

Cover Sheet

DATE: 16 August 2013

SUBJECT: Nationwide Voluntary Recall of All Products for Sterile Use from Compounding Pharmacy located in Cedar Park, Texas

For LOCAL HEALTH DEPARTMENT reference only

DPHHS Subject Matter Resource for more information regarding this HAN, contact:

**DPHHS CDCP
Epidemiology Section
1-406-444-0273**

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Please call DPHHS to update contact information at 444-0919 or 444-6906

Information Sheet

Date: August 16, 2013

Subject: Nationwide Voluntary Recall of All Products for Sterile Use from Compounding Pharmacy located in Cedar Park, Texas

Background: There have been recent reports of bacterial bloodstream infections potentially related to the company's calcium gluconate infusions. The CDC and the FDA have been working with Texas state officials to determine the scope of the contamination since August 8th, 2013.

Information: The U.S. Food and Drug Administration (FDA) is alerting health care providers and patients of a voluntary nationwide recall of all products produced and distributed for sterile use by Specialty Compounding, LLC, Cedar Park, Texas. No providers in Montana are presently known to have received or used this product; however, a small number of Montana residents have apparently been prescribed products by their physicians and received product from Specialty Compounding, LLC. It is unknown as to if these individuals received the products specifically associated with the reported infections. The patients who have been prescribed Specialty Compounding products have been informed of their potential exposure by the manufacturer.

Recommendations: Please see the attached CDC Health Advisory. If you were to receive phone calls from individuals reporting they have received the medications in question or physicians who may have patients contact them, please tell patients to contact their physician particularly if they are reporting symptoms or problems.

This is an official
CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
August 14, 2013, 16:00:00 ET (4:00:00 PM ET)
CDCHAN-00353

**Nationwide Voluntary Recall of All Products for Sterile Use from
Compounding Pharmacy located in Cedar Park, Texas**

Summary:

The U.S. Food and Drug Administration (FDA) is alerting health care providers and patients of a voluntary nationwide recall of all products produced and distributed for sterile use by Specialty Compounding, LLC, Cedar Park, Texas. There have been recent reports of bacterial bloodstream infections potentially related to the company's calcium gluconate infusions.

CDC and the FDA are working with Texas state officials to determine the scope of the contamination.

According to the FDA, information provided by the firm stated that the recalled products (i.e., all products produced and distributed for sterile use by Specialty Compounding) were distributed directly to patients nationwide, with the exception of North Carolina, which received no products. The full text of the recall is available on the FDA website at <http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery>. Also according to the FDA, information provided by the firm stated that recalled products were also distributed to hospitals and physician offices in Texas.

Background

The Texas Department of State Health Services has reported bacterial bloodstream infections in 15 patients from two Texas hospitals who received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9 percent for Injection, supplied by Specialty Compounding. According to Texas state officials, most infections were caused by *Rhodococcus equi* and are thought to be related to the infusions. Two of the 15 patients have died. CDC does not have information that the deaths are related to recalled product. Also according to Texas state officials, cultures from an intact sample of calcium gluconate compounded by Specialty Compounding show growth of bacteria that are consistent with *Rhodococcus* species. Isolates are being evaluated by CDC to confirm the identification.

Recommendations

All sterile use products produced and distributed by Specialty Compounding are being recalled, and none of these products should be used by patients or administered to patients. Facilities, health care providers, and patients who have received the products, should immediately discontinue use, quarantine the products, and return the products to Specialty Compounding (See <http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery>).

If patients who received recalled product are experiencing symptoms, especially fever, they should consult a physician.

Patients and physicians should report adverse reactions experienced with the use of any Specialty Compounding products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. Information on reporting adverse reactions can be found at:

- <https://www.accessdata.fda.gov/scripts/medwatch/>
- Download form at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm> or call 1-800-332-1088 to request a reporting form, then complete and mail to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional Information

As more information becomes available, CDC will provide updates on the situation via the Health Alert Network.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Categories of Health Alert Network messages:

- Health Alert** Requires immediate action or attention; highest level of importance
- Health Advisory** May not require immediate action; provides important information for a specific incident or situation
- Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation
- HAN Info Service** Does not require immediate action; provides general public health information

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