



THE STATE

of **ALASKA**

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

Board of Pharmacy

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[BoardofPharmacy.aspx](http://commerce.alaska.gov/dnn/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx)

PROCEDURE TO OBTAIN A WHOLESALE DRUG DISTRIBUTOR LICENSE

In accordance with AS 08.80.157, a facility engaged in the manufacture, production, or wholesale distribution of drugs or devices shall be licensed by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

NOTE: Please read the application, statutes, regulations, and all instructions carefully. It is your responsibility to be aware of licensing requirements and provide all necessary documentation. The board will not issue a license until your application is complete.

APPLICATION FOR REGISTRATION - The following must be on file before the board may review the application for approval:

1. Completed notarized application.
2. Fees required in accordance with 12 AAC 02.310; payable to the "State of Alaska."

\$ 60.00	Nonrefundable application fee
<u>\$500.00</u>	License fee
\$560.00	Total required
3. Names and resumes of all owners, principal corporate officers, directors, or primary stockholders responsible for the wholesale drug facility.
4. Federal employer identification number.
5. Name and resume of the person who will manage the wholesale distribution of drugs and the wholesale drug facility.
6. Two sets of completed fingerprint cards of the facility manager
7. List of pharmacists working in the facility.
8. Completed self-inspection report

APPLICATION FOR CHANGE OF OWNERSHIP - In accordance with 12 AAC 52.040, when ownership of a facility changes, a new license is required. The existing license must be returned and a new application, along with the appropriate fees and supporting documentation, must be submitted. The following must be on file before the board may review the application for approval:

1. Completed application and supporting documentation (see 1 through 8 above).
2. Fees required in accordance with 12 AAC 02.310; payable to the "State of Alaska."

\$ 60.00	Nonrefundable application fee
<u>\$500.00</u>	License fee
\$560.00	Total required
3. Return of the existing Alaska wholesale drug distributor license that was issued under the former owner's application.

APPLICATION FOR CHANGE OF NAME OR LOCATION - In accordance with 12 AAC 52.030, when ownership of a pharmacy changes, a new license is required. The existing license must be returned and a new application, along with the appropriate fees and supporting documentation, must be submitted. The following must be on file before the board may review the application for approval:

1. Completed application and supporting documentation (see 1 through 8 above).
2. Fees required in accordance with 12 AAC 02.310; payable to the "State of Alaska."

\$ 60.00	Nonrefundable application fee
<u>\$ 5.00</u>	Duplicate License fee
\$ 65.00	Total required
3. Return of the existing Alaska wholesale drug distributor license that was issued under the former name or location.

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 from the division's website at <http://commerce.alaska.gov/dnn/cbpl/home.aspx> 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 on the Board of Pharmacy's website at <http://commerce.alaska.gov/dnn/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx>.

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.

FINGERPRINT CARD REQUIREMENTS

A wholesale drug distributor license application must be accompanied by two complete fingerprint cards for the facility manager. Take the fingerprint cards, these instructions, and photo identification to a local law enforcement or other authorized agency to have the fingerprinting done. Please follow these instructions carefully; the back of the fingerprint card has additional information.

Fingerprint cards that do not comply with the following will be rejected:

- Only State of Alaska cards may be used; other types of cards are not acceptable.
- No staples or staple holes are permitted in the fingerprint cards. Also, do not tape, tear, or fold the cards.
- Ensure that the prints are done properly and well. Poor quality prints, smudging, or incomplete fingerprints will cause the cards to be rejected.
- All information on the card is essential; incomplete cards will be rejected. Please type or print and sign in **BLACK INK only**. No other color is permitted. Complete all applicable sections of the top portion of the card as follows:

NAME: Enter the facility manager's last name followed by a comma (,) then first name and middle name (if any); suffix denoting seniority (Jr., Sr., II, etc.) follows the middle or first name.

SIGNATURE OF PERSON FINGERPRINTED: Must be signed in black ink.

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

DATE: Date fingerprinting was done.

EMPLOYER AND ADDRESS: Enter the name and address of the wholesale drug distributing facility.

