

Iowa Board of Pharmacy Outsourcing Facility Application Instructions

Do not use this application for changes to the supervising pharmacist

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

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 the applicable section 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 background check packet will be sent to the mailing address indicated on the application. The background check 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 the Board's receipt 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 registration, these changes also require the submission of the applicable non-refundable fee for the CSA registration.

Supervising Pharmacist Change – 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 50309-4688

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 (CSA) Registration Fee	\$90.00
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 (CSA) Registration Fee	\$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 date. These fees include the timely application fee and are not in addition to the previously identified fees.	
Outsourcing Facility License Change Application Fee & Penalty	\$800.00
Controlled Substances Act (CSA) Registration Fee & Penalty	\$180.00
Reactivation Fees – These fees are due for applications submitted more than 30 days after the required submission date. These fees include the timely application fee and are not in addition to the previously identified fees.	
Outsourcing Facility License Change Application Fee & Penalty	\$1600.00
Controlled Substances Act (CSA) Registration Fee & Penalty	\$360.00

APPLICATION CHECKLIST		
License/Permit from state of residence, if outside of Iowa	Yes	N/A
Most recent inspection report as specified in Iowa Code 155A.13C(1)	Yes	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	Yes	N/A
Most recent FDA inspection report (Form 483 or EIR) in accordance with 657 IAC 41.3(1)“b”	Yes	N/A
FDA Warning Letters, and Responses	Yes	N/A
List of disciplinary actions by licensing authorities and documentation of final disciplinary orders	Yes	N/A
List of final denial orders by licensing authorities and documentation of final denial orders	Yes	N/A
List of each criminal conviction and court record(s) of the conviction(s)	Yes	N/A
Valid FDA Registration as an outsourcing facility	Yes	N/A
SUPERVISING PHARMACIST ADDENDUM – the addendum and documents are only required for initial applications		
Copy of government-issued photo ID	Yes	N/A
Supervising pharmacist’s license issued by the home state	Yes	N/A
Additional page(s) to list all licenses in other states	Yes	N/A
List of disciplinary actions by licensing authorities and documentation of final disciplinary orders	Yes	N/A
List of final denial orders by licensing authorities and documentation of final denial orders	Yes	N/A
List of each criminal conviction and court record(s) of the conviction(s)	Yes	N/A



Iowa Board of Pharmacy
 400 SW 8th St. Ste. E
 Des Moines, IA 50309-4688
 515-281-5944
Pharmacy.iowa.gov

Application for Outsourcing Facility License

Please type or print legibly in ink. Complete all application sections and sign. **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

LICENSEE INFORMATION		
Name of Licensee (DBA)		
Iowa License Number		
Legal Name		
Federal Tax ID Number		
NABP e-Profile ID Number		
Name of Supervising Pharmacist		
Type of Ownership		
Sole Proprietorship	Partnership	C Corporation
S Corporation	LLC	Government

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

Outsourcing Facility Physical Address				
Street Address				
City		State		Zip Code
Telephone #		Landline	Cell Phone	
		If cell, will you accept text messages? Y N		
Fax #		Website		
Email Address				
Emergency Contact Phone # at Facility				
Outsourcing Facility Mailing Address (if different than physical address)				
Street Address				
City		State		Zip Code

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

Outsourcing Facility Ownership – A change of ownership occurs when the owner listed on the outsourcing facility’s most recent application changes	
Owner Name	
Owner Address	
Owner Phone #	
Owner Email	
Date Established	
State of Incorporation	

Home State License Information			
State			
License Number		License Type	
Original Issue Date			
Expiration Date			

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

FACILITY DESCRIPTION	
Populations Served	
Non-patient-specific compounded human drugs	Patient-specific prescriptions to patients in Iowa

Compounding		
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	Human Sterile Low-Risk
Animal Sterile Immediate Use	Animal Sterile Hazardous Drugs	
Number of sterile compounded preparations dispensed in Iowa last year		
Human Non Sterile Complex	Human Non Sterile Moderate	Human Non Sterile Simple
Human Non Sterile Hazardous		
Animal Non Sterile Complex	Animal Non Sterile Moderate	Animal Non Sterile Simple
Animal Non Sterile Hazardous		
Number of non-sterile compounded preparations dispensed in Iowa last year		
Description of the scope of services provided (or to be) in Iowa		

CONTROLLED SUBSTANCES			
DEA Registration #		Expiration Date	
Iowa CSA Registration #		Expiration Date	
Check box if you wish to apply for a new CSA registration. Must include \$90 registration fee.			
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	

REGISTERED AGENT				
Name				
Street Address				
City		State		Zip Code

DISCIPLINARY ACTION – <i>new applicants must disclose all disciplinary action described below</i>		
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
Since the last application, has the outsourcing facility been denied a license or registration by any licensing authority?	Yes	No
Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority?	Yes	No
If you responded ‘yes’ to any of the above questions, please attach a written summary explaining the affirmative response and attach all applicable documents.		

CRIMINAL HISTORY – <i>new applicants must provide a complete history</i>		
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
If you responded ‘yes’, please attach a written summary explaining each conviction and attach court record(s) of the conviction(s) if not previously provided to this Board.		

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 this license.	
Signature of Applicant	
Date	
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.

IDENTIFICATION					
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					

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	Expiration Date

DISCIPLINARY ACTION – <i>new applicants must disclose all disciplinary action 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
Have you ever been denied a license or registration by any licensing authority?	Yes	No
Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority?	Yes	No
If you responded ‘yes’ to any of the above questions, please attach a written summary explaining the affirmative response and attach all applicable documents.		

CRIMINAL HISTORY – <i>new applicants must provide a complete 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.		
	Yes	No
If you responded ‘yes’, please attach a written summary explaining each conviction and attach court record(s) of the conviction(s) if not previously provided to this Board.		

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 attestations, you must explain why on a separate page

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.