

IDAPA 27 – BOARD OF PHARMACY

27.01.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1701

NOTICE OF INTENT TO PROMULGATE RULES – NEGOTIATED RULEMAKING

AUTHORITY: In compliance with Sections 67-5220(1) and 67-5220(2), Idaho Code, notice is hereby given that this agency intends to promulgate rules and desires public comment prior to initiating formal rulemaking procedures. This negotiated rulemaking action is authorized pursuant to Section 54-1717, Idaho Code.

MEETING SCHEDULE: A public meeting on the negotiated rulemaking will be held as follows:

Tuesday, August 1, 2017 - 8:00 a.m. (MDT)

**Idaho State Capitol Building
Room WW53
514 West Jefferson
Boise, ID 83702**

The meeting site will be accessible to persons with disabilities, if needed. Requests for accommodation must be made not later than five (5) days prior to the meeting to the agency address below.

METHOD OF PARTICIPATION: Persons wishing to participate in the negotiated rulemaking must do the following:

All written comments received by July 14, 2017 will be included in the Board's distributed meeting materials for consideration. Written comments received between July 15, 2017 and July 31, 2017 will be printed and distributed to Board members at the meeting. For those planning to attend the open, public meeting, written and verbal comments will be accepted by and/or presented before the Board.

Upon conclusion of the negotiated rulemaking, any unresolved issues, all key issues considered, and conclusion reached during the negotiated rulemaking will be addressed in a written summary. The summary will be made available to interested persons who contact the agency or, if the agency chooses, the summary may be posted on the agency website.

DESCRIPTIVE SUMMARY AND STATEMENT OF PURPOSE: The following is a statement in nontechnical language of the substance and purpose of the intended negotiated rulemaking and the principal issues involved:

The Board of Pharmacy is considering dividing its current rulebook into seven (7) different chapters grouped by subject matter. The Board does not intend to add any new regulatory requirements as part of this rulemaking; instead, as the Board better organizes its rules into chapters, it aims to simultaneously eliminate outdated regulations and those that stifle the emergence of new technology or practice models that can improve public health. The Board envisions its chapters as follows:

1. Rules of Procedure
2. Rules Governing Licensing and Registration
3. Rules Governing Pharmacy Practice
4. Rules Governing Pharmacist Prescriptive Authority
5. Rules Governing Drug Compounding
6. Rules Governing DME, Manufacturing, and Distribution
7. Rules Governing Veterinary Drug Outlets

Prior to the meeting, the Board will post drafts of all chapters on its website (<https://bop.idaho.gov/>), along with a rules crosswalk to help members of the public more easily identify what rules are proposed to be eliminated and what chapter the remaining rules are slated for.

Members of the public are encouraged to review the Board's minutes from its open, public meetings in 2017 for more background information on the Board's approach to rulemaking, specifically:

- January 13, 2017 – Licensing Strategic Planning Meeting: https://bop.idaho.gov/board_meeting/2017-04-18_Approved-Minutes_January%2012-%2013.pdf
- March 9, 2017 – Permissionless Innovation Strategic Planning Meeting: https://bop.idaho.gov/board_meeting/2017-04-18_Approved-Minutes_March%2009.pdf

Major areas of rulemaking under consideration are briefly summarized below for each individual chapter.

Chapter 1. Rules of Procedure

The Board proposes to:

- Remove definitions that merely duplicate those already defined in Sections 54-1705 and 37-2701, Idaho Code;
- Add definitions for 'ACCME,' 'CLIA-Waived Test,' 'Clinical Guidelines,' 'CPE Monitor,' and 'Student Technician;' and
- Unprofessional Conduct is proposed to be expanded to include provisions related to 'Standard of Care' and 'Unnecessary Services or Products.'

