

CHAPTER 99

Department of Labor, Licensing and Regulation— State Board of Pharmacy

(Statutory Authority: 1976 Code §§ 40-43-60 and 40-1-70)

99-15. Display of Annual Renewal Certificate.

Any person who is a licensed pharmacist and who has charge of or is employed in a pharmacy or other permitted facility within this State shall display his annual renewal certificate in a conspicuous place in the primary pharmacy or other permitted facility of which he is in charge or in which he is employed, so that the annual renewal certificate is easily and readily observable by the public.

HISTORY: Amended by State Register Volume 8, Issue No. 4, eff April 27, 1984; State Register Volume 13, Issue No. 4, eff April 28, 1989; State Register Volume 24, Issue No. 5, eff May 26, 2000.

99-43. Facility Permit Classifications.

A. Definitions

1. Unless otherwise indicated, "Board" shall mean the South Carolina Board of Pharmacy.
2. "Practice Act" shall mean the South Carolina Pharmacy Practice Act, as set forth in S.C. Code Section 40-43-10, et. seq.
3. Unless otherwise indicated, for purposes of this regulation, all words shall be defined in accordance with the definitions set forth in the Practice Act.
4. For purposes of this regulation, the word "device" is limited to devices dispensed to a patient. "Device" shall not include devices used by practitioners in the normal course of treating patients, such as dental appliances, surgical equipment, etc.

B. Pharmacy Permits

1. Resident Pharmacy Permit.

- a. A pharmacy located in South Carolina must obtain a Resident Pharmacy Permit issued by the Board to dispense legend drugs and/or devices to a patient or a patient's agent.
- b. To obtain a Resident Pharmacy Permit, an applicant located in South Carolina must:
 - (1) submit a written application in the form prescribed by the Board along with the appropriate application fee; and
 - (2) undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

2. Non-Resident Pharmacy Permit

- a. A pharmacy located outside the geographic boundaries of South Carolina must obtain a Non-Resident Pharmacy Permit issued by the Board to dispense legend drugs and/or devices to a patient, or a patient's agent, located in South Carolina.
- b. To obtain a Non-Resident Pharmacy Permit, an applicant must submit a written application in the form prescribed by the Board along with the appropriate application fee. The following information must be submitted with the application:
 - (1) A copy of the resident state pharmacy permit and DEA registration (if applicable) and a list of all additional state permits and controlled substance registrations (if applicable);

(2) A copy of all reports from operational inspections conducted within the last two years, as well as any current accreditations and/or certifications by any governmental or third-party entity;

(3) A copy of the policy and procedure for shipping refrigerated products;

(4) A copy of a dispensed label;

(5) Photographs of the exterior of the pharmacy building to include identifiable parts of adjacent buildings, the front end of the pharmacy, the consulting area, drop-off/pickup locations, and the compounding work area (if applicable); and

(6) An organizational chart setting forth the applicant's corporate structure, including its parent company, legal name and trade name. This chart must also identify any individual owners with an ownership interest equal to, or greater than, ten percent of the entity.

c. If an applicant for a Non-Resident Pharmacy Permit engages in the compounding of drugs, whether sterile or non-sterile, and regardless of whether the applicant intends to immediately ship compounded drugs into South Carolina at the time of the application, the applicant must submit the following:

(1) documentation of continuing education in the science and art of compounding for pharmacists and technicians involved in compounding. This must include six (6) hours of initial training and four (4) hours of annual training thereafter. The training does not have to be ACPE-approved;

(2) a diagram and photographs of all compounding areas;

(3) environmental control logs, to include (if applicable):

(a) refrigerator/freezer temperature monitoring;

(b) pressure differential monitoring; and

(c) temperature/humidity in compounding area monitoring;

(4) logs documenting cleaning of all areas used in the compounding process;

(5) formulas and completed logs for the applicant's top five compounded products with a copy of the actual prescription and label. Labels and beyond use dates must be submitted for each of the following types of sterile compounds produced (if applicable): minibag; large volume; TPN; syringe; and vial. Documentation must show beyond use dating and reasoning for the date assigned;

