Terri Kondeff
Director

Legislative Services Office
Idaho State Legislature

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MEMORANDUM

TO: Senators VANORDEN, Lee, Wintrow and,
Representatives VANDER WOUDE, Erickson, Chew (Rubel)

FROM: Jill Randolph - Senior Legislative Drafting Attorney

DATE: April 05, 2024

SUBJECT: Temporary Rule

IDAPA 24.36.01 - Rules of the State Board of Pharmacy - Adoption of Temporary Rule - Docket No. 24-3601-2401

We are forwarding this temporary rule to you for your information only. No analysis was done by LSO. This rule is posted on our web site. If you have any questions, please call Jill Randolph at the Legislative Services Office at (208) 334-4845. Thank you.

Attachment: Temporary Rule

IDAPA 24 – DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSES

24.36.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 24-3601-2401

NOTICE OF RULEMAKING – ADOPTION OF TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is July 1, 2024.

AUTHORITY: In compliance with Sections 67-5226, Idaho Code, notice is hereby given this agency has adopted a temporary rule. The action is authorized pursuant to Section 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule:

This temporary rule implements provisions of House Bill 527, with a concurrent effective date of July 1, 2024. Specifically, it removes the regulations eliminated in the bill, updates cross-references to Idaho Code given the changing numbering in the bill, and adds emergency medications as a carve out to regulatory requirements given their status under the bill.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons:

House Bill 527 passed the 2024 Legislature. This bill eliminated several existing Board of Pharmacy rules and changed the numbering of various sections of Idaho Code, effective July 1, 2024. This temporary rule ensures conforming edits are made to the Board of Pharmacy rules simultaneously, and therefore have an effective date of July 1, 2024.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein:

There is no fee added or changed as part of this rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS: For assistance on technical questions concerning the temporary rule, contact Nicole Chopski at 208-334-3233.

DATED this March 28, 2024.

Nicole L. Chopski
Executive Officer
Division of Occupational & Professional Licenses
11341 W. Chinden Blvd.
P.O. Box 83720
Boise, ID 83720-0063
208-334-3233

THE FOLLOWING IS THE TEXT OF THE TEMPORARY RULE FOR DOCKET NO. 24-3601-2401
(Only Those Sections With Amendments Are Shown.)

24.36.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

(BREAK IN CONTINUITY OF SECTIONS)

010. DEFINITIONS AND ABBREVIATIONS ~~(A – N)~~.
The definitions set forth in Sections 54-1705~~5~~4 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms have the meanings set forth below: ~~(3-28-23)~~(7-1-24)T

01. **ACCME**. Accreditation Council for Continuing Medical Education. (3-28-23)

02. **ACPE**. Accreditation Council for Pharmacy Education. (3-28-23)

03. **ADS – Automated Dispensing and Storage**. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-28-23)

04. **Change of Ownership**. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-28-23)

05. **CME**. Continuing medical education. (3-28-23)

06. **CPE**. Continuing pharmacy education. (3-28-23)

07. **CPE Monitor**. An NABP service that allows pharmacists to electronically keep track of CPE credits from ACPE-accredited providers. (3-28-23)

08. **DEA**. United States Drug Enforcement Administration. (3-28-23)

09. **DME Outlet**. A registered outlet that may hold for sale at retail durable medical equipment (DME) and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection. (3-28-23)

10. **Drug Outlet**. Drug outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, DME outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, mobile pharmacies, and analytical or research laboratories. (3-28-23)

11. **FDA**. United States Food and Drug Administration. (3-28-23)

12. **Flavoring Agent**. An additive in food or drugs in the minimum quantity necessary. (3-28-23)

13. **Floor Stock**. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-28-23)

~~**14.** **FPGEC Certification**. Foreign Pharmacy Graduate Examination Committee Certification. (3-28-23)~~

154. **Hazardous Drug**. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: carcinogenicity; teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low doses in humans or animals; genotoxicity; or new drugs that mimic existing hazardous drugs in structure or toxicity. (3-28-23)

165. **HIPAA**. Health Insurance Portability and Accountability Act of 1996. (3-28-23)

176. **NABP**. National Association of Boards of Pharmacy. (3-28-23)

~~**18.** **NAPLEX.** North American Pharmacists Licensure Examination. (3-28-23)~~

197. **NDC**. National Drug Code. (3-28-23)

18. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. (7-1-24)T

19. **Pharmaceutical Care Services**. A broad range of services for patients performed independently or in collaboration with other health care professionals. Pharmaceutical care services are not limited to, but may include one (1) or more of the following: (7-1-24)T

a. Diagnosing the patient's health status or condition; (7-1-24)T

b. Reviewing or formulating a drug utilization plan; (7-1-24)T

c. Monitoring and evaluating the patient's response to drug therapy; (7-1-24)T

d. Ordering and interpreting laboratory tests and imaging; (7-1-24)T

e. Performing drug product selection, substitution, medication administration, prescription adaptation, or refill authorization as provided in these rules; and (7-1-24)T

f. Prescribing drugs and devices as provided in these rules. (7-1-24)T

20. **PDMP**. Prescription Drug Monitoring Program. (7-1-24)T

21. **Prescriber**. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (7-1-24)T

