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27.01.03 – Rules Governing Pharmacy Practice

IDAPA 27
TITLE 01
CHAPTER 03

27.01.03 – RULES GOVERNING PHARMACY PRACTICE

SUBCHAPTER A – STANDARD PROVISIONS
(Rules 000 through 099 – Standard 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.
In addition to the General Provisions set forth in IDAPA 27.01.01, "General Provisions," the following title and scope shall apply to these rules: (7-1-18)

01. **Title**. The title of this chapter is "Rules Governing Pharmacy Practice," IDAPA 27, Title 01, Chapter 03. (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 drug outlet practice standards; (7-1-18)

b. Regulate and control the filling and dispensing of prescription drugs; and (7-1-18)

c. Regulate drug outlet recordkeeping and reporting requirements. (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.
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the definitions and abbreviations found at IDAPA 27.01.01.010 through 012 are applicable to these rules. (7-1-18)

011. – 099. (RESERVED)

SUBCHAPTER B – PROFESSIONAL PRACTICE STANDARDS
(Rules 100 through 199 – Professional Practice Standards)

100. PRESCRIBER PERFORMANCE OF PHARMACY FUNCTIONS.

01. Prescriber Roles. For the purposes of this chapter, any function that a pharmacist may perform may similarly be performed by an Idaho prescriber in the course of filling or dispensing prescription drugs. (7-1-18)

02. Prescriber Delegation. For the purposes of this chapter, any function that a pharmacist may delegate to a technician or pharmacist intern may similarly be delegated by an Idaho prescriber to an appropriate support personnel in accordance with the prescriber's practice act. (7-1-18)

101. DELEGATION OF PHARMACY FUNCTIONS.
A pharmacist may delegate to and allow performance by a technician or pharmacist intern only those functions performed in pharmacy operations that meet the following criteria: (7-1-18)

01. Supervision. The function is performed under a pharmacist's supervision; (7-1-18)

02. Education, Skill and Experience. The function is commensurate with the education, skill, and experience of the technician or pharmacist intern; and (7-1-18)

03. Professional Judgment Restriction. Any function that requires the use of a pharmacist's professional judgment may be performed by a pharmacist intern. (7-1-18)

102. – 199. (RESERVED)

SUBCHAPTER C – DRUG OUTLET PRACTICE STANDARDS
(Rules 200 through 299 - Drug Outlet Practice Standards)

200. DRUG OUTLETS: MINIMUM FACILITY STANDARDS.

A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: (4-11-19)

01. Security. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. An alarm or other comparable monitoring system is required for any non-institutional drug outlet that stocks controlled substances and is new or remodeled after July 1, 2018. (7-1-18)

02. Patient Privacy. All protected health information must be stored and maintained in accordance with HIPAA. In addition, a community pharmacy that is new or remodeled after March 21, 2012 must provide and maintain a patient consultation area that affords the patient auditory and visual privacy and is compliant with the Americans with Disabilities Act. (7-1-18)

03. Equipment and Storage. A drug outlet must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity. (4-11-19)

04. Staffing. A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business. (7-1-18)

05. Controlled Substances Storage. Drug outlets that dispense prescription drugs must store controlled substances in a securely locked, substantially constructed cabinet or safe. However, a pharmacy may disperse substances listed in Schedules II, III, IV and V, in whole or in part, throughout the stock of non-controlled substances if doing so would be likely to obstruct the theft or diversion of the controlled substances. (4-11-19)

06. Controlled Substances Disposal. Expired, excess or unwanted controlled substances that are owned by the drug outlet must be properly disposed of through the services of a DEA-registered reverse distributor or by another method permitted by federal law. (7-1-18)

07. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (4-11-19)

201. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM PRESCRIPTION FILLING REQUIREMENTS.

Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: (7-1-18)

01. Valid Prescription Drug Order. Prescription drugs must only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter D of these rules. (7-1-18)

02. Prospective Drug Review. Prospective drug review, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. (7-1-18)

03. Labeling. Each drug must bear a complete and accurate label as set forth in Subchapter D of these rules. (7-1-18)

04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. A compounded drug may only be verified by a pharmacist or prescriber. (7-1-18)

05. Patient Counseling. Counseling, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. (7-1-18)

202. OFFSITE PHARMACY SERVICES.
A drug outlet may provide offsite pharmacy services at one (1) or more locations. When the services being performed are related to prescription fulfillment or processing, the drug outlet must comply with the following: (7-1-18)

01. Policies and Procedures. The originating drug outlet must have written policies and procedures outlining the offsite pharmacy services to be provided by the central drug outlet, or the offsite pharmacist or technician, and the responsibilities and accountabilities of each party. (7-1-18)

02. Secure Electronic File. The parties share a secure common electronic file or utilize other secure technology, including a private, encrypted connection that allows access by the central drug outlet or offsite pharmacist or technician to information necessary to perform offsite pharmacy services. (7-1-18)

03. Exemption. A single prescription drug order may be shared by an originating drug outlet and a central drug outlet, or offsite pharmacist or technician. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section will not be construed as the filling of a transferred prescription or as a wholesale distribution. (7-1-18)

203. DRUG OUTLETS THAT DISPENSE DRUGS TO PATIENTS WITHOUT AN ONSITE PHARMACIST OR PRESCRIBER.
In addition to all other preceding rules of this subchapter, a drug outlet that dispenses drugs to patients in Idaho that does not have a pharmacist or prescriber onsite to perform or supervise pharmacy operations must comply with the following requirements: (7-1-18)

01. Security and Access. (7-1-18)

a. The drug outlet must maintain video surveillance with an adequate number of views of the full facility and retain a high quality recording for a minimum of ninety (90) days. (7-1-18)

b. Proper identification controls of individuals accessing the restricted drug storage area must be utilized and access must be limited, authorized, and regularly monitored. (7-1-18)

02. Staffing Limitations. The ratio of pharmacists to support personnel may not exceed one (1) pharmacist for every six (6) technicians and pharmacist interns in total across all practice sites. (7-1-18)

03. Technology. The video and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. (7-1-18)

04. Controlled Substances Inventories. (7-1-18)

a. A perpetual inventory must be kept for all Schedule II controlled substances; and (7-1-18)

b. If a perpetual inventory is not kept for all Schedule III through V substances, the pharmacist or prescriber must inventory and audit at least three (3) random controlled substances quarterly. (7-1-18)

05. Self-Inspection. A pharmacist or prescriber must complete and retain a monthly in-person self-inspection of the drug outlet using a form designated by the Board. (7-1-18)

06. Emergency Situations. (7-1-18)

a. A pharmacist or prescriber must be capable of being on site at the drug outlet within twelve (12) hours if an emergency arises. (7-1-18)

b. The drug outlet must be, or remain, closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, until system corrections or repairs are completed. (7-1-18)

07. Exemption for Self-Service Systems. A self-service ADS that is operating as a drug outlet is exempt from the video surveillance requirement and the self-inspection requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADS is exempt from the video and audio communication system requirements of this rule. (7-1-18)

08. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act are exempt from this rule. (7-1-18)

204. DRUGS STORED OUTSIDE OF A DRUG OUTLET FOR RETRIEVAL BY A LICENSED HEALTH PROFESSIONAL.
Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: (7-1-18)

01. Supervising Drug Outlet. Drugs stored in such a manner must remain under the control of, and be routinely monitored by, the supervising drug outlet. (7-1-18)

02. Policies and Procedures. The supervising drug outlet must develop and implement policies and procedures regarding authorized access to drugs stored in the alternative designated area, documentation of drugs used, drug returns and wastage, and regular inventory procedures. (7-1-18)

03. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. (7-1-18)

04. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. (7-1-18)

05. Stocking and Replenishing. Stocking or replenishing drugs in an alternative designated area may be performed by a pharmacist or prescriber, or by appropriate support personnel using either an electronic verification system or a two (2) person checking system. (7-1-18)

205. – 299. (RESERVED)

SUBCHAPTER D – FILLING AND DISPENSING PRESCRIPTION DRUGS
(Rules 300 through 399 - Filling and Dispensing Prescription Drugs)

300. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. (7-1-18)

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued: (7-1-18)

a. In good faith; (7-1-18)

b. For a legitimate medical purpose; (7-1-18)

c. By a licensed prescriber; (7-1-18)

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; (7-1-18)

e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; or (7-1-18)

f. In the form and including the elements specified in this Subchapter D. (7-1-18)

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. (7-1-18)

