



Iowa Board of Pharmacy

Outsourcing Facility Application Instructions

Do not use this application for changes to the supervising pharmacist

Complete the attached Iowa Board of Pharmacy Application for Outsourcing Facility License.

Effective July 1, 2021, every facility is required to submit evidence of a satisfactory inspection conducted by the home state regulatory authority or an entity approved by the Board. The inspection must have been completed within the two-year period immediately preceding the application and must demonstrate compliance with current good manufacturing practices (cGMP). In addition, the facility is required to submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the home state regulatory authority or entity approved by the Board.

Every facility registered with the FDA as an outsourcing facility that intends to distribute product into or within Iowa is required to be licensed with the Board in accordance with rule 657—41.3(155A).

Every outsourcing facility that delivers controlled substances into or within Iowa is required to have an Iowa Controlled Substances Act (CSA) registration. If the facility does not currently have an Iowa CSA registration, one may be issued by checking the box in section 3C and including an additional \$90 non-refundable CSA registration application fee.

An outsourcing facility that dispenses patient-specific prescriptions to individual patients in Iowa is also required to hold an Iowa pharmacy license in accordance with rule 657—8.35(155A). **New Applicants are required to disclose any disciplinary actions, criminal convictions, and FDA history in Sections 2, 4 & 5.** Please allow 4-6 weeks for the Board to process the completed application.

New Applicants - 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 supervising pharmacist and returned to the Board for processing.

An incomplete application for licensure 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, including submission of a completed fingerprint packet if required, will result in the application becoming null and void. Any fees submitted with the application are forfeited and will not be transferred or refunded.

Change Applications – A change to the name, ownership, or location of the facility requires the submission of an application and applicable non-refundable fee within 10 days of the FDA’s issuance of an updated registration. If the facility holds a CSA-Business registration, these changes also require submission of the applicable non-refundable fee for the CSA-Business registration.

Supervising Pharmacist Changes – A change in the supervising pharmacist requires the submission of the Supervising Pharmacist application and applicable non-refundable fee within 10 days of the FDA’s issuance of an updated registration. **DO NOT USE THIS APPLICATION.**

Submit the completed application, including the instruction checklist, all attachments, and a check or money order 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

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

Initial Application Fees	
Application Fee	\$400.00
Supervising Pharmacist Criminal Background Check Fee	\$45.00
Controlled Substances Act Registration (CSAR) Fee	\$90.00
An outsourcing facility that delivers controlled substances into or within Iowa shall obtain a CSAR	
License Change Application Fees - Changes made to the name, location, and/or ownership require the submission of a completed application and applicable fee(s). Multiple changes to a license within the same application require a single fee for the license and registration.	
Outsourcing Facility License Change Application Fee	\$400.00
Controlled Substances Act Registration (CSAR) Fee	\$90.00

APPLICATION CHECKLIST		
License/Permit from State of Residence if Outside Iowa	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Most Recent Inspection Report as specified in Iowa Code 155A.13C(1)	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Evidence of correction of all deficiencies discovered in the most recent inspection and evidence of compliance with all directives from the home state regulatory authority or entity approved by the board	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Valid FDA Registration as an Outsourcing Facility	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Most Recent FDA Inspection Report in Accordance with Rule 657—41.3(1)“b”	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
FDA Form 483s, Warnings Letters, and Responses	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Disciplinary Actions by Licensing Authorities and Documentation of Final Disciplinary Orders	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Final Denial Orders by Licensing Authorities and Documentation of Final Denial Orders	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Criminal Convictions and Court Records of the Convictions	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Supervising Pharmacist Addendum - The addendum and documents are only required for initial applicants		
Government-issued Photo ID	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Supervising Pharmacist’s License Issued by Applicant’s Home State	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Additional Pages to List All Licenses in Other States	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Disciplinary Actions by Licensing Authorities and Documentation of Final Disciplinary Orders	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Final Denial Orders by Licensing Authorities and Documentation of Final Denial Orders	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
List of Criminal Convictions and Court Records of the Convictions	<input type="checkbox"/> YES	<input type="checkbox"/> 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 OUTSOURCING FACILITY LICENSE

Please type or print legibly in ink. Applications submitted to change the license name, location, and/or owner must complete the effective date of change field(s). **Do not submit this application for supervising pharmacist changes.**

Incomplete or illegible forms will delay the issuance of the license.

