



# SC DEPARTMENT OF LABOR, LICENSING, & REGULATION

## BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

### **Upcoming Board Vacancy**

Do you live in the Sixth Congressional District? Are you interested in serving on the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy? Here is your opportunity! You must meet the following requirements:

- reside in the Sixth Congressional District;
- be licensed and actively practicing pharmacy in South Carolina; and
- before December 1, 2023, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in your respective congressional district.

The term will begin on July 1, 2024, and end on June 30, 2030. After receiving biographies and petitions, the Board executive will:

- prepare and mail ballots by January 15, 2024, to all pharmacists who have notified the Board that they reside in the Sixth Congressional District, and
- certify as true and valid all ballots postmarked before February 15, 2024, and received by the Board office before February 25, 2024.

Before March 1, 2024, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take

#### ***National Pharmacy Compliance News***

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office on July 1 of that year. If you are interested in becoming a candidate for this position and have questions, please contact the Board office at 803/896-4700.

### ***Welcome Investigator Harris***

The Board would like to welcome Jennifer Harris, PharmD, as its newest investigator. After graduating from the University of South Carolina College of Pharmacy, Jennifer started her pharmacy career in the retail setting. She later worked as an inspector for the South Carolina Department of Health and Environmental Control Bureau of Drug Control and, most recently, as an investigator for the South Carolina Board of Medical Examiners and the State Board of Nursing for South Carolina. Welcome, Jennifer!

### ***Updated Advisory Opinion on IV Hydration***

As noted in the [August Newsletter](#), the Board issued an advisory opinion regarding intravenous (IV) hydration. Since then, the Board of Medical Examiners and the Board of Nursing have joined in and created a joint advisory opinion regarding the practice of IV hydration. That joint opinion, *Joint Advisory Opinion of the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses*, can be found [here](#). Please keep in mind that this opinion is related to the growing practice of retail/concierge IV hydration and not health systems.

### ***DSCSA: Are You Ready?***

The Drug Supply Chain Security Act (DSCSA), set to go into effect in November 2023, has now received a one-year stabilization period from Food and Drug Administration to allow trading partners time to work together to be ready for full enforcement. This does not mean that DSCSA has been delayed. Trading partners, including dispensers, need to be utilizing this stabilization period to ensure that they are ready. The Board will begin an extensive training campaign later this year. More details will be forthcoming.

### ***New Board Policies***

At the September 2023 meeting, the Board reviewed and approved two new policies that had been developed and recommended by various Board committees.

#### ***Remote Order Entry by Technicians Policy 151***

The Board interprets “direct supervision” and “personal supervision,” as stated in the South Carolina Pharmacy Practice Act and its corresponding regulations and policies, to allow remote order entry by technicians registered with the Board when certain best practices are being utilized and the technician is being supervised by a South Carolina-licensed pharmacist. This policy does not waive, limit, or dissolve any requirements mandated by the Board in its rules and regulations

regarding supervision of pharmacy technician functions or the role of a pharmacist in dispensing processes. In addition, remote technicians engaging in data entry from a remote alternative worksite **are** included in the ratio requirements set forth in statute. You can find the full policy [here](#).

### ***Automated Secure Pharmacy Pickup Kiosk and Locker Systems Policy 152***

This policy allows for the utilization of a pickup kiosk to increase patient access. An automated secure pharmacy pickup kiosk and locker system (ASPLS) is a device that is loaded with patient-specific prescriptions that have been filled by a supervising South Carolina-permitted pharmacy in the presence of a South Carolina-licensed pharmacist. A kiosk/screen/camera/scanner ensures security and enables the patient to have access to a pharmacist when the technology is serving patients or the agent of the patient.

All ASPLSs, whether on site at the supervising South Carolina-permitted pharmacy or off site, will be under the pharmacy permit where the patient-specific prescriptions were filled. You can find the full policy [here](#).

### ***USP Updates***

As compounders are gearing up for the revised United States Pharmacopeia (USP) standards, it is important to keep in mind that the Board is currently limited to what is written in the South Carolina Pharmacy Practice Act. That being said, [H3592](#), if passed in its current state, would repeal all compounding language in the Pharmacy Practice Act and allow the Board to promulgate regulations regarding compounding. The legislative session will resume in mid-January 2024.

### ***Sterile Ophthalmic Drops***

Although the Board is not enforcing full USP compliance, it is critical that proper procedures for sterility continue to be a priority. In recent inspections of nonsterile compounding pharmacies, it has been found that cyclosporine ophthalmic drops/solutions are being compounded in nonsterile areas. The fact that these drops are generally used on dogs does not impact how the drops should be compounded.

Per USP <797> (version official as of November 1, 2023):

#### **1.1 Scope**

##### **1.1.1 CSPs affected:**

The requirements in this chapter must be met to ensure the sterility of any CSP.

Although the list below is not exhaustive, **the following must be sterile:**

- Injections, including infusions
- Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity)

or peritoneal cavity). [Note—Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]

- **Ophthalmic dosage forms**
- Aqueous preparations for pulmonary inhalation. [Note—Nasal dosage forms intended for local application are not required to be sterile.]
- Baths and soaks for live organs and tissues
- Implants

(emphasis added)

If you have been compounding **any** ophthalmic dosage forms in a nonsterile compounding pharmacy, you must stop this practice immediately. You should notify all prescribing providers that you will no longer be providing this product and direct them to contact a pharmacy that provides sterile compounding services. You should review your compounding records to determine if a recall needs to be initiated.

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