SOUTH DAKOTA BOARD OF PHARMACY

Wholesale & Other Drug Distributors and 503b Outsourcing Facilities

User Guide and <u>Renewal</u> Application Instructions Includes Change of Ownership – CHOW Valid through 10/31/2024



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General Information

- 1. License renewal period is November 1-December 31 each year.
- All licenses will expire December 31 each year. There is no grace period. <u>Pharmacy Law Book 2023</u>, scroll down to SD Board of Pharmacy, then select the statute or administrative rule section needed.
- 3. License fee is \$250 for all licenses except 503b is \$200.
- 4. Payment methods Mastercard, Visa or American Express ONLY.
- 5. User ID and password must be unique for <u>each</u> licensed facility once license is approved/issued.

Change Notification Form information:

- 1. If there is a change in designated representative, entity name, or entity location, please submit a completed notification form along with any supporting documentation.
- 2. Form and instructions can be found at this link: Change Notification Form

You must complete the entire application process from start to finish in one sitting

- 1. Online system does not retain any information entered until the application has been submitted and payment process is complete. If you do need to close the application and resume later, please be aware that your progress will not be saved.
- 2. Have all your information and copies of documents for upload ready before beginning the online application process.

Required Documents to be Uploaded

- 1. PDF documents are preferred.
- 2. Current home state license, its equivalent, or a written explanation why one is not available.
- 3. Most recent **home state, FDA, or NABP Drug Distributor Accreditation (formerly VAWD) inspection** conducted within the last 4 years for this facility if home state is not South Dakota.
 - a. Explain if not available.
 - b. Include deficiency corrections or 483 response documentation.
 - c. If 503B Outsourcing Facility, FDA inspection report and deficiency correction documentation is required.
- 4. Copy of Federal DEA certificate if distributing controlled substances.
 - a. If DEA Controlled substances are being distributed, a South Dakota Controlled Substance Registration (SD CSR) is required.
 - i. **IMPORTANT**: the SD CSR is changing its number system. Be sure you know your format!
 - ii. If your SD CSR <u>has recently been renewed</u>, the new 5-digit number will be used in the renewal application. There will be a box to check in the application if this is the format for this facility.
 - iii. If your SD <u>CSR has **not** recently been renewed</u>, the SD CSR number will be in the format of AB1234567.

5. If Virtual Manufacturer, provide:

- a. Contract 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
- b. 3PL's NABP Drug Distributor Accreditation (formerly VAWD) accreditation information.
- c. Contract Manufacturer name(s), address(es), and copy of agreement(s) first page and signature page only.
- d. Product/NDC List.

6. If **Virtual Distributor**, provide:

- a. Contract 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
- b. 3PL's NABP Drug Distributor Accreditation (formerly VAWD) accreditation information.
- 7. If **Private Label Distributor**, provide:
 - a. Product/NDC List.
- 8. A **list of other state(s)** entity is licensed in.
- 9. Owner or Corporate Officer Certification Form.
 - a. Form can be found at: <u>Corp Officer Certification Form</u> If a power of attorney is being used, the power of attorney document(s) must be provided <u>with</u> the Owner or Corporate Officer Certificate Form.
- 10. If ownership is a partnership, corporation, or LLC, provide a document listing the **partners/officers/members names and addresses**. If **Other** is selected as ownership, an explanation along with **document containing owner information** is needed.

- 11. **Discipline** actions. An explanation of felony, misdemeanor, or disciplinary action(s), if applicable, is required if this occurred since your last renewal.
 - a. Explanation information needed on separate sheet of paper is a signed and dated explanation with copies of court records of the charges, convictions, charges found guilty of, or entered a plea of guilty or no contest to.

Change of Ownership (CHOW) Information Needed

- 1. Application for a change of ownership should be submitted if ≥ 50% change of ownership at the parent level or below. If other percentage of change of ownership, provide letter to Board.
- 2. A diagram/listing of *previous* ownership structure and *new* ownership structure is required.

After Application Submission Information. After your application has been submitted, the Board will:

- 1. Review the application and email licensing contact if additional information is needed.
- 2. Approve or deny the application.
- 3. Once renewal is approved, an automated no-reply email will be sent.

After the profile account is set up, you will be able to do the following:

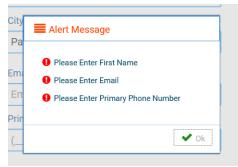
- 1. To check application status.
- 2. Print facility license: Instructions on page 6, item b.iv.
- 3. Print a payment receipt: Instructions on page 7, item g.iii.

Licensure status can also be verified at:

- 1. Verification page: <u>Online Verification Site</u>
- 2. Note: This is not your license. See item b on page 6 to print your license.

General Notes

- 1. Click on Next button to go to the next screen or click on Previous button to go back to the previous screen.
- 2. Mandatory fields are marked with a red asterisk * in all screens.
 - a. All mandatory fields must to be entered before clicking on Next.
 - b. If mandatory fields are not entered, you will get an alert message, like below, to enter those fields:



Profile/Account Set Up and My Profile Page Information

- 1. Click on this link (Bookmark this page): Online Profile (User) Login
 - a. If this is the first time this license has been renewed, click on sign up and follow the next steps.
 - b. <u>If this is not the first time this license has been renewed</u>, skip to page 8, and enter your user name and password used in a previous renewal.

ONLINE BUSINES:	S PROFILE LOGIN
User t	Login
User Name User Name Password	0
Password Log	pn • Forgot password

2. Registration page.

- a. This information must match what is on your current license.
- b. Permit Type: Select Wholesale from the drop-down menu.
- c. Permit #: Enter the last four digits of the license number.
- d. Physical Zip: Enter the zip code of the facility.
- e. Click Next.



3. Credentials page.

- a. <u>Retain this information for future reference and use this information will be used to annually renew your</u> <u>license.</u>
- b. Email: Enter a valid email.
- c. Confirm Email: Enter the same email as entered in item #3b.
- d. User Name: Enter your user name.
- e. Password: Enter a password. There is not a specified format for the password.
- f. Confirm Password: Enter same password as used in item #3e.
- g. Click Submit.

