



2024-2025 OUTSOURCING FACILITY (503B) PERMIT RENEWAL (IN-STATE)

Renewal Requirements and Instructions:

- Submit this permit renewal directly to the Board by going to:
<https://eservice.llr.sc.gov/DocumentSubmission/>. 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: **\$140**
 Postmarked on or after 6/1/2024: Late Fee \$50 + Renewal Fee \$140 = **\$190**
- Beginning July 1, 2024, lapsed permits will be assessed fees of \$10/day until the permit is reinstated.
- Submit a copy of the facility’s most recent inspection report via [document submission](#).
- 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

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

SC DHEC Controlled Substances Registration No. (if applicable): _____

DEA Registration No. (if applicable): _____ Expiration Date: _____

Legal Name of Facility: _____

DBA Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Phone No.: _____ Fax No.: _____

Name of Designated Representative: _____ Phone No.: _____

Email for Designated Representative: _____

Mailing Address where all correspondence regarding permitting will be sent if other than facility above:

Facility Name: _____

Mailing Address: _____ City: _____ State: _____ Zip: _____

Days and Hours of Operation: _____

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. Does the facility engage in HIGH-RISK compounding of sterile drug products? Yes No

2. Does the facility engage in MEDIUM-RISK compounding of sterile drug products? Yes No

3. Does the facility engage in LOW-RISK compounding of sterile drug products? Yes No
4. Does the facility engage in the compounding of NON-STERILE drug products? Yes No
5. Do you compound hazardous medication? Yes No
6. Does the 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.
7. Has the facility been inspected by the FDA? Date: _____ Yes No
8. If inspected by the FDA, was the facility issued a 483? Yes No
If Yes, provide a copy of the FDA Form 483 and your company's response to the issues noted.
9. Does your facility distribute, store or manufacture controlled substances? Yes No
- 9a. Which of the following entities do you sell/ship products to? (Check all that apply)
 Retail Pharmacies Hospital Pharmacies Permitted Clinics/Surgery Centers
 Practitioners (MD, DMD, DVM, APRN, PA-C) Other: _____
10. Does the facility hold pharmaceutical licenses or permits in any other states? Yes No
If Yes, provide the state, license number and type. Attach additional sheet if necessary.
 State: _____ License No.: _____ Type: _____
 State: _____ License No.: _____ Type: _____
 State: _____ License No.: _____ Type: _____
 State: _____ License No.: _____ Type: _____
11. Have any out-of-state licenses or permits been restricted, revoked, suspended or otherwise disciplined? **If Yes**, provide a copy of the disciplinary action. Yes No

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.

1. Since your last renewal, has any license, permit or registration that the facility, permit holder or pharmacist-in-charge holds been disciplined, denied, refused, voluntarily surrendered, agreed to permanently cease operations or revoked for violations of any federal or state pharmacy laws or drug laws, regardless of state? Yes No
If Yes, attach a full written explanation and attach copies of applicable court documents, board orders, copies of disciplinary action, and any other relevant documentation.
2. Is there any pending disciplinary action against any of the licenses, permits or registrations described in Question 1? Yes No
3. Since your last renewal has any licensee, permit holder or pharmacist-in-charge 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 federal 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/device manufacturer setting or incident to pharmacy practice, whether or not a sentence was imposed? Yes No
 - c. any offense involving fraud or dishonesty whether or not a sentence was imposed? Yes No

NAME OF PHARMACIST RESPONSIBLE FOR OVERSEEING COMPOUNDING AT THIS FACILITY:

Name: _____ License No.: _____

ATTESTATION

I hereby certify that the facility, for which this permit renewal is sought, will be conducted pursuant to federal and South Carolina law pertaining to its pharmaceutical operations, and that the facility will be under the supervision of a Consultant Pharmacist as required by the South Carolina Pharmacy Practice Act and regulations promulgated thereunder. I understand that the location for which this permit is issued is subject to inspection by the Board of Pharmacy. I understand that I am responsible for abiding by the statutes and regulations governing my role as the facility's permit holder.

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

ATTESTATION

I hereby certify that as Pharmacist-In-Charge, I will be responsible for all duties connected with the proper and lawful conduct of this facility as required by the South Carolina Pharmacy Practice Act.

_____ Pharmacist-In-Charge Signature	_____ Date
_____ Print Name of Pharmacist-In-Charge	_____ License Number
_____ Pharmacist-In-Charge 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.