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

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
(907) 465-2550
Email: *BoardOfPharmacy@Alaska.Gov*
Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy*

Instructions for Outsourcing Facility License Application

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.

APPLICATION FOR PROFESSIONAL LICENSE REQUIREMENTS

1. **APPLICATION**
   Complete, signed and notarized application form 08-4813;

2. **OWNER, DIRECTOR & STOCKHOLDER INFORMATION**
   Names and resumes of all owners, directors, or primary stockholders responsible for facility;

3. **FACILITY MANAGER INFORMATION**
   Name and resume of the facility manager;

4. **SELF-INSPECTION REPORT**
   Completed self-inspection report on form #08-0098;

5. **FINGERPRINT CARD**
   Complete fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety (additional instructions are included in this application packet. Login to myLicense through myAlaska to request fingerprint cards. If you don't have a myAlaska account, you must create one first. Please note when you receive your blank fingerprint cards, the client number to indicate is 1344;

6. **GOOD MANUFACTURING PRACTICE (GMP) INSPECTION**
   Results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA);

7. **REGISTRATION WITH THE FDA**
   An affirmative response to the 503b section of this application relating to registration with the FDA;

8. **DISTRIBUTION OF CONTROLLED SUBSTANCES**
   An affirmative response to the authorized inspection section of this application;

9. **FEES**
   Fees required in accordance with 12 AAC 02.105(3) and 12 AAC 02.310, payable to the State of Alaska.

Nonrefundable Application Fee:	$100.00
Outsourcing Facility:	$600.00
Total Required:	**$700.00**

APPLICATION FOR CHANGE OF OWNERSHIP REQUIREMENTS

1. **AFOREMENTIONED ITEMS**
   Items 1-9 as listed above;

2. **RETURN EXISTING LICENSE**
   Returned existing license (previous license will expire upon processing of new license).

APPLICATION FOR CHANGE OF NAME OR LOCATION REQUIREMENTS

1. **AFOREMENTIONED ITEMS**
   Items 1-8 as listed above;

2. **FEES**
   Submit fees required in accordance with 12 AAC 02.105(1) and 12 AAC 52.02.310, payable to the State of Alaska

Nonrefundable Application Fee:	$100.00
Duplicate License Fee:	$5.00
Total Required:	**$105.00**

3. **RETURN EXISTING LICENSE**
   Return existing license (previous license will expire upon processing of new license).

APPLICATION FOR CHANGE OF FACILITY MANAGER

1. **AFOREMENTIONED ITEMS**
   Items 3-4 listed above;

2. **CHANGE OF FACILITY MANAGER**
   Within 10 days of a change of facility manager, the new facility manager must submit the completed change of facility manager form (form #08-4064). The outgoing facility manager must also submit a notice to our department on a separate form (form #08-4825);

3. **FEES**
   The $5.00 fee required in accordance with 12 AAC 02.105(1).

CLOSURE OPERATIONS

1. Within 10 days after business closure, a complete Cessation of Operations form (form #08-4791).

APPLICATION INFORMATION

Pharmacy Information

LICENSE TERM

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.

ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Mandatory reporting began on August 1, 2011. All the necessary information regarding the Alaska PDMP can be found on the Board of Pharmacy's PDMP website at ***pdmp.alaska.gov.*** Effective July 17, 2017, reporting is required **daily**.

DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT *(12 AAC 52.991)*

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 after 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. If the application is incomplete, the applicant will be notified of the incomplete and/or incorrect documents and fees. 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 and sent to you. 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.

"YES" RESPONSES

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 both charging and closing court documentation.

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.

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.

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.

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.

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*

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 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*

US MAIL: P.O. Box 110806, Juneau, Alaska 99811-0806

Fingerprinting Requirements

This license application must be accompanied by a complete fingerprint card (may be used for the Alaska Department of Public Safety (DPS) and for the FBI national check). Fingerprint cards submitted must be those provided by the State of Alaska (printed in the pale blue ink); you may also use the standard *FBI Form FD-258*. Take the card, the instructions and photo identification to local law enforcement or other authorized agency to have the fingerprinting done. Please follow these instructions and the back of the fingerprint card.

