# Iowa Board of Pharmacy
# Limited Distributor Renewal Application Instructions

**EFFECTIVE January 1, 2019**, Every Limited Distributor as defined in rule 657—42.3(155A), no person other than a licensed limited distributor, licensed pharmacy, or practitioner, shall engage in any of the activities found herein in this state without a limited distributor license. Where operations are conducted at more than one location by a single distributor, each location shall be separately licensed. The applicant shall submit a completed application along with a nonrefundable fee.

**EVERY limited distributor**, regardless of location, engaged in the distribution of controlled substances in Iowa is required to have a Controlled Substances Act (CSA) registration. If you do not currently have a CSA registration and are engaged in distribution of controlled substances in or into Iowa, you must apply for one by checking the box in section 2C.

**License required**. A person engaged in the following activities shall obtain a limited distributor license prior to distribution in or into Iowa:

1. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.
2. Wholesale distribution of a prescription animal drug.
3. Wholesale distribution of a prescription drug, or brokering the distribution of a prescription drug at wholesale, by a manufacturer, a manufacturer's co-licensed partner, or a repackager.
4. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.
5. Distribution at wholesale of a combination product as defined by the United States Food and Drug Administration (FDA), a medical convenience kit, an intravenous fluid or electrolyte, a dialysis solution, a radioactive drug, or an irrigation or sterile water solution to be dispensed by prescription only.
6. Distribution of a dialysis solution by the manufacturer or the manufacturer's agent to a patient pursuant to a prescription drug order, provided that a licensed pharmacy processes the prescription drug order.

**License optional.** A person engaged in the following activities may, but is not required to, obtain a limited distributor license for distribution in or into Iowa:

1. Distribution of non-prescription drugs or devices with or without a patient-specific prescription.
2. Distribution of medical devices exclusively to a health care practitioner for use in the practitioner's normal course of professional practice ("professional use").
3. Distribution of blood and blood products that are not subject to the federal Drug Supply Chain Security Act (DSCSA).
4. 

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.**

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

| **Renewal Application Fees - Changes to the limited distributor's location, name, or owner cannot be made when renewing your license.** | |
|---|---|
| Renewal Application Fee – November 1-December 31 | $175.00 |
| Renewal Controlled Substance Act Registration (CSAR) Fee (if applicable) | $90.00 |

| **Late License Renewal Application Fees –** These fees are due for applications that are not timely submitted, but are submitted within 30 days of the required submission period. | |
|---|---|
| Limited Distributor Application and Penalty Fee – January 1-January 31 | $350.00 |
| CSAR and Penalty Fee – January 1-January 31 | $180.00 |
| **Reactivation Fees –** These fees are due for applications submitted more than 30 days after the required submission period. | |
| Limited Distributor Reactivation Fee | $500.00 |
| CSAR Reactivation Fee | $360.00 |

| **APPLICATION CHECKLIST** | |
|---|---|
| License/Permit from State of Residence if outside Iowa or document indicating a license is not required | ☐YES ☐N/A |
| Proof of Accreditations | ☐YES ☐N/A |
| FDA 483s, Warning Letters, and Responses | ☐YES ☐N/A |
| FDA Inspection Reports | ☐YES ☐N/A |
| Home State or other Third Party Inspection Report if not previously reported to the Board | ☐YES ☐N/A |
| List of each criminal conviction and court records of the conviction(s) not previously reported to the Board | ☐YES ☐N/A |
| List of disciplinary actions by any licensing authority and documentation of final disciplinary orders not previously reported to the Board | ☐YES ☐N/A |
| List of final denial orders by any licensing authority and documentation of final denial orders not previously reported to the Board | ☐YES ☐N/A |
| Evidence of the mandatory physical inspection of the facility pursuant to subrule 42.3(7) | ☐YES |
| **CONTROLLED SUBSTANCE REGISTRATION ACT CHECK LIST** | |
| DEA Certificate | ☐YES ☐N/A |
| **FACILITY MANAGER CHECKLIST** | |
| Acknowledgment and Attestation | ☐YES ☐N/A |
| Resume (if new facility manager) | ☐YES ☐N/A |
| Governement-issued ID (if new facility manager) | ☐YES ☐N/A |