Credentials		Step 2 / 3
	* Email	
	* Confirm Email	
	* User Name	
	* Password	
		-
	Confirm Password	
Previous		Submit
Previous		Submit

- h. User registration of online account is successful when this alert message appears.
- i. Click OK.
- j. You will be returned to the log in page.

E Alert Message	
User registration successful.	
	🗸 Ok

k. Once user registration is successful, an automated e-mail will be sent to the e-mail that you provided during your registration, like below:

S To roy@igov	Thu 10/25/2018 5:44 PM SDBOP@igovsolution.com South Dakota Board of Pharmacy Profile Registration solution.com
Thank you	for registering with the South Dakota Board of Pharmacy. Your user name is TestWholesaler1 and your password has been set as requested. Please do not reply to this email.
×Ţ	

- 4. User Login page.
 - a. Business: Click box in front of Business at the top.
 - b. User Name: Enter your User Name used to set up the account.
 - c. Password: Enter your password used to set up the account.
 - d. Click Login.
 - e. You will be directed to the My Profile page.

U	ser Login
	dual 🔲 Business
User Name	
User Name	
Password	
Password	
	Login
🚑 Sign up	A Forgot Password
South Dakota Boa	rd of Pharmacy
≜ 10 P	offe
(Click the edit butteris to ma	ke changes to your information)

My Profile Page Information

Once logged into your online account, The My Profile page is available.

- 5. MY PROFILE page.
 - a. Business Profile Information section.
 - i. This is not an editable section.
 - ii. Fields in this section include the Business Name, License Type, DBA, Ownership Type, Responsible Person, and Title.

Business Profile Information		
Business Profile Information		
Business Name	License Type	
DBA	Ownership Type	
Responsible Person	* Title	
Please use notification form at the board website to make any o	hanges to the license including pharmacy name, address, or PIC: https://doh.sd.opv/boards/pharmacy/assets/Non-ResidentPharmNotificationFormD.pdf	

- b. Registration Information section.
 - i. This is not an editable section.

- ii. Fields in this section include license information details including Type, License#, Issue Date, Exp. Date, Status, Last Renewal Date, Renewal, and Certificate.
- iii. Renewal column.
 - 1. When renewal period is open, click on the blue renew to begin renewal of license.

iv. Certificate column. Print license from this column.

1. Click on the blue print in the column to print a pdf of your license.

tration Information							
Туре	License #	Issue Date	Exp Date	Status	Last Renewal Date	Renewal	Certificate
Filters	Filters	Filters	Filters	Filters	Filters		
Wholesale						Renew	Print

c. Primary Address section.

- i. This is not an editable section.
- ii. Fields in this section include the physical location of the business including Address, City, State, County, and Zip.

Primary Address			
Address Line 1	Address Line 2	Address Line 3	
City	State	County	
		~	Ŷ
Zip			

d. Mailing Address Information section.

- i. This is an editable section.
- ii. This is the mailing address information if this is different from the primary address location.
- iii. Fields in this section include Address, City, State, County, and Zip.
- iv. To update this section, click the edit button.
 - 1. Update the necessary information.
 - 2. Once complete, click Submit.

ng Address Information (if different from Prim			Edit
Address Line 1	Address Line 2	Address Line 3	
City	State	County	~
Zip		* .	~

e. Contact Information section.

- i. This is an editable section.
- ii. This section contains the Phone, Alternate Phone, E-mail, and Fax of the business.
- iii. To update this section, click the edit button.
 - 1. Update the necessary information.
 - 2. Once complete, click Save.

Contact Information			
			Edit
Phone	Alternate Phone	Email	
	()	6	the second s
Fax			

f. Document Details section.

i. This section contains all the documents uploaded as part of the initial or renewal application.

- ii. This section can be used if the licensee would like to upload any additional documents <u>outside of the</u> <u>renewal time period.</u>
 - 1. **Note**: DO NOT upload documents here that will be uploaded during the renewal process.
- iii. To upload a document:
 - 1. Document Type: Select type of document from the drop-down list.
 - 2. Use the Attach button to select/browse the file from the local folder.
 - 3. Then click on the Upload document.
- iv. Any documents that are uploaded/showing in this Documents Details section can also be downloaded.

nent Details				
Note : Application documer	ts will be uploaded during the application process. Th	is area is to upload documents after application is submitted	d, if needed	
Document Type :				
Select		Documents Attach	Upload Document	
Date	Document Type		File Name	Download
Date Filters	Document Type Filters	Filters	File Name	Download
		Filters	File Name	Download
Filters	Filters	Filters	File Name	201110302
Filters 12/11/2019	Filters Inspection - Out of State	Filters	File Name	Download

g. Payment History section. A receipt can be printed here.

- i. This is not an editable section.
- ii. This section contains payments made for licensure. Fields include Receipt #, Payment Method, Date Received, Payer, Amount, and Receipt.
- iii. Receipt column: To print a receipt, click on the printer in the receipt column for the receipt needed to download a pdf of the receipt.

Payment History

Receipt #	Payment Method	Date Received	Payer	Amount	Receipt
Filters	Filters	Filters	Filters	Filters	
201912110	Credit Card	12/11/		\$250.00	Ð
2018122800	Credit Card	12/28/		\$250.00	Ð
		01/28/		\$200.00	Ð
Page size : 20 🗸 Records : 1 - 3 d	of 3			Pages:1 of 1 《 < 1	\checkmark > »

h. Renewal Details section.

