



IOWA WHOLESALE DISTRIBUTOR APPLICATION INSTRUCTIONS

To be used for new applicants or changes, excluding facility manager changes.

Do not submit this application for renewal of your license.

Every wholesaler as defined in rule 657—17.3(155A) that engages in wholesale distribution into, out of, or within this state must be licensed by the Board before engaging in wholesale distribution. Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be separately licensed. The applicant shall submit a completed application for each location, including a nonrefundable application fee of \$750, plus a nonrefundable fee of \$45 for completion of a criminal history background check on the facility manager. A Wholesale Distributor license expires annually on December 31.

Only information relating to the applicant-facility should be provided in this application. Do not include information or responses relating to another facility location.

CONTROLLED SUBSTANCES -- EVERY wholesale distributor that engages in or intends to engage in wholesale distribution of controlled substances into, out of, or within this state must also be registered pursuant to the Iowa Controlled Substances Act (CSA) and 657—Chapter 10 before engaging in wholesale distribution of controlled substances.. If you do not currently have a CSA registration and are engaged in wholesale distribution of controlled substances into, out of, or within Iowa, you must apply for CSA registration by checking the box in section 9. An additional \$90 non-refundable CSA registration application fee for each activity indicated in section 9 of this application must also accompany this application.

Accreditation Requirement – Applicants must provide evidence of current Drug Distributor Accreditation (DDA-formally known as VAWD) by the National Association of Boards of Pharmacy, Quality and Security Accreditation (QAS) by the National Coalition for Drug Quality and Security (NCDQS), accreditation by another Board-approved accreditation body, or compliance with a current Iowa Board of Pharmacy-approved waiver.

*** Instate location ***

The accreditation requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a Board compliance officer or other agent of the Board prior to issuance of an initial license. However, licensees must provide evidence of accreditation on or before the initial renewal of the license.

Submit the completed application, including the checklists, all attachments, and a check/money order in the appropriate amount made payable to:

**Iowa Board of Pharmacy
6200 Park Ave. Ste. 100
Des Moines, IA 50321**

FOR NEW IN-STATE APPLICANTS: If an applicant for a new license is located within Iowa, an inspection must be conducted by the Board or its authorized agent prior to the activation of the license. Once the application is approved by licensing staff, the license number will be issued with a “pending—opening inspection” status. An email will be sent to the applicant with contact information to schedule the initial inspection. Once a satisfactory opening inspection report is submitted, the license will be activated. The Board will conduct future periodic inspections of licensed facilities.

FOR NEW APPLICANTS and REACTIVATION OF EXISTING LICENSE: Once a completed application is received, a fingerprint packet will be sent to the mailing address indicated on the application. The fingerprint packet is to be completed by the facility manager and returned to the Board for processing. **DO NOT UPLOAD ANY WAIVER OR FINGERPRINT CARD WITH THIS APPLICATION. DO NOT SUBMIT A WAIVER OR FINGERPRINT CARD, BY ANY DELIVERY METHOD, BEFORE RECEIVING A BACKGROUND CHECK PACKET FROM THE BOARD. ANY WAIVER AND/OR FINGERPRINT CARD RECEIVED BEFORE THE BOARD'S PACKET IS SENT WILL BE DESTROYED.**

FOR ALL APPLICANTS: Board staff will process applications in the order received. A completed application will be reviewed and processed within 10 business days of receipt. Please allow four to six weeks for completion of the application process, including processing of the criminal history check, following return of the fingerprint packet. An incomplete application for a wholesale distributor license will be maintained for a maximum period of 6 months. Failure to submit all required information within 6 months of submission of the original application will result in the application becoming null and void.

All application fees are non-refundable and non-transferrable.

Initial Application Fees	
Initial Application Fee	\$750.00
Initial Controlled Substance Act-Business (CSA-B) Registration Fee	\$90.00
A wholesale distributor that handles controlled substances is required to obtain a CSA-B registration and submit a \$90.00 fee for each independent activity indicated in section 9 of the application	
Facility Manager Criminal Background Check Fee	\$45.00

Name/Address/Ownership Change Application Fees – Changes made to the name, ownership, and/or location require the submission of a completed application and applicable fee(s). If the facility holds one or more CSA-B registrations, a fee for each CSA-B registration is also required when any of these changes are made. Multiple changes to a license within the same application require only the single fees for the license and each registration. **For facility manager changes, use the “Facility Manager Change Application.”**

Locations in Iowa:

- Applications for license changes shall be submitted to the Board as far in advance as possible prior to the anticipated change.
- Requires an on-site inspection of the new location as provided in paragraph 17.3(1) “c.”

