

IDAPA 27 – BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-1401

NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

EFFECTIVE DATE: This rule has been adopted by the agency and is now pending review by the 2015 Idaho State Legislature for final approval. The pending rule becomes final and effective at the conclusion of the legislative session, unless the rule is approved or rejected in part by concurrent resolution in accordance with Section 67-5224 and 67-5291, Idaho Code. If the pending rule is approved or rejected in part by concurrent resolution, the rule becomes final and effective upon adoption of the concurrent resolution or upon the date specified in the concurrent resolution.

AUTHORITY: In compliance with Section 67-5224, Idaho Code, notice is hereby given that this agency has adopted a pending rule. The action is authorized pursuant to Section 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is a concise explanatory statement of the reasons for adopting the pending rule and a statement of any change between the text of the proposed rule and the text of the pending rule with an explanation of the reasons for the change.

This pending rule is necessary to allow for substitution of biological products with interchangeable biosimilars as allowed by the FDA. Changes in this pending language from the proposed language incorporate the recently released Purple Book by the FDA.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. Only those sections that have changes that differ from the proposed text are printed in this bulletin. The complete text of the proposed rule was published in the October 1, 2014 Idaho Administrative Bulletin, Vol. 14-10, pages 325 through 329.

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:

There is no fiscal impact of this rulemaking to the Board of Pharmacy; however, the state of Idaho will save money when biosimilars are dispensed to Health and Welfare recipients and state employees.

ASSISTANCE ON TECHNICAL QUESTIONS: For assistance on technical questions concerning this pending rule, contact Mark Johnston, Executive Director, (208) 334-2356.

DATED this 28th day of November, 2014.

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010. Definitions and Abbreviations (A -- I).

01. Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)

02. ACPE. Accreditation Council for Pharmacy Education. (3-21-12)

03. Acute Care Hospital. A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)

04. 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. (3-21-12)

05. Biological Product. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). ()

06. Biosimilar. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. ()

057. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

068. Central Drug Outlet. A resident or nonresident pharmacy, drug outlet or business entity employing or contracting pharmacists to perform centralized pharmacy services. (7-1-13)

079. Central Pharmacist. A pharmacist performing centralized pharmacy services. (7-1-13)

0810. Central Pharmacy. A pharmacy performing centralized pharmacy services. (7-1-13)

0911. Centralized Pharmacy Services. The processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations. (7-1-13)

102. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)

113. Charitable Clinic or Center -- Authorized Personnel. A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)

124. Chart Order. A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

135. CME. Continuing medical education. (3-21-12)

146. COE -- Central Order Entry. A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)

157. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

168. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

179. Continuous Quality Improvement Program. A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (3-21-12)

1820. Correctional Facility. Any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order. (4-4-13)

1921. CPE. Continuing pharmacy education. (3-21-12)

202. DEA. United States Drug Enforcement Administration. (3-21-12)

213. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

224. DME. Durable medical equipment. (3-21-12)

235. Drug Order. A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)

246. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

257. Drug Product Substitution. Dispensing a drug product other than prescribed. (4-4-13)

268. DTM -- Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

279. Emergency Drugs. Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)

2830. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

2931. FDA. United States Food and Drug Administration. (3-21-12)

302. Flavoring Agent. An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)

313. 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. (3-21-12)

324. FPGEC. Foreign Pharmacy Graduate Examination Committee. (4-4-13)

335. HIPAA. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(3-21-12)

346. Hospital System. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

357. Idaho State Board of Pharmacy or Idaho Board of Pharmacy. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, “the Board” or “Board” also means the Idaho State Board of Pharmacy. (3-21-12)

368. Individually Identifiable Health Information. Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)

b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)

i. Identifies the individual; or (3-21-12)

ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)

379. Institutional Pharmacy. A pharmacy located in an institutional facility. (3-21-12)

40. Interchangeable Biosimilar. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. ()

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. Parenteral Admixture.** The preparation and labeling of sterile products intended for administration by injection. (3-21-12)
- 10. 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.** Other services as allowed by law. (3-21-12)

11. Pharmacist Extern. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)

12. 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)

13. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

14. 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)

15. PIC. Pharmacist-in-charge. (3-21-12)

16. PMP. Prescription Monitoring Program. (3-21-12)

17. 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)

18. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

19. 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)

20. 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. ()

201. 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)

212. Relative Contraindication. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

223. 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)

234. 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)

245. Retail Non-Pharmacy Drug Outlet. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

256. Retail Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

267. R.N. Registered nurse. (3-21-12)

(BREAK IN CONTINUITY OF SECTION

130. Drug Product: Substitution.
Drug product substitutions are allowed only as follows: (4-4-13)

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (4-4-13)

02. Skilled Nursing Facility. At the direction of the quality assessment and assurance committee of a skilled nursing facility consisting of the director of nursing services, a physician designated by the facility, a consultant pharmacist, and at least two (2) other members of the facility's staff; or (4-4-13)

03. Drug Shortage. Upon a drug shortage, a pharmacist, using his best professional judgment, without contacting the prescriber, may substitute an alternative dose of a prescribed drug, so long as the prescriber's directions are also modified, to equate to an equivalent amount of drug dispensed as is prescribed. (4-4-13)

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if:

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; ()

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and ()

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. ()