REASON FINGERPRINTED: Enter **"Wholesale drug distributor facility manager, AS 12.62.160."**

ALIASES/AKA: List other names used by the facility manager that are different from the NAME block; also list maiden names and all previous married names. Enter **"Client #1344"** at the bottom of the block.

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

YOUR NO/OCA: Leave this space blank.

FBI NO/FBI: Enter the facility manager's assigned FBI number, if known.

ARMED FORCES NO/MNU: Leave this space blank.

SOCIAL SECURITY NO/SOC: List the facility manager's Social Security Number.

MIS NO/MNU: If the facility manager is an Alaska resident, enter the Alaska driver's license or state ID number.

ORIGINATING AGENCY IDENTIFIER (ORI): Cards are preprinted with AKAST0100, DPS, ANCHORAGE.

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

RACE: Enter race using one of the following one-character alphabetic o

A	=	Asian, Pacific Islander, Chinese, Japanese, Polynesian, Korean, Vietnamese
B	=	Black
I	=	American Indian, Alaska Native, Eskimo
W	=	White, Mexican, Latin, Puerto Rican, Cuban, Central/South American, and other Spanish cultures
U	=	Unknown

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

WEIGHT: Must be entered in pounds, fractions round off to the nearest pound.

EYES: Enter eye color using 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: Enter hair color using 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

DATE OF BIRTH/DOB: Enter birthdate as month, day, year. Note: If DOB is blank, the card will not be processed.

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.

FINGERPRINT IMPRESSION BLOCKS (Individual and simultaneous): It is very important that 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, neither too much nor too little pressure to make the impressions. To ensure legibility, all ten fingers must be rolled from nail to nail, and include the first flexion crease. Detail must be sufficient on all ten individual prints to clearly define the loop, whorl, arch, or other pattern. Roll the prints in the correct sequence (note the right- and left-hand designations in the finger blocks) and obtain simultaneous "plain" impressions. Indicate amputated finger(s) or finger(s) missing at birth.

REMEMBER: All instructions must be followed correctly. All information on the card is essential. Illegible, incomplete, or incorrect cards will be rejected and returned unprocessed.

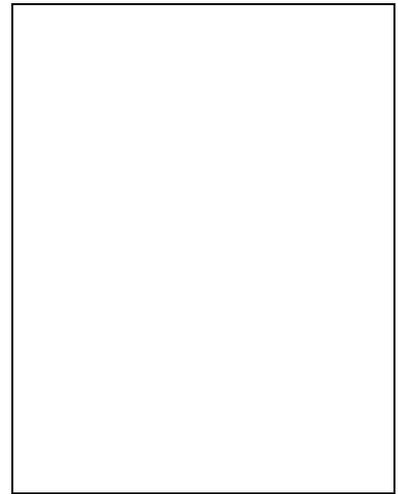


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WHOLESALE DRUG DISTRIBUTOR LICENSE APPLICATION

- Application options: New application - \$560.00, Changes, Change ownership - \$560.00, Name change only - \$65.00, Location change - \$65.00

THIS APPLICATION MUST BE COMPLETED IN FULL. If any section does not apply, please write N/A in the space provided. TYPE OR PRINT IN INK ALL INFORMATION. A personal check, certified check or money order payable to the "State of Alaska" MUST accompany this application.

Company/Owner Name: _____

Facility Name: _____ Facility Website: _____

Street Address: _____

Zip Code: _____

Mailing Address: _____

Zip Code: _____

Telephone Number: _____ Emergency Telephone Number: _____

Federal Employer Identification Number: _____

DEA Registration Number: _____

Email Agreement: By providing my email address below, I agree to receive correspondence on any matter affecting the facility license or other business with the Alaska Board of Pharmacy or the Alaska Division of Corporations, Business and Professional Licensing via email at this address. I agree to notify the Division in writing when my email address changes. I understand failure to check my email address or to keep it in good standing may result in an inability to receive crucial information, potentially resulting in the inability to obtain or retain licensure.

Print Facility Manager Email Address: _____

Ownership of Facility:

NOTE: Licenses are nontransferable and any change of name, location, ownership requires a new license.

