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
Phone: 803-896-4700 • Contact.pharmacy@llr.sc.gov • Fax: 803-896-4596
llr.sc.gov/bop

NON-RESIDENT PHARMACY PERMIT APPLICATION

This permit authorizes facilities outside of this State engaged in the business of filling mail order prescriptions to engage in the sale, distribution, or dispensing of legend drugs or devices in this State.

The pharmacist-in-charge for the applicant must attend an Application Review Committee meeting at the Board's office. Applicant will be notified by e-mail of the date and time of the meeting for which its application review hearing is scheduled. All requested information and an e-mailed confirmation are required prior to the meeting date. Using false, fraudulent, forged statement or document, or committing a fraudulent, deceitful or dishonest act or omitting a material fact in obtaining licensure is grounds for discipline or licensure denial. A South Carolina Non-Resident Pharmacy Application has a one year expiration.

Failure to complete all required fields and/or provide necessary supplemental documentation will delay the application process. If an item is not applicable, please indicate N/A. **In order to avoid delay, please do not provide the items below in a binder, folder or use dividers. Also, provide items in the order as listed below. Please write legibly.**

Submit the completed application and the following:

_____Non-refundable application fee of $420 payable to SC Board of Pharmacy

_____Copy of resident state pharmacy permit

_____Copy of recent operational inspection report. Inspection must have been conducted within the last 2 years. You must also supplement your application by providing the Board's staff with an inspection report received between the date of the application and the date of the application review hearing.

_____Copy of current DEA registration

_____Copy of state controlled substance registration

_____Copy of policy and procedure for shipping refrigerated products

_____Copy of a dispensed label

_____Letter describing in detail, the nature of your business

_____Provide a list of all pharmacy permits/licenses held in other states

_____Photographs
- __exterior of pharmacy building to include identifiable parts of adjacent buildings
- __front end of pharmacy to include consulting area and drop-off/pick-up
- __compounding area
- __work area

_____Accreditation certificates

_____Non-sterile Compounding requirements from list on page 7 of application

_____Sterile Compounding requirements from list on page 8 of application

_____ Compounding requirements **If your pharmacy compounds, even though you do not plan to ship sterile/non-sterile Compounds into SC, you must still submit all compounding information. South Carolina does not have a separate permit for sterile or non-sterile compounding.

_____ Include organizational chart. If change of ownership, include charts of before and after the change. The chart should show the legal business entities from the ultimate parent company down to and including the applicant and should include the legal business name, trade name, and type of ownership for each entity on the chart. Chart must include owners name with a ten percent or greater ownership interest in a non-publicly traded company.

*If emails have to be submitted, please provide in PDF.

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For Board Use Only	
Date Paid	
Amount Paid	
Check #	

NON-RESIDENT PHARMACY PERMIT APPLICATION

[ ] New Permit
[ ] Change to Existing Permit (Permit #_____)
  [ ] Change of Ownership **(include organizational chart before and after change)**
  [ ] Change of Name
  [ ] Change of Location

Federal Employer Identification Number (FEIN): _____

NABP e-Profile ID number: _____

Legal Name of Pharmacy_____

dba Name:_____

Street address of physical location of pharmacy_____

City_____State_____Zip code_____

Toll free number for patients to call about prescriptions:_____

Business Phone#_____Fax#_____Resident State Permit/ License#:_____

Is application based on a change in ownership? [ ] YES [ ] NO

If YES,_____ _____
Previous Owner/Name of pharmacy SC permit number

Mailing Address where all correspondence regarding licensure will be sent if other than facility physical address above:

Contact Person: _____Email:_____

Facility name: _____ Address: _____

City: _____ State:_____Zip code:_____

EMPLOYEE INFORMATION

Pharmacist-in-Charge:_____ License # and state of issuance:

_____ _____
Email Address

PHARMACIST FULL TIME (use separate sheet if necessary)	License# and state issuance:	

PHARMACIST PART TIME (use separate sheet if necessary)	License# and state issuance:	

PHARMACY TECHNICIANS (use separate sheet if necessary)	License# and state issuance:	

What is the daily working ratio of pharmacists to pharmacy technicians?_____

PHARMACY

Pharmacy website address:_____

Hours of operation:_____ Hours a pharmacist is available:_____

Do you fill prescriptions via the internet? [ ] YES [ ] NO

If YES, is there a policy and procedure to validate patient-pratictioner relationship? [ ] YES [ ] NO