Locations outside of Iowa:

- Applications for license changes shall be submitted to the Board within ten days of the wholesale distributor’s receipt of an updated license from the home state regulatory authority.
- If the home state does not license or register the facility, a completed application shall be submitted as far in advance as possible prior to the change of name, ownership, or location.

License Change Application Fees	
Wholesale Distributor Application Fee	\$750.00
CSA-B Registration Fee (if applicable)	\$90.00 per registration
Late License Change Application Fees – The following fees are due for applications that are not timely submitted, but are submitted within 30 days of required submission period.	
Wholesale Distributor Application and Penalty Fee	\$1500.00
CSA-B Registration and Penalty Fee	\$180.00 per registration
Reactivation Fees – The following fees are due for applications submitted more than 30 days after required submission period.	
Wholesale Distributor Reactivation Fee	\$2000.00
CSA-B Registration Reactivation Fee	\$360.00 per registration

APPLICATION CHECKLIST	
Most Recent Inspection Report	<input type="checkbox"/> YES <input type="checkbox"/> NO
Proof of NABP DDA, QAS, Board-Approved Accreditation, or compliance with Board- <u>approved</u> waiver	<input type="checkbox"/> YES <input type="checkbox"/> NO
Most recent FDA Inspection Report, FDA 483s, Warning Letters, and Responses	<input type="checkbox"/> YES <input type="checkbox"/> N/A
Copy of License/Permit from State of Residence (if outside Iowa)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Surety Bond (or equivalent means of security) and Proof of Annual Gross Receipts for prior tax year (if claiming \$10 million or less) <i>A government-owned wholesale distributor is exempt from the surety bond and prior tax year gross receipts requirements.</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO
List of each criminal conviction and court records of the conviction(s) and any pending criminal charges not previously reported to the Board	<input type="checkbox"/> YES <input type="checkbox"/> N/A
List of disciplinary actions taken against any professional or business license by any licensing authority and documentation of final disciplinary orders not previously reported to the Board	<input type="checkbox"/> YES <input type="checkbox"/> N/A
List of final denial orders by any licensing authority and documentation of final denial orders not previously reported to the Board	<input type="checkbox"/> YES <input type="checkbox"/> N/A
CONTROLLED SUBSTANCE REGISTRATION ACT CHECKLIST	
Copy of DEA Certificate (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> N/A
FACILITY MANAGER <i>(new applications only. Facility manager changes use the facility manager change application)</i>	
Facility Manager Resume	<input type="checkbox"/> YES
Copy of Facility Manager government-issued ID	<input type="checkbox"/> YES
List of disciplinary actions taken against any professional or business license not previously reported to the Board and documentation of final disciplinary orders	<input type="checkbox"/> YES <input type="checkbox"/> N/A
Explanation and documentation of violation(s) of any federal or state law pertaining to the possession, control, or distribution of prescription drugs not previously reported to the Board	<input type="checkbox"/> YES <input type="checkbox"/> N/A
List of each criminal conviction and court records of the conviction(s), and any pending criminal charges not previously reported to the Board	<input type="checkbox"/> YES <input type="checkbox"/> N/A

IOWA WHOLESALE DISTRIBUTOR LICENSE APPLICATION

**To be used for new applicants or changes, excluding facility manager changes.
Do not submit this application for renewal of the license.**

Please type or print legibly in ink. Applications submitted to change the license name, location, or owner must complete the effective date of change field(s). **Incomplete or illegible forms will delay the issuance of the license.**

1. FACILITY TYPE:	
Wholesale Distribution – Human Drugs	Reverse Distributor

If the business type does not fall into one of these two types, this is not the correct license or application.

2. APPLICANT/LICENSEE INFORMATION:			
Business Name (<i>name in which company is doing business</i>):		Effective Date of Change:	
Legal Name (<i>if different</i>):		Iowa License Number (<i>if currently licensed</i>):	
Federal Tax ID#:	NABP e-profile ID #:	If you do not have a NABP e-profile number, you may create one by going to nabp.pharmacy	
TYPE OF OWNERSHIP (<i>truest or publicly traded not accepted</i>):			
Sole Proprietorship	Partnership	C Corporation	
S Corporation	LLC	Government	
FACILITY ADDRESS (<i>physical location of establishment which should be reflected on all sales invoices and shipping documents</i>):			
Street Address:	Effective Date of Change:	Suite:	
Address:	City:	State:	Zip:

Note: The facility phone number must be a direct number to the proposed licensed facility

