SOUTH DAKOTA BOARD OF PHARMACY

Wholesale & Other Drug Distributors and 503B Outsourcing Facilities

Renewal Application and

Change of Ownership Application Instructions



4001 W Valhalla Blvd, Suite 106 Sioux Falls, SD 57106 pharmacyboard@state.sd.us P 605.362.2737

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Link - License Information & Applications

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 Information

Medical Devices
Third-Party Logistic Providers
Virtual Entities
Change of Ownership Parameters

List of Required Forms / Documents for Upload in Application

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GENERAL INFORMATION

- 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
- Payment methods MasterCard, Visa or American Express. A gift card for these vendors may be used.
- Application is not automatically renewed upon submission. Each renewal undergoes a multi-tier review process.
- DO NOT USE a mobile phone or tablet to submit application.
- Link to SD Pharmacy Laws & Rules

APPLICATION INFORMATION

- 1. All fees are nonrefundable and nontransferable including duplicate and error submissions.
- 2. Use this application:
 - to <u>renew</u> a SD wholesale, other drug distributor or 503B facility license <u>or</u>
 - for a change of ownership (CHOW)
- **3.** <u>Do not</u> use this application to report a change in business name or location; submit a change notification form found on the board website.
- 4. Change of Ownership Parameters
 - If entity ownership changes <u>at the parent level or below by 50% or more by any method</u>, a CHOW application must be completed.
 - If entity ownership changes at the grandparent level or above (an indirect change), board does not need to be notified.
 - If entity moves to another state, a completely "new" application must be initiated in this circumstance and the existing license surrendered.
 - If name changes due to CHOW, home state license must show new name.
 - If address changes due to CHOW, inspection must be for the new location/address.
- 5. A SD license is not required for out-of-state third-party logistics providers (3PLs).
- 6. A SD license is required for 3PLs physically located in South Dakota.
- 7. A SD license is required if a DME device contains a prescription (legend) drug.
- 8. An entity shipping controlled substances into SD must have a <u>SD controlled substance registration</u>; this includes 3PL providers.
- 9. Forms must be signed with a wet signature or an E-signature (DocuSign or AdobeSign).
- 10. Provide/save all forms in a PDF format.
- 11. Do not upload expired forms or documents.
- 12. Information in the *Business Distribution Type* section of application <u>cannot</u> be altered. If a change is needed, contact the board.
- 13. Applications that have not completed the licensing process within six months of application date will be deleted from licensing platform without notice.

APPLICATION DOCUMENTS FOR UPLOAD

Provide documents in PDF format and upload when prompted.

- Federal DEA certificate for entity or 3PL if shipping controlled substances
- 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 an inspection is not available
- Inspection deficiency responses if applicable.
- Product list with NDC if applicable.

- List of all the States entity is licensed in.
- List of the names and titles of the <u>individual persons</u> who are the owners, partners, officers, and/or members of the entity.
- Form Owner or Corporate Officer Certification form
- Court documents, if "yes" response to a regulatory question
- If CHOW application, provide a diagram/listing of the *pre-* and *post-*ownership structures and ownership percentages.

AFTER APPLICATION SUBMISSION

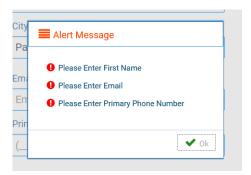
- Board reviews each application, emails <u>submitter</u> if clarification is needed, and approves/denies application.
- Check license status using verification site License Verification
- No reply automated email is sent to <u>submitter</u> upon application approval.

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 - Create Your Online Account

- 1. After an <u>initial</u> license is issued, licensee must create an online account before license can be printed, renewed or a change of ownership application submitted.
- 2. If an online account is already set-up, click link https://sdbop.igovsolution.net/online/User_login.aspx, check (Business), enter username, password for account, click (Login), and proceed to STEP 2 below.
- 3. If an online account is <u>not</u> set-up, click link https://sdbop.igovsolution.net/online/User_login.aspx, and follow steps 4-7 below to create an online account. Then proceed to STEP 2.

4. Online Profile Login Section

- Check (Business)
- Click (Sign Up)

5. Registration Section

- Select permit/license type (Wholesale & Other Drug Distributors)
- Enter last 4-digits of permit/license number (600-XXXX)
- Enter zip code for facility.
- Information entered must match what is on your current license.

6. Credentials Section

- There are no password development restrictions.
- The <u>username</u> and <u>password</u> you create is unique and cannot be used for multiple accounts.
- Write down the username and password and save them. This information will be needed in the future.
- Complete all fields marked with a red * asterisk.
- Click (Submit).
- An alert message appears when registration is successful, click (Ok).
- An automated email confirming successful account set-up will be sent to the email address entered in the Credential section.

7. Return to Login

- Click link https://sdbop.igovsolution.net/online/User-login.aspx
- Check (Business) enter username, password and click (Login).
- You are now in the My Profile Section of the online account.

Step 2 - My Profile Section of Online Account (information review)

Data in the My Profile section shows the account information on file with the board Review the information in the eight different (My Profile) sections.

1. Business Information Section

• Fields cannot be edited.

2. Registration Information Section

- Fields cannot be edited.
- Print a copy of license, click (Print) in the last column.

