DFW-APIC Government Affairs Committee
July 2020

APIC Public Policy and E-News Highlights (2019-2020)

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

8/3/2020	*The FDA issued emergency use authorizations (EUAs) to Siemens for its ADVIA Centaur SARS-CoV-2 IgG (COV2G) and Atellica IM SARS-CoV-2 IgG (COV2G) tests, which are the first COVID-19 serology tests that display an estimated quantity of antibodies present in the tested individual's blood. These tests are known as "semi-quantitative" because they do not display a precise measure, but rather, they provide an estimate of the quantity of a patient's antibodies produced against infection with the virus that causes COVID-19. Read the FDA announcement.*
8/3/2020	*The U.S. Government Accountability Office (GAO) prepared a report to Congress to help decisionmakers understand the limitations of COVID-19 data, and the uses and limitations of various methods of analyzing and interpreting those data in order to use them effectively for intervention and planning purposes. Read the GAO report.*
8/3/2020	*The FDA is recommending that hospitals and endoscopy facilities transition to use of duodenoscopes that use disposable components that make reprocessing easier, more effective, or unnecessary. The agency is also working with manufacturers to revise reprocessing manuals for use in real-word healthcare settings. Because transition to newer scopes will take time due to cost and availability, FDA is encouraging facilities to develop transition plans to facilitate the move to newer and safer devices. Read the FDA safety communication, including a list of FDA-cleared duodenoscopes with disposable components.*
8/3/2020	*The U.S. Food and Drug Administration reissued the LabCorp COVID-19 RT-PCR Test emergency use authorization (EUA) to include two new indications for use: testing for people who do not have COVID-19 symptoms or who have no reason to suspect COVID-19 infection, and to allow pooled sample testing. Read the FDA announcement.*
8/3/2020	*FDA and the Federal Trade Commission (FTC) issued a joint warning letter to 21st Century LaserMed Pain & Regenerative Medicine Institute (d/b/a Create Wellness Clinics) for offering unapproved, unlicensed, uncleared and unauthorized products for the mitigation, prevention, treatment, diagnosis or cure of COVID-19. FDA reminds healthcare providers and consumers that there are currently no FDA-approved products to prevent or treat COVID-19.*
8/3/2020	*CDC has updated its recommendations for isolation following COVID-19. The new guidance focuses on the patient's symptoms rather than test results. Below are summaries of recent changes, along with links to updated CDC guidance.*
8/3/2020	The U.S. Government Accountability Office (GAO) released a brief on Herd Immunity for COVID-19. The brief explains herd immunity and analyzes the opportunities and challenges for COVID-19 immunity. Read the GAO report.
8/3/2020	The U.S. FDA is warning consumers and healthcare providers that the agency has seen a sharp increase in hand sanitizer products that are labeled to contain ethanol (also known as ethyl alcohol) but that have tested positive for methanol contamination. Methanol, or wood alcohol, can be toxic when absorbed through the skin or ingested and can be life-threatening when ingested. Read the FDA safety alert, including a list of products that have been found to contain methanol.

8/3/2020	CDC is offering a series of weekly one-hour web-on-demand videos that will provide an overview of vaccination principles, general best practices, immunization strategies, and specific information about vaccine-preventable diseases and the vaccines that prevent them. The series will start on July 1, 2020, and a new video will be released most Wednesdays through October 14, 2020. Please visit the Pink Book series page for the schedule and additional information. Continuing Education (CE) will be available for each event.
8/3/2020	Read about important NHSN updates in the June 2020 issue of the NHSN e-Newsletter. The newsletter includes information on NHSN COVID-19 activities, delay of the release of the Neonatal Component and Late Onset Sepsis and Meningitis Module, updates on the AUR module, and NHSN training updates.
8/3/2020	The FDA has updated the list of authorized ventilator, ventilator tubing connector, and ventilator accessory products that meet the criteria for the umbrella emergency use authorization (EUA) to expand availability of ventilators to treat COVID-19 patients. The umbrella EUA was issued in March 2020. Read the EUA and the updated Appendix B list of authorized products.
8/3/2020	The FDA sent a warning letter to Curativa Bay Corporation to cease sale of Advanced Hypochlorous Skin Spray, a topical hypochlorous acid-containing product which is intended to mitigate, prevent, treat, diagnose, or cure COVID-19. FDA reminds consumers that there are currently no FDA-approved products to prevent or treat COVID-19. Read the FDA warning letter.
8/3/2020	The FDA issued a letter to clinical laboratories and healthcare providers recommending that they stop using COVID-19 antibody tests that are listed on FDA's "removed" test list, found on the FDA's FAQs on Testing for SARS-CoV-2 webpage.
8/3/2020	The FDA announced that Avet Pharmaceuticals has voluntarily recalled several lots of Tetracycline HCl Capsules USP, 250 mg and 500 mg, 100-count bottles due to low dissolution test results. Low dissolution could result in insufficient amounts of the antibiotic available in the body to fight some upper and lower respiratory infections and skin and soft tissue infections. Read the FDA announcement.
8/3/2020	Meningococcal disease, which typically presents as meningitis or meningococcemia, is a life-threatening illness requiring prompt antibiotic treatment for patients and antibiotic prophylaxis for their close contacts. *Neisseria meningitidis* isolates in the United States have been largely susceptible to the antibiotics recommended for treatment and prophylaxis. However, 11 penicillin- and ciprofloxacin-resistant meningococcal disease cases have been detected in the United States during 2019–2020. For more information, see the CDC Health Advisory notice.
8/3/2020	The FDA revoked the emergency use authorization (EUA) of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 IgM/IgG System, a SARS-CoV-2 antibody test, due to performance concerns with the accuracy of the test. Read the FDA statement.
8/3/2020	The Joint Commission resumed limited survey activities this month. The primary focus will be on elements of performance related to inspection, testing, and maintenance of equipment and utilities that could raise serious safety concerns during the public health emergency. Read The Joint Commission announcement.
8/3/2020	The FDA revoked the emergency use authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate to be used to treat

