

APPLICATION FOR REGISTRATION WHOLESALER I (WITH PRESCRIPTION) IN AND OUT OF STATE

(Expires September 30 Annually)

APPLICATION REQUIREMENTS:

□ \$525.00 application or owner/location change fee / \$625.00 if distributing or handling controlled substances.			
□ Controlled substance application* & copy of active DEA registration. *If facility does not handle controlled substances, box indicating "Not Applicable" must be marked.			
Responsible Party Attestation Form			
□ Copy of Resident State license/registration AND license/registration verification from Resident State (required only for applicants located outside of Oregon). Online license/registration verifications accepted. Business name and owners listed on this application must match resident state verification.			
Current Verified-Accredited Wholesale Distributors (VAWD) accreditation through the National Association of Boards of Pharmacy <u>OR</u> the facility must provide evidence of a \$100,000 Surety Bond that lists the Oregon Board of Pharmacy as its sole beneficiary and have a current inspection report (within the last 3 years).			
□ If you answer "YES" to any disciplinary action questions, including pending disciplinary actions, all notices, citations, etc. and fully executed Board orders must be provided along with a detailed explanation.			
*Priority processing will be given to complete applications. All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will be expired. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.			
Mail completed application and all required documentation to: Oregon Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland OR 97232	Questions? Contact us: Telephone: (971) 673-0001 www.oregon.gov/pharmacy pharmacy.licensing@bop.oregon.gov		

Please read the following instructions for applicants for registration as a Wholesaler I.

- Oregon Administrative Rule 855-065-0005(22)(a) defines a Wholesaler I. OAR 855-065-0001 and 855-065-0006 identifies wholesaler registration requirements. https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3985
- A registration will be issued once all required paperwork and fee(s) have been submitted and approved. This facility may not commence business in Oregon or permit products to be distributed into Oregon until the registration is issued.
- 3 If this facility also provides Third Party Logistics services, marketing, brokering or arranging the distribution of drugs manufactured by a manufacturer, this facility must also apply for registration as a Drug Distribution Agent in accordance with OAR 855-062-0001.
- 4. Each company or location address, even if under common ownership, must submit a separate application for registration.
- 5. You must pay a registration fee for each application for a New Registration, an Ownership Change or

a Location Change. <u>The Board can only accept payment by check or money order.</u> All fees are nonrefundable.

Examples of a required ownership change application include but are not limited to: corporate restructure; LLC to a Corporation, Corporation to LLC; acquisition of assets; or additions or deletions of an owner. An ownership change requires submission of a copy of the sales agreement or other documentation that verifies proof of new ownership.

If you are completing these forms to report a **Name Change** only, you do not pay a fee.

6. **Oregon Controlled Substance Registration**. The Controlled Substance Registration is required for all outlets that wholesale controlled substances. Be advised that the Controlled Substance Registration is not an independent registration. It must be issued in conjunction with a Wholesaler Registration.

Applications will not be processed without the completion of the Controlled Substance Application. You must submit a copy of your DEA registration along with your application. If your facility **does not handle** controlled substances, please check the box "Not Applicable" and return it with the Application. Note: The controlled substance fee is <u>not</u> required if the application is marked "Not Applicable."

7. Each Wholesaler Class I must provide a copy of a current Drug Distributor Accreditation (Formerly VAWD) through the National Association of Boards of Pharmacy

OR

• Proof of a current physical facility inspection from resident state (within last 3 years)

AND

- Evidence of a \$100,000 Surety Bond (per location) that includes the following:
 - Oregon Board of Pharmacy as its sole beneficiary
 - o Full Name
 - o Physical address of facility
- 8. License/Registration Verification in Resident State (required only for applicants located outside of Oregon) Applications for out-of-state wholesalers will not be processed without this verification.

To prevent delays in processing, submit a completed verification form or letter from your resident state licensing agency **with your application(s)**. License verifications must be original and not tampered with, including the use of whiteout. Photocopies of registrations will not be accepted in lieu of a license verification from your resident state. If your license or registration can be verified online, a recent printout from the online system may be submitted along with a copy of the facility's resident license or registration.

