DFW-APIC Government Affairs Committee
April 2021

APIC Public Policy and E-News Highlights (2021-2022)

http://cqrcengage.com/apic/home
http://apic.org/Member-Services/Publications/E-News

4/12/21	***Joint Commission to Resume Surveys*** As COVID-19 incidence and caseloads across the country are decreasing, beginning March 15, 2021, The Joint Commission will return to its usual pre-pandemic procedures, including unannounced onsite surveys. ***CMS Resumes Normal Hospital Surveys*** Effective March 23, CMS has resumed normal hospital survey activities that had been suspended during the COVID-19 public health emergency. According to the March 26 CMS memo, all non-Immediate Jeopardy complaints received since January 20, 2021 must be investigated within 45 days of the issuance of the memo.
4/12/21	The FDA recommends transition from decontaminated respirators. Based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) currently available to facilitate this transition, the FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems. Read the FDA letter to Healthcare Providers.
4/12/21	FDA warns of the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethroscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices. While the FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues, possible causes may be reprocessing or maintenance issues, or inadequate instructions for use. Read the FDA letter to providers.
4/23/21	Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume. FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review | FDA
4/24/21	The Texas Department of State Health Services has notified vaccine providers in the state that they should resume using the Johnson & Johnson COVID-19 vaccine. Texas Lifts Pause on Johnson & Johnson Vaccine
4/26/21	BD (Becton, Dickinson and Company) is recalling specified lots of the ChloraPrep Hi-Lite Orange 26 mL Applicator (2% w/w chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)) due to a defective applicator. In certain lots, the applicator end cap was improperly secured due to a manufacturing error. This can result in broken glass and solution dropping out of the applicator once activated. The product is used as an antiseptic for the preparation of the patient's skin prior to surgery to help reduce bacteria that potentially can cause skin infection. Read the FDA recall notice.
4/26/21	Sanit Technologies LLC, doing business as Durisan, has voluntarily expanded its recall of Durisan Antimicrobial Hand Sanitizer nonalcohol products due possible contamination with *Burkholderia contaminans*. Read the FDA recall notice.

4/26/21	The FDA revoked the emergency use authorization (EUA) that allowed for the investigational monoclonal antibody therapy bamlanivimab, *when administered alone*, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. The decision was based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure. Read the FDA announcement.

Texas Register (2021-2022)

http://www.sos.state.tx.us/texreg/index.shtml **Key: X Pending**

Last Review Completed: 4/23/2021

Current Search Parameters for Review:

25 TAC: Chapters 2, 97, 133, 135, 200

30 TAC: Chapter 330; Subchapter Y

X	Date Filed	Action	Title/Ch./Rules/SB/HB	Topic / Comments
	3/1/21	***Referred to Public Health***	**HB 591**	Requires vaccination against bacterial meningitis for public school students

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