(6) compounding policies and procedures, specific to the applicant's facility, as applicable, for the following: quality control; sterile compounding technique; cleaning/maintenance of compounding area and equipment; and general compounding; and

(7) a copy of the report resulting from the last inspection of the applicant's hoods, buffer, clean and ante areas (including ISO classification, particle counts, and microbiology) by a qualified individual.

d. A pharmacist or other individual knowledgeable about all aspects of the applicant's operations must personally appear at a hearing before the Board, or its duly-authorized committee, to answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

C. Non-Resident Non-Dispensing Pharmacy Permit

1. To obtain a Non-Resident Non-Dispensing Pharmacy Permit, an applicant located outside of South Carolina must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee;

b. submit a copy of all reports resulting from operational inspections conducted within the last two years, as well as photographs of the exterior and working area of the facility; and

c. attend a hearing before the Board, or its duly-authorized committee, in which a pharmacist or other individual knowledgeable about all aspects of the applicant's operations must answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person

inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

D. Outsourcing Facility (503B) Permit

1. An Outsourcing Facility Permit is required for a facility engaged in the compounding of sterile drugs which has elected to register with the U.S. Food and Drug Administration as a 503B outsourcing facility. To obtain a permit as an outsourcing facility, a facility must hold, or concurrently apply for, a South Carolina Pharmacy or Manufacturer Permit, whether or not the facility is located in South Carolina.

2. To obtain a Resident Outsourcing Facility Permit, an applicant located in South Carolina must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee;
- b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act;

3. To obtain a Non-Resident Outsourcing Facility Permit, an applicant located outside of South Carolina must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee. The following information must be submitted with the application:

- (1) a copy of the resident state pharmacy permit and DEA registration (if applicable) and a list of all additional state permits and controlled substance registrations (if applicable);
- (2) a copy of the facility's most recent FDA inspection report, including any 483s issued and the applicant's response thereto;
- (3) a copy of all reports from operational inspections conducted within the last two years; and
- (4) a copy of the policy and procedures for shipping refrigerated products and monitoring the temperature and humidity; and

- b. attend a hearing before the Board or its duty-authorized committee in which a pharmacist or other individual knowledgeable about all aspects of the applicant's operations must answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

E. Medical Gas/Legend Device Permit

1. A Medical Gas/Legend Device Permit is required for a facility to dispense medical gases and/or legend devices to a patient or a patient's agent on the order of a licensed practitioner.

2. To obtain a Resident Medical Gas/Legend Device Permit, an applicant located in South Carolina must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee; and
- b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

3. To obtain a Non-Resident Medical Gas/Legend Device Permit, an applicant located outside of South Carolina must submit:

- a. a written application in the form prescribed by the Board along with the appropriate application fee;
- b. a copy of the applicant's resident state pharmacy permit and a list of all additional state permits (if applicable); and
- c. a copy of all reports from operational inspections conducted within the last two years (if applicable).

F. Non-Dispensing Drug Outlet

1. A Non-Dispensing Drug Outlet Permit is required for a facility to store and/or administer legend drugs and/or devices. Facilities requiring a Non-Dispensing Drug Outlet Permit include, but

are not limited to, public or private health clinics, infirmaries, correctional institutions, industrial health clinics, and emergency medical service providers. A Non-Dispensing Drug Outlet Permit requires a consultant pharmacist, unless the facility is engaged in manufacturing, wholesaling or distributing.

2. To obtain a Non-Dispensing Drug Outlet Permit, an applicant must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee;
- b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

G. Wholesale Distributor Permit

1. A Wholesale Distributor Permit is required for a facility to engage in the wholesale distribution of prescription drugs and/or devices to permitted facilities and licensed practitioners. Entities requiring a Wholesale Distributor Permit include, but are not limited to: repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

2. To obtain a Resident Wholesale Distributor Permit, an applicant located in South Carolina must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee;
- b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provision of the Practice Act.