DPS/the FBI will not accept any fingerprint cards that do not comply with the following:

1. No staples or staple holes are permitted in fingerprint cards. Also do not tape, tear or fold the cards.
2. Ensure the prints are done properly and well. Poor quality prints, smudging, non-rolled or incomplete fingerprints will cause the cards to be rejected DPS, the FBI or both.
3. All applicable sections of the top portion of the card must be legible and complete. The information/signatures must be typed, printed or signed in BLACK ink; no other color is permitted. Individual information blocks on the fingerprint cards must be filled in as follows:

NAME: Applicant's last name (comma), first name, then middle name if any; suffix denoting seniority (Jr., Sr., II, etc.) follow the middle or first name.

SIGNATURE OF PERSON FINGERPRINTED: Must be signed by the applicant.

RESIDENCE OF PERSON FINGERPRINTED: Enter the applicant's physical residence address.

DATE: Date fingerprinting was done.

SIGNATURE OF OFFICIAL TAKING FINGERPRINTS: Signature of the person who rolled the fingerprints.

EMPLOYER AND ADDRESS AND REASON FINGERPRINTED: These blocks to be completed by the State of Alaska.

ALIASES/AKA: List other names used by applicant that are different than that entered in NAME block; also list maiden names and all previous married names of females. Enter client number, **1344,** at bottom of block.

CITIZENSHIP/CTZ: Enter US if a citizen of the United States; otherwise, enter correct country abbreviation.

YOUR NO./OCA: Leave this space blank (Originating Agency Case Number).

FBI NO./FBI: Enter applicant's assigned FBI number, if known.

ARMED FORCES NO/MNU: Leave this space blank.

SOCIAL SECURITY NO/SOC: List applicant's Social Security number.

MISC. NO/MNU: If Alaska resident, enter applicant's Alaska driver's license or state ID # if applicable.

ORIGINATING AGENCY IDENTIFIER (ORI): Leave blank, will be printed with AKAST0100, DPS, ANCHORAGE, AK.

SEX: F (female) or M (male). Note: Indicate if applicant is a transvestite (cross-dresser) or has had a sex change operation. List any opposite sex names used in the Aliases/AKA block.

RACE: Race must be indicated by one of the following one-character alphabetic codes:
A= Asian, Pacific Islander, Chinese, Japanese, Polynesian, Korean, Vietnamese
B= Black
I= American Indian, Alaskan Native, Eskimo
W= White, Mexican, Latin, Puerto Rican, Cuban, Central/South American and other Spanish cultures
U= Unknown

HEIGHT: Must be shown in feet and inches, fractions rounded off to nearest inch (i.e., 5'11" entered as 511)

WEIGHT: Must be expressed in pounds, fractions rounded off to nearest pound.

EYES: Indicate eye color by one of the following three-character codes:

BLK = Black	GRY = Gray	MAR = Maroon
BLU = Blue	GRN = Green	PNK = Pink
BRO = Brown	HAZ = Hazel	UNK = Unknown

HAIR: Indicate hair color by one of the following three-character codes:

BAL = Bald	BRO = Brown	SDY = Sandy
BLK = Black	GRY = Gray	WHI = White
BLN = Blonde	RED = Red	XXX = Unknown

PLACE OF BIRTH/POB: List the state, territorial possession, Canadian province, or country of birth. Use the correct abbreviation for foreign countries or correctly spell the country's name. Do not use city or county name as a POB.

DATE OF BIRTH/DOB: Enter birth date as month, day, year. Fingerprint cards of person 80+ years of age are not processed by the FBI. Note: If DOB is blank, the card will be immediately returned unprocessed.

FINGERPRINT IMPRESSION BLOCKS: (Individual and Simultaneous): It is very important care be taken to prepare the fingerprint cards properly. It will save much more time and avoid rejections to assure acceptability the first time. Use black printer's ink. Fingers should be clean and dry before being inked. Use neither too much nor too little ink nor too little nor too much pressure to make the impressions. To help ensure legibility, all 10 fingers must be rolled from nail to nail, and include the first flexion crease. Detail must be sufficient on all 10 individual prints to clearly define the loop, whorl, arch or other pattern. Roll the prints in the correct sequence.

