



Idaho State Board of Pharmacy

3380 Americana Terrace, Suite 320

P.O. Box 83720

Boise, Idaho 83720-0067

Telephone (208) 334-2356

FAX (208) 334-3536

Most Applicable Idaho Board of Pharmacy Rules Regarding the Practice of Nursing (This List May Not Be All Encompassing and Other Applicable Laws May Exist)

CONTROLLED SUBSTANCE REGISTRATION

TITLE 37 FOOD, DRUGS, AND OIL CHAPTER 27 UNIFORM CONTROLLED SUBSTANCES ARTICLE III

37-2717. REGISTRATION. (a) The board shall register an applicant to manufacture or distribute controlled substances included in sections [37-2705](#), [37-2707](#), [37-2709](#), [37-2711](#) and [37-2713](#), Idaho Code, unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors:

- (1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
- (2) compliance with applicable state and local law;
- (3) any convictions of the applicant under any federal and state laws relating to any controlled substance;
- (4) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversions;
- (5) furnishing by the applicant of false or fraudulent material in any application filed under this act;
- (6) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
- (7) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture and distribute controlled substances in schedule I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the law of this state. The board need not require separate registration under this article for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this article in another capacity. Practitioners registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this state upon furnishing the board evidence of that federal registration.

435. PREREQUISITES FOR REGISTRATION.

An applicant for an Idaho controlled substances registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances. Applicants for an Idaho controlled substances registration (excepting pharmacists and certified euthanasia technicians) must hold a valid federal DEA registration. (7-1-99)

436. ISSUANCE OF REGISTRATION.

The Board shall issue an Idaho controlled substance registration to persons who have qualified therefore in accordance with the provisions of Title 37, Chapter 27, Idaho Code. The registration shall be issued for a period of one (1) year, shall bear on its face the Seal of the Board, and the signature of the executive director, and will be effective until the first day of January following its issuance. (7-1-93)

437.FEES.

Pursuant to Section 37-2715, Idaho Code, the Board shall collect a fee for each annual registration and a fee for each annual renewal of the registration and shall deposit all registration fees in the state treasury to the credit of the "Pharmacy Fund." (7-1-93)

03. Fee for Dispensing or Conducting Research or Instructional Activities with Controlled Substances. For each registration or re-registration to dispense or to conduct research or instructional activities with controlled substances listed in Schedule II through V, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

438.TIME AND METHOD OF PAYMENT.

Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing in the form of a personal, certified, or cashier's check or money order made payable to the "Idaho State Board of Pharmacy." In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant. (7-1-93)

441.TIME FOR APPLICATION FOR REGISTRATION.

Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the registration is granted by the Board. (7-1-93)

403. DUE DECEMBER 31, ANNUALLY.

01. Controlled Substance Registration. Sixty dollars (\$60). (3-13-02)

461. RECORDS OPEN TO INSPECTION.

Any record required by these rules shall be open at all times to inspection by inspectors of the Board. It is unlawful to refuse to permit or to obstruct such inspection. (7-1-93)

190. INSPECTION REPORTS AND CITATIONS.

A person to whom a license or registration has been issued shall retain copies of inspection reports and citations issued by inspectors or investigators in the performance of their regular duties and shall maintain such reports and citations on the licensed premises in such a manner as to make them readily available upon request of the Board for a period of two (2) years or until destruction is authorized. (7-1-93)

497. INFORMATION FROM THE CONTROLLED SUBSTANCES PRESCRIPTION DATABASE.

01. Authority. These rules are adopted pursuant to the authority of Section 37-2726(4), Idaho Code. (4-2-08)

02. Definitions. The definitions set forth in Section 37-2701, Idaho Code, shall apply to these rules. (4-2-08)

03. Access to Online Prescription Monitoring Program. Access to the Board's online Prescription Monitoring Program shall be limited to licensed practitioners and licensed pharmacists who have registered with the Board. (4-2-08)

04. Registration and Access Requirements. In order to register with the Board and obtain access to the online Prescription Monitoring Program, a licensed practitioner or licensed pharmacist must: (4-2-08)

a. Complete the registration form available from the Board; (4-2-08)

b. Obtain a user account, login name, and password from the Board; and (4-2-08)

c. Agree in writing that: (4-2-08) **i.** No information shall be accessed from the Prescription Monitoring Program by a licensed practitioner having authority to prescribe controlled substances unless it relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance; (4-2-08)

