

APPLICATION FOR OKLAHOMA FACILITY LICENSE

What you need to know before submitting an application- **PLEASE READ CAREFULLY**:

- 1. New applications (including change of owner, change of location, and change of name), if submitted without deficiencies, can take up to 2 weeks for processing.
- 2. The facility **SHALL NOT** operate from a place of residence.
- 3. Please verify all information requested on the application is provided at the time of submission to avoid any further delay.
- 4. Oklahoma requires up to 2 levels of ownership. Please pay special attention to Section D of the ownership form you are directed to on Page 1 of the application.
- 5. Oklahoma licenses are not transferable; they are only valid for the name and location that reflects on the license and the owner(s) reflected in the application submitted to obtain said license. This means that for change applications, the existing license will be ended at the time the new license is issued. For "Change of Owner" applications, as long as the previous/existing license has not expired, you may be able to continue contracts/orders as long as there is a Power of Attorney in place. Please seek legal counsel for these types of situations>
- 6. For "New" or "Change of Location" applications- You cannot conduct business at the new facility until after you have been inspected and provided an Oklahoma license. Please be sure to plan ahead accordingly.
- 7. Please do not fax or email applications to the Board Office. We must have original signatures and notaries on file.
- 8. If there are any deficiencies with the application, our office will contact the designated facility manager/representative via email at the email address currently on file.
- 9. For Oklahoma facilities, once the application is processed it will be given to the proper Compliance Officer/Inspector, who will call the phone number listed on the application to schedule a time and date to perform the required inspection. The facility must pass final inspection within ninety (90) days of application or the facility must resubmit the application and fees. Fees will not be refunded. The license will be released on-site upon passage of this inspection.
- 10. OSBP Staff cannot interpret rules. For questions regarding what constitutes an ownership change, please refer to OAC 535:25-3-7.
- 11. OSBP reserves the right to request any additional information not specifically requested on this application deemed necessary to protect the public health and safety.

OKLAHOMA



State Board of Pharmacy 2920 N LINCOLN BLVD STE A • OKLAHOMA CITY OK 73105-4200

pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov Dr. Marty Hendrick, Pharm.D., D.Ph, Executive Director Phone: 405.521.3815 • Fax: 405.900.8365

November 21, 2022

For facilities located outside of the United States (US).

If you have a presence in the United States you may access our website to make payment by MasterCard, Visa, American Express or EFT from a savings or checking account:

https://pay.apps.ok.gov/OSBP/payments

If you do NOT have a US presence you will not be able to access our website.

Exception: If you are in Canada please contact the Board by phone at 405-522-3815 or by email at <u>pharmacy@pharmacy.ok.gov</u> for help processing a payment on our online store from Canada.

If you need to pay by federal ACH wire transfer, please send the email address of the person who will be making a federal ACH Wire transfer to the pharmacy email address.

The Board will email them the information to make payment. Our Oklahoma State Treasurer (OST) requires that the payment information be sent to the person who will be making the payment on behalf of the entity for security reasons.

OST requires us to send the information separately between two emails for security reasons.

If you have any questions or need assistance, please contact me.

If you haven't already, please mail / ship your completed application and documents

New applications to attention: Shakayla Gordon Renewal applications attention: Marquise Robertson

OKLAHOMA STATE BOARD OF PHARMACY 2920 N LINCOLN BLVD STE A OKLAHOMA CITY OK 73105-4212

A Constitutional Board Established in 1907



OKLAHOMA STATE BOARD OF PHARMACY

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105 Phone: (405) 521-3815 / Fax: (405) 900-8365 Web Address: www.pharmacy.ok.gov E-mail: pharmacy@pharmacy.ok.gov

OUTSOURCING FACILITY LICENSE APPLICATION

FEE: \$400 (ONLINE ONLY)

https://pay.apps.ok.gov/OSBP/payments/ (includes inspection and/or document review – physical inspection will occur for all in-state facilities)

