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 .*