

**DFW-APIC Government Affairs Committee
June 2018**

APIC Public Policy and E-News Highlights (2018)

<http://cqrcengage.com/apic/home>

<http://apic.org/Member-Services/Publications/E-News>

5/10/2018	The 2018 NHSN Patient Safety Component Training videos and slide decks are now available on the NHSN website. All videos and slide PDFs are located on the NHSN training page at: https://www.cdc.gov/nhsn/training/continuing-edu/trainingvideos.html
5/10/2018	FDA reclassifies sharps needle destruction device: The FDA has reclassified the needle destruction device, now renamed “sharps needle destruction device,” from class III (requiring premarket approval) to class II (requiring special controls) to indicate the level of regulatory controls needed to provide reasonable assurance of the safety and effectiveness of the device. The required special controls relate to performance testing, cleaning and disinfection instructions, electromagnetic compatibility and electrical safety, software verification, and labeling. Read the FDA notice .
5/10/2018	AuraMedics Pharma recalls antibiotic injection vials: AuraMedics Pharma is voluntarily recalling two lots of Piperacillin and Tazobactam for Injection, USP 3.375 g in a single-dose vial and two lots of Ampicillin and Sulbactam for Injection USP, 3 g in a single-dose vial. The products have been found to contain particulate matter in the vials. Read the FDA safety alert on Piperacillin and Tazobactam . Read the FDA safety alert on the Ampicillin and Sulbactam recall
5/16/2018	Multistate outbreak of <i>B. cepacia</i> The CDC reported ten confirmed cases of infection caused by bacteria within the <i>Burkholderia cepacia</i> complex in California, Pennsylvania, and New Jersey. The patients acquired the infections while already hospitalized for acute conditions. The infections have been linked to the Medline product, Remedy Essentials No-Rinse Cleansing Foam. Shadow Holdings dba Bocchi Laboratories has voluntarily recalled 4 ounce and 8 ounce bottles of the lots that tested positive for the bacteria. Read the FDA safety alert .
5/30/18	CDC provides update on Ebola outbreak in Congo The CDC is continuing to monitor information about the current outbreak of Ebola virus disease (EVD). The WHO Emergency Committee has determined that the current outbreak has not met the conditions for a Public Health Emergency of International Concern, so international travel and trade restrictions are not recommended. The CDC is advising U.S. healthcare providers to continue to obtain travel histories from all patients seeking care, and promptly isolate patients that have symptoms compatible with EVD and recent travel to the affected area. Read the CDC update

Texas Register (2018)

http://www.sos.state.tx.us/texreg/index.shtml				
Last Review Completed:		6/1/2018		
Current Search Parameters for Review:				
25 TAC: Chapters 2, 97, 133, 135, 200				
30 TAC: Chapter 330; Subchapter Y				
Key: X Pending				
X	Date Filed	Action	Title/Ch./Rules	Topic / Comments
	5/17/2018	Adopted	25 TAC §97.136	Amendment to comply with H.B. 2886, which amended Texas Health & Safety Code §81.09 - Provides an exception for certain health care providers who are unable to apply prophylaxis against ophthalmia neonatorum due to objection of parent, managing conservator, or guardian of the newborn infant. The HCP doesn't commit an offence & is not subject to criminal, civil, or administrative liability or professional disciplinary action. The objection must be entered into the infant's medical record.