FOR OSBP USE ONLY:

	NEW		FOR OSBP USE ONLY:			
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Check – all that	CHANGE OF LO					
apply	CHANGE OF N	AME - Formerly Known As:	RECEIP	Г		DATE
	al address, include city	ness Physical Address: /town, state/province/county,				n Physical Address) /county, ZIP & Country):
Prescription items sold in / shipped to Oklahoma:		Non-controlled (Rx) Controlled (CDS)			ed (CDS)	
armacy law inted Nar Contact	vs and rules of the Stane: temp://www.commonscience.com/ temp://wwwww.commonscience.com/ temp://www.commonscience.com/ t	<u>Oklahoma</u> . My business pra te of Oklahoma. e of any deficiencies will be on:	OK Lic #	Signature :_ ven below fo	or the <u>per</u>	son responsible]:
armacist-l	n-Charge E-Mail:					
		Facility Fax:			ri	
Owners	hip Information:					
(√ one approp	F OWNERSHIP and attach the riate form to this oplication)	SOLE PROPRIETOR (complete Form A) PARTNERSHIP (complete Form A)	CORPORATI (complete For LLC (complete For	orm B1 or B2	?)	GOVERNMENT (complete Form D)
	oes this facility fill patient specific prescriptions? Yes No If YES, list OK pharmacy license number: Expiration Date:					
		nd sterile drugs from bulk	drug substances?	Yes	No	
		to US FDA CGMP regulat				Yes No
	is facility have a wr d by OAC 535:20-6	itten Drug Diversion Detec -5? Yes (required)	tion and Prevention	n Policy on 1	file and a	vailable for review a
Does th	is facility sell / shi	o directly to veterinarians	located in Oklahor	na? Ye	s No)
		IN OKLAHOMA, complete	-	of Oklahom	ıa.	
1. FDA	A Outsourcing Faci a. FDA Facility Na b. FDA Initial Date	nse Information (required lity registration is require me: of Registration <i>(attach cop</i> ost Recent Registration:	d. Complete the fo			

- d. End Date of Last FDA Inspection Related to Compounding:___
- e. Was a Form FDA-483 or Warning Notice issued? ____ Yes ____ No (If Yes, attach copy & response)
- f. A copy of the latest FDA report regarding the drugs compounded by this facility must be attached.

2. If this facility is NOT LOCATED IN OKLAHOMA, complete the following: (attach copy of license & inspection report)

- a. Home State: _____ Type of License issued by Home State: ____
- b. Home State license number:______ Home State license expiration date:_____
- c. Date of Last Inspection:_____ Entity conducting inspection:_____

L. 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.	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.	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.	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? (<i>If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and pharmacist-in-charge,)</i>	
4.	Has any federal (e.g., FDA, DEA) or state (e.g., OBNDD) 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? (If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and pharmacist-in-charge.)	
5.	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? (If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and pharmacist-in-charge.)	Y or N
6.	Has the applicant ever had any application for a license or permit refused or denied by any licensing authority?	Y or N
7.	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:

Printed Name & Title of Responsible Person/Representative

Signature of Responsible Person/Representative

County of		
. –		

Subscribed and sworn to or affirmed before me this

_____ day of ______ , 20 _____

THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION:

- 1. \$400 Application Fee Receipt
- 2. Copy of FDA Registration / Form 483 / Warning Notice (include response)
- 3. Copy of the latest FDA report regarding drugs compounded by this facility
- 4. Copy of Home State License(s) (out-of-state facilities only)
- 5. Copy of Last Inspection Report *(out-of-state facilities only)*
- 6. Charges & Convictions Addendum (*if applicable*)
- 7. Ownership Form(s) with required attachment(s) (see Section C)
- 8. ____ Current Description of Operations

Physical inspection will occur for all in-state facilities. Board inspection must occur prior to opening for new in-state applicants.

License expires annually – 12 months from issue.

Notary Public