DFW-APIC Government Affairs Committee
May 2022

APIC Public Policy and E-News Highlights (2022-2023)

http://cqrcengage.com/apic/home
https://apic.org/publications/enews/

4/4/22	**Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes** Following FDA reports about patient infections and possible contamination issues with reprocessed urological endoscopes, Karl Storz identified reprocessing failures following high-level disinfection. The company initiated a voluntary recall and issued an urgent field safety notice to instruct users to discontinue all high-level disinfection methods for all affected urological endoscopes and discontinue liquid chemical sterilization for most of the affected urological endoscopes. The affected urological endoscopes should be sterilized after each use by an appropriate sterilization method recommended in the instructions for use. Read the FDA letter to Healthcare Providers.
4/4/22	Effective April 4, 2022, HHS and CDC announced revisions to COVID-19 laboratory reporting guidance pdf. Reporting of negative results for non-NAAT tests (rapid or antigen test results) is no longer required. However, testing sites must still report data for all positive diagnostic and screening testing completed for each individual test.
4/5/22	FDA updated duodenoscope safety communication to encourage manufacturers to transition away from fixed endcap duodenoscopes to disposable/disposable component duodenoscopes with more modern design features that facilitate or eliminate the need for reprocessing. Hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components, such as disposable endcaps, or to fully disposable duodenoscopes. Read the FDA safety communication.
4/6/22	**FDA Updates EUA for Sotrovimab** The FDA has again revised its EUA for sotrovimab to treat COVID-19. According to CDC data, Omicron sub-variant BA.2 now accounts for more than 50 percent of COVID-19 cases in every HHS region in the U.S. Since the authorized dose of sotrovimab is unlikely to be effective against this sub-variant, FDA has withdrawn authorization and recommends that healthcare providers use other approved or authorized products to treat patients with COVID-19. **Read the FDA announcement**.
4/13/22	**FDA Authorizes Extended Shelf Life for Janssen Vaccine** The FDA authorized an extension for the shelf life of the refrigerated Janssen COVID-19 Vaccine, allowing the product to be stored at 2-8 degrees Celsius for 11 months. **Read more**.
4/13/22	**FDA Authorizes New OTC COVID Tests** The FDA authorized two over-the-counter (OTC) at-home COVID-19 antigen tests. The validation data was gathered through the FDA's collaboration with the National Institutes of Health (NIH) and the Independent Test Assessment Program (ITAP). The emergency use authorizations (EUA) issued to Osang LLC were for their OHC COVID-19 Antigen Self-Test and Xiamen Boson Biotech Co., Ltd for their Rapid SARS-CoV-2 Antigen Test Card. **Read more**.
4/20/22	**Court Overrules CDC Mask Requirement on Public Transportation** As a result of a court order, effective as of April 18, 2022, CDC's order requiring masks on public transportation conveyances and at transportation hubs is no longer in effect. Therefore, CDC will not enforce the Order. CDC continues to recommend that people wear masks in indoor public transportation settings at this time. **Read more**.
4/20/22	**FDA Authorizes COVID-19 Breathalyzer Test** The FDA issued an emergency use authorization (EUA) to InspectIR Systems for their InspectIR COVID-19 Breathalyzer test. This is the first COVID-19 diagnostic test that detects chemical compounds in breath samples associated with SARS-CoV-2 infection. **Read more**.
4/20/22	**FDA and ASPR Evaluating Shelf-Life of Bamlanivimab and Etesevimab** The FDA and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) issued a **statement** that the shelf-life of bamlanivimab and/or etesevimab is being evaluated, and an update regarding shelf-life extension is planned for early May 2022.

4/20/22	**CLABSI Update to Compendium is Published** Updated CLABSI prevention guidance was published in Infection Control and Hospital Epidemiology (ICHE) on April 19. APIC is one of five organizations participating with SHEA in updating this HAI prevention guidance. Further updates to the Compendium are expected later in 2022. **Read more**.
4/27/22	**HHS Renews COVID-19 PHE** HHS Secretary Xavier Becerra renewed the COVID-19 public health emergency (PHE) through July 15, 2022. **Read more**.
4/27/22	**CDC HAN Advisory: Adenovirus Testing and Reporting of Children with Acute Hepatitis** The CDC issued a Health Alert Network (HAN) Health Advisory to notify clinicians and public health authorities of a cluster of nine children identified with hepatitis and adenovirus infection at a large children's hospital in Alabama between October 2021 and February 2022. All of the children were previously healthy and none had COVID-19. US clinicians who may encounter pediatric patients with hepatitis of unknown etiology should consider adenovirus testing and reporting of such cases to state public health authorities and to the CDC. **Read more**.
4/27/22	**CDC HAN Health Advisory: Updated Information on Treatment Options for COVID-19 Patients** The CDC issued a HAN Health Advisory to update healthcare providers, public health departments, and the public about the availability and use of recommended therapies for COVID-19 and to advise against using unproven treatments that have known or potential harms for outpatients with mild to moderate COVID-19. **Read more**.
4/27/22	**FDA Approves First COVID-19 Treatment for Young Children** The FDA expanded the approval of the COVID-19 treatment Veklury (remdesivir) to include pediatric patients ages 28 days and older with positive results of direct SARS-CoV-2 viral testing, who are hospitalized, or have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19. **Read more**.

Texas Register (2022-2023)

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

Last Review Completed: 4/29/2022

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
	1/26/22	Adopted	TAC25/Chapter 97	The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), adopts an amendment to §97.7, concerning COVID-19 school exclusion criteria

Prepared by 2022 APIC-DFW Governmental Affairs Committee:
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