- ii. No information shall be accessed by a licensed pharmacist having authority to dispense controlled substances from the Prescription Monitoring Program unless it relates specifically to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance; (4-2-08)
- iii. Information accessed from the Prescription Monitoring Program shall be kept confidential;(4-2-08)
- iv. Information accessed from the Prescription Monitoring Program shall not be disclosed to any unauthorized person; and (4-2-08)
- v. User account information, login names, and passwords shall not be shared with any person, regardless of whether or not that person is also an authorized user of the online Prescription Monitoring Program. (4-2-08)

05. Conditions of Access and Use. Each of the following conditions applies to access to the online Prescription Monitoring Program and to use of information obtained from it. (4-2-08)

- a. No licensed practitioner or licensed pharmacist authorized by the Board to access the online Prescription Monitoring Program shall share user account information, login names, or passwords with any person, regardless of whether or not that person is also an authorized user of the online Prescription Monitoring Program. (4-2-08)
- b. A licensed practitioner having authority to prescribe controlled substances shall access the online Prescription Monitoring Program only to obtain information specifically related to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance. (4-2-08)
- c. A licensed pharmacist having authority to dispense controlled substances shall access the Prescription Monitoring Program only to obtain information specifically related to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance. (4-2-08)
- d. Information obtained from the Prescription Monitoring Program shall be kept confidential.(4-2-08)
- e. No information obtained from the Prescription Monitoring Program shall be disclosed to any unauthorized person. (4-2-08)
- f. No information obtained from the Prescription Monitoring Program shall be used for a purpose outside the licensed practitioner's or licensed pharmacist's scope of professional practice. (4-2-08)
- g. No licensed practitioner or licensed pharmacist shall permit an unauthorized person to utilize the practitioner's or pharmacist's user account, account name, or password in order to access the online Prescription Monitoring Program regarding any person or for any purpose. (4-2-08)

06. Termination of Access and Discipline. Violation of these rules shall be grounds for suspension, revocation, or restriction of the licensed practitioner's or licensed pharmacist's authorization to access the online Prescription Monitoring Program and shall be grounds for discipline of the licensed practitioner or licensed pharmacist and the imposition of penalties pursuant to Sections 54-1726 and 54-1728, Idaho Code. (4-2-08)

07. Other Profile Requests. Profiles from the Prescription Monitoring Program may be obtained by those persons authorized by Section 37-2726(2), Idaho Code, to obtain such information, but who are not registered and authorized by the Board for online access or are not eligible under these rules for registration and online access, by: (4-2-08)

- a. Completing the form provided by the Board and mailing or faxing the completed form, along with any proof of identification and authorization required by the Board, to the Board's office; or (4-2-08)
- b. By serving upon the Board a lawful order of a court of competent jurisdiction directing the Board to produce the profile to that court or to such person designated by the court in its order. (4-2-08)

08. Additional Grounds for Discipline. A licensed practitioner or licensed pharmacist who obtains an individual's profile pursuant to Subsection 497.07 of these rules shall be subject to discipline and sanctions, pursuant to Sections 54-1726 and 54-1728, Idaho Code, if: (4-2-08)

- a. The profile was obtained for an individual with whom the practitioner or pharmacist did not have a current practitioner/patient or pharmacist/patient relationship at the time the profile was requested; (4-2-08)
- b. The profile was requested for an unlawful purpose; (4-2-08)
- c. The information in the profile was used for an unlawful purpose; or (4-2-08)

d. The profile or information from the profile was disclosed by the practitioner or pharmacist to an unauthorized person. (4-2-08)

09. Duties, Powers, and Immunities. Nothing in these rules shall affect the Board's duties and powers under Sections 37-2730a(2) and 37-2730a(3), Idaho Code, or the immunities granted by Section 37-2730a(4), Idaho Code. (4-2-08)

