

PENNSYLVANIA DEPARTMENT OF HEALTH
2018 - PAHAN – 405 – 04-17 - UPD
Update: *Burkholderia cepacia*
complex Infections Associated with
Use of Medline Remedy® Essentials
No-Rinse Foam



DATE:	4/17/2018
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	UPDATE: <i>Burkholderia cepacia</i> 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 Update” that provides updated information regarding an incident or situation; no immediate action necessary.

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

UPDATE:

- DOH continues to work with CDC, FDA and other state and local health departments to investigate an outbreak of *Burkholderia cepacia* complex (Bcc) infections associated with Medline Remedy® Essentials No-Rinse Foam.
- **A new affected lot has been identified. The recall now includes all lots beginning with the master batch numbers M05703, M06691, and M07247.**
- Healthcare facilities should follow the recall instructions for the recalled lots and consider avoiding the use of other lots of the product while further investigation is being conducted.
- Remain alert for additional notices in the event that additional contaminated lots are identified.

Updated Information:

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 April 16, 2018, nine confirmed and 27 probable or possible cases have been identified in residents of four states. 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.

Samples of the product collected from Pennsylvania and California hospitals have tested positive for Bcc. Molecular testing comparing clinical and product isolates in PA to isolates from CA indicate that the isolates are closely related.

Medline has issued a voluntary recall of all lots in three master batches of this product, which includes all lots beginning with the master batch numbers M05703, M06691, and M07247 (<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=162968>).

Federal, state and local health agencies continue to work with FDA to gather additional information. Investigation is ongoing to determine the underlying cause of contamination. **DOH recommends healthcare facilities avoid the use of this product until further information is available.** Discard any product from **all lots beginning with the master batch numbers M05703, M06691, and M07247.** 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 non-cystic 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 on the background for this investigation is available in [PENNSYLVANIA DEPARTMENT OF HEALTH 2018 - PAHAN – 401 – 03-30 - ADV Burkholderia cepacia complex Infections Associated with Use of Medline Remedy Essentials No-Rinse Foam](#) .

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 April 17, 2018, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.