- i. This is not an editable section.
- ii. Fields include Order ID, License Number, Renewal Date, Status, E-Signature, and Print.
- iii. Status column.
 - 1. If status is Pending, license is not yet renewed. If status is Cleared, license is renewed.
 - 2. If status is Cleared, then in the Registration Information section the updated license expiration date and last renewal date will show.
- iv. Print column.
 - 1. Click on the printer to print your renewal application that has been submitted online.

wal Details					
Order ID	License Number	Renewal Date	Status	E-Signature	Print
Filters	Filters	Filters	Filters	Filters	
2018102700000001	600-0000	10/27/2018	Clear	Test Wholesaler	Ð
2018102700000002	600-0000	10/27/2018	Pending	Test Wholesaler	0

Renewal Application Starts Here

1. ONLINE PROFILE LOGIN page.

- a. Once your online account is set up, you will return to the log in page or use this link: Online Profile (User) Login.
- b. Business: Click box in front of Business at the top.
- c. User Name: Enter your user name.
- d. Password: Enter your password.
- e. Click Login.

	User Login	
	Individual Business	5
User Name		
User Name		
Password		
Password Password	Lorin	
	Login	

2. MY PROFILE page.

a. After validating all the information in My Profile, click on the Renew icon in the Registration Information section, Renewal column. You will get a pop-up box.

Registration Information

Туре	License #	Issue Date	Exp Date	Status	Last Renewal Date	Renewal	Certificate
Filters	Filters	Filters	Filters	Filters	Filters		
Wholesale						Renew	Print

b. Click Yes to continue or No to review information on the My Profile page.

E Confirmation Message	
By continuing to renew my license/registration, I affirm that I have reviewed all the sections of my profile and the information in	n my profile is accurate.
	✓ Yes 🗙 No

- 3. Wholesale and Other Drug Distributors and 503b Outsourcing Instructions page.
 - a. You will be directed to the wholesale renewal page with a link to the application information and instructions.
 - b. Click Next to begin renewal application.

Wholesale and Other Drug Distributors and 503b Outsourcing Instructions	
For application information and instructions, please go to this link: https://doh.sd.gov/boards/pharmacy/wholesalers.aspx	
Please review this item before proceeding: • Use the <u>RENEWAL</u> application to submit a Change of Ownership for a wholesale & other drug distributor or a 503b Outsourcing facility	
	Next

4. Renew or Change of Ownership Application page.

- a. "What type of application is this?" (Check all that apply): Click on box in front of Renew or Change of Ownership.
 - i. If Renew is selected: Click Next.
 - ii. If Change of Ownership is selected:

- 1. Previous License Number: Enter the previous license number used.
- 2. Previous and New Ownership Structure: Click on Attach Document to upload document showing previous ownership structure and <u>new</u> ownership structure.
- 3. Click Next.

RENEW OR CHANGE OF OWNERSHIP APPLICATION	
What type of application is this (Check all that apply): Renew	
Change of Ownership	
Do you have either a name change or location change?	Ves No
* Previous License Number	
600	
* Previous and New Ownership Structure	
* % Attach Document	
No license is required if ONLY medical devices which do not contain a legend drug are being shipped into Previous	South Dahota.

5. **Demographics** page.

- a. Legal/Business Information section.
 - i. Listed will be the Legal Business Name, Dba (if used), License #, Address1, Address2, Address3, City, State, County, Zip Code.
 - 1. This information is non-editable.
 - ii. Name of Responsible Person at Firm: Enter the name of responsible person at firm.
 - iii. Email of Responsible Person at Firm: Enter email of responsible person at firm.
 - iv. Phone Number of Responsible Person at Firm: Enter phone number of responsible person at firm.



b. License Preparer Information section.

- i. Same as Wholesale & Other Drug Distributors Information Provided: If License Preparer is the <u>same</u> as Wholesale & Other Drug Distributors Information section, click the box.
- ii. If License Preparer is <u>different</u> than the Wholesale & Other Drug Distributors Information provided, provide the following information:
 - 1. Contact Name: Enter name of license preparer.
 - 2. Contact Title: Enter title of license preparer.
 - 3. Company Name: Enter company name of license preparer.
 - 4. Address1: Enter address of license preparer.
 - 5. Address2/Address3: Enter additional address information of license preparer, if needed.
 - 6. Zip: Enter zip code of license preparer.
 - 7. City: Enter city of license preparer.
 - 8. State: From drop-down menu, select state of license preparer.
 - 9. County: From drop-down menu, select county of license preparer. a. If county is outside of state of South Dakota, select Outside SD.
 - 10. Email: Enter email of license preparer.
 - 11. Phone: Enter phone number of license preparer.
 - 12. Fax: Enter fax number of license preparer.
- iii. Click Next to continue.

License Preparer Information		
Same as Wholesale & Other Drug Distributors Information Provided		
* Contact Name	* Contact Title	* Company Name
Contact Name	Contact Title	Company Name
* Address1	Address2	Address3
Address1	Address2	Address3
*Zip	* City	* State
Zip	City	Select State 🗸
County	Email	Phone
Select County 🗸	Emai	
Fax		
	the Name and License # do not belong to this facility, please contact the Board immediately	
Previous		Next

6. Type of Distribution page.

- a. Select all that apply.
- b. If selecting Manufacturing Distributor and/or 503B Outsourcing Facility:
 - i. FDA#: Enter the FDA number in the text box.

	pe of Distribution (Check all that apply)				
	🗆 Wholesale Distributor 🗹 Manufacturing Distributor 🗆 Repackager		Reverse Distributor	S03B Outsourcing Facility	
	Virtual Manufacturing O Virtual Distributor	or 🖸	In State Only - Third Party Logistics Provide		
	Distribution Center Other				
	FDA #				
	FDA #				
1					
	Previous				Next

- c. If selecting **Virtual Manufacturing**, the following information is needed:
 - i. Product/NDC List upload ALL product/NDC lists for ALL manufacturers: Click on Attach Document to upload a document that contains all products/NDC lists for ALL manufacturers.

