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Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN, JR.
Governor

December 24, 2013

AFL 13-35

TO: All Facilities

SUBJECT: Nationwide Recall issued by Abrams Royal Pharmacy

The California Department of Public Health (CDPH) issues this All Facilities Letter (AFL) to share information regarding the voluntary recall of all unexpired lots of sterile products dispensed nationwide by Abrams Royal Pharmacy due to concerns of lack of sterility assurance. All unexpired lots of sterile compounded products are subject to the recall. Sterile products include injectable medications, IVs, eye drops, pellet implants, nasal sprays, inhalation solutions, and eye ointments.

The recall was issued after a single, isolated report of an adverse outcome involving a patient in California who received a compounded medication from the pharmacy. Out of an abundance of caution, Abrams Royal is voluntarily recalling all unexpired sterile products. If there is microbial contamination in products intended to be sterile, patients are at risk for serious, potentially life-threatening infections.

The recalled products were distributed to health care facilities, physicians, and patients from June 17, 2013, through December 17, 2013. All recalled products have a label that includes Abrams Royal Pharmacy's name and phone as well as a lot number. While not every label contains an expiration date, consumers can call the pharmacy with the lot number and find out the expiration date. Abrams Royal Pharmacy is notifying its customers by mail and is arranging for the return of all recalled medication. To return product or request assistance related to this recall, users should contact Abrams Royal at 214-349-8000, Monday through Friday, between 9:00 a.m. and 5:00 p.m. CST.

Health facilities that carry sterile products dispensed by Abrams Pharmacy should check their medications to ensure patient safety. Those who have the recalled product should stop using it and contact the pharmacy to arrange for return of unused product.

Healthcare professionals and patients are encouraged to report any serious problems associated with administration of recalled medications or side effects related to the use of

AFL 13-35
December 24, 2013
Page 2

these products to their local health department and the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Regular mail: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

Fax: 1-800-FDA-0178

For mail or fax reporting, please use FDA form 3500, available at:
<http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf> or by request by calling 1-800-332-1088.

If you have any questions, please contact CDPH Healthcare-Associated Infections Program at (510) 412-6060 or by email at cdphhaiprogram@cdph.ca.gov.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality