

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 the 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 in accordance with 657—Chapter 10. 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 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).
- All application fees are non-refundable and non-transferrable.
- Submit the completed application, including the instruction check list, 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
6200 Park Ave., Ste. 100
Des Moines, IA 50321**

LICENSE RENEWAL FEE		
Renewal Fee		\$400.00
Renewal & Penalty Fee (if application is received after January 1)		\$800.00
Reactivation Fee (if application is received after February 1)		\$1600.00
CSA REGISTRATION RENEWAL FEE – this fee is only applicable if the outsourcing facility has a CSA registration which also expires December 31		
CSA Renewal Fee		\$90.00
CSA Renewal & Penalty Fee (if application is received after January 1)		\$180.00
Reactivation Fee (if application is received after February 1)		\$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 convictions and court record(s) of the conviction(s)	Yes	N/A
Valid FDA Registration as an outsourcing facility	Yes	N/A
SUPERVISING PHARMACIST		
Copy of government-issued photo ID	Yes	N/A
Supervising pharmacist’s license issued by home state	Yes	N/A



Iowa Board of Pharmacy
 6200 Park Ave., Ste. 100
 Des Moines, IA 50321
 515-281-5944

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 renewal of the license.**

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

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 other than physical address)					
Street Address					
City		State		Zip Code	

Outsourcing Facility Ownership	
Owner Name	
Owner Address	
Owner Phone #	
Owner Email	
Date Established	
State of Incorporation	

Home State License Information	
State	
License Number	
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 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 – <i>must be located in Iowa.</i>					
Name					
Street Address					
City		State		Zip Code	

DISCIPLINARY ACTIONS		
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		
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 or plea and attach court record(s) of the conviction(s) or plea(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 Licensee	
Date	
Name and Title	