



Notice of Proposed Changes in The Regulations of the Alaska Board of Pharmacy

Proposed Regulations - FAQ

March 2023

1. What is the purpose of the proposed regulations? What will this regulation do?

12 AAC 52.010. Classifications of licensure

- Requires an entity engaged in the manufacture of drugs or devices to obtain licensure as manufacturer. This includes:
 - existing licensees that are engaged in manufacturing services but are currently being regulated as wholesale drug distributor
 - new manufacturers seeking to provide services to Alaska
- To clarify the board's oversight of wholesale drug distributors, outsourcing facilities, third-party logistics providers (3PLs), and manufacturers as separate and distinct entities.
- This regulation will bring licensees into alignment with the requirements of national standards which leads to continuity of care from the local level across the national level. It supports consumer protection, supply chain entity accountability, and helps align the board with the requirements of the Drug Supply Chain Security Act (DSCSA).

12 AAC 52.020. Pharmacy license

- Removes the requirement for pharmacies to submit a new and separate initial application as a result of a change in name, ownership, or physical address, which currently results in a new license/registration number being assigned. Instead, the pharmacy must notify the board of the change in writing, which allows the pharmacy to maintain its license/registration #. If a change in physical address, the notification must include an attestation that a new inspection will be completed within 30 days of operating at its new location.
- To ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.
- This regulation will remove redundant requirements of submitting annual information for short periods of time after changes occur as well as set a 30 day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.120. Review of pharmacist intern license application

- This regulation will enable Pharmacy Interns to relinquish their Pharmacy Technician licenses without penalty or negative license disciplinary action.
- The purpose of this regulation is to provide Pharmacy Interns the opportunity to relinquish active Pharmacy Technician licenses without penalty.
- This regulation supports Pharmacy Interns in their path to becoming licensed Pharmacists. This regulation provides Pharmacist Interns an opportunity to relinquish their Pharmacy Technician licenses in an effort to alleviate the necessity of ensuring the requirements of the Pharmacy Technician license are maintained while at the same time practicing as a Pharmacy Intern.

12 AAC 52.200. Pharmacist-in-charge

- This regulation will expand the notification of change requirement of Pharmacists-in-Charge from 10 to 30 days from the date of assignment.
- The purpose of this regulation is to provide pharmacies more time to notify the Board of changes in Pharmacists-in-Charge and come in line with the similar requirement of other types of licensed facilities in the state of Alaska and other state Boards of Pharmacy.
- This regulation expands the window in which a pharmacist-in-charge can report a new appointment to the board. The extended timeframe will alleviate administrative processing pressures and lessen investigative complaints associated with delayed notifications.

12 AAC 52.220. Pharmacist interns

- This regulation repeals the requirement for pharmacist interns to submit a report of work experience 30 days following the completion or termination of an internship rotation.
- There is no requirement for pharmacist interns to accrue any certain number of hours once beginning an internship in the state. An intern wishing to apply in Alaska as a pharmacist by examination will not meet the requirement unless they have engaged in at least 1,500 hours of practice in pharmacy, which is a national standard.
- This regulation eliminates administrative paperwork and reduces follow-up documentation requirements for licensees.

12 AAC 52.250. Job shadowing in pharmacy

- This regulation repeals the job shadowing regulations for high-school level students.
- Student job-shadowing under a pharmacist is a career development opportunity managed by individual pharmacists and pharmacies. This regulation is being appropriately repealed as it serves only as a guideline for how to initiate a job shadow and does not authorize the licensure of students engaged in job-shadowing.
- This regulation allows pharmacies to manage student job shadowing opportunities independently.

12 AAC 52.300. License and registration renewal

- Adds manufacturer as a license type required to renew biennially on the date set by the board.
- The purpose of this regulation is to bring third party logistics providers (3PLs) and wholesale distributors into alignment with the requirements of the Drug Supply Chain Security Act (DSCSA) and ensure "Manufacturers" apply for licensure.
- Clarifies this regulation to bring third party logistics providers (3PLs) and wholesale distributors into alignment with the requirements of the Drug Supply Chain Security Act (DSCSA) and ensures "Manufacturers" apply for licensure.

12 AAC 52.420. Security

- Allows automated distribution kiosks to be kept outside of the secured prescription area of a pharmacy.
- This regulation removes redundancy in language addressing the security of prescriptions in pharmacies that utilize automated distribution kiosks and provides pharmacies with the opportunity to dispense prescriptions utilizing more efficient and secure means.