Provide all website addresses used_____

When was your last Board of Pharmacy operational inspection?_____
(Attach a copy of the inspection report)

Check all services below that apply:

[ ] Chemotherapy [ ] Diabetic Care [ ] Hemophilia [ ] IV Infusion
[ ] Nuclear [ ] Long term care [ ] Mail order [ ] Pain Management
[ ] Remote order entry [ ] Specialty Drugs [ ] Durable Medical Equipment
[ ] Other (specify) _____

Date your pharmacy began dispensing to South Carolina patients: _____

Approximate number of South Carolina patients served annually: _____

Has the **applicant or any entity** under common control with applicant ever applied for a pharmacy permit in South Carolina?
[ ] YES [ ] NO

If YES, state business name on application:_____

Month & year submitted:_____ Permit number issued:_____

Does your pharmacy dispense controlled substances? [ ] YES [ ] NO

CONTROLLED SUBSTANCES

Non-resident pharmacies permitted by the SC Board of Pharmacy that dispense controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDHEC-Bureau of Drug Control. Access the application via the website at www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/. All SC-permitted non-resident pharmacies must register with the SCDHEC-Bureau of Drug Control Prescription Monitoring Program. If you do not dispense controlled substances, you must request an exemption from reporting requirements. Contact PMP at scripts@dhec.sc.gov or (803) 896-0688.

COMPOUNDING		
Does your pharmacy do compounding?	[ ] YES	[ ] NO skip compounding questions
Sterile compounding	[ ] YES	[ ] NO
Non-sterile compounding	[ ] YES	[ ] NO

COMPOUNDING QUESTIONS Additional documentation required (see attached lists)

Do you have PCAB accreditation?
[ ] YES Expiration date of accreditation_____
[ ] NO

The pharmacist-in-charge is trained and knowledgeable in the preparation, labeling and dispensing of compounded drugs?

[ ] YES
[ ] NO If NO, the pharmacist –in-charge designates the following pharmacist employee as knowledgeable in the preparation, labeling and dispensing of compounded drug preparations.

Pharmacist name:_____License #_____

Do you use an independent lab or qualified individual for end product testing?

[ ] YES Provide a name and address:_____
[ ] NO

Do you use an independent lab or qualified individual for routine environmental testing of hood, ante room and clean room?

[ ] YES Provide name and address:_____
[ ] NO

Do you provide patient specific compounded products? [ ] YES [ ] NO

Do you provide non-patient specific compounded products? [ ] YES [ ] NO

OWNERSHIP: Check appropriate box and provide complete information

Do any of the owners of this facility own any portion of, control, or have any beneficial interest in any other pharmacy/wholesaler/3PL (whether permitted in SC or not) other than a publicly-traded corporation? [ ] YES [ ] NO
If yes, provide a list with names and addresses**.**

[ ] Sole proprietorship Name of business entity:_____

Name	City, State	Birth Year

[ ] General Partnership [ ] LLP Name of partnership:_____

Partner name	City, State	Birth Year	% of ownership

[ ] **Corporation** [ ] **LLC** Name of Corporation/LLC: Name of Parent Company_____
State of Organization**:** _____

Name of Individual Owners and principal officers	Title	City, State	Birth Year	% of ownership
1				
2				
3				

DISCIPLINARY HISTORY If you answer "yes" to any part of this section, provide a detailed explanation, attach copies of applicable court documentation and submit with this application. Include the city and state where the offense(s) occurred.

HAS THE APPLICANT: entity, the undersigned pharmacist-in-charge, undersigned permit holder, any person or entity identified in the ownership management section above, or any entity under common control with the applicant EVER:

1. Had a permit or professional license disciplined, denied, refused or revoked for violations of any federal or state pharmacy laws or drug laws? [ ] YES [ ] NO
If NO, is there any pending disciplinary action? [ ] YES [ ] NO

2. Been convicted, fined or entered in a plea of guilty or nolo contender in any criminal prosecution, felony or misdemeanor in South Carolina or any other state, or in a United States court for:

a. any offense relating to drugs, narcotics, controlled substances or alcohol, whether or not a sentence was imposed?

