

OUTSOURCING FACILITY RENEWAL APPLICATION INSTRUCTIONS

- Complete the attached Iowa Board of Pharmacy Application for Outsourcing Facility License. The application is required to be completed for renewal of your Iowa outsourcing facility license.
- **Changes to the outsourcing facility’s location, name, owner, or supervising pharmacist cannot be made when renewing your 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.
- 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 2G 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). An outsourcing facility that dispenses patient-specific prescriptions to individual patients in Iowa is also required to hold an Iowa pharmacy license.
- All application fees are non-refundable and non-transferrable.
- **Submit the completed application, including the instruction check list, 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

LICENSURE APPLICATION FEE (\$400.00)		
Renewal <input type="checkbox"/>		
RENEWAL PENALTY FEE	REACTIVATION FEE	
After January 1: \$400.00 in addition to the application fee of \$400.00 <input type="checkbox"/>	After February 1: \$1600.00 <input type="checkbox"/>	
CSA REGISTRATION RENEWAL FEE Confirm CSA registration expiration date prior to submitting application		
CSA Registration (CSAR) fee \$90.00 <input type="checkbox"/>	Penalty fee after January 1: \$90.00 in addition to the registration fee of \$90.00 <input type="checkbox"/>	Reactivation fee after February 1: \$360.00 <input type="checkbox"/>

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
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 Each Criminal Conviction and Court Record(s) of the Conviction(s)	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Supervising Pharmacist - Copy of 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
Valid FDA Registration as an Outsourcing Facility	<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/>



RENEWAL 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 your license.**

1. APPLICANT INFORMATION		
A. Name of Applicant: <i>(Name in which outsourcing facility is doing business)</i>		
Iowa License Number:		
Legal Name		
Federal Tax ID #:		
NABP e-Profile ID		
Name of Supervising Pharmacist:		
Type of Ownership (check all that apply)		
Sole Proprietorship	Partnership	C Corporation
S Corporation	LLC	Government

B. Outsourcing Facility Address <i>(Physical location of facility)</i>					
Street Address:				Suite #:	
City:		State:		Zip Code:	
Telephone #:			Landline	Cell Phone	
			If cell, will you accept text messages? Y 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 (cont.):					
City:		State:		Zip Code:	

D. Outsourcing Facility Ownership			
Owner Name:			
Owner Address:			
Owner Phone Number:		Email:	
Type of Ownership:			
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:			

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 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 your response to the FDA)</i>			

3. FACILITY DESCRIPTION	
A. Populations Served (select all that apply)	
Non-patient-specific compounded human drug	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 in 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 in 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: (Check box if you wish to apply)		\$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 (must be located in Iowa)				
Name:				
Street Address:			Suite #:	
City:		State:		Zip Code:

4. DISCIPLINARY ACTIONS		
A. 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
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 the 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		
A. 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
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:			