

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
400 SW 8th St, Ste E
Des Moines, IA 50309-4688

| 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
 400 SW 8th St. Ste. E
 Des Moines, IA 50309-4688
 515-281-5944
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 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 – 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 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 | | | | |
|-------------------------|--|--------------|--|-----------------|
| 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 | |