



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

INSTRUCTIONS – NON-RESIDENT OUTSOURCING FACILITY

A Non-Resident Outsourcing Facility permit is required for a facility engaged in the compounding of sterile drugs and has elected to register with the U.S. Food and Drug Administration as a 503(b) 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.

The permit holder for the outsourcing facility is responsible for the supervision and control of compounded drugs and must be a licensed pharmacist. The pharmacist responsible for compounding must attend an Application Review Committee meeting at the Board's office. Applicant will be notified by mail of the date and time of the meeting for which they are scheduled. All requested information and emailed 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 permit denial. A South Carolina Non-Resident Outsourcing Facility Permit Application has a one year expiration.

Submit the completed application with the following items: (If an item is not applicable, please indicate N/A)

- Non-refundable application fee of \$700 payable to SC Board of Pharmacy
- Copy of facility license from the applicant's home state
- Copy of Responsible Pharmacist's license
- Copy of recent inspection report conducted within the last 2 years.
- Copy of FDA inspection, any 483(s) issued and facility's response
- Copy of current DEA registration
- Letter describing in detail the nature of your business
- List of every state permit/license with status and expiration date
- Photographs of the facility to include: exterior of building and all compounding areas
- List of pharmacists practicing at this outsourcing facility other than the PIC
- Include organizational chart before and after change (Change of Ownership)

CONTROLLED SUBSTANCE INFORMATION

Non-resident facilities permitted by the SC Board of Pharmacy who distribute controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDHEC-Bureau of Drug Control.

Access to the application via the website at

www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/



NON-RESIDENT OUTSOURCING FACILITY PERMIT APPLICATION

- New Facility
- Change to Existing Permit (Permit No.: _____)

- Change of Ownership (**include organizational chart before and after change**)
- Change of Name
- Change of Location (From one city to another)

FOR BOARD USE ONLY	
Date Paid	
Amount Paid	
Check No.	

FDA reg. No.: _____ Resident State License No.: _____ FEIN: _____

Facility Name: _____

dba Name: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Website: _____

Contact Person at this site: _____

Name Title Email

Mailing address where all correspondence regarding licensure will be mailed if other than facility above:

Contact Person: _____ Email: _____

Facility Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

TYPE OF COMPOUNDING ACTIVITY

1. Does the outsourcing facility engage in HIGH-RISK compounding of sterile drug products? YES NO
2. Does the outsourcing facility engage in MEDIUM-RISK compounding of sterile drug products? YES NO
3. Does the outsourcing facility engage in LOW-RISK compounding of sterile drug products? YES NO
4. Does the outsourcing facility engage in the compounding of NON-STERILE drug products? YES NO
5. Does the outsourcing facility dispense compounded drugs pursuant to valid prescriptions? YES NO
 *If YES, a pharmacy permit is required. Outsourcing facilities which share the same space with a pharmacy must perform all compounding in compliance with cGMPs.
6. Do you compound and/or distribute controlled substances? YES NO
7. Has your facility been inspected by the FDA? YES NO
8. If inspected by the FDA, was your facility issued a 483? YES NO
 If YES, attach a copy of the FDA Form 483 and your company's response to the issues noted.
9. Are you currently shipping into South Carolina from this facility? YES NO
 If YES, attach a list of customers.

10. Provide licensure information for the pharmacist responsible for overseeing compounding at your facility.

Name: _____ License No.: _____ Expiration date: _____

11. Which of the following entities do you sell/ship product to? Check all that apply.

- Retail Pharmacies Hospital Pharmacies Permitted clinics/surgical centers
 Practitioners (MD, DMD, DVM, APRN, PA-C) Other: _____

OWNERSHIP

Check appropriate box and provide complete information.

Sole Proprietorship Name of Business Entity: _____

Name	City, State	Birth Year

General Partnership LLP Name of Partnership/LLP: _____

Partner Name	City, State	Birth Year	% of Ownership

Corporation LLC Name of Corporation/LLC: _____

Name of Parent Company: _____ State of Incorporation: _____

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 on a separate sheet and attach copies of applicable court documentation. Include the city and state where the offense(s) occurred.

TO THE BEST OF YOUR KNOWLEDGE HAS THE APPLICANT the entity, 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 disciplined, denied, refused or revoked for violations of any pharmacy laws or drug laws in South Carolina or any other state?
 Is there any pending disciplinary action? YES NO
 YES NO

2. Been convicted, fined or entered in a plea of guilty or nolo contendere 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 (i.e., Medicaid fraud, theft of money or drugs, or robbery) whether or not a sentence was imposed? YES NO
- 3. Had an application for a drug distributor permit, pharmacy, or pharmacist license, permit or certificate or a technician license or registration, denied, refused in South Carolina or any other state or country? YES NO
- 4. Had disciplinary action taken against you, or a pharmacy or drug distributor facility you owned, or a pharmacy or drug/device distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country? YES NO
- 5. Violated the drugs/device laws, rules, statues and/or regulations of South Carolina, or any other State or Country or the United States? YES NO

SECTION 40-43-83 (E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State

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 Code of Laws of the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation occurring during my tenure.

Signature of person acting as Permit Holder

Date

Print Name of person acting as Permit Holder

Title

Email Address of Permit Holder or Contact Person

Phone No.

I declare that 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 the location specified; and that I will comply with the Code of Laws of the South Carolina Pharmacy Practice Act.

Signature of Pharmacist responsible for compounding

Date

Print Name of Pharmacist responsible for compounding

Title

Email Address of Pharmacist responsible for compounding

Phone No.