Dear Senators VANORDEN, Wintrow, and
Representatives VANDER WOUDE, Erickson, Chew:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Division of Occupational and Professional Licenses - Pharmacy, Board of:

IDAPA 24.36.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 24-3601-2301).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 12/29/2023. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 01/26/2024.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4854, or send a written request to the address on the memorandum attached below.

Terri Kondeff
Director

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Senior Legislative Drafting Attorney - Jill Randolph

DATE: December 12, 2023

SUBJECT: Division of Occupational and Professional Licenses - Pharmacy, Board of

IDAPA 24.36.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 24-3601-2301)

Summary and Stated Reasons for the Rule

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 24.36.01. The proposed rule allows for delegation of services and duties to appropriate personnel and deletes the requirement a pharmacist or prescriber verify a compound drug. The agency notes these changes were waived for one provider under the current rule, and this proposed rulemaking will extend the waiver to allow all similarly situated persons to derive the same benefit.

Negotiated Rulemaking / Fiscal Impact

The agency states negotiated rulemaking was not conducted as this rulemaking is mandatory under section 67-5230, Idaho Code, which provides for petition for adoption, amendment, repeals, of waiver of rules. There is no anticipated negative fiscal impact to the General Fund for this proposed rule.

Statutory Authority

This rulemaking appears to be authorized pursuant to section 54-1717, Idaho Code.

cc: Division of Occupational and Professional Licenses - Pharmacy, Board of
Katie Stuart

***** PLEASE NOTE *****

Per the Idaho Constitution, all administrative rules may be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: **1)** Approve the docket in its entirety; **2)** Reject the docket in its entirety; or **3)** Reject the docket in part.

IDAPA 24 – DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

24.36.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 24-3601-2301

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. This rulemaking action is authorized pursuant to Section 67-2604, Idaho Code, and Sections 37-2702, 37-2715, 54-1717, 54-1753, and 54-1755, 67-2614, 67-9406 and 67-9409, Idaho Code.

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

Thursday, December 14, 2023, 10:00 a.m. MT

Division of Occupational and Professional Licenses
Chinden Campus Building 4
11341 W. Chinden Blvd., Bldg. #4
Boise, ID 83714

Telephone and web conferencing information will be posted on:
https://dopl.idaho.gov/calendar/ and https://townhall.idaho.gov/

The hearing 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.

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

This rulemaking is being done pursuant to Section 67-5230, Idaho Code. The Idaho State Board of Pharmacy recently granted a waiver of IDAPA 24.36.01.301.04. Pursuant to Section 67-5230, Idaho Code, the Board has initiated rulemaking proceedings to allow all similarly situated persons to derive the same benefits granted to the individual who petitioned for the waiver.

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

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(2), Idaho Code, negotiated rulemaking was not conducted because this rulemaking is mandatory pursuant to Section 67-5230, Idaho Code.

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, OBTAINING DRAFT COPIES: For assistance on technical questions concerning this proposed rule, contact Katie Stewart, Bureau Chief, at (208) 577-2489. Materials pertaining to the proposed rulemaking, including any available preliminary rule drafts, can be found on the following DOPL website: https://dopl.idaho.gov/rulemaking/.

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 December 27, 2023.

DATED this 14th Day of November, 2023.

Katie Stuart
Bureau Chief- Administration
11341 W. Chinden Blvd., Bldg. #4
Boise, ID 83714
Phone: (208) 577-2489
Email: katie.stuart@dopl.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 24-3601-2301
(Only Those Sections With Amendments Are Shown.)

011. DEFINITIONS AND ABBREVIATIONS (O – Z).
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms have the meanings set forth below: (3-28-23)

01. Parenteral Admixture. The preparation and labeling of sterile products intended for administration by injection. (3-28-23)

02. Pharmaceutical Care Services. A broad range of services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients consistent with Rule 100. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and also encompasses services provided by way of DTM under a collaborative practice agreement. Pharmaceutical care services are not limited to, but may include one (1) or more of the following: (3-28-23)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities or testing; (3-28-23)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-28-23)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-28-23)

d. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; (3-28-23)

e. Ordering and interpreting laboratory tests; (3-28-23)

f. Performing drug product selection, substitution, prescription adaptation, or refill authorization as provided in these rules; ~~and~~ ~~(3-28-23)~~( )

g. Prescribing drugs and devices as provided in these rules~~.~~; and ~~(3-28-23)~~( )

h. Delegating services and duties to appropriate support personnel. ( )

03. PDMP. Prescription Drug Monitoring Program. (3-28-23)

04. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-28-23)

05. Purple Book. The list of licensed biological products with reference product exclusivity and

biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. (3-28-23)

06. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-28-23)

07. Reconstitution. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. (3-28-23)

08. Restricted Drug Storage Area. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-28-23)

09. Therapeutic Equivalent Drugs. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). (3-28-23)

10. USP-NF. United State Pharmacopeia-National Formulary. (3-28-23)

(BREAK IN CONTINUITY OF SECTIONS)

301. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM PRESCRIPTION FILLING REQUIREMENTS.
Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements either at the drug outlet or through offsite pharmacy services: (3-28-23)

01. Valid Prescription Drug Order. Prescription drugs may only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter E of these rules. (3-28-23)

02. Prospective Drug Review. Prospective drug review must be provided. (3-28-23)

03. Labeling. Each drug must bear a complete and accurate label as set forth in these rules. (3-28-23)

04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. ~~A compounded drug may only be verified by a pharmacist or prescriber.~~ ~~(3-28-23)~~( )

05. Patient Counseling. Counseling must be provided. (3-28-23)