NATIONAL PBM COMMUNICATION · August 14, 2013

Recall of Certain Lots of Nova Max Glucose Test Strips

- On July 26, 2013, Nova Diabetes Care recalled certain lots of Nova Max Glucose Test Strips due to some strips incorrectly reporting blood glucose as abnormally elevated. See below for indicated Nova Max Glucose Test Strip lots and Nova Max Plus glucose meter kits.
- A falsely elevated high blood glucose level could result in an insulin dosing error that could possibly lead to a hypoglycemic episode requiring immediate medical attention.

PRODUCT SEQUESTERING ACTIONS

- Affected lot(s) include:

1020211346	1020212032	1020712206	1020412341
1020411347	1020512087	1020212207	1020213043
1020611348	1020212100	1020412255	1020213074
1020811350	1020212101	1020212291	1020213109
1020211355	1020212153	1020912292	

- Nova Max®Plus™ glucose meter kits that include test strips from the recalled lots are also included in this voluntary recall.
- For your convenience, you may confirm which blood glucose test strips are included in this recall by visiting www.novacares.com/news/nova-max-recall.php or by contacting Nova Diabetes Care customer service at 1-800-681-7390.
- Following the action due dates in **Product Recall Office Log # 7162** (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. Date range of the recall is between December 2011 and April 2013.
- 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:

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) 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).

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 08/27/2013), 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 .*