



Notice of proposed changes relating to the practice of pharmacy in the regulations of the Board of Pharmacy

Proposed Regulations - FAQ

April 2019

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

12 AAC 52.010. Classifications of licensure. The proposed regulations will add new licensing categories to comply with SB 37. New licensing categories will include outsourcing facilities, third-party logistics providers, and out-of-state wholesale drug distributors. Licensure requirements for these out-of-state license types are proposed to mirror those of in-state requirements.

12 AAC 52.050. Closed pharmacies. The proposed regulations is to change the requirement that when a pharmacy closes its business it must submit a form provided by the department. The form is necessary for administrative purposes and to ensure the safety of the public in properly closing a pharmacy once operations have concluded.

12 AAC 52.070. Application for pharmacist license by examination. The proposed regulations is to amend the checklist requirements for pharmacist license by examination application. This change will give more clear guidance to board staff in conducting preliminary reviews of applications in meeting criteria for licensure. There are no proposed changes to amend licensure qualifications.

12 AAC 52.095. Application for pharmacist license by reciprocity. The proposed regulations is to amend the checklist requirements for pharmacist license by reciprocity application. This change will give more clear guidance to board staff in conducting preliminary reviews of applications in meeting criteria for licensure. There are no proposed changes to amend licensure qualifications.

12 AAC 52.105. Temporary license for military personnel or the spouse of active military personnel. The proposed regulations is a new section to provide for a method to apply for licensure to an active duty military member or military spouse. This new section applies to pharmacists, pharmacy intern, and pharmacy technician license types and is supported in statute by AS 08.01.063.

12 AAC 52.110. Emergency pharmacist permit. The proposed regulations is to repeal the need to take the multi-state jurisprudence examination (MPJE). The MPJE requirement will ensure applicants are apprised of current state pharmacy law.

12 AAC 52.120. Review of pharmacist intern license application. The proposed regulations is to repeal the need to obtain sponsorship and add a new regulation that intern licenses supersede pharmacy technician licenses. This clarifies pharmacy practice roles between interns and pharmacists, allowing pharmacy interns who were previously licensed as a pharmacy intern to return their pharmacy technician license to the department.

12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs. The proposed regulations is to add new regulations around out of state licensed pharmacists providing proof of licensure when working for tribal health programs in this state. The board is currently unable to determine which pharmacists are working under the purview of the Indian Health Service, which makes identifying pharmacists required to register with the prescription drug monitoring program (PDMP) difficult. Requiring active employment notifications will help support a transparent workforce in Alaska, but will not impose any regulatory oversight of dispensers working in tribal facilities.

12 AAC 52.220. Pharmacist interns. The proposed regulations is to change the regulation that a pharmacist intern may perform any duties of a pharmacy technician. This will add clarification to scope of practice but does not expand scope of practice.

12 AAC 52.240. Pharmacist collaborative practice authority. The proposed regulations is to add that they can't result in a pharmacist dispensing or administering any schedule I, II, III, or IV controlled substance and acknowledging that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

12 AAC 52.340. Approved programs. The proposed regulations is to clarify the type of ACPE program certificates that are approved for continuing education. Proposed changes will provide more opportunity to pharmacists and pharmacy technicians to comply with continuing education requirements.

12 AAC 52.423. Remote pharmacy license. The proposed regulations is to remove the distance requirement for renewals.

12 AAC 52.425. Telepharmacy system for a remote pharmacy. The proposed regulations is to change employment requirements, shipping drugs to a remote pharmacy from the central pharmacy or wholesale distributor, maintaining records requirements, labelling requirements, and repealing the pharmacist-in-charge of the central pharmacy maintaining compliance.

12 AAC 52.465. Controlled substance prescription drug orders. The proposed regulations is a new regulation to allow partial filling of schedule II controlled substances.

12 AAC 52.470. Refills. The proposed regulations is to amend the ability to dispense up to a 100-day supply and can dispense any quantity with conditions. Changes to this section will help reduce prescription waste.

12 AAC 52.500. Transfer of a prescription drug order. The proposed regulations is to remove refills from what is allowed. Changes will allow clear guidance to access of prescription medications for patients and will assist in eliminating prescription waste, as well as prescription duplications.

12 AAC 52.510. Substitution. The proposed regulations is to add interchangeable biological products and repeal the requirement to dispense a less costly equivalent drug product over the prescribed.

12 AAC 52.530. Return or exchange of drugs. The proposed regulations is to change the ability of a patient to return medication to a pharmacy if it was filled incorrectly or was recalled by the manufacturer or FDA.

12 AAC 52.610. Wholesale drug distributor license. The proposed regulations is to amend the checklist requirements for wholesale drug distributor license application.

12 AAC 52.620. Wholesale drug facilities. The proposed regulations is to add the requirements that a wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must verify that the purchaser of the prescription drugs holds a valid license under AS 08. This will help ensure the public's safety.

12 AAC 52.625. Personnel requirements; grounds for denial or other disciplinary action. The proposed regulations is to introduce the manager position as a facility manager.

12 AAC 52.630. Drug storage. The proposed regulations is to amend temperature requirements be maintained to label requirements and remove USP that the board adopts by reference.

12 AAC 52.640 – 12 AAC 52.695. The proposed regulations in these sections are to amend authority citations to include AS 08.80.159, out-of-state wholesale drug distributors.

12 AAC 52.696. Outsourcing facilities. The proposed regulations is to establish application and requirements for outsourcing facility license.

12 AAC 52.697. Third-party logistics providers. The proposed regulations is to establish application and requirement for third-party logistics providers.

12 AAC 52.920. Disciplinary guidelines. The proposed regulations is to add sexual orientation or gender identity discrimination as a basis for potential disciplinary action and add civil fines associated with failure to meet continuing education requirements.

12 AAC 52.925. Grounds for denial or discipline for criminal history. The proposed regulations establishes newly defined grounds for denying or disciplining a licensee under the ability to practice competently and safely.

12 AAC 52.985. Emergency preparedness. The proposed regulations is to establish guidelines regarding emergency preparedness and what pharmacies can dispense under emergencies declared by the governor.

12 AAC 52.993. Executive Administrator. The proposed regulations is to establish the executive administrator duties.

12 AAC 52.995. Definitions. The proposed regulations adds a new definition for “facility manager” and “moral turpitude”.

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

For three new licensing categories: third-party logistics provider, outsourcing facility, and non-resident wholesale drug distributor, there will be \$100 initial application, \$600 initial biennial license, and \$600 biennial license renewal fees.

3. When will the regulations be effective?

After 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.