Phone #:	Extension:		
Landline:	Yes	No	Cell Phone (text messages accepted?):
Landline:	Yes	No	Cell Phone (text messages):
Fax #:			
Email Address:			
Web site:			
MAILING ADDRESS (<i>where all correspondence regarding licensure will be sent if other than facility address</i>):			
Address:	City:	State:	Zip:
			Suite #:

3. OWNERSHIP (<i>an ownership change occurs when the owner listed on the wholesale distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the wholesale distributor's most recent application</i>):	
Name of Legal Owner:	Effective Date of Change:
Address of Legal	

Owner:				
City:		State:		Zip:
Owner Phone #:		Extension:		
Fax:		Email Address:		
Date Established:		State of Incorporation:		

4. OPERATIONS

STATE AND FEDERAL PERMIT/LICENSE/REGISTRATION NUMBERS (*attach additional pages if necessary*):

State / Licensing Body:	Permit/License/Registration #:	Issue Date:	Expiration Date:	Status:

HOURS OF OPERATION: (*indicate opening and closing times each day; indicate "closed" if not open any day*)

Sunday:		Monday:	
Tuesday:		Wednesday:	
Thursday:		Friday:	
Saturday:			

CUSTOMERS: (*select all that apply*)

Other Wholesale Distributors	Hospitals	Pharmacies
Practitioners (Human)	Patients/End Users	Other (explain):

PRODUCTS DISTRIBUTED: (*select all that apply*)

DRUGS:	Human Prescription Drugs
Human Nonprescription Drugs	Human Controlled Substances
Veterinary – Companion Animal Prescription Drugs	Veterinary – Companion Animal Nonprescription Drugs
Veterinary – Companion Animal Controlled Substances	Veterinary – Food Producing Animal Prescription Drugs
Veterinary – Food Producing Animal Nonprescription Drugs	Veterinary – Food Producing Animal Controlled Substances

DEVICES/GASES/OTHER:

Prescription/Patient-Use Devices	Prescription/Professional-Use Devices
Nonprescription Devices	Medical Gases

Other (please explain):

5. ACCREDITATION:

At least one box must be checked by every applicant. A facility located outside Iowa must be accredited at least by one of the first four entities or options.
 Note: Inspection by an Iowa Board of Pharmacy compliance officer will be required at a facility located in Iowa before a new or relocated wholesale distributor license will be activated.

1. NABP - DDA	2. NCDQS - QAS	3. Board-Approved Waiver
4. Other Board-Approved Accreditation (specify)	OTHER (specify):	

6. INSPECTION INFORMATION:

Since your last application, has the facility been inspected by the FDA (inspection must be of the facility's current location, not a previously licensed location)?	YES	NO
If yes, date of most recent FDA inspection:		

Since your last application, has the FDA issued a 483 <i>(Attach the FDA's documentation and your response to the FDA)?</i>	YES	NO
Since your last application, has the FDA issued a Warning Letter <i>(Attach the FDA's documentation and your response to the FDA)?</i>	YES	NO
Has this facility ever been inspected by a state licensing authority or other third-party?	YES	NO
If yes, Most Recent Inspection Performed by:		
Date of Most Recent Inspection:		
Are you registered with the FDA as a 503(b) outsourcing facility?	YES	NO

7. REGISTERED AGENT *(agent must be located in Iowa – All applicants must have a Registered Agent that is physically located in Iowa. In the event that legal documents or correspondences must be served, they will be served to your Registered Agent.)*

Name of Registered Agent:				
Business Address:		Suite #:		
City:		State:		Zip:

8. SURETY BOND - Proof of a surety bond or other security of equal value must be submitted by all applicants who are engaged, or intend to engage, in wholesale distribution as defined by the federal Drug Supply Chain Security Act. The bond shall be in the amount of \$100,000, unless the applicant's annual gross receipts in Iowa from the previous tax year are \$10,000,000 or less, in which case the bond shall be in the amount of \$25,000. If submitting a \$25,000 bond, proof of prior tax year gross receipts in Iowa must be provided.

Is a surety bond or other equivalent means of security attached?	YES	NO
Annual gross receipts in Iowa for previous tax year are \$10,000,000 or less (please attach appropriate documentation)		
Annual gross receipts in Iowa for previous tax year are more than \$10,000,000		

9. CONTROLLED SUBSTANCES - A Controlled Substances Act-Business Registration is required for each activity involving the handling of controlled substances into, out of, or within Iowa.