03. Tampering. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. (7-1-18)

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (7-1-18)

05. Expiration. A prescription drug order is invalid after its expiration date as follows: (7-1-18)

a. A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than ninety (90) days after its date of issue. (7-1-18)

b. A prescription drug order for a controlled substance listed in Schedules III, IV or V must not be filled or refilled more than six (6) months after its date of issue. (7-1-18)

06. Digital Image Prescriptions. A digital image of a prescription drug order is invalid if it is for a controlled substance or if the patient intends to pay cash for the drug in whole. (4-11-19)

301. PRESCRIPTION DRUG ORDER: SCHEDULE II DRUG LIMITATIONS

01. Faxed and Verbal Prescriptions. A Schedule II prescription must not be dispensed pursuant to a faxed or verbal prescription drug order, except as permitted by federal law. (7-1-18)

02. Multiple Prescription Drug Orders. A prescriber may issue and a pharmacy may fill multiple prescription drug orders, written on and dated with the same date, that allow the patient to receive up to a ninety (90)-day supply of a Schedule II controlled substance in accordance with federal law. (7-1-18)

302. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.

A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, must include at least the following: (7-1-18)

01. Patient's Name. The patient's or authorized entity's name and: (7-1-18)

a. If for a controlled substance, the patient's full name and address; and (7-1-18)

b. If for an animal, the species. (7-1-18)

02. Date. The date issued. (7-1-18)

03. Drug Information. The drug name, strength, quantity and, if for a controlled substance, the dosage form. (7-1-18)

04. Directions. The directions for use. (7-1-18)

05. Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (7-1-18)

06. Signature. A signature sufficient to evidence a valid prescription of either the prescriber or, if a renewal of a previous prescription, the prescriber's agent, when authorized by the prescriber. (4-11-19)

07. Institutional Drug Order Exemptions. An institutional drug order may exempt the patient's address, the dosage form, quantity, prescriber's address, and prescriber's DEA registration number. (7-1-18)

08. Exemptions for Non-Controlled Substances. A prescriber may omit the required drug information and directions if the prescriber makes a clear indication that the pharmacist is to finalize the patient's drug therapy plan. (4-11-19)

303. FILLING PRESCRIPTION DRUG ORDERS: PRACTICE LIMITATIONS.

01. Drug Product Selection. Drug product selection is allowed only between therapeutic equivalent drugs. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug product selection is permitted. (7-1-18)

02. Partial Filling. A prescription drug order may be partially filled within the limits of federal law. The total quantity dispensed in partial fillings must not exceed the total quantity prescribed. (7-1-18)

03. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal law and only as specifically authorized by the prescriber, except that a pharmacist may refill a prescription for a non-controlled drug one (1) time in a six (6)-month period when the prescriber is not available for authorization. In such cases, a pharmacist may dispense a refill up to the quantity on the most recent fill or a thirty (30)-day supply, whichever is less. (4-11-19)

304. FILLING PRESCRIPTION DRUG ORDERS: ADAPTATION.

Upon patient consent, a pharmacist acting in good faith and exercising reasonable care may adapt drugs as specified in this rule, provided that the drug is not for a controlled substance, compounded drug, or biological product, and provided that the prescriber has not indicated by any means necessary that adaptation is not permitted. (7-1-18)

01. Change Quantity. A pharmacist may change the quantity of medication prescribed if: (7-1-18)

a. The prescribed quantity or package size is not commercially available; (4-11-19)

b. The change in quantity is related to a change in dosage form; (4-11-19)

c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or (4-11-19)

d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. (4-11-19)

02. Change Dosage Form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. (7-1-18)

03. Complete Missing Information. A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change. (7-1-18)

04. Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record. (7-1-18)

305. FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION.

Drug product substitutions are allowed only as follows: (7-1-18)

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (7-1-18)

02. Institutional Facility. At the direction of the quality assessment and assurance committee of an institutional facility; (4-11-19)

03. Drug Shortage. Upon a drug shortage, a pharmacist may exercise professional judgment, without contacting the prescriber, and 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 prescribed; or (7-1-18)

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (7-1-18)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (7-1-18)

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and (7-1-18)

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (7-1-18)

