



OKLAHOMA STATE BOARD OF PHARMACY

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Phone: (405) 521-3815 / Fax: (405) 521-3758
www.pharmacy.ok.gov / e-mail: pharmacy@pharmacy.ok.gov

**2022-2023 NOTICE OF RENEWAL
OUTSOURCING FACILITY LICENSE**

FOR OSBP USE ONLY	
RECEIPT:	
DATE:	

DUE UPON RECEIPT
FEE: \$200 (ONLINE ONLY)
<https://pay.apps.ok.gov/OSBP/payments/>
Fee doubles 15 days after expiration
 EXPIRATION: _____
 LICENSE #: _____

A. Facility Name, DBA Name & Physical Address: _____ **Mailing Address:** _____

Prescription items sold in / shipped to Oklahoma:	<input type="checkbox"/> Non-controlled (Rx)	<input type="checkbox"/> Controlled (CDS)
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B. Designated Pharmacist-In-Charge (Oklahoma licensed PIC required):
By my signature, I acknowledge that I am employed by the facility named above and that I am the pharmacist-in-charge. I certify that I am a licensed pharmacist in the State of Oklahoma. My business practices will conform to the laws and rules of the United States and the pharmacy laws and rules of the State of Oklahoma.

Printed Name: _____ **OK Lic #** _____ **Signature:** _____

C. Contact Information [notice of any deficiencies will be sent to the email given below for the PIC]:
 Pharmacist-In-Charge E-Mail: _____
 Facility Phone: _____ Facility Fax: _____ Facility hours: Mon-Fri _____

D. Does this facility fill patient specific prescriptions? ___ Yes ___ No
 1. If YES, list OK pharmacy license number: _____ Expiration Date: _____

E. Does this facility compound sterile drugs from bulk drug substances? ___ Yes ___ No

F. Does this facility conform to US FDA CGMP regulations as required by OAC 535:20-6-7? ___ Yes ___ No

G. Does this facility have a written Drug Diversion Detection and Prevention Policy on file and available for review as required by OAC 535:20-6-5? ___ Yes **(REQUIRED)**

H. Does this facility sell / ship directly to veterinarians located in Oklahoma? ___ Yes ___ No

- I. Facility Registration / License Information:**
1. **FDA Outsourcing Facility registration is required. The following must be submitted with this application:**
 - a. Copy of facility's FDA Registration
 - b. Form 483 or Warning Notice(s) issued to facility by FDA (if applicable)
 - c. Responses to FDA Form 483 or Warning Notice(s) (if applicable)
 - d. Copy of most recent FDA report regarding the drugs compounded by this facility must be attached
 2. **If this facility is NOT LOCATED IN OKLAHOMA, the following MUST be submitted with this application:**
 - a. Copy of Valid Home State License (Must provide copy of actual license, online verification printout will not be accepted)
 - b. Copy of most recent home state inspection
 - c. Current Description of Operations

J. Ownership ^{1,2}	SOLE PROPRIETOR	CORPORATION	GOVERNMENT
	PARTNERSHIP	LLC	

Has there been any Change of Name, Ownership, or Location since your last application/renewal?

Yes No *(If yes, a new application must be completed)*

For Change/Notification Requirements, please refer to Oklahoma Pharmacy Rules, Section 535:25-3-7

K. Disciplinary History:

Please answer each of the following questions YES (Y) or NO (N). For the purpose of the questions below, "applicant" means the Outsourcing Facility listed in Section A above. **All "YES" answers MUST be explained in detail in a separate addendum.**

The addendum shall identify the person/entity to whom the "Yes" answer applies and shall include the jurisdiction and all other information requested. Failure to disclose any of the requested information may result in the denial of this application and/or other appropriate action.

The 'Addendum to Application with Charges & Convictions' form that shall be used to provide this information may be found at:

<https://ok.gov/pharmacy/Licensees & Applicants/Forms & Applications/Facilities/index.html>

1.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its pharmacist-in-charge been convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. § 331 (i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering?	Y or N
2.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its pharmacist-in-charge pled guilty or nolo contendere to or been found guilty of violating federal or state requirements for licensure that present a threat of serious adverse health consequences or death to humans?	Y or N
3.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its pharmacist-in-charge pled guilty or nolo contendere to or been found guilty of violating any federal or state felony offense statutes or any federal or state misdemeanor offense statutes involving prescription drugs and/or controlled substances? Are any such charges or indictments pending?	Y or N
4.	Since the last renewal or within the last 24 months, has any federal (e.g., FDA, DEA) or state (e.g., OBND) regulatory or law enforcement agency found that the applicant or any of its owners or its pharmacist-in-charge has violated any federal, state, or local laws or foreign laws? Is there any such action pending?	Y or N
5.	Since the last renewal or within the last 24 months, has suspension, revocation or any other sanction been imposed against a license currently or previously held by the applicant or any of its owners or its pharmacist-in-charge for violating federal or state laws? Has the applicant or any of its owners or its pharmacist-in-charge surrendered a license?	Y or N
6.	Since the last renewal or within the last 24 months, has the applicant ever had any application for a license or permit refused or denied by any licensing authority?	Y or N
7.	Since the last renewal or within the last 24 months, has the applicant ever had a registration issued by a controlled substance authority revoked, suspended, surrendered, limited or restricted?	Y or N

I swear and affirm under penalty of perjury pursuant to Title 21 O.S. 491 and/or discipline by the Board of Pharmacy under the pharmacy laws and rules of the State of Oklahoma that all information I have supplied herein is true and complete.

THIS SIGNATURE MUST BE NOTARIZED:

State of _____)

County of _____)

Printed Name & Title of Responsible Person/Representative

Subscribed and sworn to or affirmed before me

this ____ day of _____, 20 ____

Signature of Responsible Person/Representative

Notary Public

THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION:

- \$200 Renewal Fee Receipt
- All FDA Information as Required in Section I
- Copy of Home State License & Most Recent Inspection Report (*Non-Resident*)
- Current Description of Operations
- Charges & Convictions Addendum (*if applicable*)

PLEASE MAKE SURE THIS APPLICATION IS COMPLETE AND ALL ATTACHMENTS ARE PRESENT BEFORE SUBMISSION. VERIFY SIGNATURES AND NOTARIES. ANY DEFICIENCIES COULD RESULT IN THIS APPLICATION BEING RETURNED. SHOULD THIS HAPPEN, YOU WILL BE SUBJECT TO ANY LATE FEES/RESINSTATEMENT FEES ASSESSED. ANY CERTIFICATE NOT RENEWED IS SUBJECT TO CANCELLATION 30 DAYS AFTER EXPIRATION.