



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

Phone: (907) 465-2550

Email: BoardOfPharmacy@Alaska.Gov

Website: ProfessionalLicense.Alaska.Gov/BoardOfPharmacy

Manufacturer License Application Instructions

You must hold an active Alaska corporate entity number for the manufacturer license to be issued. For information on how to register your entity visit: <https://www.commerce.alaska.gov/web/cbpl/Corporations.aspx>.

Faxed or emailed applications will not be accepted.

The following must be received by the division before your application for manufacturer license can be reviewed:

1. APPLICATION

A signed, completed application (#08-4990, pages 1-4).

2. FEES

Fees made payable to "State of Alaska."

Nonrefundable Application Fee: \$100.00

License Fee: \$550.00

Total Fees Due: \$650.00

3. COPY OF LICENSE

A copy of a current valid license, permit, or registration to conduct operations in the home state/jurisdiction.

4. INSPECTION

Results of the most recent Good Manufacturing Practice (GMP) inspection performed by the U.S. Food and Drug Administration (FDA). *If virtual*, results must be submitted for **all** contracted facilities.

Change of Name, Ownership, or Physical Address Requirements

A facility shall notify the board in writing not later than 30 days after a change of name, ownership, or physical address. A notification of a change of physical address must include an attestation that a new self-inspection will be completed not later than 30 days after the start of business.

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.

Closure of Operations Requirements

A completed Cessation of Operations form (#08-4791) must be submitted to the board **within 30 days** after business closure.

General Information

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.

ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP):

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

APPLICATION PROCESSING:

The average processing time varies by program. When the application is complete and correct, all supporting documents have been received and all fees have been paid, the license may 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:

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 which are issued to the next biennial expiration date. One renewal notice will be sent via email or mail at least 30 days before license expiration to the last known email or mailing address of record. Failure to receive a renewal notice does not relieve a licensee from the responsibility of renewing a license on time.

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, submit an explanation with the charging and closing court documentation showing final disposition of charge(s) (e.g. court records, fitness letters, etc.).

DENIAL OF APPLICATION:

The denial of an application for 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.

CHANGES TO LEGAL NAMES, EMAIL ADDRESSES AND/OR MAILING ADDRESSES:

It is the applicant's responsibility to notify the division of any changes to legal names, email addresses and/or mailing addresses. The email or mailing address of record will be used to send all official notifications. The name appearing on the license must be your current legal name. The name change notification form is available on the division's website. Changes to email and/or mailing addresses can be submitted through MY LICENSE. (12 AAC 02.900)

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:

A U.S. Social Security Number must be on file with the division before a professional license is issued. If you do not have a U.S. Social Security Number, complete the Request for Exemption from Social Security Number Requirement form located at ProfessionalLicense.Alaska.Gov, and include required supporting documents as noted on the form. (AS 08.01.060)

PUBLIC INFORMATION:

All information on the application will be available as public record, unless required to be kept confidential by state or federal law.

ABANDONED APPLICATIONS:

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 email or mailing address of the applicant, who then has 30 days to submit a written request for a refund of biennial license and other fees paid, if applicable. The application fee will not be refunded. If no request for a refund is received within that timeframe, no refund will be issued, and all fees will be forfeited. (12 AAC 02.910)

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)

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. A professional license does not bypass the need for a business license; if a business license is required, it must be obtained after an initial professional license is issued. For more information about business licenses, visit *BusinessLicense.Alaska.Gov*.

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*. Centralized statutes and regulations also apply to all professional licenses; those are also available on the division's website. To receive notifications of proposed regulation changes, send a request with your name, email, and the program you want to be updated on to the regulation specialist at the following email: *RegulationsAndPublicComment@Alaska.Gov*. Courtesy notifications of proposed program regulations changes will also be sent to the email address on record.



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Manufacturer License Application

PART I Payment of Fees

Required Fees:	☐ Application and License Fee (\$100 is Non-Refundable)	\$650.00
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PART II Facility Information

Corporate Entity Type:		Current Alaska Entity Number:	
Company/Owner Name:		Contact Phone:	
Facility Name: (DBA)			
Mailing Address:	P.O. Box or Street	City	State Zip
Physical Address:	Street	City	State Zip
EMAIL AGREEMENT: Providing an email address authorizes the division to send you a web authorization code to register with the MY LICENSE self-service portal. If you do not receive a code or the code you received has expired, contact the division. Once registered you may opt-in to receive all official correspondence electronically. Your account can be accessed at any time.			
Email Address:			

PART III Virtual Manufacturer

"Virtual manufacturer" means a manufacturer that sells a prescription drug or device but never physically possesses the product, as defined in 12 AAC 52.995.

Is the facility virtual?	☐ Yes ☐ No
If yes, provide a full list of all facilities contracted in manufacturing products below. Attach additional pages if needed.	
Facility Name	Facility Address

PART IV Designated Representative

Designated Representative
Name:

Email Address:

Contact Phone:

☐ I understand the email provided in Part II will be considered the main point of contact for this facility.

PART V Copy of License

☐ I have attached a copy of a current valid license, permit, or registration to conduct operations in the home jurisdiction from the state below.

State:

Expiration Date:

PART VI Attestations

☐ I understand results of the most recent Good Manufacturing Practice (GMP) inspection performed by the U.S. Food and Drug Administration (FDA) must be submitted. *If virtual*, I understand results must be submitted for **all** contracted facilities.

- AND -

☐ I attest a self-inspection of the premises using the form provided by the department was completed within the last two years.

- OR -

☐ I attest an inspection of the premises by a third party was completed within the last two years.

PART VII Alaska Law

☐ I hereby certify I have reviewed, understand and will abide by the statutes and regulations applicable. (AS 08.80 & 12 AAC 52)

PART VIII 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 explanation and documentation. 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, unless required to be kept confidential by state or federal law.

When in doubt, disclose and explain.

1. Has the 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 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.

2.a. 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

3. 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

4. Have you as the owner, or any partner, corporate officer, the designated representative, or any employee obtained remuneration by fraud, misrepresentation, or deception? ☐ Yes ☐ No

5. Have you as the owner, or any partner, corporate officer, the designated representative, 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 submit signed and dated documentation explaining the specific circumstance(s) of the incident(s).



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Signature Page

Applicant Name:		
Alaska License Number (if known):		☐ <i>Application in Process</i>

PART IX Agreement

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

I understand 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, registration, certificate, or permit to practice in the state of Alaska.

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

Applicant Signature:		Date Signed:	
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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 generally considered public records, unless required to be kept confidential by state or federal law.



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. <i>Make copies as necessary.</i>			

Did you attach all applicable documents associated with this incident?

- ☐ Court Orders ☐ Consent Agreements ☐ Disciplinary 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:		Program:	
Signature:		Date Signed:	



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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:			
Profession Type (e.g., Acupuncture):		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 (fine, exam, etc.):		
1.			
2.			
TOTAL:			

Name (as shown on credit card):			
Mailing Address:			
Phone Number:		Email (Optional):	
Signature of Credit Card Holder:			

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

1. Credit Card Number:		All 3 fields MUST be completed. This section will be destroyed after the payment is processed.
2. Expiration Date:		
3. Security Code:		