05. Prescriber-Authorized Substitution. A prescriber may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class provided the following conditions are met: (4-11-19)

a. The prescriber has clearly indicated that substitution is permissible by indicating "therapeutic substitution allowed" or a similar designation; (4-11-19)

b. The substitution is intended to ensure formulary compliance with the patient's health insurance plan, or, in the case of a patient without insurance, to lower the cost to the patient while maintaining safety; (4-11-19)

c. The patient opts-in to the substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution; and (4-11-19)

d. If a substitution is made: (4-11-19)

i. The prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as is prescribed; and (4-11-19)

ii. The pharmacist notifies the patient's original prescriber of the substitution within five (5) business days of dispensing the prescription. (4-11-19)

e. Prescriber-authorized substitution does not apply to biological products, narrow therapeutic index drugs, or psychotropic drugs. (4-11-19)

306. FILLING PRESCRIPTION DRUG ORDERS: TRANSFERS.

01. Communicating Prescription Drug Order Transfers. A prescription drug order may be transferred within the limits of federal law. A controlled substance listed in Schedules III, IV or V may be transferred only from the drug outlet where it was originally filled and never from the drug outlet that received the transfer. (7-1-18)

02. Pharmacies Using Common Electronic Files. Drug outlets using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other drug outlets sharing the common electronic file. (7-1-18)

307. LABELING: STANDARD PRESCRIPTION DRUG.

Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (7-1-18)

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business). (7-1-18)

02. Serial Number. The serial number. (7-1-18)

03. Date. The date the prescription is filled. (7-1-18)

04. Prescriber. The name of the prescriber. (7-1-18)

05. Name. (7-1-18)

a. If a person, the name of the patient or other person authorized to possess a legend drug in accordance with Idaho Code; (7-1-18)

b. If an animal, the name and species of the patient; or (7-1-18)

c. If a facility or other entity is authorized to possess a legend drug in accordance with Idaho Code, the name of the facility or entity. (7-1-18)

06. Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of each drug included (the generic name and its manufacturer's name or the brand name). (7-1-18)

07. Quantity. The quantity of item dispensed. (7-1-18)

08. Directions. The directions for use. (7-1-18)

09. Cautionary Information. Cautionary information as necessary or deemed appropriate for proper use and patient safety. (7-1-18)

10. Expiration. An expiration date that is either: (7-1-18)

a. The lesser of: (7-1-18)

i. One (1) year from the date of dispensing; (7-1-18)

ii. The manufacturer's original expiration date; (7-1-18)

iii. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (7-1-18)

iv. A shorter period if warranted. (7-1-18)

b. If dispensed in the original, unopened manufacturer packaging, the manufacturer's original expiration date. (7-1-18)

11. Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable. (7-1-18)

12. Warning. A warning sufficient to convey that 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. (7-1-18)

13. Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. (7-1-18)

308. LABELING: INSTITUTIONAL FACILITY DRUGS.
Except if dispensed in unit dose packaging, a drug dispensed for patient use while in a hospital must be dispensed in an appropriate container that bears at least the following information: (7-1-18)

01. Date. The date filled; (7-1-18)

02. Patient. The name of the patient; (7-1-18)

03. Drug. The name and strength of the drug; (7-1-18)

04. **Quantity**. The quantity of item dispensed; (7-1-18)

05. **Directions**. The directions for use, including the route of administration; (7-1-18)

06. **Caution**. Cautionary information as necessary or deemed appropriate for proper use and patient safety; (7-1-18)

07. **Expiration Date**. The expiration or beyond use date, if appropriate; and (7-1-18)

08. **Pharmacist**. The initials or other unique identifier of the dispensing pharmacist. (7-1-18)

309. LABELING: PARENTERAL ADMIXTURE.
If one (1) or more drugs are added to a parenteral admixture, the admixture's container must include a distinctive, supplementary label with at least the following information: (7-1-18)

01. **Ingredient Information**. The name, amount, strength and, if applicable, the concentration of the drug additive and the base solution or diluent; (7-1-18)

02. **Date and Time**. The date and time of the addition, or alternatively, the beyond use date; (7-1-18)

03. **Identification**. The initials or other unique identifier of the pharmacist or preparing prescriber responsible for its accuracy; (7-1-18)

04. **Prescribed Administration Regimen**. The rate or appropriate route of administration or both, as applicable; and (7-1-18)