If your resident state does not issue you any type of professional or business license, attach an original letter dated within the last 24 months, from the state agency that licenses drug outlets, or a copy of the rules or regulations stating that you do not need a license/registration.

 Oregon Revised Statues and Administrative Rules are accessible on our web site at: <u>https://www.oregon.gov/pharmacy</u>. You may purchase a set for \$25 (check the box on the application if you wish to purchase one or more sets).

Please be aware that your registration will be issued upon approval once all required paperwork and fee(s) are processed. Your registration is to be in your possession *PRIOR* to conducting business in Oregon. Wholesaler I Registrations expire September 30th, annually, and fees are not prorated.

NOTE: Registered wholesalers must complete a <u>Self-Inspection Report</u> by September 1 annually. This report form is available on our website and must be retained at the facility for 3 years and be made available to the Board upon request. Do not send this report to the Board unless it is specifically requested.

	APPLICATION FOR REGISTRA	ATION	
WHOLESALER I In and Out of State (Expires September 30 Annually) Oregon Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland OR 97232 Pharmacy.licensing@bop.oregon.gov	OF OF OF OF OF OF OF OF OF OF OF OF OF O	PERSON ID #	[0317] \$525.00 [0310] \$100.00 [0326] \$ 25.00
Please check all that apply:	1859	APPLICANT ID #	
 Wholesaler I Registration (with a controlled Substance Register Laws & Rules per set, please 	tration	TOTAL ENCLOS	
		ALL FEES ARE NO	N REFUNDABLE
Type of Application – Check all that	at apply:		
□ New Facility Application - Star	rt / Effective Date:		
Change of Ownership or Locat A change of ownership or location require			vithin 15 days.
Registration Number:			
Legal documentation of agreement and/or and exec	the change in ownership or uted contract for sale, etc.	control, for example, a	stock purchase
Registration Reinstatement (Reinstatement)	egistration has been lapsed	for a period of one year	or more)
Registration Number:			
□ Name Change Only (No fee rec	ąuired)		
Registration Number:			
Please PRINT or TYPE	WARNING: ORS 689.405(1) The fu	rnishing of false information is grou	nds to deny registration.
Trade or Business Name (DBA):			
Full Legal / Owner Name:			
Federal Tax ID # or Owner SSN:			
Physical Location Address:			
City:S	State:	Zip:	
Phone Number:	FAX #		
Registration & Renewal Mailing Addre	SS:		
Licensing Contact Person:	Title	Contact Pho	one
Licensing Contact Person E-mail Add	ress:		
Facility Website:			

Please indicate which of the following you are submitting?

\$100,000 Surety Bond that lists the Oregon Board of Pharmacy as its sole beneficiary, includes full name and location address for this facility and current inspection report (no more than 3 years).

	Bond Number:	
	OR	
	Proof of Drug Distributor Accreditation (Formerly VAWD) through the National Associat of Pharmacy	tion of Boards
	Valid From:to	
Ple	ease answer all of the following – (only "Yes" or "No" answer is accepted)	
1.	Has disciplinary action ever been taken, or is any such action currently pending or proposed against any of the persons or the facility listed on this application, by any State or Federal Authority in connection with a violation of any federal or state drug law or regulation?	□Yes □ No
	If "yes", attach a detailed explanation of the incident and describe any penalty incurred. You must provide a copy of all documents pertaining to discipline. This includes Notice of Disciplinary Actions, Board Orders and other related documents.	
2.	Per OAR 855-065-0013(b), prior to distributing any product into or within Oregon, do you verify that the recipient is registered with the Oregon Board of Pharmacy?	□Yes □No
	Note: All drug outlets, including Manufacturers, Wholesalers & 3PL's must register with the Oregon Board of Pharmacy	
3.	Per OAR 855-065-0013(c), prior to distributing any pharmaceutical product into or within Oregon, do you verify that the product's manufacturer is registered with the Oregon Board of Pharmacy?	□Yes □No
4.	Do you physically manufacture product(s) at the physical location listed on page 1 of this application for registration? *If "yes", this facility must also hold a manufacturer registration.	□Yes* □No
5.	List the types of products that you wholesale below. You must provide the products wholesale even if you do not physically have product at the location listed on page 1 of this application. drug outlets, including manufacturers, virtual manufacturers, contract manufacturers & 3PL's with the Oregon Board of Pharmacy.	Note: All
6.	Are you a Third-Party Logistics Provider?* A Third-Party Logistics Provider means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but does not take title to the drug or have general responsibility to direct the sale or disposition of the drug. *If the answer to this question is "Yes", you will need to register as Drug Distribution Agent in addition to a Wholesaler.	□Yes* □No
7.	Do you possess any drugs and/or devices at the physical location listed on page 1 of this application?	□Yes □No

