



December 11, 2019

OUTSOURCING FACILITIES, THIRD-PARTY LOGISTICS PROVIDERS, & NON-RESIDENT WHOLESALE DRUG DISTRIBUTORS

FREQUENTLY ASKED QUESTIONS

- 1. I am already registered in Alaska as an out-of-state pharmacy. Do I need to maintain my non-resident pharmacy registration in addition to obtaining an outsourcing facility, third-party logistics (3PL), or non-resident wholesale drug distributor license? Separate licenses are required for separate lines of business services being provided. For example, if you are operating as a non-resident pharmacy in addition to acting as a wholesale drug distributor, you must submit a new application to be issued a license for providing wholesale drug distributor services. If you are a pharmacy, wholesale drug distributor, outsourcing facility, and third-party logistics provider, four separate applications and licenses would be required for each. If you are currently registered as a non-resident pharmacy but are exclusively providing non-resident wholesale drug distributor activities, a new application is required to update the pharmacy registration or license type. Once the new application is processed, your old registration or license will expire, and you will be operating under the new credentials issued by the board.**
- 2. Is there a grace period to register with any of these new license types?** The authority to regulate these new license types went into effect on July 1, 2019; however, applications were not made available until October 25, 2019, and regulations did not go into effect until October 31, 2019. The board has not issued an official grace period, but applications should be submitted as soon as possible as they are processed in the order received. Entities will not be penalized for not having an application submitted or license issued by October 31st.
- 3. What is the business license versus the professional license?** The professional license is the outsourcing facility, third-party logistics provider, or non-resident wholesale drug distributor license, which must be obtained first from the Board of Pharmacy before the business licensing section can issue a business license. After the professional license is issued, please contact the business licensing section ([link below](#)).
- 4. What is the processing time for these new license applications?** Please expect 4 – 10 weeks.
- 5. My payment was processed. Why hasn't my license been issued yet?** Our standard mail processing requires payment to be receipted before licensing staff has access to the accompanying application. It typically takes 3-7 days from the date payment and mail is initially processed to the date licensing staff has access to the documents in their electronic inbox.
- 6. How will I be notified of the status of my application?** As indicated above, licensing staff may not have access to your application for up to 7 days from the date it was received and your payment was processed. Licensing staff process applications in the order received and will send an email (if provided) to the applicant informing them of the status within 10 – 14 business days. Subsequent updates will be given as time permits.
- 7. What is the license approval process?** The board reviews applications only if there are circumstances requiring further review and discussion, such as affirmative responses to the professional fitness section of the application, which deals with adverse license actions and criminal history. The board reviews applications through their online review and voting platform, OnBoard, on a monthly basis beginning the second-to-last Friday of each month for a period of 10 – 15 days. Applications will only be uploaded for board review if they are complete. If the license is



approved, it may be issued within 14 days. Applications that don't require board review may be issued administratively.

8. **How can I check the status of my license?** Our professional license search page displays licenses that have already been issued (link below).
9. **Am I only able to request fingerprint cards through myAlaska?** No, you can also use the standard FBI fingerprint form #FD-258 revised 09/09/2013 or later.
10. **How long will it take to get my fingerprint results?** Once your fingerprint cards are submitted to the department, they will be sent to the Alaska Department of Public Safety (DPS). The processing time for DPS will be 3 - 4 months.
11. **Will the time it takes DPS to process fingerprints delay issuance of my license?** No, if a complete application is on file and we have received your fingerprint cards with ink, the license can be issued. If the results reveal information inconsistent with what was indicated on the professional fitness section of the application, the application will be reviewed by the division's investigative unit.
12. **If an adverse background report is received, what options do I have to challenge its accuracy or completeness?** For your FBI report you may contact the FBI directly at www.FBI.gov. For your report from DPS, you may contact the Division of Statewide Services at dps.alaska.gov/Statewide/R-I/Background/Home. Challenges may be given no later than 30 days after you have been notified by the department of an adverse report, or no later than the next board meeting, whichever occurs first.
13. **Is a virtual wholesale drug distributor considered a non-resident wholesale drug distributor?** The short answer is yes, virtual wholesalers must now pursue license by the board as a wholesale drug distributor. The board acknowledges that virtual wholesalers are largely defined as entities which purchase drugs and devices from manufacturers, but do not own the new drug application (NDA) or an abbreviated new drug application (ANDA). Virtual wholesalers facilitates or brokers the transfer of drugs, devices, or cosmetics without taking ownership of these products. While the board does not currently or explicitly define *virtual* wholesalers or address ownership of NDAs or ANDAs, they do define "wholesale drug distributor" under AS 08.80.480(4) as:

"anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions."

