South Carolina Department of Labor, Licensing and Regulation
South Carolina Board of Pharmacy
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2021-2022 RENEWAL NON-RESIDENT PHARMACY PERMIT

Renewal Instructions/Requirements:

FOR BOARD USE ONLY	
Check No.	
Amount Paid	
Date Processed	
Returned Incomplete	

- 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 6/1/2021: **$280**
  Postmarked on or after 6/1/2021: Late Fee $50 + Renewal Fee $280 = **$330**
- Beginning July 1, 2021, 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, 2021, are lapsed and may not operate. A permit holder who allows a site to operate with a lapsed permit is in violation of Section 40-43-83 and may result in disciplinary action.
- If there has been a 50% or more change in ownership, contact the Board before renewing the permit.
- Information from this renewal may be shared.

FACILITY INFORMATION

Federal Tax ID No.: _____ SC Permit No.: _____

SC DHEC/Control Substance Registration No. (If applicable): _____

Resident State License No.: _____ Date Issued: _____ Expiration Date: _____

DEA Registration No.: _____ Expiration Date: _____

NABP No. (If applicable): _____

Facility Name: _____

Facility Address: _____ City: _____ State: ____ Zip: _____

Phone No.: _____ Email: _____

Has there been a change in ownership of 50% or more since last renewal that has not been reported to the Board?
☐ Yes – Contact the Board of Pharmacy office before completing this application. ☐ No

1. Since your last renewal, has any pharmacy license that the facility or permit holder holds been disciplined? **If Yes,** provide a copy of the disciplinary action. ☐ Yes ☐ No
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? ☐ Yes ☐ No
   If Yes, see Non-Sterile Compounding Pharmacies Document Checklist for items to be submitted on page 3.
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? ☐ Yes ☐ No
   If Yes, see Sterile Compounding Pharmacies Document Checklist for items to be submitted on page 4.

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? ☐ Yes ☐ No

ATTESTATION

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

_____ _____

Permit Holder Signature Date

_____

Print Name of Permit Holder

Permit Holder Email: _____

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 that I understand I am responsible for any violations during my tenure.

Since your last renewal, has the pharmacist-in-charge's license been disciplined? ☐ Yes ☐ No

If Yes, provide copies of the disciplinary action.

_____ _____

Pharmacist-In-Charge Signature Date

_____

Print Name of Pharmacist-In-Charge

Pharmacist-In-Charge Email: _____

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.***