



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

### **Proposed Regulations - FAQ**

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*May 2022*

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

##### **12 AAC 52.020. Pharmacy license**

- Replaces copy of inspection report with an attestation
- Updates language from “facility” to “pharmacy”
- Clarifies that a pharmacy with a name change, ownership, or physical address change must apply for a new license (from 12 AAC 52.030 for change of facility location or name section and 12 AAC 52.040 for change of facility ownership)
- New checklist language added for executive administrator and board review/approval
- Reduce administrative burden and onerous paperwork requirements

##### **12 AAC 52.030. Change of pharmacy location or name**

- Repeals change of pharmacy location or name as the language will be amended and incorporated in 12 AAC 52.020; simplifies regulations
- Standardizes requirements for wholesalers to apply for a new license if there is a change of location or name (this is to repeal and adopt into 12 AAC 52.020)
- Reduce administrative burden and onerous paperwork requirements

##### **12 AAC 52.040. Change of pharmacy ownership**

- Repeals this section as it will be cleaned up and incorporated in 12 AAC 52.020
- Standardizes requirements for facilities to apply for a new license if there is a change in ownership (this is to repeal and adopt into 12 AAC 52.020)
- Reduce administrative burden and onerous paperwork requirements

##### **12 AAC 52.070. Application for pharmacist license by examination**

- Removes the transcript and diploma requirements (NABP already requires these for scheduling exams)
- Clarifies diploma requirement for foreign graduates
- Allows verification of experience signed by employer/school to come from applicant instead of coming directly from verifier
- New checklist language added for executive administrator and board review/approval

- Replaces the requirement to have verification of 1,500 academic hours submitted by the pharmacy school on behalf of the applicant with an attestation from the applicant the hours were completed
- Clarifies applications can be administratively approved by the executive administrator under certain circumstances
- Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacists are needed to provide adequate patient care
- Reduces regulatory barriers to licensure and simplifies administrative processing of applications
- Removes redundancies for applicants

**12 AAC 52.080. Internship requirements for a pharmacist license**

- Repeals the section on internship requirements in 12 AAC 52.080 because changes proposed in 12 AAC 52.070(b)(6) already includes the requirement for the intern to attest they've completed all hours required for graduation from a pharmacy program; all pharmacy programs require at least 1,500 hours of instruction of practice
- Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacist interns are needed to provide adequate patient care
- Reduces regulatory barriers to licensure and simplifies administrative processing of applications

**12 AAC 52.092. Eligibility to sit for examination**

- Removes redundant language already in 12 AAC 52.070
- Updates language from “approval” to “eligibility” consistent with NABP terminology
- New checklist language added to clarify eligibility requirements
- Reduce administrative burden and onerous paperwork requirements
- Removes redundancies for applicants

**12 AAC 52.095. Application for pharmacist license by reciprocity**

- Removes the authorization for release of records requirement
- Removes the transcript and diploma requirement (NABP already requires these for scheduling exams)
- Clarifies diploma requirement for foreign graduates
- Allows verification of experience signed by employer/school to come from applicant instead of coming directly from verifier
- Clarifies applications can be administratively approved by the executive administrator under certain circumstances
- Removes the verification of licensure requirement and instead accepts the license transfer application
- Removes the requirement to document verification of experience and instead accepts an indication the applicant has graduated from a pharmacy curriculum
- Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacists are needed to provide adequate patient care
- Reduces regulatory barriers to licensure and simplifies administrative processing of applications

**12 AAC 52.120. Review of pharmacist intern license application**

- Removes checklist language.
- Clarifies applications can be administratively approved by the executive administrator under certain circumstances.
- Clarifies current pharmacy students and students who have graduated within a year of application may apply for an intern license.

- Removes the authorization of release of records requirement
- Extends the duration of the license from two years to five years
- Removes the affidavit of moral character requirement
- Clarifies that a pharmacist intern licensee cannot renew their license; they must reapply for licensure if the license is still needed after 5 years
- Supports the ease of qualified applicants to staff pharmacies and other institutions where pharmacist interns are needed to provide adequate patient care
- Reduces regulatory barriers to licensure and simplifies administrative processing of applications

**12 AAC 52.130. Registration of pharmacies located outside of the state**

- Simplifies fee language
- Accepts a copy of license in jurisdiction rather than requiring a certified copy
- Replaces copy of inspection report with an attestation
- Removes onerous requirements, reduces administrative burden.