491. POWERS OF ENFORCEMENT PERSONNEL.

All duly constituted peace officers of political subdivisions and municipalities within the state and all prosecuting attorneys shall have the power and responsibility to enforce the Uniform Controlled Substances Act and these rules, including, but not limited to, Sections 37-2732, 37-2733, 37-2734, 37-2737, and 37-2744, Idaho Code. This rule is not meant, nor shall it be construed, to limit in any way the general police power of peace officers within the state of Idaho, but instead is meant to supplement the enforcement provisions as they are enumerated in the Uniform Controlled Substances Act. (7-1-93)

**TITLE 37 FOOD, DRUGS, AND OIL CHAPTER 27 UNIFORM CONTROLLED SUBSTANCES
ARTICLE III**

37-2718. REVOCATION AND SUSPENSION OF REGISTRATION. (a) A registration under section 37-2717, Idaho Code, to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the board upon a finding that the registrant:

- (1) Has furnished false or fraudulent material information in any application filed under this act;
- (2) Has been found guilty of a felony or misdemeanor under any state or federal law relating to any controlled substance; or
- (3) Has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances;
- (4) Has violated any rule of the board promulgated under this chapter, or any federal regulation relating to controlled substances; provided, however, that no revocation or suspension procedure be initiated under this paragraph without the board first giving notice of the procedure to the state licensing board with authority over the registrant's professional license.

(b) The notice required in paragraph (a)(4) of this section shall be given immediately in the event action is taken without an order to show cause as allowed under section 37-2719(b), Idaho Code. In all other cases, such notice shall be given as early as reasonably practicable without risking compromise of the board's investigation but no later than the earlier of:

- (1) Issuance of an order to show cause under section 37-2719(a), Idaho Code; or
- (2) Setting of a hearing for approval of a resolution of the matter through informal proceedings.

(c) Revocation or suspension procedures arising solely from "practice related issues" shall be referred by the board to such registrant's state licensing board.

(1) Upon such referral, the registrant's state licensing board shall commence such investigation of the referred matter as it deems necessary and shall take action upon the registrant's license or shall inform the board of pharmacy, in writing, that it has investigated the referred matter and has concluded that no action is necessary.

(2) For purposes of this section, the term "practice related issues" refers to issues involving questions regarding the professional conduct of the registrant within the scope of the registrant's profession.

(d) The board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(e) If the board suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefore, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

(f) The board shall promptly notify the bureau and the state licensing board with authority over the registrant's professional license of all orders suspending or revoking registration and all forfeitures of controlled substances.

(g) In the event a state licensing board with authority over a registrant's professional license takes an action against the registrant in any fashion which suspends, restricts, limits or affects the registrant's ability to manufacture, distribute or dispense any controlled substance, the professional licensing board shall promptly notify the board of pharmacy of the action.

(1) Upon such action, the board of pharmacy shall be authorized to issue its order suspending, restricting, limiting or otherwise affecting the registrant's controlled substance registration in the same fashion as the professional licensing board action.

(2) The board of pharmacy order may be issued without further hearing or proceeding, but shall be subject to the effect of any reversal or modification of the professional licensing board action by reason of any appeal or rehearing.

460. REBUTTAL PRESUMPTION OF VIOLATION.

In a proceeding to suspend or revoke the controlled substance registration of a registrant for violation of Section 37-2720, Idaho Code, and in which there is evidence of an amount of a controlled substance that is different from the amount reflected on any record or by any inventory required by federal law and additional rules, if any, issued by the Board, there shall be a rebuttable presumption that the registrant has failed to keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and additional rules, if any, issued by the Board and is in violation of Section 37-2720, Idaho Code. (5-8-09)

467. DUTY OF PROSECUTING ATTORNEY -- REPORT NOT REQUIRED.

It shall be the duty of each prosecuting attorney, to whom the Board reports a violation of these rules, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Nothing in these rules shall be construed as requiring the executive director to report, for the institution of proceedings under these rules, minor violations if the executive director believes that the public interest will be adequately served under the circumstances by a suitable written notice or warning. (7-1-93)

PURCHASING

322. WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENT.

01. License Required. Every wholesale distributor who engages in wholesale distribution of prescription drugs must be licensed by the Board in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs, and every nonresident wholesale distributor, if it ships prescription drugs into this state, must be licensed by the Board in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs. (4-2-08)

321. 18. Wholesale Distribution. Distribution of prescription drugs to persons other than a consumer or patient, but excluding the following:

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use. (4-2-08)

54-1755. PEDIGREE.