Furthermore, 12 AAC 52.620 indicates that a wholesale drug distributor facility includes entities, "...in which, drugs are stored, repacked, or sold to persons, business, or government agencies that may legally purchase drugs." As long as the virtual wholesaler is engaged in manufacturing, repackaging, distributing, warehousing, storing, selling, or purchasing drugs, a wholesale drug distributor license is required.

14. **Is a virtual manufacturer considered a non-resident wholesale drug distributor?** Yes, AS 08.80.480(4) includes manufacturers. The board acknowledges that virtual manufacturers own a new drug application (NDA) or abbreviated new drug application (ANDA), but do not take possession or store the drug or device. The board further acknowledges virtual manufacturers operate as entities in which act as a broker, own-label distributor, private-



label manufacturer, or contract manufacturer, and contracts with other entities for the actual manufacturing of drugs or devices. By virtue of definition in AS 08.80.480(4), virtual manufacturers would be required to pursue licensure by the board.

- 15. Would a virtual manufacturer or virtual wholesaler need to designate their intention to distribute controlled substances on the wholesale drug distributor application?** There is no requirement that manufacturers or wholesale drug distributors designate their *intent* to distribute controlled substances; however, non-resident wholesale drug distributors must be registered with the DEA if distributing controlled substances and must indicate this on the Alaska license application (form #08-4812).
- 16. Is it required to have a license if we *distribute* medical devices only, without drug components? If so, what type of license should we apply for?** The board requires a wholesale drug distributor license to distribute medical devices under (AS) 08.80.030(b)(9) and AS 08.80.157(a). Although it isn't specified under AS 08.80 whether it is required to have a license to distribute prescription devices with or without drug components, an instrument, apparatus, machine, etc. is in-part defined as a "device" so long as it is required to have on the label, "Caution: Federal or state law requires dispensing by or on the order of a physician." If the device isn't required to have this indicated on the label, the board doesn't consider it a device under the definitions section of AS 08.80.480. Similarly, (9) of that section states that distribution is the delivery of a drug or device, but doesn't specify whether it is considered distributing if the device has a drug component or not.
- 17. Is it required to be licensed if assembling, packaging, or labeling a device?** No, an outsourcing facility license is not required as AS 08.80.480(20) relating to compounding only applies to sterile drugs, not devices.
- 18. We are an outsourcing facility intending on compounding patient-specific prescriptions. Is this permissible in Alaska?** Outsourcing facilities compounding patient-specific medications are 503A facilities. The board addresses compounding of medications based on a historical basis of valid prescription drug orders (within a doctor-patient-pharmacist relationship) in their *Good Compounding Practices* published in February 2008, which are appended to their statutes and regulations (link below) and adopted by reference in 12 AAC 52.440. In this guidance, the board states that compounding drugs in an amount above what has historically been produced for the patient is considered manufacturing. Manufacturing is included in the definition of wholesale distribution under AS 08.80.480(40) and would require the entity to pursue licensure accordingly.
- 19. We are an entity that will engage in the compounding non-patient-specific medications. What type of application do we submit?** You must submit an outsourcing facility (form #08-4813) for non-patient-specific compounding. Outsourcing facilities are considered 503B facilities and are defined in AS 08.80.480(20) as, "a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location."
- 20. Can a third-party logistics provider own the drug or device product?** No, AS 08.80.480(38) indicates 3PLs cannot take ownership of the product and do not have the responsibility to direct the sale or disposition of the product.
- 21. Are there online applications available?** Not at this time. The only method to apply is by downloading the PDF version.
- 22. We are not VAWD accredited. Where can I find the Board of Pharmacy's self-inspection report for non-resident wholesale drug distributors?** The non-resident wholesale drug distributor inspection report is not available, but entities can submit the in-state inspection report (link below).



Important Links

Business Licensing: <https://www.commerce.alaska.gov/web/cbpl/BusinessLicensing/NewBLOnline.aspx>

Statutes and Regulations - <https://www.commerce.alaska.gov/web/portals/5/pub/PharmacyStatutes.pdf>

Pharmacy Homepage: <https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx>

Pharmacy ListServ: <http://list.state.ak.us/mailman/listinfo/akboardofpharmacy>

Self-Inspection Report: <https://www.commerce.alaska.gov/web/portals/5/pub/pha0098.pdf>.

myAlaska: <https://my.alaska.gov/>

Professional license search: <https://www.commerce.alaska.gov/cbp/main/>