

South Carolina Department of Labor, Licensing and Regulation **South Carolina Board of Pharmacy** 110 Centerview Dr. • Columbia • SC • 29210 P.O. Box 11927 • Columbia • SC 29211-1927

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llr.sc.gov/bop

2024-2025 NON-RESIDENT PHARMACY PERMIT RENEWAL

Renewal Requirements and Instructions:

• Submit this permit renewal directly to the Board by going to: <u>https://eservice.llr.sc.gov/DocumentSubmission/</u>. You will pay the renewal fee through this document submission process via debit/credit card or electronic check.

FOR BOARD USE ONLY	
Date Paid	
Check No.	
Amount Paid	

If mailing the paper application, submit the renewal fee in the form of a check or money order (no cash) payable to SC Board of Pharmacy. (All fees are non-refundable. A returned check fee

of up to \$30, or an amount specified by law, may be assessed on all returned funds.)

- Renewal / Late Fees: Postmarked before 6/1/2024: **\$280** Postmarked on or after 6/1/2024: Late Fee \$50 + Renewal Fee \$280 = **\$330**
- Beginning July 1, 2024, lapsed permits will be assessed fees of \$10/day until the permit is reinstated.
- Attach copy of most recent inspection report.
- Permits not renewed by June 30, 2024, are lapsed and may not operate. A facility that operates with a lapsed permit is in violation of S.C. Code Ann. § 40-43-140 and may be subject to disciplinary action. A permit holder who allows a site to operate with a lapsed permit is in violation of S.C. Code Ann. § 40-43-83 and may be subject to disciplinary action.
- If there has been a 50% or more change in ownership, legal name change or relocation of the facility, contact the Board before renewing the permit.

FACILITY INFORMATION

Federal Tax ID No.:		SC Permit No.:	
SC DHEC Controlled Substances Registration No. (if a	pplicable):		
Resident State License No.:	_ Date Issued:	Expirat	tion Date:
DEA Registration No. (if applicable):	Expiration Date:		
NABP No. (If applicable):			
Legal Name of Facility:			
Facility Address:	City:	State:	Zip:
Phone No.: Email:			
Toll-free number for patients:			
Mailing Address where all correspondence regarding pern			
Facility Name:			
Mailing Address:	City:	S	tate:Zip:
 Has there been a change in ownership of 50% or more s Yes – Contact the Board of Pharmacy office before of Since your last renewal, has any pharmacy licer facility or permit holder holds been restricted, r disciplined? 	completing this applients or registree voked, suspended or	cation. \Box No ation that the	•
If Yes, provide a copy of the disciplinary acti	on.		

2024-2025 Non-Resident Pharmacy Permit Renewal (02/12/2024 v1.2)

2.	Does your pharmacy do sterile compounding?	□ Yes	🗆 No
3.	Does your pharmacy do non-sterile compounding?	□ Yes	🗆 No
4.	Do your pharmacy compound hazardous medication?	□ Yes	🗆 No
5.	Did your pharmacy add non-sterile compounding since your last renewal? If Yes, see Non-Sterile Compounding Requirements for items to be submitted on page 3.	□ Yes	□ No
6.	Is your pharmacy registered as a 503B outsourcing facility with the FDA?	□ Yes	🗆 No
7.	Has your pharmacy added sterile compounding since your last renewal? If Yes, see Sterile Compounding Requirements for items to be submitted on page 4.	□ Yes	□ No
8.	Have all personnel involved in compounding completed annual continuing education and/or training in the last year?	□ Yes	□ No
9.	Does your pharmacy dispense controlled substances?	\Box Yes	□ No
ATTESTATION			

I certify that I have read and approved the foregoing, and the statements are true and correct to the best of my knowledge and belief; that I will comply with the requirements for non-resident pharmacies as contained in the South Carolina Pharmacy Practice Act and Regulations promulgated thereunder, and that I understand I am responsible for any violations during my tenure.

