



2020-2021 RENEWAL NON-RESIDENT PHARMACY PERMIT

Renewal Instructions/Requirements:

- 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.)
- **Fee:** Postmarked before **September 30, 2020: \$280**
 Postmarked on/after **October 1, 2020: \$330**
- Permits not renewed by **September 30, 2020**, are lapsed and may incur disciplinary action by the Board.
- Completed application with required documents and fee must be postmarked before September 30, 2020.
- On October 1, lapsed permits will be assessed fees of \$10/day until the permit is reinstated.

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

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

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

DEA Registration No.: _____ Expiration Date: _____

NABP No: (if applicable) _____

Facility Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Email: _____

Resident State License No.: _____ Date Issued: _____

Date of Expiration: _____

- Has there been a change in ownership of 50% or more since last renewal that has not been reported to the Board? Yes No
 If yes, contact the Board of Pharmacy office before completing this application.
- Since your last renewal, has any pharmacy license that the facility or permit holder holds been disciplined? Yes No
 If yes, provide copies of the disciplinary action.
- Does your pharmacy do sterile compounding? Yes No
- Does your pharmacy do non-sterile compounding? Yes No
- Does your pharmacy compound hazardous medication? Yes No
- 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.
- Is your pharmacy registered as a 503B outsourcing facility with the FDA? Yes No
- 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.

9. Has all personnel involved in compounding completed annual continuing education and/or training in the last year? Yes No
10. 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 _____
Print Name of Permit Holder

Email Address of Permit Holder _____
Date

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 _____
Print Name of Pharmacist in Charge

Email Address of Pharmacist in Charge _____
Date

IMPORTANT INFORMATION ***See DOCUMENT CHECKLIST for required supporting documents***** Application will be returned if incomplete and/or missing supporting documents.**

PRIVACY DISCLOSURE

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 services. In order to better protect the information you provide, please provide the Department with the following information that may be released to the public upon request: a public mailing address, a public email address and a public telephone number.

Privacy disclosure and information from this renewal may be shared.

DOCUMENT CHECKLIST

All renewal applications, must submit the following:

- Most recent inspection report \$280 Renewal fee payable to SC Board of Pharmacy

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: * Do NOT send entire SOP library
 - a. General compounding procedures
 - b. Maintenance and cleaning of area and equipment

NON-RESIDENT PHARMACY NON-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. **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.**