Chapter 2. Rules Governing Licensing and Registration

The Board proposes to eliminate several categories of licensure or registration. Such elimination does not mean that these activities cannot occur; it merely removes the need for a separate government permission slip prior to engaging in these activities as it relates to the practice of pharmacy. The licenses and registrations proposed to be eliminated include:

- Nursing Home
- Non-Pharmacy Retail Outlet
- Veterinary Drug Technician
- Pharmacist Controlled Substances Registration
- Distributor Controlled Substances Registration

With the elimination of the pharmacist and distributor controlled substances registrations, the Board proposes to bundle these with the pharmacist license and manufacturer/wholesaler registrations, respectively, so that duplicative work is not needed by the licensee/registrant and Board staff. Fees for these license types would be adjusted so that the end result is budget neutral. The Board also proposes to set the fee for prescriber drug outlets at \$100 to cover the costs associated with on-site inspections prior to opening and annually thereafter.

The Board also proposes to amend the annual renewal deadline as follows (unless otherwise stated):

- Individuals: by the end of their birth month.
- Facilities: by December 31.

For individual licenses and registrations, the Board proposes to:

- Streamline pharmacist continuing education requirements by removing all specifically delineated requirements, and remove Board-approved credits, which duplicates a service provided commonly and more effectively by the private sector;
- Consolidate externs and interns into a single license type, now called 'pharmacist interns;' and
- Cap the technician-in-training registration period at two (2) years from the date of issuance, remove the employer requirement, and create a student technician category for individuals who are enrolled in a school-supervised program.

For facility licenses and registrations, the Board proposes to:

- Enable a temporary license number so that pharmacies can start health plan contracting prior to opening;
- Remove the requirement that a floor plan must be submitted to, and approved by, Board staff prior to a remodel; and
- Streamline the process for permanently closing a pharmacy.

Chapter 3. Rules Governing Pharmacy Practice

The Board proposes to eliminate regulations related to the *business* of pharmacy, specifically removing outdated

provisions or those that have become obsolete in a rapidly changing technology environment. For example, delineated requirements related to specific fixtures, books, equipment, or staffing patterns that pharmacies must have are proposed to be removed, and instead left to the discretion of the PIC and the prevailing community standard of care.

The Board proposes to remove delineated technology-specific regulations, and business model-specific regulations, and instead focus on “what” needs to occur as a means to improve public safety, as opposed to “how” or “where” it occurs.

Chapter 4. Rules Governing Pharmacist Prescriptive Authority

The Board proposes to draft new rules to implement the intent of House Bill 191, which passed in the 2017 legislative session with wide margins (69-0 and 33-1). This bill amended Section 54-1704, Idaho Code, and provided the Board of Pharmacy with rulemaking authority to designate drugs, drug classes, and devices that pharmacists may prescribe, provided certain conditions are met. The Board proposes to adopt some general requirements that would apply to all drugs or devices added to the rules, specifically regarding pharmacist education, patient assessment, collaboration, notification, and documentation. The Board will also take an evidence-based approach to proposing specific drugs and devices to add to the rules.

Chapter 5. Rules Governing Drug Compounding

The Board proposes no substantive changes to the drug compounding rules.

Chapter 6. Rules Governing DME, Manufacturing, and Distribution

The Board proposes no substantive changes to the rules governing DME, manufacturing, and distribution.

Chapter 7. Rules Governing Veterinary Drug Outlets

The Board proposes no substantive changes to the rules governing veterinary drug outlets, aside from removing references to Veterinary Drug Technicians, as this category of registration is proposed to be cut in Chapter 2, as described previously.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS, OBTAINING DRAFT COPIES: For assistance on technical questions concerning this negotiated rulemaking or to obtain a preliminary draft copy of the rules text, if available, contact Alex Adams at (208) 334-2356. Materials pertaining to the negotiated rulemaking, including any available preliminary rule drafts, can be found on the Board of Pharmacy website at the following web address: <http://bop.idaho.gov>.

Anyone may submit written comments regarding this negotiated rulemaking. All written comments must be directed to the undersigned and must be delivered as described above.

DATED this 3rd day of May 2017.

Alex Adams, Pharm D, MPH
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536