DFW-APIC Government Affairs Committee
March 2022

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

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

2/2/22	**FDA Warning to Stop Use of Two COVID-19 Rapid Antigen Tests** The FDA is warning people to stop using the Empowered Diagnostics CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test. These tests have not been authorized, cleared, or approved by the FDA because of concern for high risk of false results. **Read the FDA safety communication**.
2/2/22	**FDA Approves Second COVID-19 Vaccine** The FDA has granted approval of the Moderna COVID-19 vaccine for individuals ages 18 and older. The vaccine will be marketed as Spikevax. **Read the FDA announcement**.
2/2/22	**Blaine Labs Recalls Some RevitaDerm Gel** Blaine Labs Company is voluntarily recalling one lot of RevitaDerm Wound Care to the consumer level because a bottle of the 1.0 ounce RevitaDerm Wound Care Gel has been found to be contaminated with *Bacillus cereus*. **Read the FDA announcement**.
2/4/22	The U.S. Food and Drug Administration (FDA) is warning people not to use the E25Bio COVID-19 Direct Antigen Rapid Test (DART). This test has not been authorized, cleared, or approved by the FDA for distribution or use in the United States, and it may include false labeling representing that the test is authorized by the FDA . The E25Bio COVID-19 Direct Antigen Rapid Test (DART) may also be sold under the trade name E25Bio SARS-CoV-2 Antigen Test Kit.
2/8/22	**Updated CDC Guidance for Schools, Childcare, and Colleges** Guidance for Institutions of Higher Education (IHEs) - Updated by CDC 2/7/22 Schools, Child Care, and Colleges - Updated by CDC 2/7/22
2/9/22	**CDC Updates Quarantine and Isolation Documents** The CDC released updated guidance regarding quarantine and isolation in healthcare and non-healthcare settings. Specifically, they have updated the following items: • **Infection Control: SARS-CoV-2** • **Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes**
2/9/22	**FDA Warning for STANDARD Q COVID-19 Ag Home Test** SD Biosensor, Inc., is voluntarily recalling its STANDARD Q COVID-19 Ag Home Test in the U.S. due to confirmed reports that the test kits were illegally imported. The STANDARD Q COVID-19 Ag Home Test is not authorized, cleared, or approved by the FDA for distribution or use in the United States. **Read the FDA recall notice**.
2/9/22	**Support the Infectious Disease Workforce Pipeline** The Senate Health, Education, Labor, and Pensions Committee has released its PREVENT Pandemics Act, bipartisan legislation that attempts to act on lessons learned from the pandemic response. Unfortunately, this legislation does not include language from the BIO Preparedness Workforce Act, which would directly invest in the infectious disease workforce pipeline. **Contact your Members of Congress** and tell them to cosponsor H.R. 5602/S. 3244, so lawmakers understand the importance of this legislation.
2/10/22	Health care facility administrator COVID-19 vaccine letter (PDF) - CMS update 2/1/22
2/11/22	**FDA Authorizes New Monoclonal Antibody Treatment** The FDA issued an EUA for a new monoclonal antibody for the treatment of COVID-19 that retains activity against the omicron variant. The EUA for bebtelovimab is for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older) with a positive COVID-19 test, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

	Bebtelovimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. **Read the FDA statement**.
2/18/22	COVID-19 Vaccines for Moderately to Severely Immunocompromised People - CDC update 2/17/22 Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes - CDC update 2/17/22 Self-Testing - CDC update 2/16/22
2/23/22	**Revised CDC COVID Guidance for Communities Coming** CDC is expected to revise their guidance for communities, to simplify and provide greater clarity to communities around when precautions such as masking and social distancing are most important. This guidance will **not** apply to healthcare or congregate living situations such as correctional facilities, group homes, or long-term care. **Sign up** to receive the latest updates from APIC on actions by CDC and other government agencies.
2/25/22	CDC is launching **COVID-19 Community Levels**, a tool to help monitor the number of new cases in communities across the country and the burden COVID-19 is placing on local healthcare systems. **It is important to note that these COVID-19 community level recommendations do not apply in healthcare settings, such as hospitals and nursing homes.** Healthcare settings should continue to follow **CDC's infection prevention and control recommendations for healthcare settings**, which continue to use **community transmission levels** as a metric for stratifying some IPC measures (e.g., use of source control, screening testing).

Texas Register (2022-2023)

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

Last Review Completed: 2/25/2022

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:
Jasmine Cluck, Patti Grant, Stephanie Kreiling, Rachel Watson