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**IDAPA 27
TITLE 01
CHAPTER 01**

IDAPA 27 – BOARD OF PHARMACY

27.01.01 – GENERAL PROVISIONS

000. LEGAL AUTHORITY.

This chapter is adopted under the legal authority of the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; the Idaho Pharmacy Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act, Title 54, Chapter 17, Idaho Code; and specifically pursuant to Sections 37-2702, 37-2715, 54-1717, 54-1753, 54-1755, and 54-1763, Idaho Code. (7-1-18)

001. TITLE AND SCOPE.

01. Title. The title of this chapter is “General Provisions,” IDAPA 27, Title 01, Chapter 01. (7-1-18)

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board’s assigned responsibility to: (7-1-18)

a. Regulate and control the manufacture, distribution, and dispensing of controlled substances within or into the state, pursuant to the Uniform Controlled Substances Act, Section 37-2715, Idaho Code; (7-1-18)

b. Regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Section 54-1718, Idaho Code; and (7-1-18)

c. Carry out its duties in regard to drugs, devices and other materials used in the diagnosis, mitigation and treatment, or prevention of injury, illness, and disease, pursuant to Section 54-1719, Idaho Code, or in regard to professionals or other individuals licensed or registered by the Board or otherwise engaged in conduct subject to regulation under these Acts. (7-1-18)

002. WRITTEN INTERPRETATIONS.

In accordance with Title 67, Chapter 52, Idaho Code, this agency may have written statements that pertain to the interpretation of, or to compliance with the rules of this chapter. Any such documents are available for public inspection and copying at cost at the Idaho Board of Pharmacy office. (7-1-18)

003. ADMINISTRATIVE PROCEEDINGS AND APPEALS.

Administrative proceedings and appeals are administered by the Board in accordance with the “Idaho Rules of Administrative Procedure of the Attorney General,” IDAPA 04.11.01, Subchapter B -- Contested Cases, Rules 100 through 800. (7-1-18)

01. Place and Time for Filing. Documents in rulemakings or contested cases must be filed with the executive director of the Board at the Board office between the hours of 8 a.m. and 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (7-1-18)

02. Manner of Filing. One (1) original of each document is sufficient for filing; however, the person or officer presiding over a particular rulemaking or contested case proceeding may require the filing of additional copies. A document may be filed with the Board by e-mail or fax if legible, complete, and received during the Board’s office hours. The filing party is responsible for verifying with Board staff that an e-mail or fax was successfully and legibly received. (7-1-18)

004. INCORPORATION BY REFERENCE.

No documents have been incorporated by reference into these rules. (7-1-18)

005. BOARD OFFICE INFORMATION.

- 01. Street Address.** The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (7-1-18)
- 02. Mailing Address.** The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (7-1-18)
- 03. Telephone Number.** The telephone number is (208) 334-2356. (7-1-18)
- 04. Fax Number.** The fax number is (208) 334-3536. (7-1-18)
- 05. Electronic Address.** The website address is <https://bop.idaho.gov>. (7-1-18)
- 06. Office Hours.** The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (7-1-18)

006. PUBLIC RECORDS ACT COMPLIANCE.

Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 74, Chapter 1, Idaho Code. (7-1-18)

007. OFFICIAL BOARD JOURNAL.

The official journal of the Board is the electronic Idaho State Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification. (7-1-18)

008. – 009. (RESERVED)

010. DEFINITIONS AND ABBREVIATIONS (A – D).

The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms shall have the meanings set forth below: (7-1-18)

- 01. ACCME.** Accreditation Council for Continuing Medical Education. (7-1-18)
- 02. 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. (7-1-18)
- 03. ACPE.** Accreditation Council for Pharmacy Education. (7-1-18)
- 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. (7-1-18)
- 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). (7-1-18)
- 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. (7-1-18)
- 07. CDC.** United States Department of Health and Human Services, Centers for Disease Control and Prevention. (7-1-18)
- 08. Change of Ownership.** A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (7-1-18)
- 09. CLIA-Waived Test.** A test that is waived under the federal Clinical Laboratory Improvement

Amendments (CLIA) of 1988. (7-1-18)

10. Clinical Guidelines. Recommendations from a reputable organization that are evidence-based and intended to optimize patient care in specific clinical circumstances. (7-1-18)

11. CME. Continuing medical education. (7-1-18)

12. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists or pharmacies 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. (7-1-18)

13. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists or pharmacies and one (1) or more prescribers that provides for collaborative pharmacy practice. (7-1-18)

