



## **NON-RESIDENT WHOLESALE DISTRIBUTOR PERMIT APPLICATION REQUIREMENTS AND INSTRUCTIONS**

A Non-Resident Wholesale Distributor Permit is required for a facility to engage in wholesale distribution of prescription drugs and/or devices to permitted facilities and licensed practitioners pursuant to SC Code Ann. Section 40-43-89 and SC Code Reg Section 99-43(G). Regulations Section 99-43 requires a separate permit for each business practice in which a facility engages.

Facilities requiring a Non-Resident Wholesale Distributor Permit include, but are not limited to:

- own-label distributors;
- private-label distributors;
- jobbers;
- brokers;
- warehouses including manufacturers and distributors warehouses, chain drug warehouses, and wholesale drug warehouses;
- independent wholesale drug traders; and
- retail pharmacies that conduct wholesale distributions.

A separate Non-Resident Virtual Wholesale Distributor Permit is required for virtual wholesale distributors defined as a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase and sale.

If you are also a Non-Resident Third Party Logistics Provider (3PL), you will need to concurrently apply for a Non-Resident 3PL permit.

A South Carolina Non-Resident Wholesale Distributor Permit Application will remain valid for up to one year. Failure to complete the application process within one year of submission will require submission of a new application, supporting documentation and fees. If your permit application is approved **before April 1<sup>st</sup>**, you are required to renew your permit before **June 1<sup>st</sup>** to avoid a late fee.

### **REQUIRED CONTACT(S)**

A **permit holder** is an individual who is responsible for and accountable for ensuring compliance with all federal and State law related to the facility. This individual is responsible for any violation(s) of law occurring in relation to the facility as well as ensuring the information related to this application and all permit renewal applications are true and accurate.

A **designated representative** is an individual who is responsible and accountable for and actively involved in and aware of the performance and operation of the facility or entity, its personnel and as required by law, all other entities or individuals providing services related to daily operations. This individual may also be responsible for any violation(s) of law related to the handling and/or distribution of drugs and/or medical devices at or from the permitted facility or entity. An individual may only be designated representative for one permitted facility/location.

The designated representative or other individual knowledgeable about the applicant's operations may be requested to attend an application review meeting to answer questions regarding the applicant's operations.

## **CHANGE TO AN EXISTING PERMIT**

A new application should be submitted for permitted facilities that meet the requirements for any of the changes listed below. The facility may continue to operate under the facility's existing permit until the new permit is issued. Detailed information on making changes to an existing permit is located on the [Frequently Asked Questions](#) page under "Facilities" on the Board website.

**Change of Ownership:** A new application must be submitted to the Board when there is a change of 50% or more in ownership at the permitted entity parent level. The application should be submitted within 30 days post-change of ownership with organizational charts of before and after the change. The chart must show the legal business entities from the ultimate parent company down to and including the applicant and must include the legal business name, trade name, and type of ownership for each entity on the chart. The chart must include the names of owners with a ten percent (10%) or greater ownership interest in a non-publicly traded company. Do not send personnel organizational charts showing roles of personnel employed by the company.

**Change of Legal Name:** A new application must be submitted when there is a change in the legal name (not DBA name). The application should be submitted within 30 days post-name change.

**Change of Location** (to another city): A new application must be submitted within 30 days of post-facility relocation.

## **CONTROLLED SUBSTANCE PROVIDER**

In South Carolina, the Department of Public Health (SCDPH) regulates controlled substances. Please review the SCDPH's Bureau of Drug Control website for additional information: <https://dph.sc.gov/professionals/healthcare-quality/drug-control-register-verify/new-registrations>.

## **NABP DRUG DISTRIBUTION ACCREDITATION**

Non-Resident Wholesale Distributors are required to have the National Association of Boards of Pharmacy (NABP) Drug Distributor Accreditation **or** meet the standards established by NABP for its Drug Distributor Accreditation.

If this facility does not have Drug Distributor Accreditation or if the accreditation application is currently pending, please review the standards available at the NABP website (<https://nabp.pharmacy/>) and provide a notarized letter to the Board certifying the facility's compliance with these standards.

