DFW-APIC Government Affairs Committee
April 2018

APIC Public Policy and E-News Highlights (2018)

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

2/27/2018	**FDA Rule on Healthcare Antiseptics:** On December 20, 2017, the U.S. Food and Drug Administration (FDA) issued its final rule on safety and effectiveness of topical antiseptics used in healthcare. FDA requested additional scientific data from manufacturers about the safety and effectiveness of antiseptic products used in healthcare settings. **Products addressed by this rule include:** healthcare personnel handwashes and rubs, surgical hand scrubs and rubs, patient preoperative skin preparations, including pre-injection preparations, Active ingredients: alcohol and iodine. **Products not addressed by this rule include:** products containing chlorhexidine gluconate, consumer antiseptic products such as antibacterial hand soap and body washes (addressed in separate proposed rule in 2013). FDA reclassified 24 ingredients as not generally recognized as safe and effective (GRASE) and can no longer be used. Of these ingredients, only triclosan is currently used in healthcare antiseptics. **FDA deferred action for one year on six additional ingredients to allow manufacturers more time to provide data:** ethanol, isopropyl alcohol, povidone-iodine, benzalkonium chloride, benzethonium chloride, chloroxylenol. **FDA rule does not impact CDC or WHO hand hygiene guidelines.**
3/9/18	**Scope makers warned about post-market surveillance** The FDA issued warning letters to all three duodenoscope manufacturers (Olympus, Fujifilm, and Pentax) for failing to comply with federal orders requiring them to conduct post-market surveillance studies to assess the effectiveness of reprocessing the devices. Read the FDA news release.
3/26/18	The President signed an omnibus bill that will fund the government through September 31, 2018. The $1.3 trillion legislation was a compromise between Democrat and Republican priorities and provided stable funding for most APIC legislative priorities. However, when compared to FY 2017 levels, the omnibus bill did increase funding for several healthcare agencies.Some highlights of the legislation are below: • Department of Health and Human Services received an increase of $10 billion; • National Institutes of Health received an additional $3 billion; o including an additional $40 million for research into a universal flu vaccine; • Centers for Disease Control and Prevention received an increase of $840 million; and • Agency for Healthcare Research and Quality received an additional $10 million.
3/26/18	HHS Secretary Alex Azar named Robert R. Redfield, M.D. as the new CDC director.
3/26/18	The FDA is reminding consumers to be wary of unapproved products claiming to prevent, treat or cure influenza. This year's severe flu season raises new concerns about the potential for consumers to be lured into buying unproven treatments, or counterfeit antivirals online from websites that appear to be legitimate online pharmacies.
3/26/18	The FDA is alerting healthcare professionals and patients not to use drug products produced by Cantrell Drug Company of Little Rock, Arkansas, due to concerns about serious deficiencies in Cantrell's compounding operations that put patient safety at risk. The FDA has also sought legal action to prevent the company from further producing and distributing drugs, and to recall all products currently on the market. Read the FDA safety alert.
3/26/18	Hospira is voluntarily recalling three lots of Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials due to the potential that units from these lots may be empty or cracked at the bottom of the glass vial. Cracked vials may compromise product sterility. Read the FDA safety alert.
3/26/18	Sagent Pharmaceuticals announced the voluntary nationwide recall of ten lots of Methylprednisolone Sodium Succinate for Injection, USP, 40mg, 125mg, and 1g. A detailed listing of products and lots is listed in the recall notice. These products were manufactured by Gland Pharma Ltd. and distributed by Sagent Pharmaceuticals. Sagent has initiated the recall due to the discovery of high impurity results detected during routine quality testing. This impurity has not yet been identified. Read the FDA safety alert.

3/27/18	NFID has released a Call to Action on Improving Healthcare Personnel Immunization Rates to optimize practices that will lead to improved immunization rates among healthcare personnel (HCP). APIC participated in the 2017 summit convened by NFID with representatives from infection prevention and control, occupational health, and immunization which led to the development of the Call to Action. Sign up for an April 5 NFID webinar on Improving Healthcare Personnel Immunization Rates.

Texas Register (2018)

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

Last Review Completed: **3/30/2018**

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
	3/1/2018	***Proposed***	**25 TAC §97.136**	Proposed amendment concerning prophylaxis against Ophthalmia Neonatorum, to comply with Texas Health and Safety Code, §81.091, as amended by HB 2886: -A health care provider who is unable to apply prophylaxis to a newborn due to the objection of a parent, managing conservator, or guardian of the newborn infant does not commit an offense and is not subject to criminal, civil, or administrative liability or any professional disciplinary action for failure to administer the prophylaxis. -The health care provider is required to document the refusal of the parent, managing conservator, or guardian in the infant's medical record.

Prepared by 2018 APIC-DFW Governmental Affairs Committee:
Jasmine Cluck, Heather Kirby, Patti Grant, Stephanie Kreiling