22. **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. (7-1-24)T

23. **Readily Retrievable**. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (7-1-24)T

24. **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. (7-1-24)T

25. **Restricted Drug Storage Area**. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (7-1-24)T

26. **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). (7-1-24)T

27. **USP-NF**. United State Pharmacopeia-National Formulary. (7-1-24)T

~~**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;~~ ~~(SD2301)~~

~~**g.** Prescribing drugs and devices as provided in these rules; and~~ ~~(SD2301)~~

~~**h.** Delegating services and duties to appropriate support personnel.~~ ~~(SD2301)~~

~~**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)~~

01~~2~~1. – 099. (RESERVED)

SUBCHAPTER A – GENERAL PROVISIONS
(Rules 100 through 199)

100. – 101. ~~PRACTICE OF PHARMACY: GENERAL APPROACH.~~ (RESERVED)

~~To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, or whether an act can be delegated to other individuals under their supervision, a licensee or registrant of the Board must independently determine whether:~~ ~~(3-28-23)~~

~~**01. Express Prohibition**. The act is expressly prohibited by:~~ ~~(3-28-23)~~

~~**a.** The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code;~~ ~~(3-28-23)~~

~~**b.** The Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code;~~ ~~(3-28-23)~~

~~**c.** The rules of the Idaho State Board of Pharmacy; or~~ ~~(3-28-23)~~

~~**d.** Any other applicable state or federal laws or regulations.~~ ~~(3-28-23)~~

~~**02. Education, Training, and Experience**. The act is consistent with licensee or registrant's education, training, and experience.~~ ~~(3-28-23)~~

~~**03. Standard of Care**. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience.~~ ~~(3-28-23)~~

~~101. PRESCRIBER PERFORMANCE OF PHARMACY FUNCTIONS.~~

~~For the purposes of this chapter, any function that a pharmacist may perform may similarly be performed by an Idaho prescriber or may be delegated by an Idaho prescriber to appropriate support personnel, in accordance with the prescriber's practice act.~~ ~~(3-28-23)~~

102. WAIVERS OR VARIANCES.

~~01. Emergency Waiver.~~ In the event of an emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, the division administrator may waive any requirement of these rules for the duration of the emergency. ~~(3-28-23)~~(7-1-24)T

(BREAK IN CONTINUITY OF SECTIONS)

211. – 212. ~~PHARMACIST LICENSURE BY EXAMINATION.~~ (RESERVED)

~~To be considered for licensure, a person must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, submit to the Board an application for licensure by examination, and meet the following:~~ ~~(3-28-23)~~

~~**01. Graduates of U.S. Pharmacy Schools**. Graduate from an ACPE-accredited school or college of pharmacy within the United States.~~ ~~(3-28-23)~~

~~**02. Graduates of Foreign Pharmacy Schools**. Graduate from a school or college of pharmacy located outside of the United States, submit certification by the FPGEC, and complete a minimum of seventeen hundred forty (1,740) experiential hours as verified on an employer's affidavit signed by a pharmacist licensed and practicing in the United States. The Board may request verifiable business records to document the hours.~~ ~~(3-28-23)~~

~~**03. Licensure Examinations**. Qualified applicants must pass the NAPLEX 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.~~ ~~(3-28-23)~~

~~**04. Score Transfer**. Score transfers into Idaho during the examination registration process are accepted for one (1) year. After taking the exam, score transfers into Idaho must be submitted within eighty-nine (89) days.~~ ~~(3-28-23)~~

~~**212. PHARMACIST LICENSURE BY RECIPROCITY.**~~
~~An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and submit a preliminary application for licensure transfer through NABP. 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. An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may have to complete intern hours for each year away from the practice of pharmacy.~~ ~~(3-28-23)~~

(BREAK IN CONTINUITY OF SECTIONS)

350. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.
In accordance with Section 54-1705~~5~~4, Idaho Code, a pharmacist may independently prescribe provided the following general requirements are met by the pharmacist: ~~(3-28-23)~~(7-1-24)T

01. Education. Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained. (3-28-23)

02. Patient-Prescriber Relationship. Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code. (3-28-23)

03. Patient Assessment. Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. (3-28-23)

04. Collaboration with Other Health Care Professionals. Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate. (3-28-23)

05. Documentation. Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan. (3-28-23)

06. Prescribing Exemption. The general requirements set forth in this section do not apply to ~~collaborative pharmacy practice agreements,~~ the prescribing of devices~~,~~ and nonprescription drugs, prescribing under a collaborative pharmacy practice agreement, direct administration of a medication, or prescribing emergency drugs pursuant to Section 54-1735, Idaho Code. ~~(3-28-23)~~(7-1-24)T