



IOWA WHOLESALE DISTRIBUTOR RENEWAL APPLICATION INSTRUCTIONS

To be used for license renewal only. Changes to name, address, ownership, and facility manager are not permitted when renewing your license.

Every wholesaler as defined in rule 657—17.3(155A) Wholesale distributor license. Every wholesale distributor 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.

CONTROLLED SUBSTANCES -- EVERY wholesaler, regardless of location, engaged in the distribution of controlled substances in or into Iowa is required to have a Controlled Substance Act (CSA) registration. If you do not currently have a CSA registration and are engaged in wholesale distribution of controlled substances in or into Iowa, you must apply for one by checking the box in section 2C and including an additional \$90 non-refundable CSA registration application fee.

NABP VAWD Accreditation – Applicants must provide evidence of current verified-accredited wholesale distributors (VAWD) accreditation by the National Association of Boards of Pharmacy.

*** Instate location ***

The requirement for VAWD accreditation does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license. However, licensees must provide evidence of VAWD 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
400 S.W. 8th St., Ste. E
Des Moines, IA 50309-4688.**

Name/Address/Ownership Change/Facility Manager– Changes made to the name, ownership, and/or location change **cannot** be made on a renewal application and requires the submission of a separate completed application and applicable fee(s). Multiple changes to a license within the same application require only a singular fee for the license and registration.

FOR ALL APPLICANTS: Please allow four to six weeks for the Board to process your completed application. An incomplete application for a wholesale distributor license will only 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.

| Renewal Application Fees | |
|--|-----------|
| Renewal Application Fee (November 1-December 31) | \$750.00 |
| Renewal Controlled Substance Act Registration (CSAR) Fee (if applicable) | \$90.00 |
| A wholesale distributor that handles controlled substances is required to obtain a CSAR | |
| Late License Application Fees – These fees are due for applications that are not timely submitted, but are submitted within 30 days of the required submission period | |
| Wholesale Distributor Application and Penalty Fee (January 1 – January 31) | \$1500.00 |
| CSAR and Penalty Fee (if applicable) | \$180.00 |
| Reactivation Fees – The following fees are due for applications submitted more than 30 days after required submission period. | |
| Wholesale Distributor Reactivation Fee | \$2000.00 |
| CSAR Reactivation Fee | \$360.00 |

| APPLICATION CHECKLIST | |
|---|---|
| Most Recent Inspection Report | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| Proof of VAWD 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, if not previously provided to the Board. | <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 other similar security) and Proof of Annual Gross Receipts (if claiming \$25,000 bond) | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| List of each criminal conviction and court records of the conviction(s) not previously reported to the Board | <input type="checkbox"/> YES <input type="checkbox"/> N/A |
| List of disciplinary actions 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 |

IOWA WHOLESALE DISTRIBUTOR LICENSE RENEWAL APPLICATION

To be used for license renewal only. Changes to name, address, ownership, and facility manager are not permitted when renewing your 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).

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

If your 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>): | | | |
| | | | |
| Legal Name (<i>if different</i>): | | Iowa License Number: | |
| | | | |
| Federal Tax ID#: | | NABP e-profile ID #: | |
| | | | |
| TYPE OF OWNERSHIP (<i>check all that apply</i>): | | | |
| Sole Proprietorship | | Partnership | |
| S Corporation | | LLC | |
| | | C Corporation | |
| | | Government | |
| FACILITY ADDRESS (<i>physical location of establishment which should be reflected on all sales invoices and shipping documents</i>): | | | |
| Street Address: | | | |
| | | | |
| Address: | | | Suite: |
| | | | |
| City: | | State: | |
| | | Zip: | |
| | | | |

Telephone number must be direct number to the licensed facility

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

| 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>): | | | |
|--|--|--------------------------------|--|
| Owner Name: | | | |
| | | | |
| Owner Address: | | | |
| | | | |
| City: | | State: | |
| | | Zip: | |
| | | | |
| Owner Phone #: | | Extension: | |
| | | | |
| Fax: | | Email Address: | |
| | | | |
| Date Established: | | State of Incorporation: | |
| | | | |

