

**IDAPA 27
TITLE 01
CHAPTER 01**

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

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;
- 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; (3-25-16)
- m.** Ordering and interpreting laboratory tests; and (3-25-16)
- 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 or investigational drugs as permitted in Title 39, Chapter 93, Idaho Code. (~~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. (3-25-16)
- 24. **Relative Contraindication.** A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)
- 25. **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)
- 26. **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)
- 27. **Retail Non-Pharmacy Drug Outlet.** A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)
- 28. **Retail Pharmacy.** A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)
- 29. **R.N.** Registered nurse. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

140. STANDARD PRESCRIPTION DRUG LABELING.

Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (3-21-12)

- 01. Dispenser Information.** The name, address, and telephone number of the dispenser (person or business). (3-21-12)
- 02. Serial Number.** The serial number. (4-4-13)
- 03. Date.** The date the prescription is filled. (3-21-12)
- 04. Prescriber.** The name of the prescriber. (3-21-12)
- 05. Name.** (4-11-15)

 - a.** If a person, the name of the patient or other person authorized to possess a legend drug in accordance with Idaho Code; (~~4-11-15~~)()
 - b.** If an animal, the name and species of the patient; or (4-11-15)
 - c.** If a ~~school for epinephrine auto injectors pursuant to Section 33-520A,~~ facility or other entity is authorized to possess a legend drug in accordance with Idaho Code, the name of the ~~school~~ facility or entity. (~~4-11-15~~)()
- 06. Drug Name and Strength.** Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name). (3-21-12)
- 07. Quantity.** The quantity of item dispensed. (3-21-12)
- 08. Directions.** The directions for use. (3-21-12)
- 09. Cautionary Information.** Cautionary information as required or deemed appropriate for proper use and patient safety. (3-21-12)
- 10. Expiration.** An expiration date that is the lesser of: (3-21-12)

 - a.** One (1) year from the date of dispensing; (3-21-12)
 - b.** The manufacturer's original expiration date; (3-21-12)
 - c.** The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)
 - d.** A shorter period if warranted. (3-21-12)
- 11. Refills.** The number of refills remaining, if any, or the last date through which the prescription is refillable. (4-11-15)
- 12. Warning.** The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed," except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. (4-11-15)
- 13. Identification.** The initials or other unique identifier of the dispensing pharmacist or dispensing

prescriber.

(4-11-15)

(BREAK IN CONTINUITY OF SECTIONS)

204. CONTROLLED SUBSTANCES: PMP.

Specified data on controlled substances must be reported ~~weekly, or more often as required~~ by the Board, end of the next business day by all ~~pharmacies holding a DEA retail pharmacy registration~~ entities that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. (4-4-13)(_____)

01. Online Access to PMP. Online access to the Board's PMP is limited to licensed prescribers and pharmacists, or their delegates, for treatment purposes. To obtain online access, a prescriber or pharmacist, or their delegate, must: (3-21-12)(_____)

a. Complete and submit a registration application and a written agreement to adhere to the access restrictions and limitations established by law; (3-21-12)

b. Obtain Board approval for access; and (3-21-12)

c. Be issued a user account, login name, and password. (3-21-12)

02. Use Outside Scope of Practice Prohibited. Information obtained from the PMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. A delegate may not access the PMP outside of their supervisor's scope of professional practice. (3-21-12)(_____)

03. Profile Requests. Authorized persons without online access may obtain a profile by completing the required form and submitting it to the Board office with proof of identification and other credentials required to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. (3-21-12)

04. Suspension, Revocation, or Restriction of PMP Access. Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's, ~~or~~ pharmacist's, or delegate's authorization for online access to the PMP. (3-21-12)(_____)

(BREAK IN CONTINUITY OF SECTIONS)

265. LEGEND DRUG DONATION -- STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. A drug considered for donation to a qualifying charitable clinic or center must meet the following eligibility criteria or it must not be accepted for donation. (3-21-12)

a. The drug name, strength, lot number, and expiration date must appear on the package or label. (3-21-12)

b. The drug must be FDA-approved and: (3-21-12)

i. Be in the original unit dose packaging; or (3-21-12)

ii. Be an oral or parenteral drug in a sealed, single dose container approved by the FDA; or (3-21-12)

iii. Be a topical or inhalant drug in a sealed, unit-of-use container approved by the FDA; or (3-21-12)

iv. Be a parenteral drug in a sealed, multiple dose container approved by the FDA from which no doses have been withdrawn. (3-21-12)

v. Be a patient assistant program drug, which must be originally received by the qualified donor, and remain under the control and storage of the donor. (_____)

c. The drug must not be the subject of a mandatory recall by a state or federal agency or of a voluntary recall by a drug wholesaler or manufacturer. (3-21-12)

d. The drug must not require storage temperatures other than normal room temperature as specified by the manufacturer or the USP. (3-21-12)

e. The drug must not be subject to an FDA-restricted drug distribution program such as and including, but not limited to, thalidomide and lenalidomide. (3-21-12)

02. Donation Standards. (3-21-12)

a. A pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority at the qualifying charitable clinic or center must be designated as responsible for defining the drugs included in the qualifying charitable clinic or center's formulary. (3-21-12)

b. ~~Donating nursing homes~~ A qualified donor may only donate drugs that appear on the formulary. (~~3-21-12~~)(_____)

c. Prior to the delivery of donated drugs to the qualifying charitable clinic or center, a pharmacist, nurse, physician, or physician assistant from the ~~donating nursing home~~ qualified donor must sign and date a manifest that: (~~3-21-12~~)(_____)

i. Attests that the donated drugs have been maintained in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and the USP standards; (3-21-12)

ii. Attests that the drugs have been continuously under the control of a healthcare professional and have never been in the custody of a patient or other individual; (3-21-12)

iii. Attests that the donated drugs are those qualified for donation by their inclusion in the qualifying charitable clinic or center's formulary; (3-21-12)

iv. Attests that the donation is fully compliant with these rules; (3-21-12)

v. Attests that all PHI has been removed or redacted from the package; (3-21-12)

vi. Lists the name of the ~~donating nursing home~~ qualified donor and the name of the receiving qualifying charitable clinic or center; and (~~3-21-12~~)(_____)

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug donated. (3-21-12)

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. (3-21-12)

03. Receipt and Handling of Donated Drugs. Donated drugs may be received and handled at a qualifying charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or other authorized clinic or center personnel. (3-21-12)

04. Verification of Received Drugs. Qualified recipients must meet the following requirements, except in the instance in which a qualified recipient and a qualified donor are the same entity as permitted in Idaho Code: (~~3-21-12~~)(_____)

a. Each donated drug must be verified against the donation manifest by an individual authorized to receive the drugs. (3-21-12)

b. If all PHI has not been removed by the donating entity, the information must be removed or redacted prior to dispensing. (3-21-12)

c. Before donated drugs are placed with a qualifying charitable clinic or center's regular stock, a pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must: (3-21-12)

i. Using a current drug identification book, a computer program, or an online service, verify that each donated drug unit meets the criteria specified by these rules; (3-21-12)

ii. Verify that the name and strength indicated on the label of each donated drug unit is correct; and (3-21-12)

iii. Determine for each donated drug that it is not adulterated or misbranded and is safe to dispense. (3-21-12)

d. Donated drugs that do not meet the criteria of these rules must be destroyed and documentation of the destruction retained. (3-21-12)

05. Storage of Donated Drugs. (3-21-12)

a. Donated drug storage must have proper environmental controls to ensure the integrity of the drug in accordance with the manufacturer's recommendations and USP standards. (3-21-12)

b. Donated drugs may be commingled with the qualifying charitable clinic or center's regular stock of drugs only if the packaging on the donated drug has been labeled to indicate that the drug was obtained from a ~~nursing home~~ qualified donor and otherwise must be segregated. (~~3-21-12~~)()

c. The drug storage area must be secured at all times and accessible only to persons authorized to handle donated drugs. (3-21-12)

06. Dispensing Donated Drugs. (3-21-12)

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not stored in appropriate conditions must not be re-dispensed, must be destroyed, and their destruction must be appropriately documented. (3-21-12)

b. A pharmacist, physician, physician assistant, dentist, optometrist, or an advanced practice professional nurse with prescriptive authority at a qualifying charitable clinic or center who re-dispenses donated drugs to a patient must: (3-21-12)

i. Use an appropriate container; (3-21-12)

ii. Label the container as required by these rules except that the expiration date must be the same as on the original container; and (3-21-12)

iii. Initial the prescription label. (3-21-12)

c. A qualifying charitable clinic or center must retain records for each donated drug dispensed. (3-21-12)

d. Pharmacists, physicians, physician assistants, dentists, optometrists, and advanced practice professional nurses with prescriptive authority dispensing donated drugs must perform prospective drug review and provide patient counseling. (3-21-12)

07. Miscellaneous. (3-21-12)

a. The qualifying charitable clinic or center must maintain a list of the names of authorized clinic or center personnel, their individual duties, and a summary of their qualifications. (3-21-12)

b. A qualifying charitable clinic or center that receives donated drugs must adopt policies and procedures requiring and with sufficient detail to ensure that authorized clinic or center personnel will comply with applicable local, state, and federal laws. (3-21-12)

c. Drugs donated pursuant to these rules must not be sold, resold, offered for sale, traded, or transferred to another qualifying charitable clinic or center. (3-21-12)

d. Nothing in these rules precludes a qualifying charitable clinic or center from charging a dispensing fee. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

635. INFUSION CLINIC, HOME HEALTH OR HOSPICE EMERGENCY KITS.

A pharmacy may supply emergency kits ~~for~~ to an infusion clinic, or to state licensed or Medicare certified home health or hospice agencies, or both, as follows: (3-21-12)(_____)

01. Storage and Security. Emergency kits used by infusion clinics or home health or hospice agencies must be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs, except that nurses licensed by the Idaho Board of Nursing and ~~employed by~~ affiliated with the supplying pharmacy, an infusion clinic, or a state-licensed or Medicare-certified home health or hospice agency, may carry emergency kits on their person while on duty and in the course and scope of their ~~employment for~~ affiliation with the pharmacy, clinic, or agency. While not on duty or working within the course and scope of their ~~employment~~ affiliation, the nurses must return the emergency kits to a locked storage area or to the supplying pharmacy. (3-21-12)(_____)

02. Prescription Drugs. Prescription drugs included in a home health or hospice agency emergency kit must remain the property of, and under the responsibility of, the Idaho-registered supplying pharmacy. (3-21-12)

03. Controlled Substances. Emergency kits supplied to infusion clinics or home health or hospice agencies must not include controlled substances. (3-21-12)(_____)