THE STATE



SKA Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

**Board of Pharmacy** 

PO Box 110806, Juneau, AK 99811 Phone: (907) 465-2550 Email: *BoardOfPharmacy@Alaska.Gov* Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy* 

# **Outsourcing Facility License Application Instructions**

An outsourcing facility means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location. A professional license must be obtained in order to engage in these services. Prior to engaging in services, a business license is required.

# The following must be received by the division before your application for Outsourcing Facility License can be reviewed:

# **1.** APPLICATION

A completed application, signed and notarized (#08-4813, pages 1-4), including:

- (a) Doing Business Name (DBA), if applicable
- (b) Ownership information
- (c) Contact, mailing, and physical location details
- (d) Facility manager information
- (e) Inspection attestation
- (f) Copy of Good Manufacturing Practices (GMP) report and Food and Drug Administration (FDA) Acknowledgment
- (g) Professional Fitness question responses

### 2. FEES

Fees made payable to "State of Alaska" in accordance with 12 AAC 02.310.

Nonrefundable Application Fee:	\$100.00
License Fee:	\$550.00
Total Fees Due:	\$650.00

## 3. AUTHORIZATION FOR RELEASE OF RECORDS

A completed Authorization for Release of Records form (#08-4813a).

## Change of Name, Ownership, or Physical Address Requirements

A new and separate license is required when there is a change in name, ownership, or physical address. A new application must be submitted within 30 days of the change.

## The following must be received by the division before your application can be reviewed:

### **1.** APPLICATION

A completed application, signed and notarized (#08-4813, pages 1-4), including:

- (a) Doing Business Name (DBA), if applicable
- (b) Ownership information
- (c) Contact, mailing, and physical location details
- (d) Facility manager information
- (e) Inspection attestation
- (f) Copy of Good Manufacturing Practices (GMP) report and Food and Drug Administration (FDA) Acknowledgment
- (g) Professional Fitness question responses

## **2.** APPLICATION CHANGE TYPE

If there is more than one change occurring at the same time (e.g., change of location and change of name) it is not required to pay twice for the new application

## 3. FEES

Fees made payable to "State of Alaska" in accordance with 12 AAC 02.310.

Nonrefundable Application Fee:	\$100.00
License Fee:	\$550.00
Total Fees Due:	\$650.00

### 4. AUTHORIZATION FOR RELEASE OF RECORDS

A completed Authorization for Release of Records form (#08-4813a).

A change means that the information as it appears on the current license certificate is or will no longer be accurate. This includes:

- Ownership structure change at the direct parent-level or name change to the owner. This appears on the certificate in the "Licensee" field.
- Adding a DBA when there was previously no DBA listed, removing a DBA, or a DBA name change. This appears on the certificate in the "Doing Business As:" field.
- Relocating from one physical location to another.

Changes requiring a new application do NOT include the below scenarios. Please contact the board to make these corrective changes administratively by emailing *boardofpharmacy@alaska.gov*. Additional documentation may be requested to make the correction.

- Ownership changes at the grand-parent level or higher;
- Case-sensitive typos to the owner or DBA fields;
- Change in suite number or address due to city rezoning without a physical relocation.

## **Closure of Operations Requirements**

### 1. CESSATION OF OPERATIONS FORM

A completed Cessation of Operations form (#08-4791) within 10 days after business closure.

### PUBLIC INFORMATION

All information supplied with this application is available to the public unless required to be kept confidential by state or federal law. Information about licensees, including mailing addresses, is available at *https://www.commerce.alaska.gov/cbp/main/* under License Search.

### ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Mandatory reporting began on August 1, 2011. All of the necessary information regarding the Alaska PDMP can be found at *pdmp.alaska.gov* 

### 12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT

A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee in another jurisdiction not later than 30 days of the date of the disciplinary decision or conviction.

# **General Information**

#### **APPLICATION PROCESSING:**

The average time to process a paper application varies by program but can take several weeks from the date it is received in this office complete with all correct forms, supporting documents and appropriate fees paid. When the application is complete and correct, and all supporting documents have been received and all fees have been paid, the license will be issued. Start the process far enough in advance to allow for processing time. Applications are reviewed in order of receipt in our office, and walk-in customers should not expect immediate review.

#### LICENSE TERM:

There is no "inactive" status. If you choose not to renew your license, it will lapse. Licenses are issued for a two-year period and expire on June 30 of even-numbered years, regardless of the date of issuance, except licenses issued within 90 days of the expiration date are issued to the next biennial expiration date. One renewal notice will be mailed at least 30 days before license expiration to the last known address of record.

#### **PROFESSIONAL FITNESS QUESTIONS:**

A "yes" response in the application does not mean your application will be denied. If you have responded "yes" to any professional fitness questions in the application, be sure to submit a signed and dated explanation, and the charging document and judgement.

#### **DENIAL OF APPLICATION:**

Please be aware that the denial of an application of licensure may be reported to any person, professional licensing board, federal, state, or local governmental agency, or other entity making a relevant inquiry or as may be required by law.

#### **RANDOM AUDIT:**

If your program requires continuing education, the Division will audit a percentage of the license renewals. If your license is randomly selected for audit, a letter will be sent with instructions to submit documentation as proof you satisfied the continuing competency requirements as stated on this renewal form. Licensees are randomly selected by computer and may be randomly selected as often as the computer program chooses. You must save your documents for at least four years so you can respond to audits.

#### ADDRESS OR NAME CHANGE:

In accordance with 12 AAC 02.900, it is the applicant's/licensee's responsibility to notify the Division, in writing, of changes of address or name. Name and address change notification forms are available on the Division's website. The address of record with the division will be used to send renewals and all other official notifications and correspondence. The name appearing on the license must be your current legal name.

#### **CERTIFIED TRUE COPIES:**

If any of the required documents will be issued under a former name, indicate on the application and submit marriage license and/or court documents that are notarized as a "certified true copy of the original document". To obtain a certified true copy, you must present the notary with the original document along with the photocopy. You must write, "I certify this is a true copy of the original document" and sign your name. The notary will compare the original document with the copy and then notarize your signature.

#### SOCIAL SECURITY NUMBERS:

AS 08.01.060 and 08.01.100 require that a U.S. Social Security Number be on file with the division before a professional license is issued or renewed for an individual. If you do not have a U.S. Social Security Number, please complete the Request for Exemption from Social Security Number Requirement form (#08-4372) located at *ProfessionalLicense.Alaska.Gov* or contact the division for a copy of the form. This form is required with every application if you do not have a U.S. Social Security Number.

#### **PUBLIC INFORMATION:**

Please be aware that all information on the application form will be available to the public, unless required to be kept confidential by state or federal law. Information about current licensees, including mailing addresses, is available on the division's website at *ProfessionalLicense.Alaska.Gov* under License Search.

### ABANDONED APPLICATIONS:

Under 12 AAC 02.910, an application is considered abandoned when 12 months have elapsed since correspondence was last received from or on behalf of the applicant. An abandoned application is denied without prejudice. At the time of abandonment, the division will send notification to the last known address of the applicant, who has 30 days to submit a written request for a refund of biennial license and other fees paid. The application fee will not be refunded. If no request for refund is received within that timeframe, no refund will be issued, and all fees will be forfeited.

#### **BUSINESS LICENSES:**

The status of a professional license will directly impact the status of an associated business license. Renewal applications for business licenses are mailed separately. For more information about business licenses, (907) 465-2550 or *BusinessLicense.Alaska.Gov* 

#### STALE DOCUMENTS:

Application forms, authorizations and verifications older than 12 months from the date the document was received by the division will be considered stale; the document must be resubmitted as appropriate before the application will be considered by the division or a licensing board. Application documents include the application documents and verifications of licensure from other licensing jurisdictions. (12 AAC 02.915)

#### PAYMENT OF CHILD SUPPORT:

If the Alaska Child Support Enforcement Division has determined that you are in arrears on child support, you may be issued a nonrenewable temporary license valid for 150 days. Contact Child Support Services at (907) 269-6900 to resolve payment issues.

#### STATUTES AND REGULATIONS:

The complete set of statutes and regulations for this program are available by written request or online at the division's website: *ProfessionalLicense.Alaska.Gov* 

If you would like to receive notice of all proposed regulation changes for your program, please send a request in writing with your name, preferred contact method (mail or email), and the specific program you want to be updated on to the address below.

Regulations Specialist Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing EMAIL: RegulationsAndPublicComment@Alaska.Gov





FOR DIVISION USE ONLY

Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

### **Board of Pharmacy**

PO Box 110806, Juneau, AK 99811 Phone: (907) 465-2550 Email: *BoardOfPharmacy@Alaska.Gov* Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy* 

# **Outsourcing Facility License Application**

# PART I Payment of Fees

<b>Required Fees:</b> (New Application)	<ul><li>Nonrefundable Application Fee</li><li>License Fee</li></ul>	\$100.00 \$550.00
<b>Required Fees:</b> (Changes)	CHANGE TYPE CURRENT A	\$650.00

# PART II Facility Information

Company/Owner Name:			Contact Phone:		
Facility Name: (DBA)					
Jurisdiction:					
Mailing Address:	P.O. Box or Street	City		State	Zip
Physical Address:	Street	City		State	Zip
and Professional Licensing	noosing to receive correspondence on a , I agree to maintain an accurate email in good standing may result in an inabil	address through the MY LICENSE	web page. I understand	that failure to check my e	email account or
Email Address:			Select One:	Send my Correspondenc Send my Correspondenc	•
Note: If both boxes are selected above, you will receive correspondence electronically.					

# PART III Facility Manager (Designated Representative)

Faci Nam	lity Manager ne:				
Ema	il Address:	Conta	act Phone:		
	Communication Acknowledgement: If the email address provided in this section differs from the email address provided o page 1, and if this facility prefers electronic communication, I understand the email on page 1 will be considered the mai point of contact for this facility.				
	lity Manager ature:		Date	e Signed:	

# PART IV Inspection Attestation

By providing my sign	By providing my signature below, this facility attests that a:					
Self-inspection of the premises using the form provided by the department was completed within the last two years;						
- OR -						
Verification Accredited Wholesale Distributors (VAWD) inspection has been completed.						
Facility Manager Signature:		Date Signed:				

# **PART V** Good Manufacturing Practices

Attached to this application is the results of the most recent Good Manufacturing Practice (GMP) inspection performed by the U.S. Food and Drug Administration (FDA).

Date of Inspection:	Registered and fully compliant with the FDA under Sec. 503b?		Yes	No No
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# PART VI Professional Fitness Questions

The following questions must be answered. "Yes" answers may not automatically result in license denial.

**For each "yes" response to any question, you must provide an** <u>explanation</u> and <u>documentation</u>. Use the letter of explanation form (#08-4752) appended to this application; include full details, dates, locations, type of action, organizations or parties involved, and specific circumstances. A separate letter of explanation form must be provided for each "yes" answer documented below. Documentation includes copies of court orders, charging documents, board, or license actions, etc.

All disciplinary decisions or convictions must be reported to the board within thirty days, in accordance with 12 AAC 52.991. When in doubt about your response, disclose and provide the required explanation and documents. Applications submitted without the required attachments will be considered incomplete and will not be processed.

The contents of licensing files are generally considered public records. If you believe that the additional information you are attaching to explain a "yes" answer should be considered confidential, state that in the attachment. A request for confidentiality may or may not be granted.

When in doubt, disclose and explain.

1.	Has the pharmacy or facility received any disciplinary decisions or adverse actions, including a decision or action resulting in a license being denied, suspended, surrendered, revoked, conditioned, limited, or otherwise restricted by a federal, state, or local government against the pharmacy or facility's present license/registration for the manufacture, distribution, or dispensation of drugs and/or devices?		Yes		No
2.	Has an owner of the pharmacy or facility where it is currently physically located and under this specific license or registration, been convicted of a felony? For the purpose of this question, felony convictions apply to the owner of the pharmacy/facility where it is physically located as well as to any individual employed at the pharmacy or facility. This question does not apply to felony convictions of tertiary-level owners (e.g.: grandparent or higher), subsidiary companies (e.g.: holding companies or companies with differing employer identification numbers), or associated companies (e.g.: pharmacies or facilities owned by the same parent company but physically located elsewhere).		Yes		No
	If this owner holds more than one license/registration for pharmacies or facilities located in different physical locations, responses to this section must be specific to the licensee/registration this renewal application is being submitted for.				
3.	If yes to above, due to felony convictions of an owner, is the owner also individually licensed by the Alaska Board of Pharmacy under AS 08.80? For the purpose of this question, an owner is a sole-proprietor owner, individual owner, managing officer of a corporation, association, or joint- stock company owner.		Yes		No
4.	Has any employee of the facility been convicted of a crime that affects the licensee or registrant's ability to practice safely or competently?		Yes		No
5.	Have you as the owner, or any partner, corporate officer, the facility manager, or any employee obtained remuneration by fraud, misrepresentation, or deception?		Yes		No
6.	Have you as the owner, or any partner, corporate officer, the facility manager, or any employee had dealings with drugs or devices that are known or should have been known to be stolen drugs or devices?		Yes		No
	"Yes" Answers If you answered "yes" to any of the above questions, you must subr	nit sig	ned ar	nd dat	ed

documentation explaining the specific circumstance(s) of the incident(s).





Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

### **Board of Pharmacy**

PO Box 110806, Juneau, AK 99811 Phone: (907) 465-2550 Email: *BoardOfPharmacy@Alaska.Gov* Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy* 

# **Notary Signature Page**

# PART VII Notarized Signature

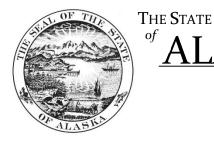
I hereby certify that I am the applicant herein named and subscribing to this application and that I have read the complete application, and I know the full content thereof. I declare that all of the information contained herein, and evidence or other documents submitted herewith are true and correct.

I understand that any falsification or misrepresentation of any item or response in this application, or any attachment hereto, or falsification or misrepresentation of documents to support this application, is sufficient grounds for denying, revoking, or otherwise disciplining a license or permit to practice in the state of Alaska.

I further understand that it is a Class A misdemeanor under Alaska Statute 11.56.210 to falsify an application and commit the crime of unsworn falsification.

A person who makes a false statement on this application may be subject to civil and criminal penalties, including prosecution for perjury (AS 11.56.200 & AS 11.56.230).

Notary Stamp	Applicant Printed Name:			
	Applicant Signature:			
	Notary Public for State of:		ibed and Sworn to me on this Day:	
i i L	Notary Signature:		My Commission Expires:	



**SKA** Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

Board of Pharmacy PO Box 110806, Juneau, AK 99811 Phone: (907) 465-2550 Fax: (907) 465-2974 Website: ProfessionalLicense.Alaska.Gov/BoardOfPharmacy

# Authorization for Release of Records

I hereby authorize the Alaska Division of Corporations, Business, and Professional Licensing and its investigators to examine my employment, educational records, and records pertaining to litigation, judgments, suits and/or settlements, and any law enforcement records pertaining to me and discuss them with persons having possession of them. I also expressly permit and authorize the release of any and all such records pertaining to me to the Alaska Division of Corporations, Business, and Professional Licensing and its investigators.

I authorize the division to discuss my records with persons or organizations that are considered appropriate by the division in connection with an official investigation, and to provide copies of my records to those persons or organizations deemed appropriate by the division.

I request that upon presentation of this release, or a Certified True Copy thereof, that you provide copies of those records to the division and/or its investigators, and/or representatives of the Office of the Attorney General of the State of Alaska.

This authorization is given expressly in connection with the application (initial, renewal, reactivation) for issuance of an Outsourcing Facility License.

I hereby release you, your organization, the Alaska Department of Commerce, Community, and Economic Development, Division of Corporations, Business, and Professional Licensing and its investigators, and all others directly and/or indirectly involved in this matter from any liability or damage which may result from furnishing the information requested.

This authorization expires one (1) year from the date of my signature below.

Name:	First	Middle		Last
Full Address:	P.O. Box or Street	City	State	Zip
Phone:			Date of Birth:	
Email:				
Signature:			Date Signed:	





ASKA Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

# Professional Licensing PO Box 110806, Juneau AK 99811 Phone: (907) 465-2550 Email: License@Alaska.Gov Website: ProfessionalLicense.Alaska.Gov

# Letter of Explanation for a Professional Fitness "Yes" Answer

Use this form only to explain and document any professional fitness "Yes" answers. A "Yes" answer is not necessarily disqualifying but concealing one may be.

Each "Yes" answer requires a separate explanation and associated documentation. Submit all relevant documentation with this form, even if you have previously provided it.

- **Explanations** include full details, dates, locations, type of action, organizations or parties involved, and specific circumstances. If the space provided is insufficient, make additional copies as needed.
- Documentation includes copies of court orders, charging documents, board or license actions, decisions against your
  professional certification, satisfaction of consent agreements (fines paid, community service completed, off probation, etc.),
  and fitness to practice letters (statement from your provider that you are safe to practice if you check "Yes" to any of the
  questions regarding mental or physical health, or drug or alcohol abuse or addiction).
- **Disciplinary actions** may include but not be limited to: suspension, surrender, revocation, probation, academic probation, reprimand, censure, restricted license, limited license, conditioned license, or letters of counseling, concern, advice, warning, caution, admonishment, or reprimand.

If you have multiple "Yes" answers or multiple incidents for any professional fitness question, you must use a separate copy of this form and provide a full explanation and documentation for each incident.

The contents of licensing files are public records. If you believe that the additional information you are attaching to explain a "Yes" answer should be considered confidential, state that in the attachment. A request for confidentiality may or may not be granted according to state law.

v	Vrite the profess	ional fitness question number	you are answerin	g "Yes" to in the box	
Location of Inciden	ıt:			Date of Incident:	
Explanation of Inci	dent:				
When in doul and exp	-				
Make copies a	s necessary.				
Did you attach al	l applicable docu	ments associated with this inc	cident?		
Court order	s 🗌	Consent agreements	Disciplinary	actions	Charging documents
Court recor	ds 🗌	Fitness to practice	All other doo	cumentation related	to this incident
		r this "Yes" answer, or "Yes" a for each incident.	nswers to other Pr	ofessional Fitness qu	estions and have attached
Full Name:				PL Code:	
Signature:				Date:	

You must submit one form for each "Yes" answer. Make copies of this form as necessary.



of ALASKA

Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

State of Alaska Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing PO Box 110806, Juneau, AK 99811 Phone: (907) 465-2550

# **Credit Card Payment Form**

All major credit cards are accepted. For security purposes, <u>do not email</u> credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee:

Profession Type (e.g., Acupuncture):

License Number (*if applicable*):

I wish to make payment by credit card for the following (check all that apply):

Application Fee:

License or Renewal Fee:

Other (fine, exam, etc.):

1.

2.

TOTAL:

Name (as shown on credit card):

Mailing Address:

Phone Number:

Email (optional):

Signature of Credit Card Holder:

08-4438

Rev 12/06/2022 Credit Card Payment Form (all major cards accepted)

CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!						
1. Credit Card Number:	All 3 fields <b>MUST</b> be completed!					
2. Expiration Date:	This section will be					
3. Security Code:	destroyed after the payment is processed.					

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