(1) In General. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leaves, or has ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

331.PEDIGREE.

05. Maintenance of Pedigree. The purchaser and the wholesale distributor of a prescription drug shall maintain the pedigree for not less than three (3) years from the date of sale or transfer. (4-2-08)

06. Availability of Records for Inspection. Pedigrees shall be made available to the Board for inspection within five (5) business days of a request from the Board. (4-2-08)

Section 1305.03. Distributions requiring a Form 222 or digitally signed electronic order. Either a DEA Form 222 or its electronic equivalent as set forth in subpart C of this part and Part 1311 of this chapter is required for each distribution of a Schedule I or II controlled substance except for the following:

- (a) Distributions to persons exempted from registration under Part 1301 of this chapter.
- (b) Exports from the United States that conform with the requirements of the Act.
- (c) Deliveries to a registered analytical laboratory or its agent approved by DEA.
- (d) Delivery from a central fill pharmacy, as defined in §1300.01(b)(44) of this chapter, to a retail pharmacy.

453. ACQUISITION OF SCHEDULE I AND II SUBSTANCES - PROCEDURE REQUIRED.

Persons authorized to manufacture, distribute, or dispense controlled substances in Schedule I or II, hospitals, and approved state institutions shall acquire these substances for sale, manufacture, administration, distribution or prescription only by executing the official written order required by Section 37-2721, Idaho Code. (7-1-93)

493. SAMPLE, COMPLIMENTARY.

No manufacturer's sales representative shall distribute a controlled substance as a complimentary sample without the written request of an individual practitioner. Such requests shall include the names and addresses of the supplier and the requester and the name and quantity of the specific controlled substance desired and shall be preserved by the supplier with the records required by Section 37-2720, Idaho Code. (7-1-93)

452. EMERGENCY DISTRIBUTION OF A DISPENSER.

In an emergency, a dispenser may distribute (without being registered to distribute) a controlled substance to a second dispenser in order for the second dispenser to dispense the substance. (7-1-93)

01. Allowable Amount. The amount distributed shall not exceed the amount required by the second dispenser for immediate dispensing. (7-1-93)

02. Records of the Distribution. The distribution must be recorded as a dispensing by the first dispenser and the receipt as a distribution received by the second dispenser. Each dispenser must retain a signed receipt of the distribution. (7-1-93)

03. Registration. The second dispenser must be registered to dispense the controlled substance to be distributed to him. (7-1-93)

04. Required Order Form. If the substance is listed in Schedule I or II, an order form must be used as required in Section 37-2721, Idaho Code. (7-1-93)

05. Emergency. For purposes of this Section, an emergency means a situation where a quantity of controlled substance must be dispensed to a person who does not have an alternative source for such substance reasonably available to him and the dispenser cannot obtain such substance through a normal distribution channel within the time required to meet the need of the person for the substance. (7-1-93)

POSSESSING

37-2720. RECORDS OF REGISTRANTS. Persons [Persons] registered to manufacture, distribute, or dispense controlled substances under this act shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.

496. CONTROLLED SUBSTANCE INVENTORY.

01. Inventories and Records for Schedule I and II. Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for Schedule I and II substances shall be maintained in a separate prescription file. (7-1-93)

02. Inventories and Records for Schedules III, IV, and V. Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy. Prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. (7-1-93)

04. Annual Inventory of Stocks of Controlled Substances. Each registered pharmacy shall annually, within seven (7) days of the prior year's inventory, take an inventory of all stocks of controlled substances on hand, following the general requirements for inventories. (5-8-09)

a. The annual inventory, required in these rules, shall be a written record resulting from a physical (or actual) count of stock on hand or in the control of the pharmacist-in-charge of a particular pharmacy. (7-1-93)

b. Automated data processing equipment may be used to provide lists of items (products) and to record receipts and issues of various items, but not to produce the annual inventory. (7-1-93)

c. The record of inventory shall be kept in the inventory book provided by the Board or in another bound book (not loose leaf) suitable to meet the needs of inventory reports. (7-1-93)

d. Upon completion, the inventory will be dated as of the day taken, indicating whether it was taken at the opening or closing of business, and signed by the party that took the inventory. (7-1-93)

