IDAPA 27 – BOARD OF PHARMACY

27.01.02 – RULES GOVERNING LICENSURE AND REGISTRATION DOCKET NO. 27-0102-1802 (FEE RULE) NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING Wednesday, October 24, 2018 – 1:00 p.m. (MDT)

Idaho State Capitol Building Room WW53 700 W. Jefferson Street Boise, ID 83702

Written comments received by October 15, 2018, will be included in the Board's distributed meeting materials for consideration. Written comments received between October 15, 2018, and October 24, 2018, 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.

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

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

With the proposed repeal of IDAPA 27.01.06, "Rules Governing Durable Medical Equipment (DME), Manufacturing, and Distribution," updates are needed in this chapter to retain critical rules from the chapter related to pharmaceutical manufacturer registration. The rules also eliminate the Multistate Pharmacy Jurisprudence Exam (MPJE) as a precondition to pharmacist licensure, a change that is consistent with nearly every other Idaho health profession. Additional technical corrections are made.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

This fee is being imposed pursuant to Section 54-1720, Idaho Code. The fee for a nonresident pharmacist registration is being increased from \$250 to \$290. The Board eliminated the requirement for pharmacists to obtain a controlled substances registration as of July 1, 2018. This proposed rule adjusts the nonresident pharmacist registration to \$290. Nonresident pharmacists who previously held both the pharmacist registration and a separate controlled substance registration will still realize a net savings of \$20 per year.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year as a result of this rulemaking: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018 Idaho Administrative Bulletin, **Vol. 18-7**, pages 156-157.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Alex Adams, Executive Director, at (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 24, 2018 as described above.

Dated this 30th day of August 2018.

Alex J. 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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0102-1802 (Only Those Sections With Amendments Are Shown.)

023. FEE SCHEDULE.

01. Licenses and Registrations -- Professionals.

License/Registration	Initial Fee	Annual Renewal Fee	
Pharmacist License	\$140	\$130	
Nonresident Pharmacist PIC Registration	\$2 <mark>59</mark> 0	\$2 <mark>59</mark> 0	
Pharmacist Intern	\$50	\$50	
Technician	\$35	\$35	
Practitioner Controlled Substance Registration	\$60	\$60	

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02. Certificates of Registration and Licensure -- Facilities.

License/Registration	Initial Fee Annual Renewal Fee	
Drug Outlet (unless otherwise listed)	\$100	\$100
Wholesale License	\$180	\$180
Wholesale Registration	\$150	\$150
Central Drug Outlet (Nonresident)	\$500	\$250
Mail Service Pharmacy	\$500	\$250

License/Registration	Initial Fee	Annual Renewal Fee
Durable Medical Equipment Outlet	\$50	\$50
Outsourcing Facility (Nonresident)	\$500	\$250
Manufacturer	\$150	\$150
Veterinary Drug Outlet	\$35	\$35

(7-1-18)

03. Late Fees and Reinstatements.

Category	Fee
Late payment processing fee	\$50
License or registration reinstatement fee	One-half (1/2) of the amount of the annual renewal

(7-1-18)

04. Administrative Services.

Category	Fee
Experiential hours certification	\$25
Duplicate pharmacist certificate of licensure	\$35

(7-1-18)

024. -- 029. (RESERVED)

030. DETERMINATION OF NEED FOR PHARMACIST LICENSE, NONRESIDENT REGISTRATION, OR NEITHER.

- **01. Practice in Idaho**. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws. (7-1-18)
- **02. Nonresident Pharmacists.** All nonresident pharmacists practicing pharmacy into the state of Idaho must be licensed in their state of practice and must additionally be licensed or registered in Idaho as follows: (7-1-18)
- **a.** Independent Practice. Pharmacists must be licensed if engaged in the independent practice of pharmacy across state lines and not practicing for an Idaho registered drug outlet. (7-1-18)
- **b.** Practice for an Idaho Registered Drug Outlet. A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be *licensed or* registered to practice into Idaho. All other nonresident pharmacists who are employed by, or affiliated with, and practicing for the Idaho registered nonresident drug outlet, but who are not the PIC, are exempt from license and registration requirements for practice into Idaho.

