AUGUST 2026

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

Newsletter to Promote Pharmacy and Drug Law Compliance.

Board Chair and Vice Chair Elected

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy elected for the current leadership to continue serving from 2026-2027:

Mary Douglass Smith, PharmD, was elected to continue as chair, and Shuler Spigener, PharmD, will continue to serve as vice chair.

Updated 503B Regulations Now in Effect

Regulations for outsourcing (503B) facilities were updated during the 2026 legislative session. The regulations as published in the *South Carolina State Register* in May 2026 are available on the Board's website, and the updates are summarized below. All permit holders and pharmacists responsible for compounding with outsourcing facility permits should review the updated regulations to ensure compliance.

Summary of updated regulations:

- All facilities are required to have a South Carolina-licensed pharmacist-in-charge (PIC), including those located outside of South Carolina.
- Specific policies and procedures to be included with an initial application were defined.
- Notice to the Board is required within 30 days of occurrence of disciplinary action, Food and Drug Administration (FDA)-issued Form 483 and/or warning letters, and recalls issued by the facility.
- The requirement to also hold a wholesale distributor permit was removed.

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Updated 503B Regulations Now in Effect *(cont)*

The Board has set the compliance deadline regarding a licensed PIC for June 30, 2027. Facilities should submit the South Carolina-licensed PIC's information to the Board by emailing the completed Notification of PIC Change form to contact.pharmacy@llr.sc.gov no later than the deadline.

New Contract Manufacturer Applications Now Available

As of June 2026, a nonresident contract manufacturer/repackager permit is required for an entity that manufactures a finished drug or device to another entity's specifications. This includes any packaging or repackaging of the drugs and/or devices, and/or labeling or relabeling of containers that will be distributed into South Carolina. If a contract manufacturer also produces a finished drug or device and owns the new drug approval, abbreviated new drug approval, or the unique device identification, a separate manufacturer/repackager permit is required. Facilities that engage in contract manufacturing must submit an application for this new permit before June 30, 2027, to comply with this new requirement. More information is available on the Board's website in the Frequently Asked Questions section regarding this new permit requirement.

If the facility is already permitted in South Carolina and only engaged in contract manufacturing, please email the Board at contact.pharmacy@llr.sc.gov within 90 days so the permit can be updated to the new permit type. Include the facility name, permit number, and a brief description of the facility's business activity.

Upcoming Pharmacist and Pharmacy Technician CE Audits

The Board conducts an annual audit of 10% of randomly selected licensed pharmacists and registered technicians. Licensees must maintain updated contact information with the Board, including email addresses. If you are audited, the Board may reach out via email to verify information. Please do not ignore these emails. Email requests for documentation regarding compliance with continuing education (CE) requirements can be expected in August for pharmacists and October for pharmacy technicians. Licensees initially licensed in South Carolina in 2025 are exempt from CE requirements during the 2026 renewal period.

Joint Protocol for Pharmacists Administering and Dispensing Hormonal Contraception Updated

The South Carolina Joint Protocol for Pharmacists Administering and Dispensing Hormonal Contraception (ie, Pharmacy Access Protocol) has been updated due to legislative changes that became effective in May 2026. Pharmacists may now dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive pursuant to a standing order by a prescriber **or** pursuant to the joint protocol. The updated protocol is available on the Board's website or by accessing this link here. Pharmacists who offer this service should be familiar with and follow all the requirements within the protocol.

Board Drafting Regulations

The Board continues to draft compounding regulations, which are continually updated and posted on our website. The Board welcomes public comments throughout this process. Several virtual meetings were scheduled for July and August to keep working on these regulations. You may find updated meeting dates and times on our website. Additionally, the Board will begin drafting regulations for collaborative practice agreements with the Board of Medical Examiners, pursuant to Act 166, which defines collaborative practice agreements and authorizes the Board of Pharmacy and the Board of Medical Examiners to promulgate regulations that govern these agreements.

Pharmacy Intern Notice Reminders

Pharmacy interns are reminded to notify the Board within 10 days of the beginning of each calendar year in which they are employed of the identity of the internship site and the designated pharmacist, even if the employment has not changed. A notification is also required within 10 days of changing employment. Any intern hours submitted without a notice of employment on file will be denied.

Forms for these notifications are available on the Board's website.

FDA Explains Policies for Compounding Drugs Under 503A and 503B of the FD&C Act

FDA is alerting compounders of the conditions needed to be fulfilled to qualify for the exceptions under Section 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

"Under section 503A: The drug product is compounded for an individual patient based on receipt of a prescription. The compounder does not compound, regularly or in inordinate amounts, any that are essentially copies of a commercially available drug product," as stated by FDA.

FDA defines compounded drug products as copies of a

FDA Explains Policies for Compounding Drugs Under 503A and 503B of the FD&C Act *(cont)*

commercially available drug product if compounded drug products and commercially available drug products contain active pharmaceutical ingredients (APIs) that are the same, similar, or alike in substitutable strength, and if both products are administered in the same manner.

As of April 1, 2026, FDA noted that it does not intend to take action against compounders for compounding a drug product that is essentially a copy of a commercially available drug product, regularly or in inordinate amounts, if the compounder fills four or fewer prescriptions of that compounded drug product during a calendar month.

FDA states that outsourcing facilities may not use bulk drug substances (or APIs) for compounded drugs unless: "the bulk drug substance appears on a list identifying bulk drug substances for which there is a clinical need, which is referred to as the 503B bulks list, or the drug compounded from the bulk drug substance is on FDA's drug shortage list at the time of compounding, distribution, and dispensing." Additional information about compounding medications is available on FDA's website.

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