Pharmacist-In-Charge Signature	Date
Print Name of Pharmacist-In-Charge	Phone Number

Pharmacist-In-Charge Email

ATTESTATION

I declare that I have read and approve the foregoing and the statements are true and correct to the best of my knowledge and belief. I will comply with the requirements contained in the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

Permit Holder Signature	Date	
Print Name of Permit Holder	Title	
Permit Holder Email	Phone Number	

PRIVACY NOTICE

South Carolina law requires the agency to collect personal information which is only disseminated as required by law. The South Carolina Freedom of Information Act ensures that the public has a right to access appropriate records and information possessed by a government agency. Therefore, some personal information on your renewal application and other documents on file may be subject to public scrutiny or release. The Department collects and disseminates personal information in compliance with The South Carolina Freedom of Information Act, the South Carolina Family Privacy Protection Act and other applicable privacy laws and regulations. Additionally, the Department shares certain information on the application with other governmental agencies for various governmental purposes, including research and statistical purposes.

NON-RESIDENT PHARMACY NON-STERILE COMPOUNDING REQUIREMENTS

*** Only submit these documents if non-sterile compounding was started since last renewal. ***

- **A.** Continuing Education: Documentation of CE in the science and art of compounding for pharmacists and technicians involved in compounding. Six (6) hours initially and four (4) hours annually. Does not have to be ACPE-approved.
- **B.** Diagram and photographs of compounding area.
- **C.** Refrigerator temperature log: Copy of one page of the most current month to include time, date, temperature, initials.
- **D.** Room temperature and humidity log: Copy of one page of the most current month to include time, date, temperature, humidity, and initials.
- E. Cleaning logs: Copy of one month of logs to include, at a minimum,
 - a. Daily cleaning log countertops, hoods, equipment, utensils, floors swept, trash discarded
 - b. Weekly cleaning log floors mopped
 - c. Monthly cleaning log shelves, refrigerator/freezer, cabinet exteriors (all sanitized)
- **F.** Documentation that equipment is routinely inspected, calibrated and cleaned.
- **G.** Copies of completed logs/completed product formula worksheets for top 5 compounded products with a copy of the actual prescription. Also provide a reprint/duplicate of the final compounded product label.
- **H.** Copies of procedures (choose any 3) done within the last 6 months to monitor the output of compounded prescriptions such as potency, capsule size and weight.
- I. A printed batch (stock) label, if applicable.
- J. Standard operating policies and procedures for:
 - a. General compounding procedures
 - b. Maintenance and cleaning of area and equipment

* Do NOT send entire SOP library.

NON-RESIDENT PHARMACY STERILE COMPOUNDING REQUIREMENTS

*** Only submit these documents if sterile compounding was started since last renewal. ***

- **A.** Documentation of training and/or continuing education in the science and art of compounding of sterile products for all pharmacists and technicians involved in compounding.
- **B.** Diagram and photographs of Sterile Compounding Area.
- C. Refrigerator temperature log:
 - Copy of one page of the most current month to include time, date, temperature, initials.
- **D.** One page of Logs monitoring:
 - pressure differential
 - room temperature/humidity in compounding area
- **E.** Logs for one full month to include:
 - cleaning of all areas used in sterile compounding process
- **F.** Copy of last inspection, by qualified individual, of hoods, buffer, clean and ante areas including ISO classification, particle counts and microbiology.
- **G.** Copies of completed logs/completed product worksheets for top 5 sterile compounded products with a copy of the actual prescription. Also provide a reprint/duplicate of the final compounded product label. Include assigned BUD and reasoning for BUD assigned.
- H. Reprint/duplicate of final dispensed product label
 - minibag
 - large volume
 - TPN
 - syringe
 - vial
- I. Compounding Policies and Procedures, specific to your facility, as applicable for the following:
 - (1) Quality control
 - (2) Sterile compounding technique
 - (3) Cleaning/maintenance of compounding area and equipment

* Do not send the entire SOP library.