**Iowa Board of Pharmacy**
**400 S.W. 8th St., Ste. E**
**Des Moines, IA 50309-4688**
**515-281-5944**
**https://pharmacy.iowa.gov**

# Limited Distributor Renewal Application Instructions

Please type or print legibly in ink. **Changes to the limited distributor's location, name, or owner cannot be made when renewing your license.** **Incomplete or illegible forms will delay the issuance of your license.**

| **1. LICENSE SUB-TYPE – Please select the one license sub-type which most accurately describes the majority of your business practice** | | |
|---|---|---|
| **Manufacturer/Repackager** ☐ | **Wholesale Broker/Virtual Manufacturer** ☐ | **Medical Gas Distributor** ☐ |
| **Durable Medical Equipment Supplier** ☐ | **Medical Device Distributor to Patients** ☐ | **Veterinary Drug Distributor** ☐ |
| **Intracompany Distributor** ☐ | **Active Pharmaceutical Ingredient Distributor** ☐ | **Other DSCSA-Exempt Wholesale Distribution of Human Prescription Drugs** ☐ |
| **Non-Prescription Drug/Device Distribution** ☐ | **Medical Devices Distribution Exclusively to Health Care Providers for Professional Use** ☐ | **Blood and Blood Products Distributor (DSCSA-exempt)** ☐ |
| **Returns Processer** ☐ | **Other:** | |

| **2. LICENSEE INFORMATION** | |
|---|---|
| **A. Name of Licensee** *(name in which company is doing business)*: | |
| **Legal Name** *(if different)*: | |
| **Federal Tax ID#:** | |
| **Iowa License Number:** | |
| **Facility Manager:** | |
| **NABP e-profile #:** | |

If you do not have an NABP e-profile number, you may create one by going to nabp.pharmacy

| **B. Type of Ownership** *(check all that apply)*: | | |
|---|---|---|
| **C Corporation** ☐ | **Government** ☐ | **LLC** ☐ |
| **Partnership** ☐ | **S Corporation** ☐ | **Sole Proprietorship** ☐ |
| **Date Established:** | | |
| **State of Incorporation:** | | |

| C. Facility Address *(physical location of establishment which should be reflected on all sales invoices and shipping documents)* | | | | | |
|---|---|---|---|---|---|
| **Street Address:** | | | | **Suite #:** | |
| **Address:** | | | | | |
| **City:** | | **State:** | | **Zip Code:** | |

The facility phone number must be a direct number to the licensed facility

| | | | |
|---|---|---|---|
| **Telephone #:** | | **Landline ☐ Cell Phone# ☐** **If cell, will you accept text messages? ☐Y ☐N** | |
| **Alternate Phone#:** | | **Landline ☐ Cell Phone# ☐** **If cell, will you accept text messages? ☐Y ☐N** | |
| **Email Address:** | | **Fax #:** | |
| **Web Site:** | | | |
| **Mailing Address *(where all correspondence regarding licensure will be sent if other than facility address)*:** | | | |
| **Street Address:** | | **Suite #:** | |
| **Address:** | | | |
| **City:** | **State:** | **Zip Code:** | |

| D. Ownership | | | |
|---|---|---|---|
| **Owner Name:** | | | |
| **Owner Address:** | | | |
| **City, State, Zip:** | | | |
| **Owner Phone Number:** | | **Fax #:** | |
| **Owner Email:** | | | |

| 3. LICENSEE INFORMATION | | | | |
|---|---|---|---|---|
| **A. Hours of Operation** | | | | |
| **Sunday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Monday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Tuesday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Wednesday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Thursday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Friday:** | **Open:** | **Close:** | **Closed** | ☐ |
| **Saturday:** | **Open:** | **Close:** | **Closed** | ☐ |

| **B. Accreditations** ***(attach proof of accreditation, as applicable)*** | | | |
|---|---|---|---|
| ☐ **VAWD** | ☐ **DMEPOS** | ☐ **CHAP** | ☐ **ACHC** |
| ☐ **Joint Commission** | ☐ **Other:** | | ☐ **None** |

