SOUTH DAKOTA BOARD OF PHARMACY

Wholesale & Other Drug Distributors and 503B Outsourcing Facilities

Initial Application Instructions

Revised 9/2025



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Table of Contents

Link - License Information & Application

Software requirements – for a better user experience we recommend using the most current version of Chrome or IE/Edge. Access to the licensing platform may be affected by the computer technology used and IT constraints you or your agency may have in place, including malware, firewalls, cookies, pop-up blocker, browsers, outdated software, etc. **Do not use a tablet or mobile phone to complete application.**

Application General Information

List of Required Forms & Documents for Application Upload

STEP 1

Begin Initial Application

Link to begin initial application

STEP 2

After license has been issued

Find license/registration number Create Your Online Account

STEP 3

Review My Profile Information

How to print your license How to print a receipt

STEP 4

Trouble Shooting and Tips

Computer or online licensing platform problems Tips

Account Password Reset

Application General Information

- License fee \$500 for all license types.
- Payment method MasterCard, Visa or American Express. A gift card for these vendors may be used.
- All fees are nonrefundable for any reason including duplicate submissions or applications submitted in error
- All licenses expire December 31st each year. There is no grace period.
- **DO NOT USE** a mobile phone or tablet to submit application
- Application must be completed in one sitting. Information entered is not saved unless application is submitted.
- Current South Dakota Statutes and Rules at SD Laws and Rules

DO NOT USE this application if entity has <u>ever</u> been issued a South Dakota wholesale license in the past. Applicant should complete a "Renewal" or a "Change of Ownership" application.

Applications that have not completed the licensing process within six months of application submission date will be deleted from licensing platform without notice.

Required Documents to Upload

Provide documents in PDF format

- Home state license, primary source verification or written explanation why document is not available
- Inspection report less than 4 years old. Report can be a state inspection, FDA inspection, NABP DDA certificate or an explanation why document is not available
- 503B entities must provide a FDA inspection
- Inspection deficiency correction responses if applicable
- Federal DEA certificate for entity or 3PL if distributing controlled substances
- South Dakota Controlled Substance Registration (SD CSR)- if distributing controlled substances

Virtual Manufacturer

- o Contract 3PL name, address, and copy of agreement first page and signature page only
- o 3PL's NABP Drug Distributor Accreditation (formerly VAWD) accreditation certificate
- o Contract Manufacturer name, address, and copy of agreement first page and signature page only
- Product/NDC List

Virtual Distributor

- Contract 3PL name, address, and copy of agreement first page and signature page only
- o 3PL's NABP Drug Distributor Accreditation (formerly VAWD) accreditation information

• Private Label Distributor

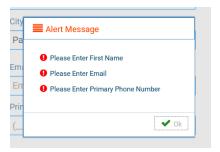
- o Product/NDC List
- List of all the States entity is licensed in
- Form Owner or Corporate Officer Certification form. Form at Corp Officer Certification Form
- List of the names and titles of the <u>individual persons</u> who are the owners, partners, officers, and/or members of the entity
- Disciplinary Actions: An explanation of any felony conviction(s) or disciplinary action(s) occurred in last seven years. Provide copies of court records of the charges, convictions, guilty charges, or entered a plea of guilty or no contest to.

After Application Submission

- Board reviews application, emails submitter if clarification is needed, and approves/denies application.
- Automated email is sent to submitter upon application approval
- Go to STEP 2 in this document:
 - ✓ To find the license number issued to entity
 - ✓ To create an online account to print license and payment receipt

General Notes

- Required fields are marked with a red * asterisk
- An alert message (below) will appear if information is incomplete
- You cannot advance to the next page until required fields are completed



Step 1 – Begin Initial Application

Click link to start Wholesale Drug Application

- Review instructions
- · Click Next to proceed

Wholesale & Other Drug Distributors and 503B Outsourcing Information

- Enter Business
- Select "county" for business; if business is not in SD, select "Outside of SD" from dropdown list

Legal name of Parent Company Headquarters/Corporate Office section

Enter Parent Company / Corporate Office information

License Preparer Information

- Check box if license Preparer is the same as Wholesale & Other Drug Distributors Information section OR
- Enter license preparer's information

Type of Distribution (check all that apply)

Only check options that reflect how the business will operate in the state of South Dakota

If entity is virtual, review definitions below to select the correct Type of Distribution

Virtual Manufacturer - entity owns the NDA and/or ANDA but does not take physical possession of the drug or device. Entity contracts with a contract manufacturing organization for the physical manufacture of the drug or device and is not involved in the physical manufacture of the drug or device. Often contracts with Third Party Logistics Provider (3PL) for receipt, storage, and distribution of drug.

Virtual Distributor – entity does not own the NDA or ANDA and does not take physical possession of products; however, purchases the drug or device from a Manufacturer and must be registered as a business entity with the FDA and must operate out of a commercial facility and not out of a residence or personal dwelling.