3. Primary Address Section

• Fields cannot be edited and show the business/facility's physical address.

4. Mailing Address Section

- If entity has a difference address for receiving mail, enter it here.
- Fields can be edited.
- Click (Edit) to make corrections/changes, click (Submit) to capture changes.

5. Contact Information Section

- Fields can be edited.
- Click (Edit) to make corrections/changes, click (Submit) to capture changes.

6. Document Details Section

- Documents that appear in this section were uploaded during application process.
- Do not upload the same document twice during the application process.
- To upload a document, not previously uploaded during application process.
 - a. Select (Document Type)
 - b. Click (Attach) to browse and select document; Click (Upload Document).

7. Payment History Section

• Print payment receipt, click on the (Printer Icon) in the last column.

8. 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 3 – Begin Renewal or Change of Ownership Application

- 1. Return to the *Registration Information* in My Profile section (Step 2, #2 above).
- 2. Click on the word (Renew) in the second to last column.



2. Click link to read instructions or (Next) to begin renewal and/or change of ownership application process.

3. APPLICATION SECTION

Application Type

- Check all that apply click (Renew), (Change of Ownership) or both if changing ownership at renewal. See CHOW threshold requirements on page 3 of this document.
- Has business name or location change (Yes or No)
 - a. If name changed, home state license must show new name.
 - b. If location changed, inspection must be for the new location/address.
- Enter South Dakota license number for business (600-XXXX)
- If CHOW, **click** (Attach Document) and **upload** document showing <u>previous</u> ownership structure, <u>new</u> ownership structure and ownership percentages.

Business Entity Information

- Enter legal business name and information for entity.
- Business name must match name as shown on entity's Federal DEA certificate.

Home State License

- Out-of-state entity must provide copy of current (1) home state license, (2) primary source verification or (3) a written explanation why document cannot be provided.
- Upload home state license, primary source verification or explanation why document is not available.

Inspection

- Out-of-state entity must provide inspection or explanation why document is not available.
- Upload inspection report less than 4 years old. Report can be a state inspection, FDA inspection,
 NABP DDA certificate or an explanation why an inspection is not available
- Deficiencies click (Yes) or (No)
- Upload corrective action response document if deficiencies were noted in inspection.

NABP Drug Distributor Accreditation (formerly VAWD)

- Click (Yes) or (No)
- If (Yes) upload document

Business Function in South Dakota (example: In SD, business entity will function as a wholesaler)

- This section of application cannot be altered by applicant. Contact the board if a change is needed.
- Enter business' FDA # if entity is a manufacturing distributor or 503B.
- Upload product list with NCD if entity virtual.

Prescription Drugs/Products Provided

Check all that apply

If shipping controlled substances into South Dakota,

- Enter business' South Dakota controlled substance registration number (CSR).
- Enter business' Federal DEA controlled substance registration number.
- Upload business' or third-party logistics provider's current Federal DEA certificate.

Ownership Structure (select one option)

Sole Proprietor (one person owns 100% of business)

• Click (Click Here) to enter sole proprietor information.

Partnership / Corporation / LLC

- Upload a list of the names and titles of the <u>individual persons</u> who are the owners/partners/ officers/managing members for business.
- Upload completed form Owner or Corporate Officer Certification Form
 - Follow instructions at top of form.
 - A new form must be completed for each application.
 - <u>Person</u> signing form must appear on the partners/members/officers list uploaded in application.
 - Form signature may be original/wet ink or e-signature (DocuSign or AdobeSign).
- Upload power of attorney document <u>if</u> form is completed by a person not on the partners/members/officers list.

Disciplinary Actions Section

- Check (Yes) or (No)
- Upload legal documentation of the felony, misdemeanor, or disciplinary actions.

4. Registered Agent in SD

- Out-of-state entities must have a registered agent in the State of South Dakota.
- Enter registered agent information.

5. Application Submitter Information (person board will contact regarding application)

- Check box if submitter information is the same as information in Business Information section of application.
- If not the same, enter submitter's information.

6. Application Input Preview Section

- Before submitting, review application input using the scroll bar on right-hand side.
- Click (Next) to continue or (Previous) to return to a page needing correction.

7. Affirm and Submit Section

- All application fees are nonrefundable including duplicate and error submissions.
- Check attestation box.
- Type application submitter's name (E-Signature)
- Select (debit/credit), card type (only Mastercard, Visa, or American Express are accepted), name on credit card, card number, expiration date, and 3-digit security code number.
- Click Submit button online application is complete.
- DO NOT click submit button again contact the board if you have questions about submission.
- Alert message appears with confirmation number for submission.
- Completed application appears; click (Printer Icon) in right-hand corner for copy of application.

Step 4 - Troubleshooting / Tips / Account Password Reset

Having trouble getting through application?

- **Do Not Use** 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 uploaded during application process 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)

- Check (Business)
- Enter username
- Click (Forgot Password) Alert Message appears
- Click (Ok)

At Password Recovery page

- Click (Business)
- Select (License Type)
- Enter (License # as 600-XXXX)
- Enter (zip code for physical location)
- Click (Next)
- A "temporary" password is generated.
- Write down the "temporary" password or copy and paste 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 the "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