14. Community Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (7-1-18)

15. 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. (7-1-18)

16. CPE. Continuing pharmacy education. (7-1-18)

17. CPE Monitor. An NABP service that allows pharmacists to electronically keep track of CPE credits from ACPE-accredited providers. (7-1-18)

18. DEA. United States Drug Enforcement Administration. (7-1-18)

19. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (7-1-18)

20. DME. Durable medical equipment. (7-1-18)

21. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (7-1-18)

22. Drug Product Substitution. Dispensing a drug product other than prescribed. (7-1-18)

23. DTM – Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative pharmacy practice agreement or statewide protocol agreement. (7-1-18)

011. DEFINITIONS AND ABBREVIATIONS (E – N).

The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms shall have the meanings set forth below: (7-1-18)

01. Emergency Drugs. Drugs necessary 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. (7-1-18)

02. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (7-1-18)

03. FDA. United States Food and Drug Administration. (7-1-18)

04. Flavoring Agent. An additive in food or drugs when used in accordance with the principles of

- good pharmacy practices and in the minimum quantity necessary to produce its intended effect. (7-1-18)
- 05. 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. (7-1-18)
- 06. FPGEC.** Foreign Pharmacy Graduate Examination Committee. (7-1-18)
- 07. 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: (7-1-18)
- a.** Carcinogenicity; (7-1-18)
 - b.** Teratogenicity or developmental toxicity; (7-1-18)
 - c.** Reproductive toxicity in humans; (7-1-18)
 - d.** Organ toxicity at low doses in humans or animals; (7-1-18)
 - e.** Genotoxicity; or (7-1-18)
 - f.** New drugs that mimic existing hazardous drugs in structure or toxicity. (7-1-18)
- 08. HIPAA.** Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (7-1-18)
- 09. 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. (7-1-18)
- 10. Institutional Pharmacy.** A pharmacy located in an institutional facility. (7-1-18)
- 11. 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. (7-1-18)
- 12. Limited Service Outlet.** Limited service outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, durable medical equipment outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, and analytical or research laboratories. (7-1-18)
- 13. Maintenance Drug.** A drug intended for the treatment of a health condition or disease that is persistent or otherwise expected to be long lasting in its effects. (7-1-18)
- 14. Medication Synchronization Program.** An opt-in program provided by a pharmacy for aligning the refill dates of a patient’s prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently. (7-1-18)
- 15. MPJE.** Multistate Pharmacy Jurisprudence Exam. (7-1-18)
- 16. NABP.** National Association of Boards of Pharmacy. (7-1-18)
- 17. NAPLEX.** North American Pharmacists Licensure Examination. (7-1-18)
- 18. NDC.** National Drug Code. (7-1-18)

012. 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 shall have the meanings set forth below: (7-1-18)

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

02. 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 also encompasses services provided by way of DTM under a collaborative practice agreement, statewide protocol agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and Medication Therapy Management. 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: (7-1-18)

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; (7-1-18)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (7-1-18)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (7-1-18)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (7-1-18)

e. Documenting the care delivered; (7-1-18)

f. Communicating essential information or referring the patient when necessary or appropriate; (7-1-18)

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; (7-1-18)

h. Conducting a drug therapy review consultation with the patient or caregiver; (7-1-18)

i. Preparing or providing information as part of a personal health record; (7-1-18)

j. Identifying processes to improve continuity of care and patient outcomes; (7-1-18)

k. Providing consultative drug-related intervention and referral services; (7-1-18)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; (7-1-18)

m. Ordering and interpreting laboratory tests; and (7-1-18)

n. Other services as allowed by law. (7-1-18)

03. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (7-1-18)

04. PDMP. Prescription Drug Monitoring Program. (7-1-18)

05. 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. (7-1-18)