05. **Special Instructions**. Any special handling, storage, or device-specific instructions. (7-1-18)

310. LABELING: PREPACKAGED PRODUCT.
The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label with at least the following information: (7-1-18)

01. **Drug Name and Strength**. The name and strength of the drug; (7-1-18)

02. **Expiration Date**. An expiration date that is the lesser of: (7-1-18)

a. The manufacturer's original expiration date; (7-1-18)

b. One (1) year from the date the drug is prepackaged; or (7-1-18)

c. A shorter period if warranted (A prepackaged drug returned unopened from an institutional facility and again prepackaged must be labeled with the expiration date used for the initial prepackaging.); (7-1-18)

03. **Conditional Information**. If not maintained in a separate record, the manufacturer's name and lot number and the identity of the pharmacist or provider responsible for the prepackaging. (7-1-18)

311. DISPENSING CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.
A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. (7-1-18)

01. **Positive Identification Presumed**. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: (7-1-18)

a. The controlled substance will be paid for, in whole or in part, by an insurer; (7-1-18)

b. The patient is being treated at an institutional facility or is housed in a correctional facility; or (7-1-18)

c. The filled prescription is delivered to the patient or patient's provider. (7-1-18)

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: (7-1-18)

a. The recipient's name (if other than the patient); (7-1-18)

b. A notation indicating that the recipient was known to the staff member; and (7-1-18)

c. The identity of the staff member making the personal identification. (7-1-18)

03. Acceptable Identification. A valid government-issued identification must include an unaltered photograph and signature to be acceptable. (7-1-18)

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and include: (7-1-18)

a. A copy of the identification presented; or (7-1-18)

b. A record that includes: (7-1-18)

i. The recipient's name; (7-1-18)

ii. A notation of the type of identification presented; (7-1-18)

iii. The government entity that issued the identification; and (7-1-18)

iv. The unique identification number. (7-1-18)

312. DISPENSING CONTROLLED SUBSTANCES: NON-PRESCRIPTION DISPENSING LIMITATIONS.

Limited quantities of a Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted by federal law. (7-1-18)

313. PRESCRIPTION DELIVERY: RESTRICTIONS.

01. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions in accordance with federal law, as long as appropriate measures are taken to ensure product integrity and safety. (4-11-19)

02. Pick-up or Return by Authorized Personnel. Filled prescriptions may be picked up for or returned from delivery by authorized personnel when the drug outlet is closed for business if the prescriptions are placed in a secured delivery area outside of the restricted drug storage area that is equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion. (4-11-19)

314. DESTRUCTION OR RETURN OF DRUGS OR DEVICES: RESTRICTIONS.

A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise a dispensed drug or prescription device must only be accepted for return as follows: (7-1-18)

01. Error. Those that were dispensed in a manner inconsistent with the prescriber's instructions may be returned for quarantine and destruction purposes only. (7-1-18)

02. Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned if product

integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care. (7-1-18)

03. Donation. Those that qualify for return under the provisions of the Idaho Legend Drug Donation Act as specified in Section 54-1762, Idaho Code. (7-1-18)

315. REPACKAGING DRUG PREVIOUSLY DISPENSED.

A drug outlet may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: (7-1-18)

01. Pharmacist Verification. The repackaging pharmacist verifies the identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within. (7-1-18)

02. Intermingled Drugs. The drugs are never intermingled with the repackaging pharmacy's regular stock. (7-1-18)

03. Labeling. The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes: (7-1-18)

a. The original dispensed prescription's serial number; (7-1-18)

b. The name, address, and phone number of the original dispensing pharmacy; and (7-1-18)

c. A statement that indicates that the drug has been repackaged, such as the words “repackaged by” followed by the name of the repackaging pharmacy. (7-1-18)

316. – 399. (RESERVED).