8. Are you a repackager as defined in OAR 855-065-0005(16)?	
*If "yes", list your FDA Labeler Code #: submit a detailed description of all repackaging functions performed at this location in the space below. Per OAR 855-060-0004(3), this facility will also need to register as a Manufacturer.	
9. This facility meets the safety, security and maintenance as required in 855-065-0012. This means that this facility is in a commercial nonresidential building, which is suitable for the monitoring, maintenance and storage of wholesaled products in accordance with labeling or in compliance with official compendium standards.	□Yes □No
10. This facility distributes controlled substances. If "yes", you must complete pages 6 and 7 of this application.	□Yes □No
Oregon Schedules of Controlled Substances may be found at: <u>https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3987</u> and may be different from the Federal schedules. You must comply with the most stringent.	
10a. This facility is a virtual Wholesaler I with controlled substances and has verified that the distributor has obtained the required DEA Controlled Substance registration. (*If yes, you must attach a copy of the distributor's DEA registration with this application)	□Yes* □No
11. Is this facility a small business? A small business is defined as a corporation, partnership, sole proprietorship or legal entity, which is independently owned and operated from all other businesses and which has 50 or fewer employees?	□Yes □No

Product Manufacturer(s): Please list the primary manufacturers you distribute for or also provide third–party logistics services. If there is insufficient space on this form, you may attach additional sheets.

Name:	Oregon Registration Number:
Physical Address:	
City, State Zip:	
	Oregon Registration Number:
Physical Address:	
City, State Zip:	
	Oregon Registration Number:
Physical Address:	
City, State Zip:	

Ownership Information

Parent Company Name (If owned by another entity)			
Owner Name			
Government / Educational Institution			
Partnership – Including Limited	d Liability Partn	ership and Limited Partnership	□ Charitable Organization
□ Publicly Held Corporation □	Corporation	□ Limited Liability Company	□ Sole Proprietorship
Type of Ownership:			

Complete the information below for all owners. You must include at least one of the following: CEO, President, Owner, or Members of LLC and Registered Agent. If a corporation, include the names of the corporate officers and the names of the stockholders who own the five largest interests.

1.	Name	
	Title	
	SSN/Federal Tax ID	
	Address	
	City, State, Zip	
	Phone Number	
	Email Address	
2.	Name	
	Title	
	SSN/Federal Tax ID	
	Address	
	City, State, Zip	
	Phone Number	
	Email Address	
3.	Name	
	Title	
	SSN/Federal Tax ID	
	Address	
	City, State, Zip	
	Phone Number	
	Email Address	

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Attestation Form

Part 1 – Responsible Party Information - To be completed by an authorized individual of the applicant. This must be an individual who may legally sign on behalf of the business and is responsible for compliance with Oregon Laws and Rules.

First Name :	Last Name:	
Title		
Facility Name:		
Facility Address:		
Facility City, State, Zip:		

Part 2 – Attestation - To be completed by the responsible party listed above (person who may legally sign for the business). Must be manually signed in ink.

Per Oregon Revised Statue 689.401(1) The furnishing of false information is grounds to denv registration.

I swear or affirm that all information, statements, answers, and representations made in this application and the documents attached are true and correct, that the individuals at this facility are familiar with the laws and rules of the Oregon Board of Pharmacy as well as applicable federal laws, and that the business will be operated in compliance with all applicable laws and regulations.

I certify that if disclosed disciplinary action has been taken or is currently pending or proposed, the required documentation is attached to this application. I understand that failure to provide the required documentation may be grounds for denial of my application or disciplinary action against this facility.