**12 AAC 52.140. Pharmacy technician license**

- Removes redundant renewal language
- Adds administrative/executive checklist language
- Creates processing efficiencies

**12 AAC 52.200. Pharmacist-in-charge**

- Removes redundant language in (a) since this is already addressed in 12 AAC 52.020
- Replaces "ensuring" with "establishing"
- Removes requirement to furnish names of all pharmacists employed by pharmacy upon request as the intent behind this is unclear; if it is for investigative purposes, this is already part of the process
- Clarifies a change form must be submitted for licensed (in-state) and registered (out-of-state) pharmacies
- Adds language to limit the number of locations a pharmacist may be the pharmacist-in-charge for/creates a mechanism to request permission to be responsible for more than one pharmacy
- Clarifies pharmacist-in-charge duties and limits the number of pharmacies a pharmacist can be responsible for to ensure adequate oversight of pharmacy personnel and patient care

**12 AAC 52.230. Pharmacy technicians**

- Clarifies duties requiring a pharmacy technician license
- Clarifies who may qualify to be a pharmacy technician

**12 AAC 52.240. Pharmacist cooperative practice authority**

- Conforms title to State Medical Board regulation, 12 AAC 40.983 by replacing "collaborative" with "cooperative"
- Removes redundant language that is already in 12 AAC 40.983
- Removes requirement for board to approve the agreement and instead endorses it if approved by the medical board
- Adds requirement for applicant to provide documentation the medical board or its delegate approved the agreement
- Reduces regulatory barriers, streamlines the approval process, and supports access to certain types of care

**12 AAC 52.470. Refills**

- Removes unnecessary language; simplifies regulation

**12 AAC 52.585. Patient counseling**

- Obligates a pharmacist or pharmacist intern to offer but not provide patient counseling
- Removes examples of the topics that may be included in counseling
- Clarifies the methods in which counseling can take place, e.g.: verbal, written, electronic
- Adds requirements for patient counseling when an opioid is being dispensed for the first time
- Simplifies regulations and adds mandatory counseling for opioids to educate the public on risks of use

**12 AAC 52.610. Wholesale drug distributor license**

- Clarifies applications can be administratively approved by the executive administrator under certain circumstances
- Removes notary requirement
- Removes requirement to provide names and resumes for facility managers, officers, directors, or primary stockholders
- Removes the requirement to provide an inspection report and instead accepts an attestation that either a self-inspection or VAWD inspection was completed
- Removes the requirement to submit fingerprints
- Clarifies that within 30 days of a change in location, ownership, or name, the wholesaler must apply for a new and separate license
- Removes requirement for the new facility manager to submit a new application as a result in a change
- Simplifies regulations and reduces barriers to providing medications to pharmacies

**12 AAC 52.620. Wholesale drug facilities**

- Include devices to the wholesale drug facilities regulations

**12 AAC 52.635. Facility manager**

- Creates a new section for facility manager
- Creates standardization amongst facilities to submit a change in facility manager form within 10 days (is currently in 12 AAC 52.610 for wholesalers with a 30-day timeframe, 12 AAC 52.696 with a 10-day requirement for outsourcing facilities, and in 12 AAC 52.697 with a 10-day requirement for 3PLs)
- Allows a facility manager to be in charge of more than one location
- Standardizes regulations

**12 AAC 52.696. Outsourcing facilities**

- Clarifies applications can be administratively approved by the executive administrator under certain circumstances
- Removes notary requirement
- Removes requirement to provide names and resumes for facility managers, officers, directors, or primary stockholders
- Removes the requirement to provide an inspection report and instead accepts an attestation that a self-inspection was completed
- Removes the requirement to submit fingerprints
- Clarifies that within 30 days of a change in location, ownership, or name, the wholesaler must apply for a new and separate license

- Removes requirement for the new facility manager to submit a new application as a result in a change
- Corrects the FDA citation
- Simplifies regulations and reduces barriers to providing medications to pharmacies

**12 AAC 52.697. Third-party logistics providers**

- Removes notary requirement
- Removes requirement to provide list of officers, directors, or stockholders
- Removes fingerprint requirement
- Removes resume requirement
- Replaces copy of inspection report with an attestation.
- Removes language regarding DEA registration (already a DEA requirement, board does not require documentation)
- Adds language addressing new license when change occurs
- Reduces onerous paperwork requirements, alleviates time constraints by expanding change deadline from 10 days to 30 days
- Removes onerous paperwork requirements, improves administrative efficiencies, removes redundant language

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

- Add a definition for “state medical examiner”

**12 AAC 52.865. Reporting and reviewing PDMP information**

- Update the reporting and reviewing of PDMP information

**12 AAC 52.990. Display of license certificate**

- Remove outdated language and regulations

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

None known.

**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](mailto:RegulationsAndPublicComment@alaska.gov) so it can be added.