

Iowa Board of Pharmacy

Outsourcing Facility Application Instructions

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

Effective January 1, 2018, 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.

Effective January 1, 2018, every outsourcing facility that delivers controlled substances into or within Iowa is required to have an Iowa Controlled Substances Act (CSA) registration. If you do not currently have an Iowa CSA registration, you must apply for one by checking the box in section 2G and including an additional \$90 non-refundable CSA registration application fee.

New Applicants—you are required to disclose any disciplinary actions, criminal convictions, or FDA history in Sections 3, 4 & 5. Please allow 4-6 weeks for the Board to process your completed application.

An outsourcing facility that dispenses patient-specific prescriptions to individual patients in Iowa is also required to hold an Iowa pharmacy license.

New applicants or licensees submitting an application to change facility manager - 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.

An incomplete application for licensure 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, including submission of a completed fingerprint packet if required, 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

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

Initial Application Fees	
Initial Application Fee	\$400.00
Supervising Pharmacist Criminal Background Check Fee	\$45.00
Initial Controlled Substance Act Registration (CSAR) Fee	\$90.00
An Outsourcing Facility that delivers controlled substances into or within Iowa is required to obtain a CSAR	
License Change Application Fees - Changes made to the name, location, ownership, and/or supervising pharmacist requires the submission of a completed application and applicable fee(s). Multiple changes to a license within the same application requires only a singular fee for the license and registration.	
Outsourcing Facility License Change Application Fee	\$400.00
Supervising Pharmacist Criminal Background Check Fee *This fee is only required when changing the supervising pharmacist	\$45.00
Controlled Substance 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	<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 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 Each Criminal Conviction and Court Record(s) of the Conviction(s)	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Supervising Pharmacist Addendum - The addendum and documents are only required for initial applicants and applications to change the supervising pharmacist		
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 Each Criminal Conviction and Court Record(s) of the Conviction(s)	<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, facility manager, or owner must complete the effective date of change field(s). **Incomplete or illegible forms will delay the issuance of your license.**

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

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

B. Outsourcing Facility Address <i>(Physical location of facility)</i>			Effective Date of Change:	
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 <i>(where all correspondence regarding licensure will be sent if other than facility address)</i>			
Street Address:		Suite #:	
Address:			
City:		State:	Zip Code:

D. Outsourcing Facility Ownership - <i>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.</i>			Effective Date of Change:	
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 (<i>if not located in Iowa attach a copy of home state license, permit, or registration</i>)				
State:			License Number:	
License Type:				
Original Date Issued:			Expiration Date:	
Not Applicable:				

2. INSPECTION INFORMATION			
Most Recent Inspection Performed by:			
Date of Most Recent Inspection:			
Since your last renewal, has the outsourcing 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?		Yes	No
Since your 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 (check all that apply)			
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 in 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 in or into Iowa last year:			
Description of the scope of services provided in Iowa			

C. Controlled Substances (Attach copy of DEA registration)			
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:	
Check schedules of controlled substances that you intend to dispense in Iowa			
Schedule II Narcotic		Schedule II Nonnarcotic	
Schedule III Narcotic		Schedule III Nonnarcotic	
Schedule IV		Schedule V	

D. Registered Agent							
Name:							
Street Address:				Suite #:			
City:			State:			Zip Code:	

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 <i>(new applicants must disclose all disciplinary actions described below)</i>		
A. Since your 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
B. 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
C. Since your last application, has the outsourcing facility been denied a license or registration by any licensing authority?		
	YES	NO
D. 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
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

5. CRIMINAL HISTORY <i>(new applicants must provide a complete history)</i>		
A. Since your 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
B. 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 my license.			
Signature of Applicant:			
Date:			
Business Telephone #:		Business Email:	
Name and Title:			

SUPERVISING PHARMACIST ADDENDUM

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

Effective Date of Change:					
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:					
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>			
A. Since your last application have you 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 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
C. Since your last application have you been denied a license by any licensing authority?			
		YES	NO
D. 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>		
A. Since your last application have you 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
B. 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 section of 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, 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.