From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, September 01, 2017 4:09 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Unexpired Lots of Oxytocin Compounded with Either Lactated Ringers or Lactated Ringers and Dextrose by PharMEDium - Recall - Sub-Potency

ISSUE: PharMEDium Services, LLC (PharMEDium) is voluntarily recalling all unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose products that were produced between July 6, 2017 and August 29, 2017 to the hospital/user level. The recall is being issued based on laboratory test results indicating a lower than expected potency on certain lots of Oxytocin compounded with Lactated Ringers and Oxytocin Compounded with Lactated Ringers and Dextrose which would lead to a lower dose being administered. Although oxytocin is titrated based on clinical response, an extreme and unexpected reduction in dose than expected could lead to a delay in treatment, disruption of clinical care of the patient, and worsening of patient's conditions.

BACKGROUND: These products were packaged in ready to use intravenous bags. All unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose are included in this recall. The product can be identified by referring to the sample labels provided. These products were distributed nationwide in the USA to hospitals/clinics.

RECOMMENDATION: PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information: www.pharmedium.com.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at shasan@pharmedium.com.

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including link to the Recall Notice, at https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574582.htm