- Sole Proprietorship
- Partnership
- Corporation
- LLC

Name of Owners/Partners/Officers

Title

Personnel:

Name of Facility Manager: _____ License Number: _____

Physical Address: _____

Telephone: _____ Email Address: _____

Professional Fitness:

The following questions must be answered. "Yes" answers may not automatically result in license 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. Online print outs are not acceptable. All disciplinary decisions or convictions must be reported to the board within thirty days, in accordance with 12 AAC 52.991.

1. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee 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 have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending? Yes No
2. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee 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 contendere or no contest, or having been given probation, a suspended imposition of sentence, or a fine. 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

WARNING: The Board of Pharmacy may deny, suspend, or revoke the license of a person who has obtained or attempted to obtain a license to practice by fraud or deceit. The person may also be subject to criminal charges for perjury or unsworn falsification. (AS 11.56.210 and AS 11.56.230)

I HEREBY CERTIFY that the information in this application is true and correct. I understand that any false or fraudulent information may result in failure to obtain licensure as a wholesale drug distributor in Alaska, or subsequent revocation of license. I understand that information supplied with this application is considered public, unless required to be kept confidential pursuant to state or federal law.

SIGN HERE 

Signature of Owner or Officer

SUBSCRIBED AND SWORN to before me this _____ day of _____, 20_____.

NOTARY SEAL

Notary Public

My Commission Expires: _____

SIGN HERE 

Signature of Facility Manager

SUBSCRIBED AND SWORN to before me this _____ day of _____, 20_____.

NOTARY SEAL

Notary Public

My Commission Expires: _____

ARTICLE 6. WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

Section

610. Wholesale drug distributor license

620. Wholesale drug facilities

625. Personnel requirements; grounds for denial or other disciplinary action

630. Drug storage

640. Written policies and procedures

645. Examination of drug shipments

650. Records and inventories

660. Returned, damaged, and outdated drugs

670. Drug recalls

680. Inspections

685. Prohibition against direct distribution

690. Salvage and reprocessing

695. Provisions not applicable

12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (a) An applicant for a wholesale drug distributor license shall

(1) apply on the form provided by the department;

(2) pay the fees required in 12 AAC 02.310;

(3) provide a list of the names and résumés of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provide the name and the résumé of the person who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submit a completed self-inspection of the premises questionnaire on a form provided by the department; and

(6) submit completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(b) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (a) of this section; and

(2) be registered with the DEA.

(c) Within 30 days of a change in facility manager, the new facility manager must meet the requirements of (a) (4) and (6) of this section.

12 AAC 52.620. WHOLESALE DRUG FACILITIES. (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR OTHER DISCIPLINARY ACTION. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs.

12 AAC 52.630. DRUG STORAGE. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements or official United States Pharmacopoeia (USP), 1995 revision, compendium requirements, to help ensure that the identity, strength, quality, and purity of the products are not affected. If a temperature requirement is not listed for a drug, the drug may be stored at controlled room temperature as defined in the USP.

(b) A wholesale drug distributor shall ensure that a separate quarantine storage area is provided for drugs that are deteriorated, outdated, damaged, misbranded, adulterated, or are in a secondary container that has been opened or the seal of which has been broken.

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored.

Editor's notes: A copy of the United States Pharmacopoeia may be obtained from the United States Pharmacopoeial Convention, Inc., P.O. Box 560, Williston, VT 05495.

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES. A wholesale drug distributor shall prepare and follow a written procedure to

- (1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;
- (2) identify, record, report to the board, and correct any error found in an inventory;
- (3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;
- (4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;
- (5) ensure the proper handling and disposal of returned drugs;
- (6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;
- (7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS. (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

12 AAC 52.650. RECORDS AND INVENTORIES. (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

- (1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;
 - (2) the identity and quantity of the drug received, distributed, or disposed of; and
 - (3) the date of receipt and of distribution or other disposition.
- (b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS. (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

- (1) a voluntary action on the part of the manufacturer;
- (2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or
- (3) the replacement of an existing drug with an improved drug or new package design.

12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

12 AAC 52.695. PROVISIONS NOT APPLICATIONS. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 –12 AAC 52.690:

- (1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;
- (2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this paragraph, "emergency medical reasons" includes a transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12-consecutive-month period;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.