12 AAC 52.423. Remote pharmacy license

- Removes the requirement for pharmacies to submit a new and separate initial application as a result of a change in name, ownership, or physical address, which currently results in a new license/registration number being assigned. Instead, the pharmacy must notify the board of the change in writing, which allows the pharmacy to maintain its license/registration #. If a change in physical address, the notification must include an attestation that a new inspection will be completed within 30 days of operating at its new location.
- The purpose of this regulation is to ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.
- This regulation will remove requirements of submitting annual information for short periods of time after changes occur as well as set a 30-day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.530. Return or exchange of drugs

- Removes unnecessary language
- Simplifies regulation

12 AAC 52.595. Automated distribution kiosks

- Allows automated distribution kiosks to be kept outside of the secured prescription area of a pharmacy.
- This regulation adds language addressing the security of prescriptions in pharmacies that utilize automated distribution kiosks and provides pharmacies with the opportunity to dispense prescriptions utilizing more efficient and secure means.

12 AAC 52.596. Remodeling

- This regulation is proposed to amend and streamline the notification process during remodeling.
- This regulation amends language addressing the reporting requirements during remodeling

12 AAC 52.610. Wholesale drug distributor license

- This regulation is proposed to amend the term "facility manager" to "designated representative" to come into alignment with the national industry standard.
- Brings Alaska into alignment with the national industry standard

12 AAC 52.635. Designated representative

- This regulation is proposed to amend the term "facility manager" to "designated representative" to come into alignment with the national industry standard and ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.

- Brings Alaska into alignment with the national industry standard and will remove requirements of submitting annual information for short periods of time after changes occur as well as set a 30-day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.670. Drug recalls

- This section is proposed to be repealed.

12 AAC 52.696. Outsourcing facilities

- This regulation is proposed to amend the term "facility manager" to "designated representative" to come into alignment with the national industry standard and ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.
- Brings Alaska into alignment with the national industry standard and will remove requirements of submitting annual information for short periods of time after changes occur as well as set a 30-day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.697. Third-party logistics providers

- This regulation is proposed to amend the term "facility manager" to "designated representative" to come into alignment with the national industry standard and ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.
- Brings Alaska into alignment with the national industry standard and will remove requirements of submitting annual information for short periods of time after changes occur as well as set a 30-day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.698. Manufacturer license

- Adds manufacturer as a license type required to renew biennially on the date set by the board.
- The purpose of this regulation is to bring third party logistics providers (3PLs) and wholesale distributors into alignment with the requirements of the Drug Supply Chain Security Act (DSCSA) and ensure "Manufacturers" apply for licensure.
- Clarifies this regulation to bring third party logistics providers (3PLs) and wholesale distributors into alignment with the requirements of the Drug Supply Chain Security Act (DSCSA) and ensures "Manufacturers" apply for licensure.

12 AAC 52.800. Drug room license

- Removes the requirement for drug rooms to submit a new and separate initial application as a result of a change in name, ownership, or physical address, which currently results in a new license/registration number being assigned. Instead, the pharmacy must notify the board of the change in writing, which allows the pharmacy to maintain its license/registration #. If a change in physical address, the notification must include an attestation that a new inspection will be completed within 30 days of operating at its new location.
- The purpose of this regulation is to ensure proper notifications of changes in name, ownership, or physical addresses of pharmacies occur in a timely manner while at the same time combining

multiple regulations and removing redundant requirements of submitting annual information for short periods of time after changes occur.

- This regulation will remove requirements of submitting annual information for short periods of time after changes occur as well as set a 30-day standard for notification of changes while combining multiple regulatory sections into one section which will provide clarity to licensees.

12 AAC 52.855. Registration with the prescription drug monitoring program

- This regulation standardizes language and removes the requirement for a non-dispensing pharmacist to submit a dispensation exemption form at time of licensure. A pharmacist who has a change in dispensing status is required to register with the PDMP prior to dispensing.
- Brings Alaska into alignment with the national industry standard.

12 AAC 52.860. Access to and conditions for use of the prescription drug monitoring program

- This regulation standardizes language.
- Removes outdated language.

12 AAC 52.995. Definitions

- Provide definitions for “manufacturer”, “virtual manufacturer”, “virtual wholesaler”, “automated distribution kiosks”, and “designated representative”.
- Proposed to amend the term "facility manager" to "designated representative" to come into alignment with the national industry standard.
- Brings Alaska into alignment with the national industry standard.

2. What are the costs to comply with the proposed regulations?

Manufacturer license fees – \$100 initial application; \$550 initial biennial license; \$550 biennial license renewal.

3. When will the regulations be effective?

After the public comment deadline, comments received are compiled and given to the Board for consideration. The Board may adopt the regulation as written/publicly noticed, may amend and adopt them, choose to take no action, or may withdraw the proposed regulations in part or in its whole. After Board action, the adopted regulations goes to Department of Law (DOL) for final review/approval. DOL either approves or disapproves regulations. Once approved by DOL, it goes to the Lt. Governor for filing. Regulation takes effect on the 30th day after they have been filed by the Lt. Governor.

Do you have a question that is not answered here? Please email RegulationsAndPublicComment@alaska.gov so it can be added.