05. Separate Inventories for Each Location. A separate inventory shall be made by a registrant for each registered location and shall be kept at the registered location. (7-1-93)

06. Inventory Must Be In Written Form. An inventory must be maintained in a written, typewritten or printed form. If taken by use of an oral recording device it must be promptly transcribed. (7-1-93)

07. Maintaining Written Inventory. Such inventory must be maintained on the premises for a minimum of three (3) years. (7-1-93)

08. Additions to Schedules of Controlled Substances. On the effective date of a rule adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on a schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand, and thereafter, such substance shall be included in each inventory made by the registrant pursuant to Subsection 496.04 of these rules. (7-1-93)

471. THEFT LOSS REPORTS.

It is the duty of every registrant to report any theft or loss of controlled substances to the Board, even if the theft or loss has been accounted for and the employee disciplined internally. The report of the theft or loss required hereunder shall contain all of the information reported to the DEA, as required under 21 CFR 1301.74(c), and shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

PRESCRIBING

TITLE 54 PROFESSIONS, VOCATIONS, AND BUSINESSES CHAPTER 17 PHARMACISTS 54-1705.DEFINITIONS

(30) "Prescription drug or legend drug" means a drug which, under federal law is required, prior to being dispensed or delivered, to be labeled with one (1) of the following statements:

(a) "Caution: Federal law prohibits dispensing without a prescription"; or

(b) "Rx Only"; or

(c) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(31) "Prescription drug order" means a lawful written or verbal order of a practitioner for a drug or device for an ultimate user of the drug or device, issued and signed by a practitioner, or an order transmitted verbally from a practitioner or the practitioner's agent to a pharmacist in a pharmacy, or transmitted verbally from a practitioner and immediately reduced to writing by a licensed practical nurse or licensed professional nurse in a health care facility for a patient or resident of such facility.

351. DEFINITIONS.

04. Controlled Substances. A controlled substance, also referred to as "basic class" or "class drugs," is any substance classified by the federal Food and Drug Administration or the Board in Schedule I through V of the state or federal Controlled Substances Act. (7-1-93)

06. Non-Legend Drug. Any drug that is properly labeled and established as safe and effective by the FDA for sale and use by consumers and approved for sale without a prescription or a practitioner's order. (7-1-93)

TITLE 54 PROFESSIONS, VOCATIONS, AND BUSINESSES CHAPTER 17 PHARMACISTS 54-1733.VALIDITY OF PRESCRIPTION DRUG ORDERS (1)

A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose. A prescription or drug order may be issued either:

(a) By a practitioner acting in the usual course of his profession; or

(b) By a physician, dentist, veterinarian, scientific investigator or other person, other than a pharmacist, who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to dispense, conduct research with respect to or administer the prescribed legend drugs in the course of his professional practice or research in such jurisdiction, so long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription or drug order.

(c) The prescription drug order may be signed and sent electronically pursuant to chapter 50, title 28, Idaho Code.

(d) Transmission of prescription drug order. In addition to delivery of the original signed written prescription to a licensed pharmacy:

(i) A prescription drug order that has been signed by the practitioner may be received by a licensed pharmacy for dispensing purposes through a facsimile transmission from the prescribing practitioner or the practitioner's agent, or from a health care facility for a patient or resident in such facility;

(ii) A prescription drug order may also be received by a licensed pharmacist verbally from the practitioner, the practitioner's agent or from a licensed practical nurse or licensed professional nurse in a health care facility for a patient or resident in such facility;

(iii) A prescription drug order received verbally from the practitioner by a licensed practical nurse or licensed professional nurse in a licensed health care facility for a patient or resident in such facility may also be sent by facsimile transmission from the health care facility to a licensed pharmacy for dispensing purposes provided the transmitted document includes the name of the prescriber issuing the prescription drug order, the name of the nurse who transcribed the order and the name of the person who sent the facsimile.

(2) It is unlawful for a practitioner to knowingly issue an invalid prescription or drug order for a legend drug.

(3) It is unlawful for a pharmacist or veterinarian to knowingly fill an invalid prescription or drug order for a legend drug.