APPLICATION TYPE			
New	Name Change	Ownership Change	Location Change
Anticipated Date of Opening:	Effective Date of Change:	Effective Date of Change:	Effective Date of Change:

1. LICENSEE/APPLICANT INFORMATION			
A. Name of Applicant: <i>(Name in which outsourcing facility is doing business)</i>			
Iowa License Number:		New Applicant:	
Legal Name			
Federal Tax ID #:			
NABP e-Profile ID			
Name of Supervising Pharmacist:			

If the facility does not have an NABP e-profile number, one may be created by going to nabp.pharmacy

B. Outsourcing Facility Address <i>(Physical location of facility)</i>			
Street Address:		Suite #:	
City:		State:	Zip Code:

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

Telephone #:		Landline <input type="checkbox"/> Cell Phone# <input type="checkbox"/>
		If cell, will you accept text messages? <input type="checkbox"/> Y <input type="checkbox"/> N
Web Site:		Fax:
Email Address:		
Emergency Contact Phone at facility:		

C. Mailing Address (where all correspondence regarding licensure will be sent if other than facility address)					
Street Address:		Suite #:			
Address:					
City:		State:		Zip Code:	

D. Outsourcing Facility Ownership - A change of ownership occurs when the owner listed on the outsourcing facility's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the outsourcing facility's most recent application.					
Owner Name:					
Owner Address:					
Owner Phone Number:		Email:			
Type of Ownership:					
Sole Proprietorship	Partnership		C Corporation		
S Corporation	LLC		Government		
Date Established:					
State of Incorporation (if applicable):					

E. Home State License Information (if not located in Iowa, attach a copy of home state license, permit, or registration)			
State:		License Number:	
License Type:			
Original Date Issued:		Expiration Date:	
Not Applicable:	<input type="checkbox"/>		

2. INSPECTION INFORMATION (must comply with Iowa Code 155A.13C(1) which dictates specific inspection requirements)			
Most Recent Inspection Performed by:			
Date of Most Recent Inspection:			
Since the last renewal, has the outsourcing facility been inspected by the FDA:	Yes	No	
If yes, date of most recent FDA inspection:			
Since the last application, has the FDA issued a Form 483?	Yes	No	
Since the last application, has the FDA issued a Warning Letter?	Yes	No	
<i>(attach the FDA's documentation and any responses to the FDA)</i>			

3. FACILITY DESCRIPTION	
A. Populations Served <i>(select all that apply)</i>	
Non-patient-specific compounded human drug products	Patient-specific prescriptions to patients in Iowa

B. Compounding <i>(check all that apply)</i>		
Human Sterile High-Risk	Human Sterile Medium-Risk	Human Sterile Low-Risk
Human Sterile Immediate Use	Human Sterile Hazardous Drugs	Animal Sterile High-Risk
Animal Sterile Medium-Risk	Animal Sterile Low-Risk	Animal Sterile Immediate Use
Animal Sterile Hazardous Drugs	Number of sterile compounded preparations dispensed/shipped within or into Iowa last year:	
Human Non-Sterile Complex	Human Non-Sterile Moderate	Human Non-Sterile Simple
Human Non-Sterile Hazardous Drugs	Animal Non-Sterile Complex	Animal Non-Sterile Moderate
Animal Non-Sterile Simple	Animal Non-Sterile Hazardous Drugs	
Number of non-sterile compounded preparations dispensed/shipped within or into Iowa last year:		

C. Controlled Substances <i>(Attach copy of DEA registration)</i>			
DEA Registration #:		Expiration Date:	
Iowa CSA Registration #:		Expiration Date:	
New Iowa CSA Registration: <i>(Check box if you wish to apply)</i>		\$90 Registration Fee Included:	
Responsible Individual:			
Check schedules of controlled substances intended to be dispensed within or into Iowa			
Schedule II Narcotic		Schedule II Nonnarcotic	
Schedule III Narcotic		Schedule III Nonnarcotic	
Schedule IV		Schedule V	

D. Registered Agent <i>(must be located in Iowa)</i>			
Name:			
Street Address:		Suite #:	

City:		State:		Zip Code:	
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The regulatory questions only require an affirmative answer if there has been a reportable offense specific to the licensed location since the last application.