Private Label Distribution – a firm that does not participate in the manufacture or processing of a drug but instead markets and distributes under its own trade name, and labels a drug product made by someone else.

Manufacturing Distributor and/or 503B Outsourcing Facility

Enter your FDA number

Virtual Manufacturing

Product List

Click "Attach Document" to upload one Product/NDC list showing all products

Third-Party Logistic Provider / 3PL

- Click "Click Here to Add More" to enter 3PL information
- Click "Attach Document" to upload 3PL agreement (first page and signature page)
- Click "Attach Document" to upload NABP Drug Distributor Accreditation
- To add more 3PLs, click "Click Here To Add More" or
- Click Save

Contract Manufacturer

- Click "Click Here to Add More" to enter for Contract Manufacturer information
- Click "Attach Document" to upload Contract Manufacturer Agreement (first page and signature page)
- Click Save
- To add more Contract Manufacturers, click "Click Here To Add More"

Virtual Distributor

- Click "Click Here to Add More" to enter 3PL information
- Click "Attach Document" to upload 3PL agreement (first page and signature page)
- Click "Attach Document" to upload NABP Drug Distributor Accreditation
- Click Save
- To add more 3PLs, click "Click Here To Add More"

Private Label Distributor

Product List

Click "Attache Document" to upload one Product/NDC list showing all manufacturer products

In-State Third-Party Logistics Provider

- South Dakota does not license out-of-state third-party logistics (3PL) providers
- 3PLs in South Dakota may be licensed as a Third-Party Logistics Provider.

Other

Enter explanation

Type of Prescription Drugs/Products (check all that apply)

DEA Controlled Substance

- Enter facility's DEA number
- Click "Attach Document" to upload current Federal DEA Certificate
- Enter facility's South Dakota controlled substance registration number. A SD CSR is required when shipping controlled substances into South Dakota

Other

Enter explanation

Types of Customers you sell/distribute to (check all that apply)

Other

Enter explanation in text box

Type of Ownership (select one option)

Sole proprietorship - one individual person owns 100% of the entity/facility

- Click "Click Here" to enter Sole Proprietorship information
- Click "Save"
- Click "Next"

Partnership

- Click "Click Here" to enter Partnership information
- Click Save
- Click "Attach Document" to upload a list of the names, titles, and addresses for the partners/managing members/officers for the entity/facility
- Click "Next"

Corporation

- Click "Click Here" to enter Corporation information
- Click Save
- Click "Attach Document" to upload a list of the names, titles, and addresses for the partners/managing members/officers for the entity/facility
- Click "Next"

LLC

- Click "Click Here" to enter LLC information
- Click Save
- Click "Attach Document" to upload a list of the names, titles, and addresses for the partners/managing members/officers for the entity/facility
- Click "Next"

Other

- Enter information in text box
- Click "Attach Document" to upload a list of the **names**, **titles**, and **addresses** for the partners/managing members/officers for the entity/facility
- Click "Next"

Business Information - Registered Agent in SD

Page appears only if licensee is outside the state of South Dakota

- Enter licensee's South Dakota registered agent information
- Click "Next"

Home State License

Page appears only if licensee is outside the state of South Dakota

- Click Yes or No
- If no, enter explanation in text box and click "Attach Document" to upload the explanation
- If yes,
 - Select home state license
 - Enter home state license number and expiration date
 - Click "Attach Document" to upload the current home state license or primary source verification for entity

Inspection

Inspection report <u>must</u> be less than 4 years old. Report can be a state inspection, FDA inspection, NABP DDA certificate <u>or</u> an explanation why inspection is not available

- Out-of-state entity must provide inspection or explanation why document is not available
- 503B Outsourcing Facilities must provide an FDA inspection; other inspections will not acceptible
- Select inspection type
- Enter inspection date
- Click "Attach Document" to upload inspection or explanation why no inspection
- Click Yes or No, "were there any inspection deficiencies identified"
- If yes, click "Attach Document" to upload the inspection corrections response documentation.

NABP Drug Distributor Accreditation (formerly VAWD)

- Click Yes or No, NABP DD Accredited
- If yes, provide accreditation expiration date

List of Other States Entity Is Licensed In

- Click "Attach Document" to upload a list of the U.S. states entity is licensed in (OR)
- Enter the two-letter state abbreviation separated by commas in text box

Owner Structure

- Download Owner or Corporate Officer Certification form. Click on link (Form)
- Follow instructions at top of form
- Form must be signed with original ink or an E-Signature (Adobe Sign or DocuSign document)
- Click "Attach Document" to upload completed form

Disciplinary Actions

- Click "Yes" or "No"
- If Yes
 - o Provide an explanation in text box and
 - Click "Attach Document" to upload legal documentation of the felony, misdemeanor, or disciplinary actions.

