## Pennsylvania Department of Health 2018 - PAHAN – 401 – 03-30 - ADV Burkholderia cepacia complex Infections Associated with Use of Medline Remedy Essentials No-Rinse Foam



DATE:	3/30/2018
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	Burkholderia cepacia complex Infections Associated with Use of
	Medline Remedy Essentials No-Rinse Foam
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	Statewide
COUNTY:	Statewide
MUNICIPALITY:	Statewide
ZIP CODE:	Statewide

This transmission is a "Health Advisory": provides important information for a specific incident or situation; may not require immediate action.

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

**EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE** 

FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE

LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE

PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

LONG-TERM CARE FACILITIES: PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

## **Summary**

- The Pennsylvania Department of Health (DOH) is actively investigating a cluster of Burkholderia cepacia complex (Bcc) infections associated with a single acute care facility.
- To date, a total of 10 positive cultures have been identified, including the following sources: urine (5), peritoneal fluid (2), wound (2), and sputum (1).
- At this time, DOH continues to work with our partners including the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) following evidence of a potentially contaminated product.
- A similar cluster of infections simultaneously occurred in California. Both the PA and CA facilities identified links between cases and Medline Remedy® Essentials No-Rinse Foam.
- In addition to active case finding, healthcare facilities are being advised to avoid use of the product until further information is available.

## **Background**

DOH and the California Department of Public Health (CDPH) are obtaining support from CDC as both states continue to investigate simultaneous clusters of Bcc infections. Cases have been identified in PA and CA from November 2017 through March 2018. As of March 23, 2018, five of the ten patients from the Pennsylvania cluster and six of the eight patients from the California cluster have had Bcc isolated from urine; other body sites positive for Bcc included wounds and sputum. No patients in either cluster had cystic fibrosis. Ongoing investigation in both states has identified a potential association between Bcc infection and Medline Remedy® Essentials No-Rinse Foam, a product used for skin and perineal care. This product is widely distributed throughout the United States.

DOH submitted multiple samples of Remedy® Essentials No-Rinse Foam to the PA Bureau of Laboratories for analysis. Lots M05703/7235 and M06691/7256 tested positive for Bcc. Molecular testing on clinical and product isolates indicate that they are closely related. Cultures from additional product are pending. Unfortunately, it is not known which lots were used on the patients who developed infections.

Federal, state and local health agencies continue to work with FDA to gather additional information. **DOH recommends healthcare facilities avoid the use of this product until further information is available.** Discard any product from lots **M05703/7235 and M06691/7256.** For facilities with identified clusters of Bcc, sequester and save any Remedy® Essentials No-Rinse Foam from *other* lots. Lot numbers are printed on the bottom of the bottle or along the side of the label.

DOH requests that healthcare facilities that have used this product since November 2017 conduct a retrospective review of microbiology laboratory records for Bcc infections among noncystic fibrosis patients occurring **on or after 1/1/2018**.

DOH requests that healthcare facilities and/or local health departments notify DOH Bureau of Epidemiology immediately about similar clusters of Bcc among non-cystic fibrosis patients occurring **on or after 1/1/2018** by contacting their local health department or by calling 1-877-PA-HEALTH.

More information regarding this active, ongoing investigation is likely to be available next week.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of March 30, 2018, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.