All instructions must be followed correctly. All information on the card is essential. Please double check your work before sending the card. Illegible, incomplete or incorrect cards will be rejected and returned unprocessed.

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Outsourcing Facility License Application

PART I Payment of Fees

New Application:	☐ Nonrefundable Application Fee ☐ Outsourcing Facility License	**$100.00** **$600.00**	**$700.00**
Change Application:	☐ Ownership Change ☐ Name Change Only ☐ Location Change Only	Existing License Number: _____	**$700.00** **$65.00** **$65.00**

PART II License Information

Company/Owner Name:			
Outsourcing Name (DBA):			
Current License #:		**Jurisdiction:**	
Mailing Address:			
Physical Address:			
Contact Phone:			

EMAIL AGREEMENT: By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.

Email:		☐ Send my Correspondence by Email ☐ Send my Correspondence by US Mail

PART III Professional Fitness Questions

- The following questions must be answered. "Yes" answers may not automatically result in registration denial, however you must explain dates and circumstances under separate cover on a signed and dated statement. Send supporting documents, such as a copy of court records, including charging documents and judgments showing disposition of the charges, and/or all board orders pertaining to a licensing action.
- If you answered "Yes" to Question #1 or #2, include the name of the board, licensing or disciplinary authority and the date of the order, and, if applicable, the date of the termination of the condition and/or probation.
- Online print-outs are not acceptable. All disciplinary decisions or convictions must be reported to the board no later than 30 days, in accordance with 12 AAC 52.991.

When in doubt, disclose and explain.

1. Has the pharmacy, owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy ever had a professional license denied, revoked, suspended, or otherwise restricted, conditioned, or limited or have you surrendered a professional license, been fined, placed on probation, reprimanded, disciplined, or entered into a settlement with a licensing authority in connection with a professional license you or the pharmacy have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending?

☐ **Yes**
☐ **No**

* *If "Yes", have you previously disclosed this to the Board?*

☐ **Yes**
☐ **No**

2. Have you as the owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy, ever been convicted of a crime or are you currently charged with committing a crime? For purposes of this question, "crime" includes a misdemeanor, felony, or a military offense, including but not limited to, driving under the influence (DUI) or driving while intoxicated (DWI), driving without a license, reckless driving, or driving with a suspended or revoked license. "Convicted" includes having been found guilty by verdict of a judge or jury, having entered a plea of guilty, nolo contender or no contest, or having been given probation, a suspended imposition of sentence, or a fine.

☐ **Yes**
☐ **No**

* *If "Yes", have you previously disclosed this to the Board?*

☐ **Yes**
☐ **No**

3. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee furnished false or fraudulent material in an application made in connection with drug or device manufacturing or distribution?

☐ **Yes**
☐ **No**

4. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had a suspension or revocation by federal, state, or local government of a license currently or previously held for the manufacture or distribution of drugs or devices, including controlled substances?

☐ **Yes**
☐ **No**

5. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee obtained remuneration by fraud, misrepresentation, or deception?

☐ **Yes**
☐ **No**

6. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, 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**

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Email: *License@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. Do not assume that the division has documentation that you have already provided. Submit all relevant documentation with this form.

- **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, 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).
- **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.

☐ ⇦ ***Write the professional fitness question number you are answering "Yes" to in the box.***

Location of Incident:		**Date of Incident:**	
Explanation of Incident:			
When in doubt, disclose and explain. **Make copies as necessary.**			

Did you attach all applicable documents associated with this incident?

☐ Court orders ☐ Consent agreements ☐ License actions ☐ Charging documents
☐ Court records ☐ Fitness to practice ☐ All other documentation related to this incident
☐ I have additional incidents for this "Yes" answer, or "Yes" answers to other Professional Fitness questions and have attached a separate copy of this form for each incident.

