

Document No. 5339
DEPARTMENT OF LABOR, LICENSING AND REGULATION
STATE BOARD OF PHARMACY
CHAPTER 99

Statutory Authority: 1976 Code Sections 40-1-70, 40-43-60(D)(8), 40-43-83(I), and 40-43-86(B)(3)(c)

99-43. Facility Permit Classifications.

Synopsis:

The South Carolina Board of Pharmacy proposes amending various sections of Chapter 99, to include changes required to confirm with H.3592, which passed during the 2024 legislative session.

The Notice of Drafting was published in the *State Register* on May 24, 2024.

Instructions:

Print the regulation as shown below. All other items remain unchanged.

Text:

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;

290 FINAL REGULATIONS

(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.

3. Resident Central Fill Pharmacy Permit

a. A Central Fill Pharmacy Permit is required for a pharmacy facility that, upon the request of an originating pharmacy, fills a prescription drug order and returns the filled prescription to the originating pharmacy for delivery to the patient or patient's agent. A central fill pharmacy that returns filled prescriptions to an originating pharmacy must not be required to obtain a wholesaler/distributor permit. A Central Fill Pharmacy Permit is required, in addition to a SC Pharmacy permit, if a pharmacy is engaging in central fill as well as dispensing.

b. To obtain a Central Fill Pharmacy Permit, an applicant must:

(1) submit a written application in the form prescribed by the Board along with the appropriate application fee which is equal to the amount of a Resident Pharmacy Permit application fee;

(2) present the name of the owner, permit holder, and pharmacist-in-charge of the pharmacy for service of process;

(3) present evidence of the applicant's ability to provide the Board a record of a prescription drug order dispensed by the applicant to a resident of this State not later than seventy-two hours after the time the Board requests the record;

(4) present an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and regulations relating to central fill pharmacy in this state.

4. Non-Resident Central Fill Pharmacy Permit

a. A Central Fill Pharmacy Permit is required for a pharmacy facility that, upon the request of an originating pharmacy, fills a prescription drug order and returns the filled prescription to the originating pharmacy for delivery to the patient or patient's agent. A central fill pharmacy that returns filled prescriptions to an originating pharmacy must not be required to obtain a wholesaler/distributor permit. A Central Fill Pharmacy Permit is required in addition to a SC Non-Resident Pharmacy Permit if a pharmacy is engaging in central fill as well as dispensing.

b. To obtain a Non-Resident Central Fill Pharmacy Permit, an applicant must:

(1) Submit a written application in the form prescribed by the Board along with the appropriate application fee which is equal to the amount of a Non-Resident Pharmacy Permit application fee;

(2) present evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(3) present the name of the owner, permit holder, and pharmacist-in-charge of the pharmacy for service of process;

(4) present evidence of the applicant's ability to provide to the Board a record of a prescription drug order dispensed by the applicant to a resident of this State not later than seventy-two hours after the time the Board requests the record;

(5) present an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and regulations relating to central fill pharmacy in this state.

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 Wholesale Distributor Permit, whether or not the facility is located in South Carolina.

a. "Outsourcing Facility" means a facility at one geographic location or address that:

(1) is engaged in the compounding of sterile drugs;

(2) is registered as an Outsourcing Facility with the FDA; and

(3) complies with all of the requirements of Section 503B of the Federal FD&C Act.

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:

292 FINAL REGULATIONS

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. A Wholesale Distributor Permit is required for virtual wholesale distributors defined as a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase and sale.

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 and any federal requirements, including but not limited to the Drug Supply Chain Security Act (DSCSA).

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 Drug Distributor Accreditation (if applicable) or a notarized statement certifying that the applicant meets the standards necessary to obtain this accreditation; and

(6) produce to the Board policies and procedures establishing that the facility meets all current Drug Supply Chain Security Act (DSCSA) standards.

b. attend a hearing before the Board or its duly-authorized committee in which an individual knowledgeable about all aspects of the applicant's operations must respond to operational questions. 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.

294 FINAL REGULATIONS

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. A Manufacturer/Repackager Permit is required for Virtual Manufacturers or any company that sells their own prescription drug products and/or medical devices but outsources the manufacturing and distribution operations.

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;

(5) produce to the Board policies and procedures establishing that the facility meets all current Drug Supply Chain Security Act (DSCSA) standards;

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/or distribute patient-specific, labeled drugs and/or devices received from a permitted FQHC pharmacy or contracted pharmacy.

2. A FQHC Drug Outlet Permit is required for an FQHC delivery site to store and/or administer any legend drug or device.

3. 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.

a. “Third-Party Logistics Provider” means an entity that:

(1) provides or coordinates warehousing, Distribution or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug’s sale or disposition; and

(2) is licensed as a Third-Party Logistics Provider.

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.

K. Hospital-Owned Health System – Non-Dispensing Drug Outlet Permit

1. A Hospital-Owned Health System is defined as facilities within a health system where the sites are owned by a hospital and associated with a Hospital Pharmacy Permit in good standing with the SC Board of Pharmacy.

296 FINAL REGULATIONS

2. A Hospital-Owned Health System is not required to obtain separate Non-Dispensing Drug Outlet Permits for additional facilities within the health system which store and/or administer legend drugs and/or devices provided it complies with all the requirements set forth in this subsection.

3. The Pharmacist-in-Charge of the hospital pharmacy permit will be responsible for all facilities associated with the hospital pharmacy permit.

4. To obtain a Non-Dispensing Drug Outlet Permit containing multiple facilities with a Hospital-Owned Health System, an applicant must:

a. Submit a written application on the form prescribed by the Board along with the appropriate application fee;

b. Provide a list of each facility covered by the Hospital Non-Dispensing Drug Outlet Permit;

c. Undergo an inspection by the Board in which the applicant demonstrates compliance with the applicable provisions of the Act.

5. Prior to the addition of any facilities to the permit, the SC Board of Pharmacy must be notified in writing in a manner prescribed by the Board.

6. Upon inspection of the permitted site, the Pharmacist-in-Charge must present monthly inspections from all facilities covered by the permit.

L. All non-resident facilities required by statute or regulation to be permitted must be operational and must have undergone a successful operational inspection before a permit may be issued by the Board.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will correct a scrivener's error. Specifically, Section 99-43(D)(1) currently references a "Manufacturer Permit", and it should reference a "Wholesale Distributor Permit."

Document No. 5300

DEPARTMENT OF LABOR, LICENSING AND REGULATION COMMISSIONERS OF PILOTAGE

CHAPTER 136

Statutory Authority: 1976 Code Sections 40-1-50, 40-1-70, 54-15-10, and 54-15-140

136-012. Apprentice Selection Process.

136-013. Pilot and Apprentice Age Limitations.

136-015. Previous Maritime Experience, Apprentice Applicants.

136-060. Marine Casualties, Accidents and Other Reports.

136-061. Reports of Coast Guard Investigations.

136-075. Pilotage Areas.

Synopsis: