Iowa Board of Pharmacy
Limited Distributor Application Instructions

Complete the attached Iowa Board of Pharmacy's **Application for Limited Distributor License**. Be sure to check the box for the relevant application type (New, Name Change, Ownership Change, or Relocation).

657—42.3(155A) Limited distributor license. Beginning January 1, 2019, no person other than a licensed wholesale 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 of $175.

42.3(1) License required. A person engaged in the following activities shall obtain a limited distributor license prior to distribution in or into Iowa:
a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.
b. Wholesale distribution of a prescription animal drug.
c. 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.
d. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.
e. Distribution at wholesale of a combination product as defined by the United States food and drug administration, 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.
f. 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.

42.3(2) 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:
a. Distribution of non-prescription drugs or devices with or without a patient-specific prescription.
b. Distribution of medical devices exclusively to a health care practitioner for use in the practitioner's normal course of professional practice ("professional use").
c. Distribution of blood and blood products that are not subject to the federal Drug Supply Chain Security Act (DSCSA).

LICENSE CHANGES – a change of name, ownership, or location requires the submission of a limited distributor license application and fee.

In-state location change- if the new location was not a licensed limited distributor immediately prior to the relocation, you are required to complete a self-inspection prior to relocating.

Ownership change - a change of ownership occurs when the owner listed on the limited distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the limited distributor's most recent application

FOR ALL APPLICANTS: An incomplete application for a limited 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 and any fees submitted with the application are forfeited and will not be transferred or refunded.

Submit the completed application, including the instruction check lists, all attachments, and a check in the appropriate amount made payable to the Iowa Board of Pharmacy to:

Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines, IA 50309-4688

Initial Application Fees	
Initial Application Fee	$175.00
Initial Controlled Substance Act Registration (CSAR) Fee	$90.00

License Change Application Fees – Changes made to the name, location, and/or owner require the submission of a 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.	
Instate Licensees – The application for license change must be submitted as far in advance as possible prior to the anticipated change.	
Nonresident Licensees - If the home state licenses or registers the facility, a completed application shall be submitted within 10 days of receipt of an updated license or registration from the home state. 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.	
Limited Distributor Application Fee	$175.00
CSAR Fee (if applicable)	$90.00
Late License Change 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	$350.00
CSAR and Penalty Fee	$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	
Evidence of the mandatory physical inspection of the facility pursuant to subrule 42.3(7)	☐YES
License/Permit from State of Residence	☐YES ☐N/A
Facility Manager's Resume	☐YES
Government Issued Identification for Facility Manager	☐YES
DEA Certificate	☐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	☐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

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

APPLICATION FOR LIMITED DISTRIBUTOR 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 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 ☐	**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. APPLICANT INFORMATION		
A. Name of Applicant ***(name in which company is doing business)*****:**		**Effective Date of Change:**
Legal Name:		
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. Facility Address ***(physical location of establishment which should be reflected on all sales invoices and shipping documents)***					**Effective Date of Change:**
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:**	

C. Ownership			**Effective Date of Change:**		
Owner Name:					
Owner Address:					
City, State, Zip:					
Owner Phone Number:		**Fax #:**			
Owner Email:					
Type of Ownership:					
Sole Proprietorship ☐		**Partnership** ☐		**C Corporation** ☐	
S Corporation ☐		**LLC** ☐		**Government** ☐	
Date Established:					
State of Incorporation:					

D. Hours of Operation			
Sunday:		**Monday:**	
Tuesday:		**Wednesday:**	
Thursday:		**Friday:**	
Saturday:			

E. State and Federal Permit/License/Registration Numbers ***(attach additional pages if necessary)***

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

3. 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?			
If yes, most recent inspection performed by:			
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	☐	**Drug Establishment**	☐
Medical Devices	☐	**Radiation –Emitting Products**	☐
Vaccines	☐	**Blood**	☐
Biologics	☐	**Other:**	
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? ***(attach the FDA's documentation and your response to the FDA)***		**☐Yes**	**☐No**
Since your last application, has the FDA issued a Warning Letter? ***(attach the FDA's documentation and your response to the FDA)***		**☐Yes**	**☐No**

4. FACILITY INFORMATION					
A. 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**	☐
Other DSCSA-Exempt Wholesale Distribution of Human Prescription Drugs	☐	**Non-prescription Drug Distribution**	☐	**Non-prescription Device Distribution**	☐
Medical Device Distribution Exclusively to Health Care Practitioners for Professional Use	☐	**Blood and Blood Product Distribution (DSCSA-Exempt)**	☐	**Returns Processor**	☐
API Distribution	☐	**Other:**			

B. 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

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

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

5. 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.