3. To obtain a Non-Resident Wholesale Distributor Permit, an applicant located outside of South Carolina must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee. The following information must be submitted with the application:

- (1) a copy of the resident state permit and DEA registration (if applicable) and a list of all additional state permits and controlled substance registrations (if applicable);
- (2) a copy of the facility's most recent FDA inspection report, including any 483s issued and applicant's response(s) thereto;
- (3) a copy of all reports from operational inspections conducted within the last two years;
- (4) a copy of the policy and procedures for shipping refrigerated products and monitoring the temperature and humidity;
- (5) a copy of the NABP's Verified-Accredited Wholesale Distributors certification (if applicable) or a notarized statement certifying that the applicant meets the standards necessary to obtain this certification; and
- (6) a sample Transaction History, Transaction Information, and Transaction Statement ("T3") report.

b. attend a hearing before the Board or its duly-authorized committee in which a pharmacist or other individual knowledgeable about all aspects of the applicant's operations must answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

H. Manufacturer/Repackager

1. A Manufacturer/Repackager Permit is required for a facility to engage in the manufacturing of prescription drugs or devices, including any packaging or repackaging of the drugs and/or devices, and/or labeling or re-labeling of containers.

2. To obtain a Resident Manufacturer/Repackager Permit, an applicant located in South Carolina must:

- a. submit a written application in the form prescribed by the Board along with the appropriate application fee; and

b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

3. To obtain a Non-Resident Manufacturer/Repackager, an applicant must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee. The following information must be submitted with the application:

(1) a copy of the resident state pharmacy permit and DEA registration (if applicable) and a list of all additional state permits and controlled substance registrations (if applicable);

(2) a copy of the facility's most recent FDA inspection report, including any 483s issued and the applicant's response(s) thereto;

(3) a copy of all reports from operational inspections conducted within the last two years;

(4) a copy of the policy and procedures for shipping refrigerated products and monitoring temperature and humidity;

b. attend a hearing before the Board or its duly-authorized committee in which a pharmacist or other individual knowledgeable about all aspects of the applicant's operations must answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

I. Federally Qualified Health Center ("FQHC") Drug Outlet Permit

1. A Federally Qualified Health Center ("FQHC") Drug Outlet Permit is required for an FQHC delivery site to store, administer, and distribute patient-specific, labeled drugs and/or devices received from a permitted FQHC pharmacy or contracted pharmacy.

2. To obtain a Federally Qualified Health Center ("FQHC") Drug Outlet permit, an applicant must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee; and

b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

J. Third-Party Logistics ("3PL") Provider

1. A Third-Party Logistics Provider Permit is required for a facility to provide or otherwise coordinate warehousing, or other logistics services, of drugs and/or devices in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of drugs and/or devices. A 3PL Provider does not take ownership of the drugs and/or devices and is not responsible for the sale and/or distribution of the drugs and/or devices to permitted facilities and/or licensed practitioners.

2. To obtain a Resident Third-Party Logistics Provider permit, an applicant located in South Carolina must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee;

b. undergo an inspection by the Board in which the applicant demonstrates that it is in compliance with the applicable provisions of the Practice Act.

3. To obtain a Non-Resident Third-Party Logistics Provider permit, an applicant must:

a. submit a written application in the form prescribed by the Board along with the appropriate application fee. The following information must be submitted with the application:

(1) a copy of the resident state permit and DEA registration (if applicable) and a list of all additional state permits and controlled substance registrations (if applicable) and

(2) a copy of all reports from operational inspections conducted within the last two years; and

b. attend a hearing before the Board or its duly-authorized committee in which a pharmacist or other individual knowledgeable about all aspects of the applicant's operations must answer questions regarding the applicant's operations. This appearance shall be in lieu of an in-person

inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection.

HISTORY: Added by State Register Volume 23, Issue No. 6, eff June 25, 1999. Amended by SCSR 44-6 Doc. No. 4927, eff June 26, 2020.

99-45. Administrative Citations and Penalties.