Signature:_____Date:_____

Printed Name:

APPLICATION FOR REGISTRATION WHOLESALER CLASS I In and Out of State (Expires September 30 Annually) Oregon Board of Pharmacy 800 NE Oregon Street, Suite 150

Portland OR 97232 Telephone: (971) 673-0001 www.oregon.gov/pharmacy

Designated Representative of Facility

Designated Representative requirements are in Oregon Administrative Rule 855-065-0009. Note: You must notify the Board in writing of a change in designated representative within 15 days of the change by resubmitting this form.

Designated Rep Name	
Business Name	
Business Address	
City, State, Zip	
Phone Number	
Fax	
Email Address	
Facility Business Hours	

Please answer all of the following:

- [] Yes [] No Are you the designated representative of more than one wholesale distributor? If "yes", attach a sheet with an explanation and details.
- [] Yes [] No Are you actively involved in and aware of the daily operations of the wholesale distributor? If "no", attach a sheet with an explanation and details.
- [] Yes [] No Are you physically present at the wholesale distributor during normal business hours? If "no", attach a sheet with an explanation and details.

The designated representative signing this document acknowledges reading and understanding the responsibilities of a designated representative in <u>Oregon Administrative Rule 855-065-0009</u> and the requirement to comply with Oregon laws and rules.

Designated Representative Signature

Date

CONTROLLED SUBSTANCE APPLICATION	
APPLICATION FOR REGISTRATION UNDER	
OREGON CONTROLLED SUBSTANCE ACT	

OREGON BOARD OF PHARMACY 800 NE OREGON STREET, SUITE 150 PORTLAND OR 97232 pharmacy.licensing@bop.oregon.gov



FOR BOARD U	SE ONLY	[0310] \$ 100.00
RECEIPT #		
CHECK #		
PERSON ID #		

CONTROLLED SUBSTANCE APPLICATION FEE \$100.00 ALL FEES ARE NONREFUNDABLE

Type of Application – Check all	that apply:	
□ Not Applicable. This facility	does not handle or distrib	oute Controlled Substances.
☐ This is a new registration.		
□ This is a change in owner or	location.	
□ I wish to add a Controlled Su	bstance registration to my	y existing facility.
Oregon Registration Nun	nber:	
□ I wish to reinstate a Controll	ed Substance registration	to my existing facility.
Oregon Registration num	1ber:	
Please PRINT or TYPE	WARNING: ORS 475.135(1)(e)) The furnishing of false information is grounds to deny registration.
Trade or Business Name (DBA):		
Full Legal / Owner Name:		
Federal Tax ID # or Owner SSN:		
Physical Location Address:		
City:	_State:	Zip:
Phone Number:	FA>	X #
Registration & Renewal Mailing Add	dress:	
City, State, Zip:		
Licensing Contact Person:	Title	Contact Phone
Licensing Contact Person E-mail A	ddress:	
DRUG SCHEDULES (Check appro	opriate box(es):	
□ Schedule I □ Schedule II □ Sc	hedule II N \Box Schedule III [\Box Schedule III N \Box Schedule IV \Box Schedule V
Attach a list of stocked Schedule	I Drugs: [] Narcotic [] Non-Narcotic

ALL APPLICANTS MUST ANSWER THE FOLLOWING:

1. Are you currently registered to manufacture, distribute or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the Federal Government?	□Yes □ No	
2. Have any of the persons or establishments listed on this application been convicted of a felony in connection with controlled substances under state or federal law?	□Yes □No	
3. If the applicant is a corporation, association, or partnership, has any officer, partner or stockholder been convicted of a felony in connection with controlled substances under state or federal law?	□Yes □No	
4. Have any of the persons or establishments listed on this application ever surrendered a previous Federal Controlled Substances Registration (FCSA) or had a FCSA Registration revoked, suspended or denied?	□Yes □No	
5. If the applicant is a corporation, association or partnership, has any officer, partner, or stockholder surrendered a FCSA Registration or had a FCSA Registration revoked, suspended or denied?	□Yes □No	
IF THE ANSWER IS YES TO ANY OF QUESTIONS 2 THROUGH 5, YOU MUST ATTACH A LETTER SETTING FORTH THE CIRCUMSTANCES.		
CURRENT FEDERAL REGISTRATION NUMBER (You must submit a copy of your DEA registration along with this application.)		

