

**DFW-APIC Government Affairs Committee
September-October 2021**

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

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

<https://apic.org/publications/enews/>

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| 9/1/21 | <p>FDA Warns Against Using Shanghai Dasheng Products The FDA is alerting healthcare facilities to stop using N95 respirators manufactured by Shanghai Dasheng Health Products Manufacture Co., Ltd. (Shanghai Dasheng). NIOSH revoked all respirator approvals previously issued to Shanghai Dasheng because the firm did not implement, maintain, and control a quality management system. All previously authorized Shanghai Dasheng respirators are no longer authorized for emergency use as a result of the loss of NIOSH-approval. Read the FDA announcement</p> |
| 9/1/21 | <p>CDC/FDA Warn Against Use of Ivermectin for COVID-19 The CDC and FDA are reminding retail pharmacies and veterinarians that ivermectin is not authorized or approved for prevention or treatment of COVID-19. The CDC issued a Health Advisory noting increasing adverse events related to misuse and overdose of veterinary formulations of the drug. The FDA has issued a letter to pharmacies and veterinarians to ask for help in sharing important safety information about the danger to people misusing ivermectin in animal concentrations to prevent or treat COVID-19.</p> |
| 9/8/21 | <p>CDC Report: The Impact of COVID-19 on HAIs in 2020 The CDC published a report summarizing the impact of the COVID-19 pandemic on rates of HAIs in U.S. hospitals in 2020. Data reported to CDC's NHSN found a significant increase in the following HAIs: CLABSIs, CAUTIs, VAEs, MRSA bacteremia</p> |
| 9/15/21 | <p>WH Issues COVID-19 Vaccination Mandates President Biden issued Executive Orders requiring all federal employees and federal contractors to be vaccinated against COVID-19. For more information read: Executive Order on Requiring COVID-19 Vaccination for Federal Employees & Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors</p> |
| 9/15/21 | <p>COVID-19 Vaccination Required for All Staff in Medicare/Medicaid-Certified Facilities CMS, in collaboration with the CDC, announced that emergency regulations requiring COVID-19 vaccinations for nursing home workers will be expanded to include hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies, among others, as a Condition of Participation in the Medicare and Medicaid programs. The decision was based on the continued and growing spread of the virus in healthcare settings, especially in parts of the U.S. with higher incidence of COVID-19. Read the CMS news release</p> |
| 9/15/21 | <p>Azurity Recalls Some Vancomycin Products Azurity Pharmaceuticals, Inc., is voluntarily recalling one lot of Firvanq® (vancomycin hydrochloride for oral solution), Vancomycin 50 mg/mL Kit ("Firvanq®"), as some products in the affected lot have been found to incorrectly contain a First Omeprazole (FIRST-PPI) diluent instead of the Firvanq® diluent bottle. Firvanq® is indicated for use in adults and pediatric patients less than 18 years of age for the treatment of <i>Clostridium difficile</i>-associated diarrhea and Enterocolitis caused by <i>Staphylococcus aureus</i> (including methicillin-resistant strains). Read the FDA announcement.</p> |
| 9/15/21 | <p>BYD Issues Respirator User Notice BYD Precision Manufacture Co., Ltd. issued a respirator user notice about a small subset of model DE2322 N95 respirator units that do not meet the NIOSH N95 criteria. Read the BYD notice to customers, including list of affected models.</p> |
| 9/22/21 | <p>CDC Announces \$2.1 Billion to Strengthen IPC The CDC announced a \$2.1 billion investment to enhance IPC activities across the U.S. public health and healthcare sectors. This investment will be used to strengthen and equip state, local, and territorial public health departments and other partner organizations with the resources needed to better fight infections in U.S. healthcare facilities, including COVID-19 and other known and emerging infectious diseases. Read the CDC press release.</p> |
| 10/6/21 | <p>CDC: COVID-19 Vaccination Recommended for Pregnant People The CDC recommends urgent action to increase COVID-19 vaccination among people who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future. CDC strongly recommends COVID-19 vaccination</p> |

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| | either before or during pregnancy because the benefits of vaccination outweigh known or potential risks. Learn more. |
| 10/13/21 | FDA Increases Regulation of Surgical Staplers and Staples The FDA announced updates to improve regulatory oversight of surgical staplers and staples. The agency issued a final order reclassifying surgical staplers for internal use from Class I to Class II and requiring them to undergo premarket review. Read more |

Texas Register (2021-2022)

| http://www.sos.state.tx.us/texreg/index.shtml | | Key: X Pending | | |
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| Last Review Completed: 10/13/2021 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/H B | Topic / Comments |
| | 3/1/21 | <i>Referred to Public Health</i> | HB 591 | Requires vaccination against bacterial meningitis for public school students |
| | 6/15/21 | <i>Signed by Governor – takes effect 9/1/21</i> | HB 2211 | Pertaining to in-person hospital visitation during periods of disaster: The state government cannot issue a no visitor hospital order & all patients may have a visitor unless they fail screening or a physician documents they may not. Hospitals are allowed by law to require visitor PPE. |
| | 10/7/21 & 10/12/21 | <i>In Committee</i> | HB 155 & SB 51 | Prohibiting COVID vaccine mandates |

**Prepared by 2021 APIC-DFW Governmental Affairs Committee:
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