Application Input Preview

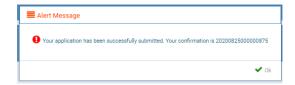
- Review application using the vertical scroll bar on the right-hand side of application
- Click on "Previous" or "Next" to change screens
- Click "Next" to continue

Affirm and Submit

- Read attestation, check box to confirm understand
- Type the full name of person completing the application
- Date and License Fee fields auto populate
- Select "Debit" or "Credit" for card used
- From drop-down menu select Mastercard, VISA, or American Express
- Enter cardholder's name (as it appears on their credit card)
- Enter credit card number
- Enter credit card expiration date
- Enter 3-digit number for MasterCard/Visa cards
- Enter 4-digit number for American Express/AMEX card
- Click box in front of "I am not a Robot"
- Click "Submit" if you are confident the application is complete
- All fees are nonrefundable for any reason including duplicate submissions or applications submitted in error

DO NOT click "Submit" button multiple times. This will result in duplicate submissions If a submission issue occurs (spinning wheel, transmission interruption) contact the board DO NOT submit another application

Upon successful application submission, you receive a system generated confirmation number



Print Application

Click on the printer icon in the upper right-hand corner



Step 2 – After License Issued / Create An Online Account

Find license number assigned to applicant

- Click link License Verification
- Click (Business Verification)
- Select License/Permit Type (Wholesale), enter (Verification Code) shown, enter (legal business name exactly as it appears on application). DO NOT complete any other fields. Click (Search).
- Click (Print Icon) in last column to obtain a primary source verification showing assigned number. This
 document is <u>NOT</u> your official license.

Click link https://sdbop.igovsolution.net/online/User login.aspx to create an account

Online Business Profile Login Section

- Check (Business)
- Click (Sign Up)

Registration Section

- Click (Business)
- Select permit/license type (Wholesale)
- Enter last four digits of license number (600-XXXX)
- Enter zip code for facility

Credentials Section

- There are no password restrictions
- <u>Username</u> and <u>password</u> created are unique and cannot be used for multiple accounts
- Write down username and password. Save them for future use.

- Complete all fields marked with a red * asterisk
- Click "Submit"
- Alert message appears when registration is successful, click "Ok
- Automated email confirming account set-up is sent to email address entered in the Credential section.
- Click "Ok" to continue

Return to Login

- Click link https://sdbop.igovsolution.net/online/User login.aspx
- Click "Business"
- Enter username, password and click "Login"
- You are now in the My Profile section of the online account

Step 3 - My Profile Sections in Online Account

Data in this section is from the nonresident initial application
There are eight different **My Profile** sections of information for review and/or edit

Business Information

· These fields cannot be edited

Registration Information

- These fields cannot be edited
- To print license, click on the word "Print" in the last column

Primary Address

These fields cannot be edited and are for the physical location of the business

Mailing Address

- If entity has a different address for mail, enter it here.
- These fields can be edited
- Click "Edit" to make corrections/changes, click "Submit" to capture changes

Contact Information

- These fields can be edited
- Click "Edit" to make corrections/changes, click "Submit" to capture changes

Document Details

- Documents that appear in this section were uploaded in application process and can be downloaded
- To upload a document, not previously uploaded during application process
 - Select "Document Type"
 - o Use the "Attach" to browse files and select desire document
 - Click "Upload Document"
- Do not upload the same document twice during the application process

Payment History

To print payment receipt, click on the "Printer Icon" in the last column

Renewal Details Section

- Application status can be viewed in Status column (Pending or Clear)
- (Clear) indicates application has been processed, approved and license is ready to print

Step 4 - Trouble Shooting / Tips / Account Password Reset

Having trouble getting through application?

- Do Not Use a mobile phone or tablet to complete online application
- Change browsers (Internet Explorer, Google Chrome)
- Computer firewalls and malware software can impact application completion/submission
- Turn pop-up blockers off

Tips

- Provide documents in PDF format
- TIF and jpeg document formats do not always open which delays application processing
- Upload documents only when prompted in the application
- **DO NOT UPLOAD** documents on the My Profile page that were already uploaded in the application as this will result in duplicate documents in the application
- If your document says (This is a Primary Source Verification) at the top, THIS IS NOT YOUR OFFICIAL SOUTH DAKOTA LICENSE

Account Password Reset Instructions

Go to Login page (https://sdbop.igovsolution.net/online/User_login.aspx)

- Click (Business)
- Enter your username
- Click (Forgot Password); alert Message appears
- Click (Ok)

At Password Recovery page

- Click (Business)
- Select (License Type)
- Enter License # (600-XXXX)
- Enter (zip code for physical location)
- Click (Next)
- A "temporary" password is generated
- Write "temporary" password down or copy and paste temporary password to a Word document to eliminate miss keying.
- Click (Ok)

Return to Login page

- Click (Business)
- Enter username
- Enter "temporary" password in the password field
- Click (Login)

At Credentials page

- Enter "temporary" password in the "Old" password field
- Enter "new" password, confirm new password
- Click (Submit)

Return to Login page

- Click (Business)
- Enter username
- Enter "new" password