Health Advisory: *Recall of Docusate Sodium*

Minnesota Department of Health July 20, 2016 12:00 CDT

Action Steps:

Local and tribal health departments: Please forward to hospitals, clinics, and long-term care facilities in your jurisdiction.

Hospital and clinics: Please distribute to health care providers, infection preventionists, and pharmacists.

Healthcare providers:

- Do not use any liquid docusate sodium product as a stool softener or for any other medical purpose.
- Remain on alert for infections caused by *Burkholderia cepacia* complex and report cases and clusters to MDH at 1-877-676-5414 (toll-free) or 651-201-5414.
- Subscribe to CDC's Multistate Outbreak of *Burkholderia cepacia* Infections (http://www.cdc.gov/hai/outbreaks/b-cepacia/index.html) for updates on this outbreak.

Summary:

The Centers for Disease Control and Prevention (CDC) is working with the Food and Drug Administration (FDA), health departments, and multiple health care facilities to investigate a multistate outbreak of Burkholderia cepacia infections. As of July 18, 2016, CDC has confirmed 49 cases from five states. None of the confirmed cases are from Minnesota.

On June 24, 2016, CDC released preliminary information that a contaminated liquid docusate product might be related to B. cepacia cases in one state, and recommended that facilities not use any liquid docusate products for patients who are critically ill, ventilated, or immunosuppressed. On July 8, 2016, this recommendation was expanded to include all patient populations. MDH communicated these messages with laboratories, infection preventionists, and infectious disease physicians in Minnesota when they became available.

On July 16, 2016, FDA announced a voluntary recall of all non-expired lots of Diocto Liquid, a docusate sodium solution manufactured by PharmaTech LLC, Davie, Florida, and distributed by Rugby Laboratories, Livonia, Michigan. The agency confirmed the product has been contaminated with Burkholderia cepacia. FDA and CDC continue to investigate this issue to identify other potentially contaminated liquid docusate sodium products.

FDA and CDC will provide additional information when it is available.

Burkholderia cepacia is a type of bacteria that can be found in soil and water. It poses little medical risk to healthy people; however, people with weakened immune systems and certain health problems, particularly cystic fibrosis, may be more susceptible to infections with B. cepacia. It is a known cause of infections in hospitalized patients and has been linked to health care-associated outbreaks.

For more information:

- FDA announces voluntary nationwide recall of oral liquid docusate sodium manufactured by PharmaTech and distributed by Rugby Laboratories (http://www.fda.gov/Drugs/DrugSafety/ucm511527.htm)
- CDC Burkholderia cepacia in Healthcare Settings (https://www.cdc.gov/HAI/organisms/bCepacia.html)
- MDH's Healthcare Associated Infections (HAI) page (http://www.health.state.mn.us/divs/idepc/dtopics/hai/) Subscribe for updates on a variety of HAI topics.

A copy of this HAN is available in PDF and Word format at www.health.state.mn.us/han/ .