Update: *Burkholderia cepacia* complex Infections Associated with Use of Medline Remedy® Essentials No-Rinse Foam --2018

The CDPH Healthcare-Associated Infections (HAI) Program continues to work with CDC, FDA, and affected state and local health departments to investigate an outbreak of *Burkholderia cepacia* complex (Bcc) infections associated with Medline Remedy® Essentials No-Rinse Foam, a product used for skin and perineal care. 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](https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=162968)). The lot number is located at the bottom of the bottle. (See example below). The investigation is ongoing to determine the underlying cause of contamination.

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.

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. Facilities should remain alert for additional notices in the event that additional contaminated lots are identified.

Health care facilities that either (a) use Medline Remedy® Essentials No-Rinse Foam and have at least one case of Bcc since February 1, 2018 OR (b) identify clusters (two or more cases) of Bcc in non-cystic fibrosis patients occurring since February 1, 2018 should notify their local public health department and the CDPH HAI Program at: [HAIprogram@cdph.ca.gov](mailto:HAIprogram@cdph.ca.gov).

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Subject: *Burkholderia cepacia* complex Infections Associated with Use of Medline Remedy Essentials No-Rinse Foam

The CDPH Healthcare-Associated Infections (HAI) Program is working with CDC and state and local health departments in Pennsylvania and California to investigate clusters of *Burkholderia cepacia* complex (Bcc) infections at two acute care hospitals between November 2017 and March 2018. As of March 23, 2018, five of ten patients from the Pennsylvania cluster and six of eight patients from the California cluster have had Bcc
isolated from urine; other specimen sites positive for Bcc included wounds and sputum. No patients in either cluster had cystic fibrosis. The investigation has identified a potential association between Bcc infection and Medline Remedy® Essentials No-Rinse Foam, a product used for skin and perineal care in both hospitals. Samples of this product collected at the Pennsylvania facility from lots M05703/7235 and M06691/7256 tested positive for Bcc. However, it is not known which lots were used on the patients who developed infections. Molecular testing on patient and product isolates indicate that they are closely related. Cultures from additional product are pending. The investigation is ongoing.

CDC recommends health care facilities using Medline Remedy Essentials No-Rinse Foam consider avoiding use of this product, at least in patients at greater risk for Bcc infections (e.g., patients with chronic lung disease, especially cystic fibrosis, or who are immunocompromised) until further information is available.

Health care facilities that identify similar clusters of Bcc (two or more cases with at least one positive urine culture) occurring since February 1, 2018 should notify their local public health department and the CDPH HAI Program at: HAIprogram@cdph.ca.gov.