159. PRESCRIPTION REQUIREMENTS.

01. Prescription Requirements. All prescriptions shall at a minimum indicate the following: the name of the patient; the date written; the directions for use; the name, strength, and amount of the medication; the name of the prescriber; and, if written, the pre-printed, stamped or hand-printed name of the prescriber and the handwritten signature of the prescriber. No prescription is refillable unless specifically indicated by the prescriber. Further requirements for controlled substance prescriptions are contained in Subsection 433.10. of these rules. (7-1-98)

433. DEFINITIONS -- (H - Z).

10. Prescription. The term "prescription" means a prescription for a controlled substance in Schedules III, IV, or V that is an oral order given individually for the person for whom prescribed directly from the prescriber or by the prescriber's employee or agent to the pharmacist, or indirectly by means of an order written in ink, indelible pencil, typewritten, or a computer-generated hard copy signed by the prescriber, and contains the address of the prescriber, the prescriber's federal registry number, the name and address of the patient, the name and quantity of the drug prescribed, directions for use, and dated as of the date on which it is written. Written prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all respects to federal and state laws, regulations, and rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules. (4-11-06)

252. PHARMACY PRACTICE IN INSTITUTIONS.

01. Definitions. For purposes of these rules the following apply: (7-1-93)

f. Chart Order is a lawful order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or his designated agent for a drug or device and shall be considered a prescription drug order provided that it contains: (5-8-09)

i. The full name of the patient; (5-8-09)

ii. Date of issuance; (5-8-09)

iii. Name, strength, and dosage form of the drug prescribed; (5-8-09)

iv. Directions for use; and (5-8-09)

v. If written, the prescribing practitioner's signature or the signature of the practitioner's agent, including the name of the prescribing practitioner; or, if electronically submitted, the prescribing practitioner's electronic or digital signature. (5-8-09)

255. DRUG DISTRIBUTION AND CONTROL.

06. Physician's Orders. Drugs may be dispensed from the institutional pharmacy only upon written orders, or direct copies thereof, from authorized physicians, including chart orders. (5-8-09)

07. Authorization of Physicians. The appropriate committee of the institutional facility shall, from time to time, as appropriate, designate those physicians who are authorized to issue orders to the pharmacy. (7-1-93)

08. Use of Abbreviations and Chemical Symbols. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility. (7-1-93)

09. Drug Orders for Inpatient Use. Orders for drugs for use by inpatients shall, at a minimum contain the information required of a chart order by Paragraph 252.01.f. of these rules. (5-8-09)

10. Drug Orders for Outpatient Uses. Orders for drugs for use by outpatients shall, at a minimum, contain all of the items required by the preceding rule and in addition, the quantity, physician's address, and DEA identification number, if applicable, and the patient's address, if applicable. (7-1-93)

37-2723. FORM AND CONTENTS OF PRESCRIPTION. No person shall write a prescription and no person shall fill, compound or dispense a prescription for a controlled substance in schedule II unless it is dated as of, and signed on, the day when issued and bears the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner should sign a prescription in the same manner as he would sign a check or legal document. Prescriptions shall be written with ink or indelible pencil and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to federal and state law, rules and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by law.

Section 1306.04 Purpose of issue of prescription. A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

**37-2725. PRESCRIPTION REQUIRED—PRESCRIPTION BLANKS POSSESSION--
TRANSFERENCE -- CONTENTS.**

(1) A prescription shall be required for all scheduled drugs. Except as provided in subsection (7) of this section, written prescriptions shall comply with federal law and shall utilize noncopyable paper that contains security provisions against copying that results in some indication on the copy that it is a copy and therefore rendering it null and void. Board rules, policies or requirements promulgated or issued to implement the provisions of house bill no. 331 of the first regular session of the fifty-sixth Idaho legislature

that amended this section 37-2725, Idaho Code, shall be null and void and without effect after June 30, 2002. The board shall adopt rules using negotiated rulemaking procedures to implement the provisions of this section that are consistent with, but no more stringent than the requirements of this section and the federal requirements for prescription blanks.

(2) Prescription blanks shall not be transferable. Any person possessing any such blank otherwise than is herein provided is guilty of a misdemeanor.

