



**PHARMACY STANDARDS COMMITTEE TELECONFERENCE**  
**TUESDAY, MARCH 27, 2018**

11am Pacific/ 2pm Eastern

Phone # 866-423-8755 and enter Passcode 858324# (Officers add 7#)

Press \*6 to mute and un-mute your line.

Present: Dawn Holcombe, (*Chair*); Wendy Alfaro; Nichole East; Warren Fong, MD; Diane Gerards-Benage; Jose Gonzalez; Denise Johnstone; Mariana Lamb; Ricky Newton; and Tammy Thiel.

Absent: Lisa Chew, RN; Shelley Davidson, RN; Karen Haughey, RN; Lynn Staudter; and LaTayna Wooten.

**MINUTES**

I. **Pharmacy Standards Committee Charge**

NOSN will facilitate dissemination, education, preparation and resources for member states and groups on the activities, talking points, and compliance and advocacy opportunities related to pharmacy standards.

II. **USP Compliance Standards**

USP is a non-profit that has created the compliance standards, however, they do not enforce them. NOSN has obtained a copy of the USP compliance standards. There are tight restrictions on what information can be shared. Dawn will be dissecting and summarizing for all: 1) Biggest issues; 2) Responsibilities; 3) Parameters; 4) Tools to move forward. She will divide the list into two categories of “should” and “must”.

**(Attached)**

**Discussion:**

USP 797 is undergoing a revision as 800 is pending, unsure when those <797> changes will be published. USP 800 was to go into effect on July 1, 2018, but was later modified to December 1, 2019. However, USP is not the enforcer and it varies per state. USP will also not interpret the language. It is up to each practice to interpret and implement changes and to understand state enforcement when it arises. Some enforcers could be Board of Pharmacy, Board of Medicine, OSHA, etc. Chapter 797 covers sterile compounding and the quality of the drugs and 800 covers hazardous drugs and the protection of the people. The standards are different for each enforcer, there is no way to write one general standard for everyone.

**Action:**

1. In order to avoid any potential liability issues, NOSN will NOT distribute standards for practices to follow.
2. This Committee will create 1) factual summary of 797 as it is now, 2) factual summary of 800, both will be organized in a list of “Should” vs. “Must”.
3. There will also be a statement stating “this information is subject to individual state regulations.”
4. NOSN will collaborate where possible with ASCO and ONS.
5. Dawn will create a separate document with a list of talking points when questions arise.
6. Dawn will help NOSN to provide perspective and resources on a state by state basis as questions arise.

III.

**Old Business:**

Known State Activities.

1. California – (*Jose*) AB1202 Occupational safety and health standards: hazardous drugs, passed 10/09/2013. In the language, there is no reference to USP Chapters nor Standards. The NIOSH guidelines have not been finalized, but have been in “draft form” for three years. If and when the language is finalized, there will be a 45-day comment period. Currently, there is no new USP legislation being written. DGH noted that the core group that wrote the NIOSH guidelines wrote or has been closely aligned with the core group that wrote the USP <797> and <800> standards, so there is significant overlap in the details.
2. Maryland – Study and Recommendations on Senate Bill 1108 (Chapter 580 of the Acts of 2014) (*LaTayna*)
3. Michigan –
4. New Jersey (*Denise*) Hazardous Drug Safe Handling Act on May 11, 2017, which requires promulgation of standards and regulations concerning safe handling of hazardous drugs by certain healthcare personnel. The NJ Legislature determined that it is the public policy of the state to provide for the appropriate regulation of the handling of hazardous drugs consistent with the [2004 NIOSH alert](#) as well as any updates to the NIOSH list of hazardous drugs. New Jersey is the fourth state to pass similar legislation following California, North Carolina and Washington.
5. North Carolina - HB644 Prevent Hazardous Drug Exposure (signed by Governor 7/22/2014).
6. Virginia – 2015 - Board of Pharmacy (*Ricky*)
7. Washington – WAC 296-62-500 new Hazardous Drugs Regulations Adopted 1/1/2015.

**Status:**

The goal is to monitor legislative activity in each state and provide assistance to move through it.

IV.

**New Business:**

1. Ricky distributed Opinions regarding Frier Levitt Catalogue of State Laws Regulating PBM's on the COPA website.
  - i. *PBM Licensure Requirements*: Provisions of state law regarding PBM licensure requirements, if any.
  - ii. *Any Willing Provider*: Relevant statutes prohibiting insurers and PBMs from creating exclusive provider networks, or unduly barring entry to such networks, to which insured patients are directed to the detriment of non-network providers.
  - iii. *Prohibition on Pharmacy DIR*: Applicable language preventing PBMs from imposing Direct and Indirect Remuneration Fees on pharmacies or other providers dispensing prescription medications.
  - iv. *Prompt Pay*: Relevant state law provisions regarding the prompt payment requirements PBMs must adhere to.
  - v. *Fair Pharmacy Audit*: Applicable language ensuring protection of pharmacies from oppressive audit techniques engaged in by PBMs.
  - vi. *MAC Appeal*: Relevant provisions of legislation designed to protect pharmacies and dispensers from the institution of MAC pricing without fair and adequate notice, and the applicable appeal procedures, if any.
  - vii. *PBM and DIR legislation*: Provide interpretation and analysis of language with what is good and bad. Include language that should be incorporated into bills being proposed at the state level. Model language that would include state-level DIR prohibitions and other pro-physician dispenser laws that the practices could lobby their states to adopt.
2. Map of Activities. Dawn is creating a map of the states with list of legislative activities.

- V. **Next Meeting:**  
The next meeting will be scheduled in six weeks via email.

The meeting adjourned at 11:55AM.