New CSA-B Registration(s) <i>(check the box if you wish to apply)</i>				
DEA Registration #:		Expiration Date:		
FDA # :		Expiration Date:		
IA CSA-B Registration #:		Expiration Date:		
BUSINESS TYPE <i>(A separate CSA-B registration and \$90 fee is required for each activity checked below):</i>				
Manufacturer	Analytical Lab	Distributor/Reverse Distributor		
Importer/Exporter	Researcher – Business	Outsourcing Facility		
PROPOSED DISTRIBUTION <i>(check all schedules of controlled substances that you intend to distribute or otherwise handle within, out of, or into Iowa):</i>				
Schedule I (research or analytical lab only)		Schedule II Narcotic		
Schedule II Nonnarcotic		Schedule III Narcotic		
Schedule III Nonnarcotic		Schedule IV		Schedule V
RESPONSIBLE INDIVIDUAL <i>(whose signature is authorized on Federal Controlled Substances Order Form 222 or CSOS and who is responsible for the security and control of controlled substances within the facility)</i>				
Name:		Title:		
Social Security Number:		Date of Birth(mm/dd/yyyy):		
Address of Responsible Individual:				
City:		State:		Zip:
Primary Phone Number:				
Email Address:				

LOST OR STOLEN CONTROLLED SUBSTANCES:					
During the past two years have any controlled substances under your control or ownership been lost or stolen? If yes, indicate the number of incidents next to the applicable reason(s).			YES	NO	
Break-In:		Armed Robbery:		Employee Pilferage:	
Customer Theft:		Lost in Transit:		Other (explain):	
As the responsible individual, I, _____, attest that I have adequate experience in prescription drug distribution. I have and will maintain a functional understanding of federal and state laws, rules, and regulations pertaining to drug distribution and controlled substances, as applicable.					
I hereby swear or affirm that I, _____, have no felony convictions or convictions related to prescription drug and device distribution including distribution of controlled substances except those that may have been disclosed in this or previous applications to the Board.					
Signature:					
Date:					

10. Facility Manager – the facility manager is the individual responsible for the day-to-day operations of the wholesale distributor (provide full legal name)					
First Name:					
Middle Name:		Last Name:			
Previous Name(s) Used					
Street Address:					
City:		State:		Zip:	
Phone #:		Extension:			
Landline:	Yes	No	Cell Phone (will accept text message):	Yes	No
Alternate Phone #:		Extension:			
Landline:	Yes	No	Cell Phone (will accept text message):	Yes	No
Email:					
Date of Birth:		Social Security Number:			
Date started as Facility Manager at this Facility:					
As Facility Manager, I, _____, attest that I have adequate experience in prescription drug and device distribution, as applicable, and am actively involved in the daily operation of the distribution facility. I have and will maintain a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution, as applicable.					
I hereby swear or affirm that I, _____, have no felony convictions or convictions related to prescription drug and device distribution including distribution of controlled substances except those that may have been disclosed in this or previous applications to the Board.					
Signature:					
Date:					

11. CRIMINAL HISTORY (new applicants must provide a complete history)
--

<p>A. Since the last application have any of the applicant(s), owners, and/or facility manager been convicted of, or entered a plea of guilty, nolo-contendere, or no contest to a crime, other than a minor traffic offense, in any jurisdiction? You must include all misdemeanors and felonies, even if adjudication was withheld by the court so that you would not have a record of conviction. (For example, you must report if your conviction was expunged, you received a deferred judgment, or you received an executive pardon.)</p>		
	YES	NO
<p>B. Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court records of the conviction(s). Do not include criminal records relating to another facility or location. Only include records and information for crimes relating to operations, activities, and licenses/registrations at this facility</p>		
Attachment included:	YES	NO

<p>12. DISCIPLINARY ACTIONS (new applicants must disclose all disciplinary actions described below)</p>		
<p>A. Since the last application has the applicant, or any owner, officer, partner, or facility manager been disciplined by any licensing authority? Discipline includes, but is not limited to, citations, reprimands, fines, and license/registration restrictions, probation, suspension, revocation, or surrender.</p>		
	YES	NO
<p>B. Include a separate sheet of paper listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary order. Do not include discipline relating to another facility or location. Only include records and information for discipline relating to operations, activities, and licenses/registrations at this facility.</p>		
Attachment included:	YES	NO
<p>C. Since the last application has the applicant been denied a license by any licensing authority?</p>		
	YES	NO
<p>D. Include a separate sheet listing the final denial orders by any licensing authority and include documentation of any final denial orders.</p>		
Attachment included:	YES	NO
<p>E. Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority?</p>		
	YES	NO
<p>F. Include an explanation for any pending investigations, complaints, or charges.</p>		
Attachment included:	YES	NO

<p>13. SIGNATURE</p>		
<p>I hereby swear or affirm under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against this license.</p>		
Signature of Applicant:		
Date:		
Printed Name and Title:		
Business Telephone #:	Business Fax #:	