A. The board may issue administrative citations and cease and desist orders in person, or by certified mail, and may assess administrative penalties against an entity or individual for the violations listed below. If the licensee is working at his or her primary place of employment listed with the Board, the licensee must have his or her license or registration displayed. If the licensee is not working at his or her primary place of employment, the licensee must have a wallet card available for inspection. The citation must be signed by the Chief Drug Inspector.

1. Failure to Display Permit (Pharmacist-in-Charge)	\$50
2. Failure to Display License or Possess Wallet Card	\$100
3. Failure to Display Intern Certificate or Possess Wallet Card (PIC and Intern)	\$25
4. Failure to Display Pharmacy Technician Registration or Possess Wallet Card	\$25
5. Pharmacy Technician Working Without Registration (Permit Holder)	\$500
6. Pharmacy Technician Working Without Registration (PIC)	\$500
7. Pharmacy Technician Working With Lapsed Registration (Permit Holder)	\$500
8. Pharmacy Technician Working With Lapsed Registration (PIC)	\$500
9. Pharmacy Technician Working With Lapsed Registration (Technician)	\$50
10. Pharmacy Operating with greater than 4:1 Technician to Pharmacist Ratio (PIC)	\$250
11. Pharmacy Operating with greater than 4:1 Technician to Pharmacist Ratio	\$500

(Permit Holder)

12. Failure to Notify Board of Facility Relocation	\$100
13. Failure to Notify Board of PIC Change	\$100
14. Immunization Protocol-Technical Violation	\$500
15. Failure to Notify Board of Change in Ownership	\$100

B. Separate citations and administrative penalties may be assessed for each violation.

C. Administrative citations authorized under this section are separate from, and in addition to, all other remedies, either civil or criminal.

D. A licensee assessed an administrative citation may appeal the citation to the board within thirty (30) calendar days of the receipt of the citation. If an appeal is filed, the department shall schedule a hearing before the board or its designee for a final determination on the matter. If no appeal is filed, the citation is deemed a final administrative order, and penalties are due within ninety calendar days of receipt of the citation, or other written demand.

E. Extensions to pay citations must be submitted in writing, and will be at the discretion of the Chairman.

F. Failure to pay a citation is considered a violation of this regulation, and may subject the entity to discipline under S.C. Code Ann. § 40-43-140(A)(1)(a).

G. Should a licensee or permittee receive one or more administrative violations of the same type in a five year period, any subsequent violation(s) must be referred to the board for disciplinary action.

HISTORY: Added by State Register Volume 39, Issue No. 6, Doc. No. 4521, eff June 26, 2015. Amended by SCSR 43-5 Doc. No. 4822, eff May 24, 2019.

99-46. Fines.

A. Upon determination by the board that one or more grounds for disciplining a licensee or permittee exists, the board may impose a fine of \$500 per violation, not to exceed a total amount of \$25,000 total per action, plus the costs of the disciplinary action. Fines are payable immediately upon the effective date of discipline unless otherwise provided by the board. Interest accrues after the fines are due at the maximum rate allowed by law. No licensee or permittee against whom a fine is levied is eligible for reinstatement until the fine has been paid in full.

B. An individual who has been found by the board to have unlawfully engaged in the practice of pharmacy under S.C. Code Ann. § 40-43-160(A) may be fined in an amount not to exceed \$25,000.

HISTORY: Added by State Register Volume 39, Issue No. 6, Doc. No. 4521, eff June 26, 2015.

99-47. Compounding of Veterinary Drug Preparations.

A. A licensed pharmacist, practicing in a permitted pharmacy, may compound veterinary drug preparations to be used by veterinarians in their offices for administration to animals.

B. Compounded office use drug preparations may be dispensed by a veterinarian to an owner of an animal for the treatment of a bodily injury or disease of the animal only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 168-hour supply.

C. The compounded veterinary drug preparations may not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations. This does not prohibit administration of a compounded drug preparation in a veterinary health care setting or dispensing of a compounded drug preparation pursuant to a prescription drug order executed in accordance with federal and state law.

HISTORY: Added by SCSR 44-6 Doc. No. 4926, eff June 26, 2020.