



# SC DEPARTMENT OF LABOR, LICENSING, & REGULATION

## BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

### ***A Word From Our Outgoing Chair***

As my tenure as the chair of the South Carolina Board of Pharmacy comes to a close, I am filled with deep gratitude and appreciation for the unwavering support and dedication of each and every one of my fellow Board members. Their commitment to upholding the highest standards of pharmacy practice and regulation has been truly inspiring.

Together, we have achieved significant milestones and made impactful strides in advancing the pharmacy profession and, most importantly, safeguarding public health in our state. The Board members' collective expertise, professionalism, and tireless efforts have been instrumental in advancing the mission of our Board and ensuring the safety and well-being of the citizens of South Carolina. I am honored to have had the opportunity to work alongside such dedicated individuals.

To the exceptional Board staff, your hard work behind the scenes has not gone unnoticed. Your diligence, efficiency, and professionalism have been crucial in facilitating the smooth operation of our Board and supporting me in my role as chair. Your dedication to serving the needs of the citizens of South Carolina is commendable, and I am grateful for your invaluable contributions.

Last but certainly not least, I want to express my heartfelt gratitude to my family. Your continued support, understanding, and encouragement have sustained me throughout my tenure as chair. Your patience and unwavering belief in my abilities have been essential to my success, and I am forever grateful for your love and support.

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

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As I step down from my position as chair, I do so with a sense of pride in all that we have accomplished together and with confidence in the future of the Board. It has been an honor and privilege to serve in this role. Thank you, once again, to each one of you for your support, dedication, and commitment to excellence. It has been an incredible journey, and I am grateful to have shared it with all of you.

With warmest regards,

Heather Harris

Outgoing Chair, South Carolina Department of Labor, Licensing, & Regulation –  
Board of Pharmacy

### ***Welcome Board Member Dottie Farfone***

On February 6, Dottie Farfone was confirmed by the senate as the Board of Pharmacy representative for the First Congressional District.

Dottie is originally from the town of McColl in South Carolina. Dottie attended Converse University for undergraduate studies and graduated from the Medical University of South Carolina (MUSC) College of Pharmacy in 1999.

Dottie has practiced in community retail pharmacy for 25 years. She spent her early career working for a chain pharmacy but has spent most of her career working for independent pharmacies. Dottie assisted in the development and opening of two independent pharmacies that are still in operation today. Dottie also managed employee health benefits and hospice pharmacy services before she and her husband, Scott, opened Dottie's Pharmacy on James Island in 2013. The idea behind Dottie's Pharmacy was to serve all aspects of a patient's needs by offering traditional pharmacy services as well as compounding pharmacy services, acknowledging the shift from traditional pharmacy to a focus on more specialized medications. In 2015, Dottie's Pharmacy became one of only three pharmacies in South Carolina to become Utilization Review Accreditation Commission accredited for specialty pharmacy. In 2020, Dottie's Pharmacy further expanded into a long-term care pharmacy. Dottie's Pharmacy has two locations in Charleston, SC, employs eight pharmacists, and is licensed along the South Atlantic seaboard from Florida to Virginia.

Dottie is a strong supporter of the MUSC College of Pharmacy and believes in giving back to the community through various charitable organizations.

### ***Technician Renewals and Continuing Education***

If you validate your email address with the Board, you can complete the online renewal process. To access your renewal online, you will need your user ID and password. The email renewal notice contains a link that will allow you to reset your user ID and password. To make the process

smoother for all, please make sure your correct email is on file with the Board. If you do not know your password, visit [eservice.llr.sc.gov/SSO/Login/RecoverPass](https://eservice.llr.sc.gov/SSO/Login/RecoverPass) to change it. To change your email address, send a request to [contact.pharmacy@llr.sc.gov](mailto:contact.pharmacy@llr.sc.gov). Please allow 24 hours for updates.

If you choose not to renew online, you may request a paper renewal from the Board office and renew by mailing in the completed form and proper fees. Applications for renewal must be filed no later than June 30, 2024. Pharmacy technicians who do not renew **prior** to July 1, 2024, must immediately cease practice and refrain from performing any duties as a pharmacy technician. Failure to do so may result in disciplinary action for both you and the pharmacist-in-charge (PIC).

If you are a state-certified pharmacy technician and your **national** certification has expired, you must also submit a copy of your current national certificate to the Board. Please remember that your national certification is different than your state pharmacy technician registration. Continuing to practice as a state-certified technician without the proper, current documentation may result in disciplinary action for both you and the PIC.

### ***NABP e-Profile ID***

You must have a National Association of Boards of Pharmacy® (NABP®) e-Profile® ID for CPE Monitor® to renew online. CPE Monitor is a service used to document and report your continuing pharmacy education (CPE) credits. You will be asked to provide your e-Profile ID number on the renewal form. To create an e-Profile ID, visit <https://nabp.pharmacy>. Click on “e-Profile Login” at the top right side of the page, then select “Individual or Business Customers” to create a login. For common questions about creating an e-Profile or internet browser requirements, visit the [Help section](#) of the NABP website.