[ ] YES [ ] NO

b. any offense involving the practice of pharmacy, or relating to acts committed within a pharmacy or drug distributor setting or incident to pharmacy practice, whether or not a sentence was imposed? [ ]YES [ ] NO

c. any offense involving fraud, dishonesty or moral turpitude whether or not a sentence was imposed?

[ ] YES [ ] NO

3. Had:

a. an application for a pharmacy; pharmacist license, permit or certificate denied, refused, or not issued in South Carolina or any other state or country? [ ] YES [ ] NO

If YES, please explain_____

b. operated, or allowed the facility to operate without a valid permit? [ ] YES [ ] NO

4. Violated the drug laws, rules, statutes and/or regulations of South Carolina or any other state or country?

[ ] YES [ ] NO

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 South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

_____ _____

Pharmacist-in-Charge Signature Print name of Pharmacist-in-Charge

_____

Email Address of Pharmacist –in-Charge

I declare that the foregoing statements are true and correct to the best of my knowledge and belief; the permit applied for is to cover only the pharmacy indicated above and at the location specified; and that I will comply with the South Carolina Pharmacy Practice Act.

_____ _____

Permit Holder signature Print Name Title

_____

Email address of Permit Holder

Information from this application may be shared.

Mail completed application to: SC Board of Pharmacy, 110 Centerview Dr, Suite 201, Columbia SC 29210

Compounded medications cannot be re-sold, therefore the compounded medications must be sent and billed to the patient or sent to a physician/facility to be administered on site.

SECTION 40-43-86 *(CC)(2) Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound products based on an order from a practitioner for use by practitioners for patient use in institutional or office settings. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services, e.g., chemicals, devices, and information, when requested; however, they may not solicit business by promoting to compound specific drug products, e.g., like a manufacturer;*

The pharmacy must keep all records and a pharmacist must be present during all compounding functions.

SECTION 40-43-89 *(N)(1) A facility located outside this State, whose primary business is mail order prescription service, shall have a permit issued by the board to ship, mail, or deliver a controlled substance or dangerous drug or device into this State pursuant to a prescription of a licensed practitioner. The facility shall report to the board:*

(b) that it complies with the applicable laws for operation in the state in which it is located and with the provisions of this section. The facility shall have a valid unexpired license, permit, or registration in compliance with the laws of the state in which it is located and must be constantly under the personal and immediate supervision of a licensed pharmacist. The facility shall submit to the board with its initial application and with each renewal application a copy of its most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located. These inspections are deemed to meet all inspection requirements contained in this chapter;

(c) that it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this State so that the records are readily retrievable.

If the state in which the pharmacy is located does not have a pharmacist to auxiliary personnel ratio, a pharmacist is not allowed to supervise more than two pharmacy technicians at one time.

SECTION 40-43-89 *(N)(3) If the state in which the facility is located does not establish, by statute or regulation, a ratio describing the number of auxiliary personnel that a pharmacist may supervise, or otherwise define the role of the pharmacist in the compounding and dispensing of prescription drugs, then that facility may not allow a pharmacist to supervise more than two pharmacy technicians at any time in the compounding and dispensing of prescription drugs.*

The pharmacy label must contain a toll-free number and have a pharmacist available during its regular house of operation, but not less than 6 days or 40 hours a week.

SECTION 40-43-89 *(N)(4) A pharmacy, as described in this section, during its regular hours of operation but not less than six days or forty hours a week, shall provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist at the pharmacy who has access to their records. This telephone number must be printed on a label affixed to the container for the substance, drug, or device.*

NON-RESIDENT PHARMACY
NON-STERILE COMPOUNDING REQUIREMENTS

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: * Do NOT send entire SOP library**

   a. **General compounding procedures**
   b. **Maintenance and cleaning of area and equipment**

NON-RESIDENT PHARMACY

STERILE COMPOUNDING REQUIREMENTS

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. **Logs for one full month to include:**

- **monitoring of refrigerator/freezer temperature**

D. **Logs for one full month to include:**

- **pressure differential monitoring**
- **monitoring of 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. **Formulas for top five non-sterile to sterile compounded products with a copy of the actual prescription. Also provide a reprint/duplicate of the final compounded product label.**

H. **List of top five CSPs including beyond use dating. Include reasoning for BUD assigned.**

I. **Reprint/duplicate of final product label**

- **minibag**
- **large volume**
- **TPN**
- **syringe**
- **vial**

J. **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 sent the entire SOP library.**