Wholesale or Other Drug Distributors and 503B Outsourcing Facilities

Link - License Information & Applications

https://doh.sd.gov/licensing-and-records/boards/pharmacy/licensing-requirements/

Renewal Schedule and Fees

- All licenses expire December 31st each year. There is no grace period.
- Online renewal application is available 60 days prior to license expiration date.
- Renewal fee is \$500 for all license types
- A \$50.00 late fee will be assessed for renewals submitted after December 31st
- · All fees are nonrefundable for any reason including duplicate submissions and applications submitted in error
- Application is not automatically renewed upon submission. Each renewal undergoes a multi-tier review process.
- Link to SD Pharmacy Laws & Rules

Notify Board of a Change

- For entity change of name, in-state address, designated representative, closure, or license surrender, submit a Change Notification form (Notification Form).
- To verify a requested change has been processed, use the board's license verification website link below.
- If entity moves to another state, existing license is surrendered to the board.

Change of Officer/Director/Managing Member/Partner

- The board requires the reporting of officers, partners, directors, and managing members, at initial and renewal application.
- Licensee is not required to inform board of changes that occur outside these times.

Change of Ownership Guidance (CHOW)

- If entity ownership changes at the parent level or below by 50% or more by any method, a CHOW application must be completed.
- If entity ownership changes at the grandparent level or above (indirect change), board does not need to be notified.
- If entity moves to another state, existing license is surrendered to the board.
- If there is a name change with CHOW, home state license and DEA must show new name
- If there is an address change with CHOW, inspection must be for the new location/address
- To complete a CHOW application, click (https://sdbop.igovsolution.net/online/User_login.aspx), login using licensee's username and password, select "renew" and then "change of ownership".
- If questions, contact the board before starting CHOW application process.

License Verification / Primary Source Verification

- Go to (License Verification).
- Direct anyone requesting a verification of your license to site.
- A verification is not an entity's official license.

Verification Instructions

Select verification type (Business)

Select license type (Wholesale)

Enter business license number as (600-XXXX)

Enter verification search code

Do not complete any other fields

Click Search, click print icon to view license details

Medical Devices / Durable Medical Equipment (DME)

If device contains a prescription (legend) drug, a South Dakota license is required.

Third-Party Logistic Providers (3PL)

- South Dakota does not license out-of-state 3PLs.
- However, a South Dakota license is required for in-state 3PLs (those physically located in SD)

Definitions – Virtual Manufacturer / Virtual Distributor / Private Label Distributor

- Virtual Manufacturer owns the product but does not manufacture it or distribute it but does direct those activities.
- <u>Virtual Distributor</u> Does not direct the manufacturing of the product; does not take possession of the product and uses a 3PL to
 distribute.
- <u>Private Label Distribution</u> firm does not participate in the manufacture or processing of a drug but instead markets and distributes
 under its own label.

Reporting Discipline

- Licensee may report discipline to the board by email (<u>pharmacyboard@state.sd.us</u>).
- If discipline is reported by email, do not send a duplicate, hard copy of the information to board.