

## IDAPA 27 - BOARD OF PHARMACY

### 27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

#### DOCKET NO. 27-0101-1505

#### 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:** Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

The hearing site(s) 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:

This rulemaking clarifies and adds missing language in definitions. The changes provide needed updating and additional language to definitions. Pharmaceutical Care Services is updated by adding the ability to order and interpret laboratory tests. Reconstitution definition is also added to provide clarification as to what is considered compounding as opposed to reconstitution of a drug.

**FEE SUMMARY:** The following is a specific description of the fee or charge imposed or increased: None.

**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 resulting from 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 under Docket No. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, [Vol. 15-7, page 71](#) and in the August 5, 2015 Idaho Administrative Bulletin, [Vol. 15-8, page 106](#).

**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 28, 2015.

DATED this 4th Day of September 2015.

Alex Adams  
Executive Director  
Board of Pharmacy  
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P. O. Box 83720  
Boise, ID 83720-0067  
Phone: (208) 334-2356  
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**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1505**  
**(Only Those Sections With Amendments Are Shown.)**

**011. DEFINITIONS AND ABBREVIATIONS (J -- R).**

- 01. LTCF -- Long-Term Care Facility.** An institutional facility that provides extended health care to resident patients. (3-21-12)
- 02. Mail Service Pharmacy.** A nonresident pharmacy that ships, mails, or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law. (7-1-13)
- 03. MPJE.** Multistate Pharmacy Jurisprudence Exam. (3-21-12)
- 04. MTM -- Medication Therapy Management.** A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)
- a.** Medication therapy review; (3-21-12)
  - b.** Personal medication record; (3-21-12)
  - c.** Medication-related action plan; (3-21-12)
  - d.** Intervention or referral, or both; (3-21-12)
  - e.** Documentation and follow-up. (3-21-12)
- 05. NABP.** National Association of Boards of Pharmacy. (3-21-12)
- 06. NAPLEX.** North American Pharmacists Licensure Examination. (3-21-12)
- 07. NDC.** National Drug Code. (3-21-12)
- 08. Non-Institutional Pharmacy.** A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)
- 09. Outsourcing Drug Outlet.** A drug outlet that is registered by the United States Food and Drug Administration pursuant to 21 U.S.C. Section 353b and either registered or endorsed by the Board. (4-6-15)
- 10. Parenteral Admixture.** The preparation and labeling of sterile products intended for administration by injection. (3-21-12)
- 11. Pharmaceutical Care Services.** A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Except as permitted pursuant to a collaborative practice agreement, nothing in these rules allows a pharmacist, beyond what is statutorily allowed, to engage in the unlicensed practice of medicine or to diagnose, prescribe, or conduct physical examinations. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (4-4-13)

- a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)
  - b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)
  - c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)
  - d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)
  - e. Documenting the care delivered; (3-21-12)
  - f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)
  - g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)
  - h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)
  - i. Preparing or providing information as part of a personal health record; (3-21-12)
  - j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)
  - k. Providing consultative drug-related intervention and referral services; (3-21-12)
  - l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; ~~and~~ (3-21-12)( )
  - ~~m.~~ Ordering and interpreting laboratory tests; and ( )
  - ~~n.~~ Other services as allowed by law. (3-21-12)
- 12. Pharmacist Extern.** A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)
- 13. Pharmacist Intern.** A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)
- 14. Pharmacy Operations.** Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)
- 15. PHI -- Protected Health Information.** Individually identifiable health information that is: (3-21-12)
- a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)
  - b. Maintained in electronic media; and (3-21-12)
  - c. Transmitted or maintained in any other form or medium. (3-21-12)
  - d. PHI excludes individually identifiable health information in: (3-21-12)

- i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)
- ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)
- iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)
- 16. PIC.** Pharmacist-in-charge. (3-21-12)
- 17. PMP.** Prescription Monitoring Program. (3-21-12)
- 18. Prepackaging.** The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)
- 19. Prescriber.** An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)
- 20. Prescriber Drug Outlet.** A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)
- 21. 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. (4-11-15)
- 22. Readily Retrievable.** Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)
- 23. 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. ( )
- 234. Relative Contraindication.** A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)
- 245. Remote Dispensing Site.** A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)
- 256. Remote Office Location.** A secured area that is restricted to authorized personnel, adequately protects private health information, and shares a secure common electronic file or a private, encrypted connection with a pharmacy, from which a pharmacist who is contracted or employed by a central drug outlet performs centralized pharmacy services. (7-1-13)
- 267. Retail Non-Pharmacy Drug Outlet.** A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)
- 278. Retail Pharmacy.** A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)
- 289. R.N.** Registered nurse. (3-21-12)