Т	ype of Distribution (Check all	l that apply)				
	Wholesale Distributor Manuf. Virtual Manufacturing Virtual Distribution Center Other	I Distributor		Reverse Distributor In State Only – Third Party Logistics Provider	503B Outsourcing Facility	
	Product/NDC List-upload ALL product/	t/NDC lists for ALL mar	nufacturers			S Attach Document
	3PL details					

- ii. **3PL Details** section. Enter the following information:
 - 1. Name of Business: Enter name of 3PL.
 - 2. Address 1: Enter address of 3PL.
 - 3. Address2/Address3: Enter additional address information for 3PL, if needed.
 - 4. City: Enter city of 3PL.
 - 5. State: From drop-down menu, select state of 3PL.
 - 6. Country: From drop-down menu, select country of 3PL.
 - 7. Zip: Enter zip code of 3PL.
 - 8. Copy of 3PL agreement, first page along with signature page: Click on Attach Document to upload a copy of the 3PL agreement (first page and signature page).
 - 9. 3PL NABP Drug Distributor Accreditation (formerly VAWD) upload: Click on Attach Document to upload a copy of the NABP Drug Distributor Accreditation.
 - 10. If there is more than one 3PL being used, click on Click here to add more 3PL details. You will get a pop-up box. Provide the following information:
 - a. Name of Business: Enter name of 3PL.
 - b. Address1: Enter address of 3PL.
 - c. Address 2/Address 3: Enter additional address information for 3PL, if needed.
 - d. Zip: Enter zip code of 3PL.
 - e. City: Enter city of 3PL.
 - f. State: Enter state of 3PL.
 - g. Country: Enter country of 3PL.

- h. Copy of 3PL agreement, first page, along with signature page: Click on Attach Document to upload a copy of the 3PL agreement (first page and signature page).
- i. 3PL NABP Drug Distributor Accreditation (formerly VAWD) upload: Click on Attach Document to upload a copy of the NABP Drug Distributor Accreditation.
- j. Click Save.

Neme of Business *Address1 Address2 Address3 Name of Business Address1 Address2 Address2 City *state *country Zip City Select State * Country Zip Copy of JPL agreement, first page, along with signature page * * Zip NABP Drug Distributor Accreditation (formerly VAMD) Upload * *	Attach Document
City * State * Country Zp City Select State Select Country Zp Copy of 3PL agreement, first page, along with signature page Select Country Zp NABP Drug Distributor Accreditation (formerly VAWD) Upload V V	N Attach Document
City Select State Select Country Zp Copy of 3PL agreement, first page, along with signature page NABP Drug Distributor Accreditation (formerly VAWD) Upload Zp	Attach Document
Copy of 3PL agreement, first page, along with signature page NABP Drug Distributor Accreditation (formerly VAWD) Upload	Attach Document
NABP Drug Distributor Accreditation (formerly VAWD) Upload	* N Attach Document
To add more 3PL Details, please click the button provided here. Click here to add more 3PL details	* Attach Document
= 3PL Details	×
* Name of Business * Address1 Address2	
Name of Business Address1 Address2	ר
Address3 Zip City	-
Address3 Zip City	ן ר
* State * Country	-
Select State V United States V	
Copy of 3PL agreement, first page, along with signature page	
Document	3
. 3PL NABP Drug Distributor Accreditation (formerly VAWD) upload	_

- iii. Contract Manufacturer section. Enter the following information:
 - 1. Name of Business: Enter name of Contract Manufacturer.
 - 2. Address 1: Enter address of Contract Manufacturer.
 - 3. Address2/Address3: Enter additional address information for Contract Manufacturer, if needed.
 - 4. City: Enter city of Contract Manufacturer.
 - 5. State: From drop-down menu, select state of Contract Manufacturer.
 - 6. Country: From drop-down menu, select country of Contract Manufacturer.
 - 7. Zip: Enter zip code of Contract Manufacturer.
 - 8. Copy of Contract Manufacturer Agreement (CMA), first page along with signature page: Click on Attach Document to upload a copy of the Contract Manufacturer Agreement (first page and signature page).
 - 9. If there is more than one Contract Manufacturer being used, Click on Click Here to Add More for Contract Manufacturer. You will get a pop-up box to enter the following information:
 - a. Name: Enter name of Contract Manufacturer.
 - b. Address 1: Enter address of Contract Manufacturer.
 - c. Address2/Address3: Enter additional address information for Contract Manufacturer, if needed.
 - d. Zip: Enter zip code of Contract Manufacturer.
 - e. City: Enter city of Contract Manufacturer.
 - f. State: From drop-down menu, select state of Contract Manufacturer.
 - g. Country: From drop-down menu, select country of Contract Manufacturer.
 - h. Copy of agreement, first page and signature page: Click on Attach Document to upload a copy of the Contract Manufacturer Agreement (CMA, first page and signature page).
 - i. Click Save.

* Address1	Address2	Address3
Address1	Address2	A009893
* State	* Country	Zp
Select State V	Select Country 🗸	Zp
along with Signature page		N Atlack Document
provided here.	Click here to add more Contract manufacturer	
	Address1 State	Address1 Address2 *State *Country Select State V Select Country v arrang with Signature page •

Name		* Address1		Address2	
Name		Address1		Address2	
Address3		* Zip		City	
Address3		Zip		City	
* State		* Country			
Select State	~	United States	~		
Copy of Agreement firs	t page and signa	ture page			Attach cument

- c. If selecting **Virtual Distributor**, the following information is needed:
 - i. **3PL Details** section.
 - 1. Name of Business: Enter name of 3PL.
 - 2. Address1: Enter address of 3PL.
 - 3. Address2/Address3: Enter additional address information for 3PL, if needed.
 - 4. City: Enter city of 3PL.
 - 5. State: From drop-down menu, select state of 3PL.
 - 6. Country: From drop-down menu, select country of 3PL.
 - 7. Zip: Enter zip code of 3PL.
 - 8. Copy of 3PL agreement, first page along with signature page: Click on Attach Document to upload a copy of the 3PL agreement (first page and signature page).
 - 9. NABP Drug Distributor Accreditation (formerly VAWD) Upload: Click on Attach Document to upload a copy of the NABP Dug Distributor Accreditation.
 - 10. If there is more than one 3PL being used, click on Click here to add more 3PL details. You will get a pop-up box. Provide the following information:
 - a. Name of Business: Enter name of 3PL.
 - b. Address1: Enter address of 3PL.
 - c. Address 2/Address 3: Enter additional address information for 3PL, if needed.
 - d. Zip: Enter zip code of 3PL.
 - e. City: Enter city of 3PL.
 - f. State: Enter state of 3PL.
 - g. Country: Enter country of 3PL.
 - h. Copy of 3PL agreement, first page, along with signature page: Click on Attach Document to upload a copy of the 3PL agreement (first page and signature page).
 - i. 3PL NABP Drug Distributor Accreditation (formerly VAWD) upload: Click on Attach Document to upload a copy of the NABP Drug Distributor Accreditation.
 - j. Click Save.

