## DFW-APIC Government Affairs Committee December 2018-January 2019

## **APIC Public Policy and E-News Highlights (2018)**

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| nttp://apic. | .ora/Member | -Services | /Publicatio | ns/E-News |

| ittp://apic.org/iv | lember-Services/Publications/E-News   |  |  |  |  |
|--------------------|---|--|--|--|--|
|                    | Read about the release of updates to NHSN, including the releases of Version 9.2, 2019 Patient          |  |  |  |  |
| 12/19/18           | Safety Component protocols, and the new Outpatient Procedure Component.                                 |  |  |  |  |
|                    | NIOSH clarifies policy on facial hair and respirators   |  |  |  |  |
|                    | Conformity Assessment Interpretation Notice 2018-1005 Rev 1 clarifies that people who serve as          |  |  |  |  |
|                    | test subjects for product evaluation or fit testing of respirators must be clean-shaven, as facial hair |  |  |  |  |
| 12/19/18           | can interfere with the face-to-face piece seal or valve function.                                       |  |  |  |  |
|                    | The FDA is providing interim results from the ongoing mandated postmarket surveillance studies          |  |  |  |  |
|                    | ("522 study") to inform patients, hospitals and healthcare facilities of higher-than-expected           |  |  |  |  |
|                    | contamination rates with duodenoscopes after reprocessing. Facilities and staff that reprocess          |  |  |  |  |
|                    | duodenoscopes are reminded of the importance of manual cleaning prior to disinfection or                |  |  |  |  |
| 12/12/18           | sterilization and proper servicing of duodenoscopes. Read the <u>FDA safety communication</u> .         |  |  |  |  |
|                    | The National Academies of Science, Engineering, and Medicine conducted a study on the use of            |  |  |  |  |
|                    | half-facepiece reusable elastomeric respirators in health care. A pdf version of the prepublication     |  |  |  |  |
|                    | copy of that report Reusable Elastomeric Respirators in Health Care: Considerations for Routine         |  |  |  |  |
| 12/12/18           | and Surge Use can be downloaded at no cost through the National Academies webpage.                      |  |  |  |  |
|                    | The FDA is alerting healthcare professionals and patients not to use drugs produced and                 |  |  |  |  |
|                    | distributed by Promise Pharmacy due to lack of sterility assurance. FDA inspectors found                |  |  |  |  |
| 12/12/18           | insanitary conditions and poor sterile production practices. Read the FDA safety alert.                 |  |  |  |  |
|                    | Post-Acute Care (PAC) provider reports for long-term acute care hospitals (LTCH) and inpatient          |  |  |  |  |
|                    | rehabilitation facilities (IRF) based on Q2 2017–Q1 2018 quality reports are available for provider     |  |  |  |  |
|                    | preview until January 2, 2019 before being posted to the LTCH Compare and IRF                           |  |  |  |  |
| 12/5/18            | <u>Compare</u> websites. See instructions to access preview reports for <u>LTCH</u> and <u>IRF</u> .    |  |  |  |  |
|                    | The FDA announced that an emergency use authorization (EUA) has been issued for a rapid,                |  |  |  |  |
| 11/14/18           | single-use test for the detection of Ebola virus (Zaire ebolavirus). Read the FDA news release.         |  |  |  |  |
|                    | CDC published the 2016 Healthcare-Associated Infection Progress Report, to help highlight               |  |  |  |  |
|                    | progress in HAI prevention and target areas that need improvement. This is the first annual report      |  |  |  |  |
|                    | measuring year-to-year progress using the 2015 baseline. This is also the first progress report to      |  |  |  |  |
| 10/24/18           | be published in CDC's AR Patient Safety Atlas.  |  |  |  |  |
|                    | Promise Pharmacy is voluntarily recalling one lot of Prednisolone and Gatifloxacin Ophthalmic           |  |  |  |  |
|                    | Solution 1%/0.5% sterile, 3ml vials because the product has been found to have unidentified small       |  |  |  |  |
| 10/24/18           | particulate floating in the solution. Read the <u>FDA safety alert</u> .                                |  |  |  |  |
|                    | The FDA has approved Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated              |  |  |  |  |
|                    | influenza in patients 12 years of age and older who have been symptomatic for no more than 48           |  |  |  |  |
| 10/01/10           | hours. This is the first new antiviral flu treatment approved by the FDA in nearly 20 years. Read       |  |  |  |  |
| 10/24/18           | the FDA announcement.   |  |  |  |  |
|                    | The FDA notified healthcare providers that LivaNova issued a Medical Device Correction letter to        |  |  |  |  |
|                    | announce the availability of a design upgrade and updated instructions to reduce the potential risk     |  |  |  |  |
| 10/01/15           | of infection from the Stockert 3T Heater-Cooler System during cardiac surgery. Read the FDA             |  |  |  |  |
| 10/24/18           | safety communication.   |  |  |  |  |

## Texas Register (2018)

| 10/45 11081501 (2020)   |            |        |                 |  |  |  |  |
|---|------------|--------|-----------------|--|--|--|--|
| http://www.sos.state.tx.us/texreg/index.shtml Last Review Completed: 12/28/2018 Current Search Parameters for Review: 25 TAC: Chapters 2, 97, 133, 135, 200 |            |        |                 |  |  |  |  |
| 30 TAC: Chapter 330; Subchapter Y   |            |        |                 | Key: X Pending                                       |  |  |  |
| X   | Date Filed | Action | Title/Ch./Rules | Topic / Comments                                     |  |  |  |
|   |            |        |                 | No proposed or adopted rules affecting us this month |  |  |  |