



DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING Juneau Office

> P.O. Box 110806 Juneau, AK 99811-0806 Main: 907.465.2550 Toll free fax: 907.465.2974

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

## **Proposed Regulations - FAQ**

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

## 12 AAC 52.235. Pharmacy technician with national certification

• This amendment will allow pharmacy technicians with a national certification to perform a final check of and distribute a non-controlled substance prescription if the pharmacy uses software that displays the image or graphical description of the correct drug being verified or the institutional facility uses software that performs and verifies a barcode scan before administration.

• With this barrier removed, pharmacies will be more efficient which will benefit patients throughout Alaska.

## 12 AAC 52.240. Pharmacist collaborative practice authority

• This amendment will remove the requirement for Board approval of collaborative practice agreements, and will clarify that the written protocol only need be submitted to the Board for awareness purposes.

• This change will allow pharmacists to practice at the top of their scope of practice, which will improve patient care, remove administrative burden, and improve efficiency, benefitting patients throughout Alaska.

## 12 AAC 52.430. Guidelines relating to sterile pharmaceuticals

• This amendment will remove the reference to the document adopted by reference "Sterile Pharmaceuticals", dated February 2008, and instead clarify that pharmacies and pharmacists preparing or dispensing sterile pharmaceuticals adhere to the acceptable standard of care defined in 12 AAC 52.995(a).

• This will ensure that pharmacies and pharmacists are following up to date guidelines.

## 12 AAC 52.698. Manufacturer license

This change will add the requirement that an applicant for a manufacturer license must submit the results of the most recent Good Manufacturing Practice (GMP) inspection by the FDA.
This requirement will bring manufacturer regulations into alignment with outsourcing facilities requiring GMP inspection results being made available to the board. This will ensure licensed manufacturing facilities are following FDA GMP guidelines.

#### 12 AAC 52.855. Registration with the prescription drug monitoring program

• This change will clarify the language outlining who is required to register with the Prescription Drug Monitoring Program (PDMP).

• This clarification will relieve administrative burden for PDMP staff, as well as for licensed pharmacists who do not dispense controlled substances in Alaska.

## 12 AAC 52.930. Terms of probation

• Proposes a technical change to replace the obsolete term 'will, in it's discretion' with 'may'.

## 12 AAC 52.940. Use of alcohol or controlled substances

• The addition of this regulation will allow the board to grant non-punitive alternatives to probation for licensees that self-refer for addiction treatment. This will enable the licensee to receive assistance with their recovery and addiction while still maintaining the ability to practice safely in Alaska.

• Punitive actions hurt Alaska and Alaskans by removing otherwise fully functioning licensees from pharmacies due to license actions. This regulation will open the opportunity for those that have identified a need for care to receive that care while continuing to practice and serve Alaskans.

• This will keep pharmacies open, pharmacists practicing safely, and result in less interrupted patient care. This is an opportunity to remove the stigma associated with addiction and treat it in the same manner as all other health related issues.

## 12 AAC 52.995. Definitions

• This change will add a clarification of the word 'ownership' as referenced in AS 08.80.480 and add a definition for the term 'change of ownership'.

• Currently, the terms are unclear which creates confusion for licensed facilities, pharmacies, and licensees as to when they are required to report changes, and at what level of change they are required to report. This confusion creates additional work for licensing staff, as processing changes on every level is an administrative burden that takes time away from processing licenses.

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

There are no known costs to implement these changes.

## 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 <u>RegulationsAndPublicComment@alaska.gov</u> so it can be added.