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CDC HEALTH ADVISORY

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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

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, epidemiologists, HAN coordinators, and clinician organizations##

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