- 06. Prescriber.** An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (7-1-18)
- 07. 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. (7-1-18)
- 08. Readily Retrievable.** Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (7-1-18)
- 09. 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. (7-1-18)
- 10. Restricted Drug Storage Area.** The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (7-1-18)
- 11. Sample.** A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (7-1-18)
- 12. Skilled Nursing Facility.** An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (7-1-18)
- 13. Student Technician.** A student who is enrolled in a high school or college supervised program, and who does not otherwise meet the requirements for registration as a technician-in-training or certified technician. (7-1-18)
- 14. Technician.** Unless specifically differentiated, a term inclusive of pharmacy technician, certified technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (7-1-18)
- 15. Telepharmacy.** The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (7-1-18)
- 16. 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). (7-1-18)
- 17. Unit Dose.** Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (7-1-18)
- 18. USP.** United States Pharmacopeia. (7-1-18)
- 19. USP-NF.** United State Pharmacopeia-National Formulary. (7-1-18)
- 20. USP 795.** The current edition of the United States Pharmacopeia-National Formulary, Chapter 795. (7-1-18)
- 21. USP 797.** The current edition of the United States Pharmacopeia-National Formulary, Chapter 797. (7-1-18)
- 22. VAWD – Verified Accredited Wholesale Distributor.** An accreditation program for wholesale distributors offered through NABP. (7-1-18)

013. – 019. (RESERVED)

020. PRACTICE OF PHARMACY: GENERAL APPROACH.

To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, a licensee or registrant of

the Board must independently determine whether: (7-1-18)

01. Express Prohibition. The act is expressly prohibited by: (7-1-18)

a. The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code; (7-1-18)

b. The Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; (7-1-18)

c. The rules of the Idaho State Board of Pharmacy; or (7-1-18)

d. Any other applicable state or federal laws, rules or regulations. (7-1-18)

02. Education and Training. The act is consistent with licensee or registrant's education, training or practice experience. (7-1-18)

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. (7-1-18)

021. WAIVERS OR VARIANCES.

01. Criteria. The board may grant or deny, in whole or in part, a waiver of, or variance from, specified rules if the granting of the waiver or variance is consistent with the Board's mandate to promote, preserve and protect public health, safety and welfare, and based on consideration of one (1) or both of the following: (7-1-18)

a. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; or (7-1-18)

b. The waiver or variance requested would test an innovative practice or service delivery model. (7-1-18)

02. Content and Filing of a Waiver or Variance Petition. A written petition for waiver or variance should include at least the following: (7-1-18)

a. The name, address, and telephone number of the petitioner or petitioners; (7-1-18)

b. A specific reference to the rule or rules from which a waiver or variance is requested; (7-1-18)

c. A statement detailing the waiver or variance requested, including the precise scope and duration; (7-1-18)
and

d. A description of how the waiver or variance, if granted, will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. (7-1-18)

03. Invalid Requests. A waiver or variance request that is contrary to federal law or Idaho Code or that seeks to delay or cancel an administrative deadline will not be considered or granted by the Board. (7-1-18)

04. Time Period of Waiver or Variance. Waivers or variances may be granted on a permanent or temporary basis. Temporary waivers or variances have no automatic renewal, but may be renewed if the Board finds that sufficient grounds to allow the waiver or variance continue to exist. (7-1-18)

05. Cancellation or Modification of a Waiver or Variance. A waiver or variance granted by the Board may be canceled or modified by the Board at any time. (7-1-18)

022. BOARD INSPECTIONS AND INVESTIGATIONS.

01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (7-1-18)

02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)

03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, one (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection and must pay within ninety (90) days of inspection. (7-1-18)

04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18)

05. Investigations. Licensees or registrants must also fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, to gather information pertinent to a complaint received by the Board, or to enforce disciplinary actions. (7-1-18)

023. UNPROFESSIONAL CONDUCT.

The following acts or practices by any licensee or registrant are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (7-1-18)

01. Unethical Conduct. Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (7-1-18)

02. Lack of Fitness. A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (7-1-18)

03. On-Duty Intoxication or Impairment. Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (7-1-18)

04. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (7-1-18)

05. Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (7-1-18)

06. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. (7-1-18)

07. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (7-1-18)

08. Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (7-1-18)

- 09. Failure to Counsel or Offer Counseling.** Failing to counsel or offer counseling, unless specifically exempted or refused. (7-1-18)
- 10. Substandard, Misbranded, Adulterated, or Expired Products.** Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock. (7-1-18)
- 11. Prescriber Incentives.** Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (7-1-18)
- 12. Exclusive Arrangements.** Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (7-1-18)
- 13. Failure to Report.** Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (7-1-18)
- 14. Failure to Follow Board Order.** Failure to follow an order of the Board. (7-1-18)
- 15. Use of False Information.** Knowingly using false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (7-1-18)
- 16. Standard of Care.** Providing health care services which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting. (7-1-18)
- 17. Unnecessary Services or Products.** Directly promoting or inducing for the provisions of health care services or products that are unnecessary or not medically indicated. (7-1-18)
- 024. – 999. (RESERVED)**

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