| **C. Business Practices** ***(select all that apply)*****:** | | | |
|---|---|---|---|
| **Manufacture (not virtual)** | ☐ | **Repackage** | ☐ |
| **Brokerage of Sales** | ☐ | **Virtually Manufacture** | ☐ |
| **Medical Gas Distribution** | ☐ | **Durable Medical Equipment Supply** | ☐ |
| **Medical Device Distribution to Patients** | ☐ | **Veterinary Drug Distribution** | ☐ |
| **Intracompany Distribution** | ☐ | **Active Pharmaceutical Ingredient (API) Distribution** | ☐ |
| **Other DSCSA-Exempt Wholesale Distribution of Human Prescription Drugs** | ☐ | **Non-prescription Drug Distribution** | ☐ |
| **Non-prescription Device Distribution** | ☐ | **Medical Device Distributor Exclusively to Health Care Practitioner for Professional Use** | ☐ |
| **Blood and Blood Product Distribution (DSCSA Exempt)** | ☐ | **Returns Processor** | ☐ |
| **Other:** | | | |

| **D. Customers** | | | |
|---|---|---|---|
| **Wholesaler Distributors** | ☐ | **Intracompany Distribution (e.g., Pharmacy Distribution Centers)** | ☐ |
| **Hospitals** | ☐ | **Pharmacies** | ☐ |
| **Practitioners (Human)** | ☐ | **Veterinarians** | ☐ |
| **Patients (pursuant to prescription orders)** | ☐ | **Patients (without prescription order)** | ☐ |
| **Other:** | | | |

| **E. Products distributed *(check all applicable boxes)*** | | |
|---|---|---|
| **Drugs:** | | |
| **Human Prescription Drugs** ☐ | **Human Controlled Substances** ☐ | **Human Nonprescription Drugs** ☐ |
| **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** ☐ |
| **Active Pharmaceutical Ingredients** ☐ | | |
| **Devices:** | | |
| **Patient Use Prescription Medical Devices** ☐ | **Non-prescription Medical Devices** ☐ | **Professional Use Prescription Medical Devices** ☐ |
| **Other Products:** | | |
| **Prescription Combination Products, Medical Convenience Kits, IV Fluids/electrolyte, Radioactive drugs, Irrigation/sterile Water Solution** ☐ | | **Dialysis Solution** ☐ |
| **Blood and/or Blood Products** ☐ | **Medical Gases** ☐ | **Other:** |

In the event that legal documents or correspondences must be served, they will be served to your Registered Agent. Business located outside the state of Iowa must have a Registered Agent physically located in Iowa

| **F. Registered Agent *(must be located in Iowa)*** | | | | | |
|---|---|---|---|---|---|
| **Name:** | | **Title:** | | | |
| **Street Address:** | | | | **Suite #:** | |
| **City:** | | **State:** | | **Zip Code:** | |

**4. CONTROLLED SUBSTANCES** You are required to apply for and maintain a Controlled Substances Act-Business Registration for each activity involving the handling of controlled substances in or into Iowa. The fee for each type of registration is $90 and is renewed biennially.

| | | | |
|---|---|---|---|
| **Federal DEA Registration #:** | | **Expiration Date:** | |
| **CSA Registration #:** | | **Expiration Date:** | |

**Select each business activity in which you will be handling controlled substances and <u>for which you are not currently registered by the Iowa Board of Pharmacy</u>. Do not select an activity from this list if you hold a current CSA-Business registration to engage in that activity in Iowa.**

| | | |
|---|---|---|
| **Manufacture** ☐ | **Distributor** ☐ | **Importer/Exporter** ☐ |

**Check schedules of controlled substances that you intend to handle:**

| | | |
|---|---|---|
| ☐ **Schedule II Narcotic** | ☐ **Schedule II Nonnarcotic** | ☐ **Schedule III Narcotics** |
| ☐ **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 #:** | | **DOB** ***(mm/dd/yyyy)*** | |
| **Email Address:** | | | |

| | |
|---|---|
| **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 below):** | |