### ***Passage of H3592 Regarding Compounding***

On Wednesday, March 20, **H3592** passed the General Assembly and was enrolled for ratification as an act. Once signed by the governor, this act will repeal all compounding legislation found in the current South Carolina Pharmacy Practice Act and instruct the Board to promulgate regulations related to compounding.

### ***DSCSA Is Here***

The Drug Supply Chain Security Act (DSCSA) went into effect in November 2023, designed to require interoperable, electronic tracing of products to identify and trace certain prescription drugs as they are distributed throughout the United States. However, to increase adoption and prevent drug shortage issues, Food and Drug Administration announced a one-year “stabilization” period. It is important to note that the stabilization period does not change the effective date of DSCSA; it merely provides a one-year period during which the act will not be enforced to allow all stakeholders to fully implement DSCSA requirements.

As November 2024 approaches, bringing full enforcement of DSCSA, here are a few key questions to help you assess your level of compliance as a dispenser:

- 1) Are your suppliers authorized trading partners, meaning they are properly licensed with the state and properly contracted with the manufacturers to distribute their products?
- 2) Where are you storing your product trading information? If asked for your trading information as part of an investigation, do you know where it is being stored and how to access it in a timely manner?
- 3) What is your process for determining if a product is suspect or illegitimate? What do you do if you have a suspect product?
- 4) Do you have detailed policies and procedures about how you document staff training and how you document that you are following DSCSA requirements?

## **Board Meeting Updates**

At the meeting on March 20, the Board made several determinations based on questions from licensees and other discussions.

- **Health System Compounding**

The Board interprets South Carolina Code of Laws Annotated §40-43-86 (CC)(2)(f) “Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound preparations based on an order from a practitioner for administration to a patient in institutional or office settings” to prohibit central compounding by a health system, ie, where the health system sends bulk compounds to an outpatient pharmacy to be further dispensed. It is also a violation of this provision of the Pharmacy Practice Act for a 503A compounding pharmacy to compound products prior to receiving a patient-specific prescription and to instead compound products for a practitioner who then dispenses the products to a specific patient.

- **Remote Compounding Supervision (not on site)**

The Board interprets the Pharmacy Practice Act to allow interim checks conducted during compounding to be completed remotely; however, all final-product verification must be completed by a pharmacist on site in the location where the compound is being made.

- **Health System Non-Dispensing Drug Outlet (NDDO) Permits (Regs §99-43(K))**

In interpreting the requirements of SC Code Ann Regs §99-43(K), the Board provides the following answers to frequently asked questions:

1. The regulation defines a “hospital-owned health system” as a facility within a health system where the sites are owned by a hospital and associated with a hospital pharmacy permit in good standing with the Board.

What is a “hospital-owned health system”?

- The Board interprets this definition broadly to mean common ownership, regardless of corporate structure, and would include health-system-owned hospitals and other similar corporate structures.

What does “associated with” mean?

- The Board interprets this definition to mean a voluntary association at the discretion of the pharmacy permit holder, usually characterized by common ownership regardless of corporate structure.

What is considered a “hospital pharmacy permit”?

- Any pharmacy permit held by the hospital. This would not include an NDDO permit or a central fill pharmacy permit unless the central fill pharmacy is also dispensing.

2. If an entity does not qualify for a hospital-owned health system NDDO permit, or for some reason does not wish to be associated with a hospital-owned health system NDDO permit, can a single NDDO permit be issued for a single facility or for multiple facilities in the same region (instead of each facility in the region having to obtain its own NDDO permit)?

- A hospital-owned health system NDDO permit is **only** appropriate for those hospital facilities/clinics that the holder of a hospital pharmacy permit wishes to “roll up” under that pharmacy permit. All facilities/clinics that are not rolled up under a hospital pharmacy permit must have a traditional NDDO permit and would not qualify for a hospital-owned health system NDDO permit.

3. For a facility/clinic that chooses to obtain a hospital-owned health system NDDO permit, what is important to know that differs from a regular NDDO permit?

- A hospital-owned health system NDDO permit does not require a consultant pharmacist. Instead, the hospital pharmacy PIC is responsible for ensuring that consultant-pharmacist duties are completed.
- Inspections of a facility with a hospital-owned health system NDDO permit must be conducted monthly and must be available at each facility and at the

hospital pharmacy for inspection. The hospital pharmacy PIC determines who completes these inspections. They do not have to be completed by a pharmacist; however, the PIC is responsible for all such inspections.

- Any entity not covered by a hospital-owned health system NDDO permit must obtain a traditional NDDO permit and adhere to all statutory requirements, including having a consultant pharmacist.
- The Board expected full compliance with NDDO permitting regulations by the June 2024 renewal cycle as the related regulations were passed in May 2023.

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*Traci Collier, PharmD, Administrator - State News Editor  
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor  
Megan Pellegrini - Publications and Editorial Manager*

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**Kingstree Bldg, 110 Centerview Dr | Columbia, SC 29210 | [www.llr.sc.gov/bop](http://www.llr.sc.gov/bop) | 803/896-4700**

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