Type of Distribution (Check all that apply)			
Wholesale Distributor Manufacturing Distributor Priv Distribution Center Other Othe	ackager Creverse Distributor ate Label Distributor In State Only – Third Party Logistics Provider	503B Outsourcing Facility	
* Name of Business Name of Business	* Address1 Address1	Address2 Address2	Address3 Address3
* City City	* State Select State	* Country US V	Zip Zip
Copy of 3PL agreement, first page, along with signature page NABP Drug Distributor Accreditation (formerly VAWD) Upload To add more 3PL Details, please click the button provided here.		Click here to add more 3PL details	 Adatah Document Adatah Document
Previous			Next

Name of Business	* Address1	Address2
Name of Business	Address1	Address2
Address3	Zip	City
Address3	Zip	City
State	Country	
Select State 🗸	United States	~
	ccreditation (formerly VAWD)	Document

- d. If selecting **Private Label Distributor**, the following is needed:
 - i. Product List -upload ALL product lists for ALL manufacturers: Click on Attach Document to upload your Product/NDC list.

Type of Distribution (0	Check all that apply)			
Wholesale Distributor Virtual Manufacturing Distribution Center			Reverse Distributor In State Only – Third Party Logistics Provider	St38 Outsourcing Facility
Product List - upload ALL pro	duct lists for ALL manufacturers	1		
		3		
Previous				Nut

- e. If selecting In State Only Third-Party Logistics Provider:
 - i. Only a third-party logistics providers located <u>in</u> South Dakota may be licensed as a Third-Party Logistics Provider.
 - ii. ****Note**: If the license is Out of State (outside the state of South Dakota), then you will not see the In State Only Third Party Logistics provider option under Type of Distribution tab.

Type of Distribution (Check all th	nat apply)		
Wholesale Damburor D Manufactur Winala Manufacturing D Winala Distr Distribution Center Distribution Center Other		□ Reverse Dambour. 1	soto Outsourchip Feolity
Previous			Rei I

f. If selecting Other,

i. Other: Enter an explanation in the text box as to the type of distribution done.

Wholesale Distributor 🛛 Manufacturing Distributor	Repackager	Reverse Distributor	5038 Outsourcing Facility
Virtual Manufacturing Virtual Distributor Distribution Center Other	Private Label Distributor	In State Only – Third Party Logistics Provider	

g. Click Next when all information and upload(s) are completed.

- 7. Type of Prescription Drugs/Products page.
 - a. Click box in front of each type that applies.
 - b. If **DEA Controlled Substance** is selected:
 - i. Please check this box if a new 5-digit SD CSR number has been issued for this facility: Mark this box if your South Dakota Controlled Substance Registration (SD CSR) has recently renewed with a 5-digit number.
 - ii. SD Controlled Substance #: If box was checked due to facility recently renewing your SD CSR, enter the 5digit number. If box was not checked, enter your SD CSR in the format AB1234567.
 - iii. DEA #: Enter the facility DEA number in text box.
 - iv. Copy of the licensee's DEA: Click on Attach Document to upload a copy of your current Federal DEA Certificate.

ype of Prescription Drugs/Products	
CDA Controlled Ducklance Depressive or previoue(head/head/head/head/head/head/head/head/	Inge (factor at logend)
	* South Dakota Controlled Substance #
Please check this box if a new 5-digit SD CSR number has been issued for this facility	Controlled Substance #
DEA #	
DEA#	
Copy of current Foderal DEA Certificate Beauty	
registration is needed.contact the SD Dept. of Health , Attrix Licensure & Certification ,615 E 4th St, Pierre , SD 5750 tp://doi.net.gov/previden/seeto/applie.pdf	01 for information regarding SD controlled substance registration. Phone 605-773-3356 or download application from
revious	Nud

c. If **Other** is selected,

i. Enter Explanation: Enter information in the text box about type of product(s) facility provides in the text box.

pe of Prescription Drugs/Products	
DEA Controlled Substance DEphedrine or pseudoephedrine	products D Noncontrolled prescription drugs (federal legend)
Over-the-counter drugs Veterinary prescription drugs	Medical Gases
C Other	
Enter Explanation	
Enter Explanation	
revious	Next

d. Click Next when all information and upload(s) are completed.

8. Types of Customers you sell/distribute page.

- a. Click box in front of each type that applies.
- b. If **Other** is selected:
 - i. Enter Explanation: Enter an explanation in the text box explaining who facility sells/distributes to.

Types of Customers you sel/distribute (Check all that apply)
Pharmacies Inoppitals Other Wholesalers
Practitioners/Clinics Patients Chier
Enter Expansion
Enter Explanation
Previous

c. Click Next to continue when all information is completed.

9. Ownership page.

- a. Select one option: Select box in front of either Sole Proprietorship, Partnership, Corporation, LLC, or Other.
- b. If selecting Sole proprietorship:
 - i. Name of Person/Owner: Enter the name of the person/owner.
 - ii. Address1: Enter address of the person/owner.
 - iii. Adddress2/Address3: Enter additional address information of the person/owner, if needed.
 - iv. City: Enter city of the person/owner.
 - v. State: From drop-down menu select state of the person/owner.
 - vi. Zip: Enter zip code of the person/owner.
 - vii. Click Next to continue.