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.

Failure to complete all required fields and/or provide necessary supplemental documentation will delay the application process. **In order to avoid delay, please do not provide the items below in a binder, folder or use dividers.**

**An application is not complete until receipt of the required items below.**

### **Required items:**

- Check or money order only (no cash) in the amount of \$700 made payable to SC Board of Pharmacy. (Application fee is non-refundable. A returned check fee of up to \$30, or an amount specified by law, may be assessed on all returned funds.)
- Copy of all operational inspection reports conducted within the last two years

- Copy of FDA registration
- Copy of licensure from resident state
- A letter describing, in detail, the nature of your business
- Photographs of:
  - Entrance, including company signage
  - Exit
  - Product storage area
  - Quarantine area
  - Controlled substance safe, cage, or vault (if applicable)
- Organizational chart from the ultimate parent company down to and including the applicant
- Copy of policy and procedures for the following:
  - Security
  - Disaster plans
  - Storage
  - Shipping refrigerated products
  - Monitoring temperature and humidity
- Copy or reprint of an actual invoice/packing slip or T3, one incoming and one outgoing
- Copy of Drug Distributor Accreditation or notarized letter that facility meets the requirements for accreditation

**Other documentation, check N/A if not applicable. Please include this checklist with the completed application.**

**Included   N/A**

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of current DEA registration   |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of resident state controlled substance registration   |
| <input type="checkbox"/> | <input type="checkbox"/> | List of all pharmacy permits/licenses, license types, and license numbers held in other states   |
| <input type="checkbox"/> | <input type="checkbox"/> | If a change of ownership, include organizational charts of before and after the change. Chart must include names of owners with a 10% or greater ownership interest if a non-publicly traded company.  |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of FDA inspection, any 483(s) issued, and applicant's response (all unredacted)   |
| <input type="checkbox"/> | <input type="checkbox"/> | Provide the name, address, contact person and South Carolina permit number of all 3PLs and/or wholesale distributors you will be using. If available, provide the Drug Distributor Accreditation certificate or a notarized letter certifying the facility is in compliance with NABP standards. |



**NON-RESIDENT WHOLESALE DISTRIBUTOR PERMIT APPLICATION**

- New Facility (\$700)
- Change to Existing Permit (\$700)  
 Permit No.: \_\_\_\_\_
  - Change of Name
  - Change of Location (from one city to another)
  - Change of Ownership (include organizational chart before and after change)

For Board Use Only	
Date Paid	
Amount Paid	
Check No.	

**FACILITY INFORMATION**

Federal Tax ID No.: \_\_\_\_\_ NABP e-Profile ID No.: \_\_\_\_\_ Resident State License No.: \_\_\_\_\_

Legal Facility Name: \_\_\_\_\_

DBA Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_

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

Mailing Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Days and Hours of Operation: \_\_\_\_\_

**OWNERSHIP**

Business Type:  Sole Proprietorship  Partnership  Corporation  Other (Specify): \_\_\_\_\_

1. Is this facility/company publicly traded?  Yes  No

Name of Parent Company: \_\_\_\_\_ State of Incorporation: \_\_\_\_\_

List the names of owners with 10% or greater ownership if a corporation. This is not required for publicly traded companies.

Name of Individual Owners, Partners or Principal Officers	Title	% of Ownership
1.		
2.		
3.		

**PERMIT HOLDER**

A permit holder is the individual who is responsible for and accountable for ensuring compliance with all federal and State law related to the facility. This individual is responsible for any violation(s) of law occurring in relation to the facility as well as ensuring the information related to this application and all permit renewal applications are true and accurate.

Name of Permit Holder: \_\_\_\_\_

Email for Permit Holder: \_\_\_\_\_ Phone: \_\_\_\_\_

(Must be a direct email address for the permit holder. Staff will contact the permit holder directly with questions related to the application or permit.)

**DESIGNATED REPRESENTATIVE**

The Designated Representative is the individual who is responsible and accountable for and actively involved in and aware of the performance and operation of the facility or entity, its personnel, and as required by law, all other entities or individuals providing services related to daily operations. This individual may also be responsible for any violation(s) of law related to the handling and/or distribution of drugs and/or medical devices at or from the permitted facility or entity.