SUBCHAPTER E – DRUG OUTLET RECORDKEEPING AND REPORTING REQUIREMENTS
(Rules 400 through 499 - Drug Outlet Recordkeeping and Reporting Requirements)

400. RECORDKEEPING: MAINTENANCE AND INVENTORY REQUIREMENTS.

01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)

02. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained as follows: (7-1-18)

a. Schedule II Prescriptions. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file. (7-1-18)

b. Schedule III through V Prescriptions. Paper prescription drug orders for Schedules III, IV and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV and V controlled substances only or in a readily retrievable manner from other prescription records as required by federal law. (7-1-18)

c. Electronic Prescriptions. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location. The electronic application must be capable of printing or otherwise converting the records into a readily understandable format at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filled. (7-1-18)

03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An inventory must be conducted as follows: (7-1-18)

a. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. A separate controlled substances inventory must be taken and retained at each DEA-registered location. (7-1-18)

b. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory. (7-1-18)

c. Drugs Stored Outside a Drug Outlet. In addition to the annual inventory requirements, drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. (7-1-18)

d. Closing of Pharmacy. A closing inventory must be conducted and retained. (7-1-18)

04. Rebuttal Presumption of Violation. Evidence of an amount of a controlled substance that differs from the amount reflected on a record or inventory required by state or federal law creates a rebuttable presumption that the registrant has failed to keep records or maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law. (7-1-18)

05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. The records must include at least: (4-11-19)

a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (4-11-19)

b. The identity and quantity of the drugs received and distributed or disposed of; (4-11-19)

c. The dates of receipt and distribution or other disposition of the drugs; and (4-11-19)

d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)

06. Central Records Storage. Records may be retained at a central location in compliance with federal law. (7-1-18)

07. Electronic Records Storage. Any record required to be kept under this section may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. (7-1-18)

401. RECORDKEEPING: ELECTRONIC SYSTEM FOR PATIENT MEDICATION RECORDS.
A drug outlet that is new or remodeled after the effective date of this rule must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. (7-1-18)

01. Real-time Online Retrieval of Information. The electronic recordkeeping system must be capable of real-time, online retrieval of information stored therein for a minimum of fifteen (15) months from the date of entry. (7-1-18)

02. Immediately Retrievable Refill Data. The electronic recordkeeping system must have functionality that allows refill data to be immediately retrievable and produced upon request; for example, a refill-by-

refill audit trail for a specified strength and dosage form of a drug. (7-1-18)

03. Audit Trail Documentation. The electronic recordkeeping system must also have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited. Drug outlets that utilize offsite pharmacy services for product fulfillment or processing must track the identity and location of each individual involved in each step of the offsite pharmacy services. (7-1-18)

04. System Security. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (7-1-18)

a. Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and (7-1-18)

b. Functionality that documents any alteration of prescription drug order information after a prescription drug order is dispensed, including the identification of the individual responsible for the alteration. (7-1-18)

05. System Downtime, Backup and Recovery. The pharmacy must have policies and procedures in place for system downtime, backup and recovery. (7-1-18)

06. Exemption. Drug outlets are exempt from this section if they fill on average fewer than twenty (20) prescriptions per business day, and paper records must be maintained. (7-1-18)

402. REPORTING REQUIREMENTS.

01. Theft or Loss of Controlled Substances. A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law. (7-1-18)

02. Individual Information Changes. Changes in employment or changes to information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change. (7-1-18)

03. Reporting Adulteration or Misappropriation. A licensee or registrant must report to the Board any adulteration or misappropriation of a controlled drug in accordance with Section 37-117A. Idaho Code. (7-1-18)

04. Drug Distributor Monthly Reports. An authorized distributor must report specified data on drugs distributed at least monthly to the Board in a form and manner prescribed by the Board. (4-11-19)

403. – 499. (RESERVED)

SUBCHAPTER F – PRESCRIPTION DRUG MONITORING PROGRAM REQUIREMENTS
(Rules 500 through 999 – Prescription Drug Monitoring Program Requirements)

500. CONTROLLED SUBSTANCES: PDMP.

Specified data on controlled substances must be reported by the end of the next business day by all drug outlets 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. (7-1-18)

01. Online Access to PDMP. Online access to the Board's PDMP 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 complete and submit a registration application and agree to adhere to the access restrictions and limitations established by law. (7-1-18)

02. Use Outside Scope of Practice Prohibited. Information obtained from the PDMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. A delegate may not access the PDMP outside of their supervisor's scope of professional practice. (7-1-18)

03. Profile Requests. Authorized persons without online access may obtain a profile by completing a Board 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. (7-1-18)

04. Suspension, Revocation, or Restriction of PDMP Access. Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's, pharmacist's, or delegate's authorization for online access to the PDMP. (7-1-18)

501. – 999. (RESERVED)

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