Do you intend to distribute, dispense, manufacture, or prepare controlled substances for patient administration in or into Iowa? ☐ **Yes** ☐ **No**

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** ☐

New CSA Registration(s) ***(check the box if you wish to apply)***	☐	**$90 Registration fee included per activity selected**	☐

DEA Registration #:		**Expiration Date:**	
FDA # :		**Expiration Date:**	
IA CSA Registration #:		**Expiration Date:**	

Check schedules of controlled substances that you intend to handle:

☐ **Schedule I** ☐ **Schedule II Narcotic** ☐ **Schedule II Nonnarcotic**

☐ **Schedule III Narcotic** ☐ **Schedule III Nonnarcotic** ☐ **Schedule IV** ☐ **Schedule V**

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 ***(new applicants must provide a complete history; renewal and change applications must include information not previously reported and provided to the board)***	
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 ***(new applicants must disclose all disciplinary actions described below; renewal and change applications must include information not previously reported and provided to the board)***	
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
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 applicant 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, college student loan 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.

IOWA BOARD OF PHARMACY

LIMITED DISTRIBUTOR
SELF INSPECTION
657 IAC Chapter 42

Limited Distributor Information

Distributor Name	IA License #	Date of Inspection

Street Address	City	State	Zip

Phone Number	Email Address

Inspection Items

Policies and Procedures 657-42.7			
Are policies and procedures available for the following?			
Security of the facility and patient information	YES	NO	N/A
Storage of products and records	YES	NO	N/A
Handling of outdated, recalled and returned products	YES	NO	N/A
Record retention	YES	NO	N/A
Security for products and records in possession of employee off site	YES	NO	N/A
Employee education and experience appropriate to responsibilities	YES	NO	N/A
Physical Requirements 657—42.10			
Is adequate space available for the storage of products and records?	YES	NO	N/A
Is adequate space available for operations?	YES	NO	N/A
Is adequate space available for cleaning and maintenance?	YES	NO	N/A
Is the necessary equipment available for all operations?	YES	NO	N/A
Is the security adequate for operations?	YES	NO	N/A
What is the temperature of the area where drugs are stored?			
How often do you document this temperature?			

IOWA BOARD OF PHARMACY

LIMITED DISTRIBUTOR
SELF INSPECTION
657 IAC Chapter 42

What is the humidity level of the area where drugs are stored?			
How often do you document the humidity?			N/A
Is a space specifically designated for outdated, damaged, unsafe, deteriorated, misbranded, adulterated or suspect products?	YES	NO	N/A
Is the facility clean and orderly?	YES	NO	
Is the facility free of infestation by insects, rodents, birds, or vermin of any kind?	YES	NO	
Purchasing/Distribution 42.10(2)			
Are all products received from legitimate sources that are properly licensed in the state in which they are located?	YES	NO	N/A
How are sources verified?			
How are verified sources records maintained/updated?			
Is verification of legitimate source of products supplied with each product received?	YES	NO	N/A
Are all products examined upon receipt?	YES	NO	N/A
How is the examination documented?			N/A
Are products verified prior to distribution?	YES	NO	N/A
How is the verification documented?			N/A
Transaction Records 657—42.12			
Do transaction records include the following?			
Source of product	YES	NO	N/A
Identity and quantity	YES	NO	N/A
Date of receipt or distribution	YES	NO	N/A
Name, address license number of supplier or purchaser	YES	NO	N/A
How long are receipt and distribution records maintained?			N/A
How are patient specific records maintained?			N/A

IOWA BOARD OF PHARMACY

LIMITED DISTRIBUTOR SELF INSPECTION
657 IAC Chapter 42

Prescription Records 657—42.12			
Do you distribute directly to patients?	YES	NO	N/A
Are prescriptions retained in their original format?	YES	NO	N/A
How long are prescriptions retained?			N/A
Are prescription records accessible?	YES	NO	N/A
Do all prescriptions contain the following?			
Date of issue	YES	NO	N/A
Patient's name, address or owner if the patient is an animal	YES	NO	N/A
Drug/Device name, drug strength, quantity	YES	NO	N/A
Prescriber's name, address, written or electronic signature, DEA	YES	NO	N/A
Do all faxes of prescriptions document source's name, address and fax number; time of transmission; receiver's name, address, fax number?	YES	NO	N/A
How are prescriptions determined to be valid?			N/A
How many months is a non-controlled prescription valid?			N/A
How many months is a medical gas prescription valid?			N/A
Who provides the patient with directions for use of prescription products?			N/A
What are the qualifications of the person providing directions to the patient?			N/A

By signing below, I attest that the information provided is true and correct and further attest that all staff have reviewed the applicable rules for all items answered with NO.

This self-inspection will be reviewed by board staff. I understand that the Iowa Board of Pharmacy has the authority to conduct an inspection per 657 IAC Chapter 42.

Inspection Completed By (printed name): _____

_____

Signature Date