**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:** | |

| **5. INSPECTION INFORMATION** ***(Limited Distributors are required to complete and submit a self-inspection on forms provided by the Board)*** | | | |
|---|---|---|---|
| **Date of last self-inspection:** | | | |
| **Have you ever been inspected by a state licensing authority or other third party?** | | | ☐ **YES** ☐ **NO** |
| **If yes, most recent inspection performed by:** | | | |
| **State Agency** ☐ | **Accreditation Program** ☐ | **Other:** | |
| **Date of Most Recent Inspection:** | | | |
| **Food and Drug Administration (FDA) Registration** | | | |
| **Is your facility registered with the FDA:** | | | ☐ **YES** ☐ **NO** |
| **Registration Number:** | | **Expiration Date:** | |
| **Type of Registration** ***(select all that apply)*****:** | | | |
| **Animal and Veterinary Drugs** ☐ | | **Medical Devices** ☐ | |
| **Radiation-Emitting Products** ☐ | | **Vaccines** ☐ | |
| **Blood** ☐ | | **Biologics** ☐ | |
| **Drug Establishment** ☐ | | **Other:** | |
| **Since your last application, has the facility been inspected by the FDA:** | | | ☐ **YES** ☐ **NO** |
| **If yes, date of most recent FDA inspection:** | | | |
| **As a result of the inspection, was the company issued an FDA Form 483** | | | ☐ **YES** ☐ **NO** |
| **Has the company responded to the 483?** | | | ☐ **YES** ☐ **NO** |
| **Has the company ever been issued an FDA Warning Letter** | | | ☐ **YES** ☐ **NO** |
| **If yes, provide the date of the most recent Warning letter.** | | | |
| **Has the company responded to the Warning Letter?** | | | ☐ **YES** ☐ **NO** |

| **6. Facility Manager – the facility manager is the individual responsible for the day-to-day operations of the limited distributor *(provide full legal name)*** | | | | | |
|---|---|---|---|---|---|
| **First Name:** | | | | | |
| **Middle Name:** | | **Last Name:** | | | |
| **Previous Name(s) Used** | | | | | |
| **Street Address:** | | | | | |
| **City:** | | **State:** | | **Zip:** | |
| **Telephone #:** | | **Landline ☐ Cell Phone# ☐** **If cell, will you accept text messages? ☐Y ☐N** | | | |
| **Alternate Phone#:** | | **Landline ☐ Cell Phone# ☐** **If cell, will you accept text messages? ☐Y ☐N** | | | |
| **Email Address:** | | | | | |
| **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:** | | | | | |

*The regulatory questions only reauire an affirmative answer if there has been a reportable offense specifically to the licensed location since the last application*

| **7. CRIMINAL HISTORY** | | |
|---|---|---|
| **Since the last application, has the limited distributor, any owner, or facility manager been convicted of or entered a plea of guilty, nolo contendere, or no contest to any crime related to prescription drugs, controlled substances, healthcare, or the practice of pharmacy 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?** | | |
| | ☐ **YES** | ☐ **NO** |
| **Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court records of the conviction(s)** | | |

| **8. DISCIPLINARY ACTIONS** | | |
|---|---|---|
| **Since the last application has the licensee, 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** |
| **Include a separate sheet of paper listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary order** | | |
| **Since the last application has the licensee been denied a license by any licensing authority?** | | |
| | ☐ **YES** | ☐ **NO** |
| **Include a separate sheet listing the final denial orders by any licensing authority and include documentation of any final denial orders.** | | |
| **Do you have any knowledge of any pending investigations, complaints, or charges.** | | |
| | ☐ **YES** | ☐ **NO** |
| **Include an explanation for any pending investigations, complaints, or charges.** | | |

| **9. 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 #:** | |

*Privacy Act Notice: Disclosure of your Social Security number on this application is required by 42 U.S.C. § 666(a)(13) and Iowa Code §§ 252J.8(l), 261.126(1), and 272D.8(1). The number will be used in connection with the collection of child support obligations and debts owed to the state of Iowa, and as an internal means to accurately identify registrants, and may be shared with taxing authorities as allowed by law including Iowa Code § 421.18.*