Full Name:		**PL Code:**	
Signature:		**Date:**	

PART IV Pharmacy Information

1. OWNERSHIP:

☐ Sole ☐ Partnership ☐ Corporation ☐ LLC

Names of Owners, Directors, and/or Primary Stakeholder	Title	Did you attach resume?
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No

2. FACILTY MANAGER:

Full Name:		**Title:**	
Phone Number:			
Email:			

3. AUTHORIZED INSPECTIONS:

Will this outsourcing facility permit an authorized inspector/law enforcement official to enter and inspect the facility, including delivery vehicles, records, & written operation procedures?	☐ Yes ☐ No

4. 503b REGISTRATION:

Is this outsourcing facility registered with the Food and Drug Administration as a 503b outsourcing facility?	☐ Yes ☐ No

Date of initial registration: _____

Date of most recent registration: _____

5. ATTACHMENT REQUIREMENTS, OTHER THAN RESUMES:

☐ **Completed self-inspection report**
☐ **Completed results of most recent Good Manufacturing Practice (GMP) inspection**

PART V Notarized Signature

By signature below, I attest to the following (refer to AS 08.80.158):

That this facility acknowledges it must first verify that the purchaser of the prescription drugs holds a valid license issued by the Department of Commerce, Community, and Economic Development, Division of Corporations, Business, and Professional Licensing under AS 08. *(12 AAC 52.696)*

That this facility must obtain an Alaska business license prior to engaging in any business activity.

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's Printed Name:			
	Applicant's Signature:			
	Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
	Notary's Signature:		**My Commission Expires:**	

Before mailing this license application, have you...

- ✓ Completed all questions in the form?
- ✓ Attached your check for fees payable to the State of Alaska or credit card payment form?
- ✓ Signed and dated the form?
- ✓ Attached explanations and supporting documents for any "Yes" responses?
- ✓ Obtained necessary signatures?
- ✓ Attached required documents?

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Fingerprint Card Cover Sheet

To assist the Board of Pharmacy in tracking your fingerprint card request for processing by the Alaska Department of Public Safety (DPS), please complete this form and return it to our office. This form must accompany the facility manager's *completed* fingerprint cards.

Remember to check fingerprint card details for accuracy *(other than full name)***:**

- Employer and address field = *State of Alaska will complete*
- Reason fingerprinted = *State of Alaska will complete*
- Aliases/AKA (bottom of this block) = *1344*

This form is **not** for:

- requesting blank fingerprint cards
- any pharmacy category application not listed below

PART I Facility Type

☐ **Resident or Non-resident Wholesale Drug Distributor** (12 AAC 52.610(b)(6))

☐ **Outsourcing Facility** (12 AAC 52.696(b)(6))

☐ **Third-Party Logistics Provider** (12 AAC 52.697(b)(6))

Application:	☐ First time applying for licensure by the board of pharmacy _____ ☐ Changing owner or DBA name *Existing Alaska Facility License #:* _____ _____ ☐ Change in physical address *Existing Alaska Facility License #:* _____
Facility Manager:	☐ New facility manager

CONTINUED ON FOLLOWING PAGE

PART II	Facility Details	*Exactly as it appears on your license application*

Name of Facility Manager:				
Name of Facility Owner:				
Doing Business As (DBA) Name:				
Mailing Address:	PO Box/Street	City	State	Zip Code
Physical Address:	Street	City	State	Zip Code
Facility Phone Number:				
Facility Email:				

Signature

☐ ***I have attached the facility manager's completed fingerprint cards along with this cover sheet.***

Full Name:			
Signature:		**Date:**	

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PO Box 110806, Juneau, AK 99811
Phone: (907) 465-2550

Credit Card Payment Form

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

Name of Applicant or Licensee: _____

Program Type: _____ License Number *(if applicable)*: _____

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

- ☐ Application Fee: _____ _____
- ☐ License or Renewal Fee: _____ _____
- ☐ Other *(name change, wall certificate, fine, duplicate license, exam, etc.)*:
  1. _____ _____
  2. _____ _____

TOTAL: 0

Name *(as shown on credit card)*: _____

Mailing Address: _____

Phone Number: _____ Email *(optional)*: _____

Signature of Credit Card Holder: _____

08-4438 Rev 12/26/18 Credit Card Payment Form (all major cards accepted)

CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!

1. Account Number: _____
2. Expiration Date: _____
3. Billing ZIP Code: _____
4. Security Code: _____

All four fields **MUST** be completed!

This section will be destroyed after the payment is processed.