Ownership				
Sole Proprietorship				
Name of Person / Owner	* Address1	Address2	Address3	
Name of Person / Owner	Address1	Address2	Address3	
City	* State	Zip		
City	Select State	✓ Zip		
Previous				Next

c. If selecting Partnership:

- i. Name and Address of Partnership: Click on Click Here to Add More button. You will get a pop-up box to enter the following partnership business information:
 - 1. Name of partnership: Enter name of partnership.
 - 2. Address1: Enter address of partnership.
 - 3. Address2/Address3: Enter additional address information for partnership, if needed.
 - 4. Zip: Enter zip code of partnership.
 - 5. City: Enter city of partnership.
 - 6. State: From drop-down menu select state of partnership.
 - 7. When completed, click Save.
- ii. Attach Name and Address of Partners: Click on Attach Document to upload document containing name(s) and address(es) of the partners.
- iii. Click Next to continue.

Ownership	
Sole Proprietorship Pertnership Corporation LLC Other Name and Address of Partnership	Click Here To Add More
Attach Name and Address of Partners	N Attach Bocument
Please	include the Name and Address of Partner/Officer/Member
Previous	Next
Name and Address Of Partnership	×
Name of partnership	* Address1
Business Name	Address1
Address2	Address3
Address2	Address3
Zip	City
Zip	City
State	
Select State	~
-	Save Cancel

d. If selecting **Corporation**:

- i. Name and Address of Corporation: Click on Click Here to Add Corporation button. You will get a pop-up box to enter the following corporation business information:
 - 1. Name of Corporation: Enter name of corporation.
 - 2. Address1: Enter address of corporation.
 - 3. Address2/Address3: Enter additional mailing information for corporation, if needed.
 - 4. Zip: Enter zip code of corporation.
 - 5. City: Enter city of corporation.
 - 6. State: From drop-down menu select state of corporation.
 - 7. When completed, click Save.
- ii. Attach Name and Address of Corporate Officers: Click on Attach Document to upload document containing name(s) and address(es) of the officers.
- iii. Click Next to continue.

Sele Poprietorship Pentnership Corporation LL D Other Name and Address of Corporation Citation Research and Address of Corporation Freeze include the Name and Address of Partner/Officer/Member Protoco Note	Ownership	
Previous Note Image: Corporation * Address1 Mame of Corporation * Address1 Address2 Address3 Address2 Address3 Zip * City Zip * City Zip City Zip City Zip City State City		Click Here To Add Corporation
Eventual Corporation X [•] Name Of Corporation [•] Address1 Address2 Address3 Address2 Address3 Address2 Address3 Zip [•] City Zip [•] City Zip [•] City Zip [•] City [•] State [•] City	Attach Name and Address of Corporate Officers.	Attach Document
Corporation Address1 Address1 Address2 Address2 Address3 Zip Zip Zip City Zip City City State	Please include the	: Name and Address of Partner/Officer/Member
Corporation Address1 Address1 Address2 Address2 Address3 Zip Zip Zip City Zip City City State		
Corporation Address1 Address1 Address2 Address2 Address3 Zip Zip Zip City Zip City City State		
* Name Of Corporation Name of Corporation Address1 Address2 Address3 Zip Zip Zip Zip City City State	Previous	Next
* Name Of Corporation Name of Corporation Address1 Address2 Address3 Zip Zip Zip Zip City City State		
Name of Corporation Address1 Address2 Address3 Address2 Address3 Zip * City Zip City * State City	Corporation	×
Address2 Address3 Address2 Address3 Zip * City Zip City	* Name Of Corporation	Address1
Address2 Address3 Zip * City Zip City * State City	Name of Corporation	Address1
Zip City Tip State	Address2	Address3
Zip * State	Address2	Address3
*State	Zip	City
	Zip	City
Select State	* State	
	Select State	~
Save Cancel		Save Cancel

- e. If selecting **LLC**:
 - i. Name and Address of LLC: Click on Click Here to Add LLC button. You will get a pop-up box to enter the following LLC business information:
 - 1. Name of LLC: Enter name of LLC.
 - 2. Address1: Enter address of LLC.
 - 3. Address2/Address3: Enter additional mailing information for LLC, if needed.
 - 4. Zip: Enter zip code of LLC.
 - 5. City: Enter city of LLC.
 - 6. State: From the drop-down menu, select the state of LLC.
 - 7. When completed, click Save.
 - ii. Attach Name and Address of LLC Members: Click on Attach Document to upload document containing name(s) and address(es) of the members.
 - iii. Click Next to continue.

Ownership	
Sole Proprietorship Partnership Corporation Corporation COLC Other Name and Address of LLC	Click here to add more
Attach Name and Address of Members	Attach Bocarneet
	Please include the Name and Address of Partner/Officer/Member
Previous	Next

* Name Of LLC	* Address1	
Name Of LLC	Address1	
Address2	Address3	
Address2	Address3	
Zip	* City	
Zip	City	
State		
Select State	~	

f. If selecting **Other**,

- i. Enter Explanation: Enter the explanation on type of company in text box.
- ii. Partner/Member/Officer Information: Click on Attach Document to upload a document that includes name(s) and address(es) of owner(s).

Ownership	
🛛 Sole Proprietorship 🗋 Partnership 🗋 Corporation 🗋 LLC 🕑 Other	
* Enter Explanation	
Enter Explanation	
Partner/Member/Officer Information	_
* S Attach Document	
Previous	Next

10. Registered Agent in SD page.

- a. Note: this page will only appear if the licensee is <u>outside</u> the state of South Dakota.
- b. If user needs a list of South Dakota registered agents, click on the link.
- c. Name: Enter name of South Dakota registered agent.
- d. Address1: Enter address of South Dakota registered agent.
- e. Address2/Address3: Enter additional address information of South Dakota registered agent, if needed.
- f. City: Enter city of South Dakota registered agent.
- g. State: From drop-down menu select South Dakota.
- h. Zip: Enter zip code of South Dakota registered agent.
- i. Click Next to continue.