(7-1-18)()

O3. Exemption from Separate Controlled Substance Registration. All pharmacists who are practicing in or into Idaho are exempt from obtaining a separate controlled substance registration, but must maintain compliance with all requirements under Title 37, Chapter 27, Idaho Code. (7-1-18)

031. PHARMACIST LICENSURE BY EXAMINATION.

To be considered for licensure, a person must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, and submit to the Board an application for licensure by examination. (7-1-18)

- **01. Graduates of U.S. Pharmacy Schools.** An applicant must be a graduate of an ACPE-accredited school or college of pharmacy within the United States. (7-1-18)
- **O2. Graduates of Foreign Pharmacy Schools.** An applicant who is a graduate of a school or college of pharmacy located outside of the United States must submit certification by the FRGEC, and verification of completion of a minimum of seventeen hundred forty (1,740) experiential hours. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours.

 (7-1-18)
- **03. Licensure Examinations.** Qualified applicants must pass the NAPLEX and the MPJE in accordance with NABP standards. A candidate who fails the NAPLEX three (3) times must complete at least thirty (30) hours of continuing education accredited by an ACPE-accredited provider prior to being eligible to sit for each subsequent reexamination. Candidates are limited to five (5) total NAPLEX attempts to pass each exam.

(7-1-18)(____)

032. PHARMACIST LICENSURE BY RECIPROCITY.

An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and this rule to obtain an Idaho license. An applicant whose pharmacist license is currently restricted by a licensing entity in another state must appear before the Board to petition for licensure by reciprocity. (7-1-18)

- **01. Transfer Application**. The applicant must submit a preliminary application for licensure transfer through NABP. (7-1-18)
 - **62.** MPJE. The applicant must pass the Idaho based MPJE within five (5) total attempts. (7-1-18)
- **032. Intern Hours.** An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may also be required to complete intern hours for each year away from the practice of pharmacy.

 (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

034. PHARMACIST LICENSE: REINSTATEMENT.

The Board may, at its discretion, consider reinstatement of a pharmacist license upon receipt of a completed application, background check, and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested.

(7-1-18)

- **01. Satisfactory Evidence**. Reinstatement applicants must provide satisfactory evidence of completion of a minimum of thirty (30) CPE hours within the twenty-four (24) months prior to reinstatement and compliance with any direct orders of the Board. (7-1-18)
- **O2.** Additional Requirements. A pharmacist reinstatement applicant may be required to appear before the Board. If a pharmacist license has lapsed for more than twenty four (24) months, the applicant must pass the MPJE prior to returning to practice. The Board may also, at its discretion, impose additional requirements on a pharmacist reinstatement applicant who has not practiced as a pharmacist for the preceding twelve (12) months or longer that may include taking and passing an examination, completion of intern hours, completion of additional CPE hours, or other requirements determined necessary to acquire or demonstrate professional competency.

(7-1-18)(_____

035. NONRESIDENT $\frac{PHARMACIST}{PIC}$ REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.

To be registered to practice pharmacy into Idaho as a nonresident PIC, an applicant must submit an application on a Board form including, but not limited to:

(7-1-18)(_____)

- **01. Individual License Information**. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (7-1-18)
- **02. Facility License Information**. The license or registration number of the facility for which the applicant will be practicing. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

080.	MANUFA	CTURER	REGISTR	ATION.
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- <u>01.</u> <u>Resident Manufacturers.</u> A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing.
 - <u>02.</u> <u>Nonresident Manufacturers.</u> Non-resident manufacturers <u>must be registered as follows:</u> (
- <u>b.</u> Those engaged in wholesale distribution must be registered as a manufacturer and comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. (____)