4. DISCIPLINARY ACTIONS (new applicants must disclose all disciplinary actions described below)		
Since the last application, has the outsourcing facility, any owner, or Supervising Pharmacist 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 listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary orders issued if not previously provided to this Board.		
Attachment included:	YES	NO
Since the last application, has the outsourcing facility and/or the Supervising Pharmacist been denied a license or registration by any licensing authority?		
	YES	NO
Include a separate sheet listing all final denial orders by any licensing authority and include documentation of any final denial orders issued if not previously provided to this Board.		
Attachment included:	YES	NO
Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority?		
	YES	NO
Include an explanation for any pending investigations, complaints, or charges.		
Attachment included:	YES	NO

5. CRIMINAL HISTORY (new applicants must provide a complete history)		
Since the last application, has the outsourcing facility, any owner, or Supervising Pharmacist 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 record(s) of the conviction(s) if not previously provided to this Board.		
Attachment included:	YES	NO

6. SIGNATURE			
I hereby swear or affirm under the 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 the license.			
Signature of Applicant:			
Date:			
Business Telephone #:		Business Email:	
Name and Title:			

SUPERVISING PHARMACIST ADDENDUM

The addendum is only required for initial applicants

Please type or print legibly in ink. **Incomplete or illegible forms will delay the issuance of the license.**

1. IDENTIFICATION <i>(attach copy of government-issued identification)</i>					
First Name:					
Middle Name:					
Last Name:					
Previous Name(s):					
Street Address:					
City:		State:		Zip:	
Date of Birth:		SSN:			
Primary Phone:		Landline	Cell Phone		
		If cell, will you accept text messages?	Y	N	
Email Address:					

2. LICENSE INFORMATION <i>(List all states where you are or have previously been licensed as a pharmacist, attach additional pages if necessary, and attach a copy of home state license)</i>		
State	License Number	Active
		YES NO
		YES NO
		YES NO

3. DISCIPLINARY ACTIONS <i>(new applicants must disclose all disciplinary actions described below)</i>		
Have you ever 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 listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary orders not previously reported to the Board.		
Attachment included:	YES	NO
Have you ever been denied a license by any licensing authority?		
	YES	NO
Include a separate sheet listing all final denial orders by any licensing authority and include documentation of any final denial orders not previously reported to the Board.		
Attachment included:	YES	NO

4. CRIMINAL HISTORY <i>(new applicants must provide a complete criminal history)</i>		
Have you ever 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. (For example, you must report if your conviction was expunged, you received a deferred judgment, or you received an executive pardon.)		
	YES	NO
Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court record(s) of the conviction(s) if not previously provided to the Board.		
Attachment included:	YES	NO

5. PERSONAL ATTESTATIONS	
Initial each statement to indicate your understanding and agreement to abide by applicable federal and state laws relating to compounding:	
	I have reviewed the Applicant's Outsourcing Facility License application and it is complete and accurate to the best of my knowledge.
	I am currently the supervising pharmacist of the Applicant's outsourcing facility.
	I will notify the Iowa Board of Pharmacy if/when I no longer serve as the supervising pharmacist of the Applicant's outsourcing facility.
	I understand Iowa's laws and rules governing outsourcing facilities.

If you are unable to attest to any of the above you must explain why on a separate page.

6. SIGNATURE	
By signing this application, I solemnly swear or affirm under the penalty of perjury that the contents of this addendum to the application are true to the best of my knowledge, information, and belief.	
Printed Name:	
Signature:	
Date:	

Privacy Act Notice: Disclosure of your Social Security number on this registration application is required by 42 U.S.C. §666(a)(13) and Iowa Code §§252J.8(1), 261.126(1), and 272D.8(1). The number will be used in connection with the collection of child support obligations or 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.