| 4. OPERATIONS | | | | |
|--|--------------------------------|--|------------------|---------|
| STATE AND FEDERAL PERMIT/LICENSE/REGISTRATION NUMBERS <i>(attach additional pages if necessary):</i> | | | | |
| Licensing Body: | Permit/License/Registration #: | Issue Date: | Expiration Date: | Status: |
| | | | | |
| | | | | |
| | | | | |
| HOURS OF OPERATION: <i>(indicate opening and closing times each day; indicate "closed" if not open any day)</i> | | | | |
| Sunday: | | Monday: | | |
| Tuesday: | | Wednesday: | | |
| Thursday: | | Friday: | | |
| Saturday: | | | | |
| CUSTOMERS: | | | | |
| Other Wholesalers | Hospitals | Pharmacies | | |
| Practitioners | Patients/End Users | Other: | | |
| PRODUCTS DISTRIBUTED: <i>(check all that apply)</i> | | | | |
| 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: | | | | |
| Prescription/Patient-Use Devices | | Prescription/Professional-Use Devices | | |
| Nonprescription Devices | | Medical Gases | | |
| Other <i>(please explain):</i> | | | | |

| 5. ACCREDITATIONS <i>(National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributor (VAWD) accreditation is required for licensure.)</i> | | |
|--|--------|------|
| VAWD | ACHC | CHAP |
| JOINT COMMISSION | DMEPOS | NONE |
| OTHER: | | |

| 6. INSPECTION INFORMATION: | | |
|--|-----|----|
| Since your last application, has the facility been inspected by the FDA: | 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 |
| 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 (must be located in Iowa) | | | | |
|---|--|--------|----------|------|
| Name: | | | | |
| Street 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 less than \$10,000,000, in which case the bond shall be in the amount of \$25,000. | |
|---|--------|
| Is a surety bond or other equivalent means of security attached? | YES NO |
| Annual gross receipts in Iowa for previous tax year are less than \$10,000,000 (please attach appropriate documentation) | |
| Annual gross receipts in Iowa for previous tax year are \$10,000,000 or more | |

| 9. CONTROLLED SUBSTANCES | | |
|--|-----------------------|---------------------------------|
| New CSA Registration(s) (check the box if you wish to apply) | | |
| DEA Registration #: | | Expiration Date: |
| FDA #: | | Expiration Date: |
| IA CSA Registration #: | | Expiration Date: |
| BUSINESS TYPE: | | |
| Manufacturer | Analytical Lab | Distributor/Reverse Distributor |
| Importer/Exporter | Researcher – Business | Outsourcing Facility |
| PROPOSED DISTRIBUTION (check all schedules of controlled substances that you intend to distribute or otherwise handle within or into Iowa): | | |
| 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 (whose signature is authorized on Federal Controlled Substances Order Form 222 or CSOS) | | |
| Name: | | Title: |
| Social Security Number: | | Date of Birth:(mm/dd/yyyy) |
| 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). | | |
| Break-In: | Armed Robbery: | Employee Pilferage: |
| Customer Theft: | Lost in Transit: | Other: |
| 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, 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. | | |
| Signature: | | |
| Date: | | |

| 10. FACILITY MANAGER – the facility manager is the individual responsible for the day-to-day operations of the wholesale distributor (<i>provide full legal name</i>) | | | | | |
|---|-----|------------|--|------|----|
| 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: | | |
| 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 | | | | | |
| Signature: | | | | | |
| Date: | | | | | |

| 11. CRIMINAL HISTORY | | |
|---|-----|----|
| 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 received an executive pardon.) | | |
| | YES | NO |
| B. Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court records of the conviction(s) | | |
| Attachment included: | YES | NO |

| 12. DISCIPLINARY ACTIONS | | |
|---|-----|----|
| 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. | | |
| | YES | NO |
| B. Include a separate sheet of paper listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary order. | | |
| Attachment included: | YES | NO |
| C. Since the last application has the applicant been denied a license by any licensing authority? | | |
| | YES | NO |

| | | |
|---|------------|-----------|
| D. Include a separate sheet listing the final denial orders by any licensing authority and include documentation of any final denial orders. | | |
| Attachment included: | YES | NO |
| E. Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority? | | |
| | YES | NO |
| F. Include an explanation for any pending investigations, complaints, or charges. | | |
| Attachment included: | YES | NO |

| | | |
|--|--|------------------------|
| 13. SIGNATURE | | |
| 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 my license. | | |
| Signature of Applicant: | | |
| Date: | | |
| Name and Title: | | |
| Business Telephone #: | | Business Fax #: |