Name	* Address1		Address2	Address3	
Name	Address1		Address2	Address3	
City	* State		* Zip		
City	Select State		Zip		
or a net or op registered agents	go to https://sdsos.gov/docs/business/CR	A_list.pdf			
i a nor or on registered agents	go to https://sdsos.gov/docs/business/CR	A_list.pdf			
or a not or our registered agents	go to https://sdocs.gov/docs//business/CR	A,Jist.pdf			

11. Home State License page.

- a. **Note**: this page will only appear if the licensee is <u>outside</u> the state of South Dakota.
- b. Home State License section.
 - i. Home State: From drop-down menu select home state licensed in.
 - ii. Home State License #: Enter the home state license number.
 - iii. License Expiration Date: Enter the home state license expiration in MM/DD/YYYY format.
 - iv. Home State License: Click on Attach Document to upload a copy of your current/active home state license.

Home State License			
Home State License			
Home State		* Home State License#	* License Expiration Date
Select State	~	Home State License#	MM/DD/YYYY
Home State License			N Attach Document

- c. Home State or Other Inspection section.
 - i. Type of Inspection: From the drop-down menu select type of inspection.
 - ii. Date of most recent inspection: Enter the date of the most recent inspection in MM/DD/YYYY format.
 - iii. Were there any deficiencies in the inspection identified above: Click yes or no box.
 - iv. Inspection document (if there is no inspection, please upload a document stating reason why there is none): Click on Attach Document to upload a copy of the most recent inspection or a document stating reason for no inspection.
 - v. Inspection corrections: If answered yes to "Were there any deficiencies in the inspection identified above": Click on Attach Document to upload inspection corrections from most recent inspection.
 - vi. Enter a list of all other states where licensed in:
 - 1. List each and every state licensed in by listing in text box using a comma between each state listed. Please use state abbreviations.
 - 2. <u>OR</u> click on box in front of See Attached. Click on Attach Document to upload a document listing states currently licensed in.

ype of Inspection	* Date of most recent Inspection
Select Type of Inspection	MM/DD/YYYY
/ere there any deficiencies in the inspection identified above?	Yes No
rspection document (If there is no inspection, please upload a document stating reason why ther Inspection corrections	e is none) 🔦 Attach Document
Enter a list of all other states where licensed in (Please use comma to enter the values or if	See Attached
ploading a list, click on 'See attached', then use the attach document feature to upload a list of II other states where licensed in.)	S Attach Document

d. Click Next to continue once all information is completed and document(s) are uploaded.

12. NABP Drug Distributor Accreditation (formerly VAWD) page.

- a. "NABP Drug Distributor Accredited (formerly VAWD) accredited?": Click yes or no box.
- b. If answered no, click Next to continue.
- c. If answered yes:
 - i. NABP Drug Distributor Accreditation (formerly VAWD) Expiration date: Enter the expiration date of the accreditation in MM/DD/YYYY format.
 - ii. Click Next to continue.

BP Drug Distributor Accreditation (formerly VAWD)		
NABP Drug Distributor Accredited (formerly VAWD) Accredited?	🗆 Yes 🔲 No	
NABP Drug Distributor Accreditation (formerly VAWD) Expiration Date		
MM/DD/YYYY		
Previous		
Trevious		

13. Attachments page.

- a. Owner or Corporate Officer Certification Form: Click on Attach Document to upload the completed Owner or Corporate Officer Certification Form.
 - i. The Owner or Corporate Officer Certification Form must be signed with original ink or an e-signature will be accepted that is similar to E-Signature by Adobe Sign.
 - ii. If a power of attorney is being used, the power of attorney document(s) must be provided <u>with</u> the Owner or Corporate Officer Certificate Form.
- b. Click Next to continue.

Attachments	
Owner or Corporate Officer Certification Form. Please refer the link below for more details.	S Attach Document
http://doh.sd.gov/boards/pharmacy/wholesalers.aspx	
Previous	Next

14. Disciplinary Actions page.

- a. "Have any misdemeanor or felony convictions or disciplinary actions (including pending) been taken against the applicant and/or licensed entity since the last renewal?": Click yes or no box.
 - i. If answered no: click Next to continue.
 - ii. If answered yes:
 - 1. Explanation: In text box, provide an explanation of convictions/disciplinary action(s).
 - 2. Click on Attach Document button to upload legal documentation of the felony, misdemeanor, or disciplinary actions.
 - 3. Click Next to continue when complete.

Disciplinary Actions		
Have any misdemeanor or felony convictions or disciplinary actions (including pending) been take	an against the applicant and/or licensed entity since the last renewal? 🗹 Yes $\ \square$ No	
Explanation		
Explanation	[™]	
Previous		Next

15. Application Input Preview page.

- a. After completing the application, you will be able to review the application for any errors and correct the information by clicking on Previous button and correct in the appropriate screens.
- b. Use the vertical scroll bar to review the completed application.
- c. Once review is complete, click Next to continue.

PLICATION INPUT PREVIEW			
Wholesale and Other Drug Distributors an	503b Outsourcing Instructions		
For application information and instructions, please go	to this link: https://doh.sd.gov/boards/pharmac	cy/wholesalers.aspx	
Please review this item before proceeding:			
Use the <u>RENEWAL</u> application to submit a Change of the second seco	f Ownership for a wholesale & other drug distrib	butor or a 503b Outsourcing facility	
RENEW OR CHANGE OF OWNERSHIP APP	LICATION		
* What type of application is this (Check all that apply):			
C Renew			
Change of Ownership			
No license is required if ONLY medical devices which d	not contain a legend drug are being shipped into	South Dakota.	
Demographics			
Legal/Rusiness Name	DRA		Next
revious			Next