Name of Designated Representative: \_\_\_\_\_

Email for Designated Representative: \_\_\_\_\_ Phone: \_\_\_\_\_

(Must be a direct email address for the designated representative. Staff will contact the designated representative directly with questions related to the application or permit.)

**LICENSES**

- 1. Are you permitted in any state other than your resident state?  Yes  No  
**If yes**, provide a list of all pharmacy permits and/or licenses, license types, and license numbers held in other states.

**SUPPLIERS**

- 1. Does this facility purchase either from an FDA registered manufacturer and/or from an accredited Drug Distributor that purchased the drug/device directly from the manufacturer?  Yes  No
- 2. Will the facility utilize a 3PL or wholesaler to distribute the product?  Yes  No  
**If yes**, list all names, addresses, contact persons, and SC permits of distributors.

**FDA**

- 1. Has this facility been inspected by the FDA?  Yes  No
- 2. If inspected by the FDA, was this facility issued a 483?  Yes  No  
**If Yes**, provide a copy of the FDA Form 483 and this facility’s response to the issues noted.
- 3. Is this facility reporting licensure information annually to the FDA?  Yes  No

**FACILITY OPERATIONS**

- 1. Type of products distributed. Check all that apply:  
 Prescription Drugs       Legend Devices       OTC drugs  
 Non-Legend Devices       Controlled Substances       Medical gases
- 2. Are you currently distributing product(s) into South Carolina from this facility?  Yes  No  
**If yes**, provide a list of customers and history of products distributed.

**CONTROLLED SUBSTANCES**

- 1. Do you distribute controlled substances?  Yes  No  
 If the facility distributes controlled substances and the resident state requires a state-level controlled substance registration, a copy of the DEA and state-level registrations need to be included with the application.

**DISCIPLINARY HISTORY**

For any “Yes” answers below, please provide and submit a detailed explanation for each person or entity to whom a Yes answer applies. Official documentation of judgment(s) or disposition(s) must also be provided by the applicable person and/or the entity’s authorized agent, as well as the city and state where the offense(s) or discipline occurred.

**To the best of your knowledge, has the applicant, the entity, undersigned permit holder, designated representative, any person or entity identified as holding a position in ownership/management, or any entity under common control of the applicant:**

- 1. Had a professional license or permit disciplined, denied, refused, voluntarily surrendered, agreed to permanently cease operations, or revoked?  Yes  No
  - a. Have any pending disciplinary action or currently under investigation?  Yes  No
- 2. Been convicted, fined, or entered in a plea of guilty or nolo contendere to a crime (other than a minor traffic offense)?  Yes  No
  - a. Have any legal action pending or currently under investigation related to violations of any federal or state pharmacy laws or drug laws regardless of the jurisdiction of legal action?  Yes  No
- 3. Operated, or allowed any facility to operate, without a valid permit?  Yes  No

**PERMIT HOLDER ATTESTATION**

- I hereby affirm that I have read and approved the forgoing application. I affirm that all information and statements contained herein are true and accurate to the best of my knowledge and belief.
- Should additional explanation and/or documentation be required, I accept responsibility to ensure additional explanation and documentation will be provided, if necessary. I further understand that this application will not be processed until all documentation is received.
- I understand that pursuant to S.C. Code Ann. § 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.

\_\_\_\_\_  
Permit Holder Signature

\_\_\_\_\_  
Date

**DESIGNATED REPRESENTATIVE ATTESTATION**

- I hereby affirm that I have read and approved the foregoing application. I affirm that all information and statements contained herein are true and accurate, to the best of my knowledge and belief.
- I understand that I am responsible for abiding by the statutes and regulations governing my role as the facility’s designated representative.
- I affirm responsibility to ensure this facility shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.
- I hereby certify that the facility for which this permit is sought will be operated in full compliance with all applicable federal and South Carolina laws.
- I understand that pursuant to S.C. Code Ann. § 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.

\_\_\_\_\_  
Designated Representative Signature

\_\_\_\_\_  
Date

**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.