NOVEMBER 2024

SC DEPARTMENT OF LABOR LICENSING, & REGULATION – BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Board Seeks Committee Members

The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy is looking to add licensed pharmacists, pharmacy technicians, and pharmacy interns to the following Board advisory committees:

- **Practice and Technology** – recommends policies, procedures, and guidelines pertaining to pharmacy practice and standards; assists in the development of informational materials for circulation to licensees and registrants; and provides input related to the use of health information technology, health information exchange systems, telemedicine/telepharmacy, telehealth, and other nontraditional service delivery models.
- **Pharmacy Technician** – recommends policies and decisions that reflect the real-world experiences and challenges faced by pharmacy technicians; provides input on how technicians can practice to the height of their training and education when providing pharmacy services to improve pharmacy operations and, ultimately, patient care; and collaborates across practice areas (eg, community, hospital, residential care) to ensure a cohesive approach to common issues unique to pharmacy technicians.
- **Legislative** – reviews and comments on existing legislation and rules governing the practice of pharmacy; recommends pharmacy practice legislation needed to improve and protect public health to the Board; and provides input and suggestions regarding the fiscal impact and practice implications of new statutes and regulations and/or the amendment or repeal of existing statutes and regulations.

Serving on a Board committee gives you the opportunity to positively

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Board Seeks Committee Members

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impact pharmacy practice in this state. You will work collaboratively to provide your unique perspective, experience, and expertise on timely issues. Committees meet at least four times per year, and meetings are typically held virtually. To be considered for a seat on a Board committee, please submit a letter of interest along with a current resume to contact.pharmacy@llr.sc.gov.

Expanded Practice During State of Emergency Declarations

To facilitate disaster preparedness and response, South Carolina Code Section 40-43-170 allows the following during the state of emergency:

Out-of-State Pharmacists

A pharmacist not licensed in South Carolina but currently licensed in another state may dispense prescription medications in affected counties during the time that a state of emergency exists if:

- The pharmacist has some type of identification to verify current licensure in another state; and
- The pharmacist is engaged in a legitimate relief effort during an emergency situation.

Emergency Refills

A pharmacist may dispense a one-time emergency refill of up to a 30-day supply of a prescribed medication if:

- The pharmacist has all the prescription information necessary to accurately refill the prescription;
- In the pharmacist's professional opinion, the medication is essential to the maintenance of life or the continuation of therapy;
- The pharmacist reduces the information to a written prescription marked "Emergency Refill," files the prescription as required by law, and notifies the prescribing physician within 15 days of the emergency refill; and
- The prescription is not for a controlled substance (CS).

If a pharmacy computer is not working, prescriptions may be dispensed manually with labels typed or handwritten using a waterproof pen. Since printed drug information may not be available, patient counseling should clarify any questions the patient may have.

For questions regarding the impact of a state of emergency declaration on the dispensing of CS, please contact the South Carolina Department of Public Health.

Emergency Key Boxes

The Board has recently received numerous questions about whether an emergency key can be made available for first responders in the event of a fire. The Board discussed this topic at its meetings in March 2019 and again in June 2019, when the Board determined that it is the duty of the pharmacist-in-charge (PIC) to maintain the security of the pharmacy while remaining in compliance with the fire code.

Each town and/or county may have differing requirements and laws, so this can look different for each pharmacy or other permitted facility. This decision will be left up to the PIC and/or permit holder in conjunction with the local fire chief, and best practice would include a written policy with a copy of the fire code for your location.

Clarification of DSCSA Exemptions for Small Business Dispensers

On June 12, 2024, Food and Drug Administration (FDA) issued exemptions for small business dispensers and – in limited circumstances – their trading partners from certain requirements in Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A revised letter clarifying these exemptions was issued by FDA on July 12, 2024. FDA is issuing these exemptions to accommodate the additional time that small business dispensers may need beyond November 27, 2024, to fully transition to interoperable, electronic product tracing at the package level under the Drug Supply Chain Security Act (DSCSA). These exemptions end on November 27, 2026.

For this exemption, a dispenser is considered a "small business dispenser" if the corporate entity that owns it has a total of 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians.

FDA does not exempt small dispensers or their trading partners from their existing compliance obligations under DSCSA.

The exemptions relate to the enhanced drug distribution security requirements in Section 582(g)(1) and 582(d)(4) of the FD&C Act. Specifically, they exempt small dispensers from using electronic and interoperable methods for all the following:

- Exchanging transaction information and transaction statements with trading partners.
- Conducting product verifications, including suspect and illegitimate products.

Clarification of DSCSA Exemptions for Small Business Dispensers

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- Gathering transaction information for recalls at the package level.
- Gathering information to respond to a regulator for circumstances when they identify a suspect or illegitimate product.

Dispensers may continue to rely on current methods for performing the functions above.

Small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA, but FDA strongly recommends that small business dispensers relying on the exemptions communicate such reliance to their trading partners as needed to further facilitate the distribution of products without difficulty or delay.

FDA's July 12, 2024 letter can be found at *https://www.fda.gov/media/179256/download?attachment.*

Additional information on the small dispenser exemption can be found at *https://nabp.pharmacy/news/blog/fdas-small-dispenser-dscsa-exemption/.*

Compounding Confusion: Guidance for Pharmacies Seeking to Compound Under Section 503A

The compounding pharmacy market size is estimated to almost double from $16.19 billion in 2023 to a projected $30.97 billion by 2033. As community pharmacies explore the role that compounding should play in their business models, it is essential to understand the regulatory framework surrounding the practice.

Section 503A of the FD&C Act provides criteria that must be met to exempt a human drug product compounded by a licensed pharmacist in a state-licensed pharmacy from requirements such as approval of new drug applications, certain detailed federal labeling requirements, and implementation of current Good Manufacturing Practice.

One of the conditions that must be met by a "503A pharmacy" is to only use bulk drug substances in compounding drug products that:

- comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if one exists, and the USP chapter on pharmacy compounding;
- are components of FDA-approved drug products, if an applicable USP or NF monograph does not exist; or
- appear on FDA's list of bulk drug substances, which can be used in compounding (the 503A bulks list), if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

FDA has not yet finalized the 503A bulks list; however, it issued a draft guidance titled *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act* in December 2023 describing the agency's interim policy regarding compounding. This guidance can be found here.

Another resource available from FDA is a recorded webinar titled *FDA Drug Topics – Regulatory Framework for Human Drug Compounding,* which is available on demand and provides a general overview suitable for anyone interested in compounding. It is viewable on YouTube.

Finally, additional FDA guidance related to drug compounding can be found here.

National Diabetes Month Toolkit for Pharmacists

November is National Diabetes Month. Centers for Disease Control and Prevention (CDC) estimates that about one in four health care dollars are spent on people diagnosed with diabetes. About one in three adults in the United States have prediabetes, and more than eight in 10 of them do not know they have it.

Because of the frequency of patient encounters, knowledge of preventive care, and relationships with providers and patients, pharmacists are uniquely poised on the front line of the fight against diabetes. CDC's National Diabetes Prevention Program has developed a toolkit just for pharmacists that includes resources and action plans designed to help them reach high-risk patients and prevent new cases of type 2 diabetes. The toolkit can be found at *https://www.cdc.gov/diabetes-prevention/hcp/pharmacists/index.html.*

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