16. Affirm and Submit page.

- a. Read and understand the statement at the top, then check the affirmation checkbox.
- b. E-Signature of the person filling out the renewal: Enter full name of person filling out the renewal.
- c. Date and Fee amount will be auto populated.
- d. Select Debit or Credit: From drop-down menu select debit or credit for type of credit card being used.
- e. Card Type: From drop-down menu select type of credit card you are using.
 - i. Mastercard, VISA, or American Express accepted.
- f. Person's Name on Card: Enter name of person that appears on the credit card.
- g. Card #: Enter Mastercard, Visa, or American Express credit card number.
- h. Expiration date: Enter credit card expiration date in MM/YY format.
- i. Security Code: Enter 3-digit number for MasterCard/Visa or 4-digit number for American Express/AMEX that is on the back of the credit card.
- j. I am not a Robot: Click box in front of this statement.
- k. Once confident that the application is complete, click on Submit.
- 1. Submit application one time. Do not click the submit button more than one time. If submission issue occurs (spinning wheel, transmission interruption, etc.), contact the board. DO NOT complete/submit another application.
- m. You will get a confirmation number if successful.
- n. You **must** click on the affirmation checkbox to the attestation information, enter your credit card information and click on Submit button to complete the application.

Affirm and Submit	
I certify that the applicant will operate in a manner prescribed by federal and state laws and rul been examined by me, and to the best of my knowledge and belief, is in all things true and correct.	es adopted by the board. I declare and affirm under the penalties of perjury that this application has
* E-Signature of the person filling out this renewal (Type in full name)	
Please enter your full name	
Date	Renewal Fee
10/26/2022	250.00
* Select Debit or Credit :	* Card Type
Select Debit or Credit 🗸	Select Card Type 🗸
* Person's Name on Card	Card #
Person	Card #
* Expiration Date (MM/YY)	* Security code (3-digit number or 4-digit number if American Express/Amex)
MM/YY	Security Code
Previous	bot Control New Arrow Submit

o. If any invalid information was entered, an alert message will appear indicating that your credit card was invalid.
i. Click on Ok and re-enter the correct information and click on Submit to complete the application.

🔳 Ale	ert Message				
! Y	our application	wasn`t succ	essful. Cred	it Card Nur	nber Invalid.

p. Once successfully submitted, you will get a system generated auto reference number, if needed, you can note the system generated auto reference number for your future reference. Click OK when complete.

■ Alert Message	
• Your application has been successfully submitted. Your confirmation is 2020082500	0000875
	🗸 Ok

17. Print Application page.

- a. When application has been submitted, the application can be printed by clicking on the printer button.
- b. By clicking on My Profile in the upper right corner, you will return you to your My Profile page as described in beginning on page 5.

)	South Dakota Board of Pharmacy	WHOLESALE RENEWAL	My Profile
	Print Application		Ð
	South Dakota Board of Pharmacy	WHOLESALE RENEWAL	
	Wholesale and Other Drug Distributors and 50		
	For application information and instructions, please go to this RENEW OR CHANGE OF OWNERSHIP APPLIC		
	What type of application is this (Check all that apply):		
	Change of Ownership	Please note that after you click the Submit button, you cannot make changes to your application.	

I'm having trouble getting through the licensing process.

- 1. Try a different browser. Example: If you've tried Internet Explorer, switch to Google Chrome.
- 2. This platform does not support the use of a mobile phone.
- 3. If a tablet is being used, it must be Microsoft based. (Not an Apple product.)
- 4. Be sure your pop-up blocker is turned off.
- 5. Firewalls or anti-malware protections on your system may be preventing the ability to get through the licensing process.

Tips

- 1. PDF documents are the preferred type of documents for required uploads.
- 2. Only upload documents during the licensing process. DO NOT UPLOAD documents on the My Profile page for a new or renewal application.
- 3. Submit application one time. Do not click the submit button more than one time. If submission issue occurs (spinning wheel, transmission interruption, etc.), contact the board. DO NOT complete/submit another application.
- 4. At the top of your licensure documentation, if it includes "This is a Primary Source Verification" **NOTE: THIS IS NOT YOUR LICENSE.**
 - a. Refer to item #b on page 6 to see how to print your license.

Reset Password

1. At the User Login page, click on Forgot Password.

	User	Login		
User Name				
User Name				
Password				
Password				
	Lo	ogin		
	up		ot password	

- 2. You will get a pop-up alert message.
 - a. **PLEASE NOTE THIS**: Please be prepared to write down your temporary password after filling out the details.
 - b. Click OK.



3. Password Recovery Page

- a. Business: Click box in front of Business at the top.
- b. License type: Select Wholesaler from the drop-down menu.
- c. License number: Enter your license number in 600-XXXX format.
- d. Zip: Enter first 5 digits/characters of zip code.
- e. Click Next.

ssword	Recovery	Step 1 /
	🗆 Individual 😿 Business	
	* Permit Type	
	Wholesale ~	
	Permit #	
	Permit Number	
	* Physical Zip (If outside the United States, please enter the first 5 digits/characters of zip including space).	
	Zip	

4. An Alert message will appear. BE SURE TO RETAIN THIS PASSWORD.

Helpful hint: Open a word document, then copy/paste the temporary password into the word document. a. Once the temporary password has been written down, Click OK.

Γ	■ Alert Message
	• Your temporary password is Q*s8iD5&\$mS Please use this as your password in the next screen.
L	VR.

5. Return to the **User Login** page.

- a. Business: Click box in front of Business at the top.
- b. User Name: Enter your User Name.
- c. Password: Input the <u>temporary password</u> from the Alert Message. If you copied password into a word document, copy and paste the temporary password into the password text box.
- d. Click Log In.

User Login	
	Individual Business
User Name	
User Name	
Password	
Password	
	Login
🚑 Sign u	Port Porgot password

6. Credentials Page

- a. Old Password: Enter your <u>temporary password</u> from the Alert Message as the Old Password. If you copied password into a word document, copy and paste the temporary password into the password text box.
- b. New Password: Enter a new password.
- c. Confirm the New Password: Enter your new password.
- d. Click Submit.
- e. You will return to the log in page.
- f. Business: Click box in front of Business at the top.
- g. User Name: Enter your User Name.
- h. Password: Enter new password from item #b.
- i. Click Log In.