Print or Type Name of Authorized Individual

Signature of Authorized Individual

Date

ALL RETURNED CHECKS WILL BE ASSESSED A \$35.00 RETURNED PAYMENT FEE PURSUANT TO ORS 30.701(5)

FINAL CHECKLIST:		
1.	Appropriate Fee Included?	
 \$525.00 new application or owner/location change fee \$100.00 new Controlled Substance application or owner/location change fee (If required) NOTE: Fees are not prorated. Any registration issued prior to September 30 will require renewal and payment of the renewal fee. Renewal information will be provided with the newly issued registration. All renewals submitted on October 1st or later are subject to a late fee of \$100.00. 		
Total Fee Enclosed:		
2.	Required Documentation* – an application is incomplete if all requested documentation is not provided.	
	All communication regarding this application and any application deficiencies will be emailed to the Licensing Contact Person listed on page 1 of this application.	
	*Priority processing will be given to complete applications. All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will expire. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.	
Α.	Copy of <u>Resident State license/registration</u> AND <u>license/registration verification from Resident</u> <u>State</u> (required only for applicants located outside of Oregon). Online license/registration verifications accepted. Business name and owners listed on this application must match resident state verification.	
В.	□ If you answer "YES" to any disciplinary questions, you must be provide disciplinary actions, pending disciplinary actions and fully executed Board orders along with a detailed explanation.	
C.	Responsible Party Attestation Form	
D.	□ Controlled substance application & copy of active DEA registration, if applicable. Please be sure to check the correct box on page 6.	
E.	A copy of the current Verified-Accredited Wholesale Distributors (VAWD) accreditation through the National Association of Boards of Pharmacy. OR	
	Copy of \$100,000 Surety Bond that has the following elements clearly listed:	
	 Principal – Full name and physical address of location listed on bond Sole Beneficiary – Oregon Board of Pharmacy Amount: \$100,000.00 	
	 Amount: \$100,000.00 Copy of current inspection report (no more than 3 years) 	
F.	□ All signatures	

The undersigned hereby states that all the information contained in this application for registration is complete, true and correct; that they have read and are familiar with the applicable laws and rules of the Oregon Board of Pharmacy; and that such provisions of the law will be faithfully observed.

Signature

Title (Owner, Partner, Etc.)

Date

ALL RETURNED PAYMENTS WILL BE ASSESSED A \$35.00 RETURNED PAYMENT FEE PURSUANT TO ORS 30.701(5)

LICENSE VERIFICATION REQUEST FORM



OREGON BOARD OF PHARMACY 800 NE OREGON STREET, SUITE 150 PORTLAND OR 97232 TELEPHONE: (971) 673-0001 www.oregon.gov/pharmacy

Out-of-State Establishments Only

Verification Form of License/Registration in Resident State (required for all facilities located outside the State of Oregon). Applications for out-of-state facilities will not be processed without this verification.

To prevent delays in processing, submit a completed verification form or letter from your resident state licensing agency with your application(s). License verifications must be original and not tampered with, this includes the use of whiteout. Photocopies of registrations will not be accepted in lieu of a license verification from your resident state. If your license or registration can be verified online, a recent printout from the online system may be submitted along with a copy of your license or registration. If your resident state does not issue you any type of professional or business license, attach an original letter from the state agency that licenses drug outlets stating that you do not need a license.

To be completed by Applicant. You are responsible for sending this document to your resident State licensing agency for their verification and state seal. You must also attach a photocopy of your registration or license.

Resident State License Number	
License Type	
Business Name	
Physical Address	
City, State, Zip Code	

To be completed by Resident State licensing/regulatory board or agency and returned to the applicant:

The outlet listed above has applied for a Wholesaler I registration with the Oregon Board of Pharmacy. This registration is required of any Wholesaler I located within or out of this state that is engaged in the distribution of drugs within Oregon.

Written verification that this establishment has a current license or registration and is in good standing with its resident state is required for our licensing process. Please complete the section below and return it to the applicant.

- [] The outlet listed above holds a current, unrestricted license or registration with our agency and has no disciplinary action pending.
- [] Other (please explain):

Print Name & Title

Authorized Signature

Date

(State Seal Required)