	certain hospitalized patients with COVID-19. Based on its ongoing analysis, the agency determined that the potential benefits of these drugs no longer outweigh the known and potential risks. Read the FDA statement.

Texas Register (2019-2020)

http://www.sos.state.tx.us/texreg/index.shtml

Key: X Pending

Last Review Completed: 7/24/2020

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
	12/2/19	***Adopted***	**25 TAC §§200.1 - 200.6**	Rule amendment to comply with S.B. 384. The new law alters the list of HAIs that health care facilities must report to DSHS by removing the language outlining the specific medical procedures required for HAI reporting by facility type, and replacing it with a requirement for all health care facilities to report the list of HAIs that the CMS require facilities participating in the Medicare program to report. These changes have the effect of aligning state reporting requirements with federal CMS reporting requirements. In reference to NHSN, the rule eliminates the wording "or its successor."
	3/29/19	***Adopted***	**25 TAC §133.50**	Requires that a hospital provide a patient the opportunity to designate a caregiver to receive aftercare instructions on admission or before the patient is discharged or transferred to another facility. Also outlines the hospital's responsibility to document information, in the patient's medical record, regarding the designated caregiver or the patient's declination to designate a caregiver.
	1/18/19	***Signed by Governor***	**S.B. No. 384**	**Effective 9/1/19.** **For HAIs occurring on or after 1/1/2020** Expands what HAIs must be reported by hospitals and ambulatory surgical centers to the Texas Department of State Health Services. A hospital or ambulatory surgical center must report each HAI to the Texas Department of State Health Services regardless of the facility's participation in Medicare. The legislation would also require the pathogen to be identified if the infection is laboratory confirmed. https://capitol.texas.gov/BillLookup/Text.aspx?LegSess=86R&Bill=SB384
X	2/4/19	***Referred to Human Services committee (2/27/19)***	**HB 1360**	Relating to prevention of communicable diseases in certain long-term care facilities. https://capitol.texas.gov/BillLookup/Text.aspx?LegSess=86R&Bill=HB1360

	2/14/19	***Signed by Governor***	**HB 1848**	**Effective 9/1/19** Companion to HB 1360 – relating to prevention of communicable diseases in certain long-term care facilities. https://capitol.texas.gov/BillLookup/History.aspx?LegSess=86R&Bill=HB1848
X	1/10/19	***Left pending in committee (4/23/19)***	**SB 329**	Relating to requirements for and the transparency of epidemiological reports and certain immunization exemption information and reports. The dept shall prepare & submit "(1) report of outbreaks of vaccine preventable diseases in this state; and (2) de-identified immunization exemption information, including the number of persons claiming an exemption from the immunization requirements"
X	2/7/19	***Referred to Public Health 2/27/19***	**HB 1490**	Relating to claiming an exemption from required immunizations for public school students. "The department may not maintain a record of the number of affidavit forms submitted or the names of individuals who submit [request] an affidavit form under this section."
	3/27/20	***Effective 3/27/20-7/24/20***	**25 TAC §135.2, §135.26**	The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 25 Texas Administrative Code, Chapter 135, Ambulatory Surgical Centers (ASCs), amendments to §135.2 and §135.26, in order to expand ASCs' treatment capabilities and modify current reporting requirements to mitigate issues caused by patient surge due to COVID-19. (complete text was posted in the APIC-DFW GAC section)

Prepared by 2020 APIC-DFW Governmental Affairs Committee:
Jasmine Cluck, Heather Kirby, Patti Grant, Stephanie Kreiling