(3) The prescription blank shall contain the name and address of the practitioner. Prescription blanks may contain the printed names of multiple practitioners who are affiliated; provided however, such prescription blanks shall contain a means (in addition to the signature of the practitioner), such as a box or a check, for clear identification of the printed name and address of the practitioner issuing the prescription.

(4) Prescriptions written by a practitioner in a hospital, nursing home, ambulatory surgery center or other health care facility in which a practitioner may attend a patient, other than his or her regular place of business, may be written on prescription blanks kept or provided by that facility that contains the name and address of that facility (but not necessarily of the practitioner) provided the practitioner's name must be stamped, written or printed on the completed prescription in a manner that is legible to a pharmacist.

(5) Failure of a practitioner to clearly mark the practitioner's printed name and address on the prescription as required in subsection (3) of this section, or to stamp, write or print the practitioner's name legibly as required in subsection (4) of this section shall subject the practitioner to appropriate discipline by the board. The disciplinary measures shall be established by the board in a rule developed through negotiated rulemaking.

(6) Except as provided in section 37-2722, Idaho Code, if a prescription is for a schedule II substance, the practitioner shall indicate the desired quantity of the scheduled drug on the prescription blank by both writing out the quantity and by indicating or writing the quantity in numerical form.

(7) Prescription blanks issued or approved by the board prior to the effective date of this act shall remain valid and may be used by practitioners after the effective date of this act.

(8) Prescription blanks or drugs lost or stolen must be immediately reported to the board.

470. REQUIREMENTS FOR PRESCRIPTION FORM -- DISCIPLINE OF PRACTITIONERS.

01. Prescription Form. A prescription for a controlled substance, including a prescription blank used for a controlled substance prescription, shall conform to the requirements of Section 37-2725, Idaho Code. (3-20-04)

02. Discipline of Practitioners. A practitioner who issues a prescription for a controlled substance that does not comply with the requirements of Section 37-2725, Idaho Code, shall be subject to discipline by the Board as follows: (3-20-04)

a. Definition of "offense." For purposes of this Subsection the term "offense" shall mean clear evidence of a pattern of prescription writing by a practitioner in violation of the requirements of Section 37-2725, Idaho Code. (3-20-04)

b. First offense. A letter with a representative copy or copies of prescriptions giving rise to the letter shall be sent by certified mail, with a return receipt requested, to the practitioner at the practitioner's registration address. The letter shall describe the offense and the basis for required action and a copy of the letter and prescription shall be sent to the practitioner's respective licensing board. The practitioner shall thereafter have thirty (30) days from the date of mailing to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the practitioner's licensing board shall be notified of such failure, allowed thirty (30) days from receipt of notice from the Board to take appropriate action and shall be requested to immediately notify the Board when action is taken. If the Board is not notified of an action taken by the licensing board within the thirty-day period, the Board shall take disciplinary action under Paragraph 470.02.c. of these rules. (3-20-04)

c. Second offense. The practitioner's controlled substance registration shall be suspended for a period of one (1) week, pursuant to Section 37-2718, Idaho Code, and an administrative fine assessed, pursuant to

Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the suspension action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension of registration. The notice shall be sent by certified mail, return receipt requested, to the practitioner at the practitioner's registration address. To avoid the suspension, practitioners may send to the Board a written explanation for the offense, a written plan of action setting forth how the practitioner will avoid offenses in the future, and a payment of one hundred dollars (\$100) within thirty (30) days of the date postmarked on the notice of the offense. The practitioner shall have thirty (30) days from the date postmarked on the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the Board shall take disciplinary action under Paragraph 470.02.d. of these rules. (3-20-04)

d. Third offense. The practitioner's controlled substance registration shall be suspended for a period of thirty (30) days, pursuant to Section 37-2718, Idaho Code, and an administrative fine assessed, pursuant to Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension of registration. The notice shall be sent by certified mail, return receipt requested, to the practitioner at the practitioner's registration address. To avoid the suspension action, practitioners may send to the Board a written explanation for the offense, a written plan of action setting forth how the practitioner will avoid offenses in the future, and a payment of five hundred dollars (\$500) within thirty (30) days of the date postmarked on the notice of the offense. The practitioner shall have thirty (30) days from the date postmarked on the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the Board shall take disciplinary action under Paragraph 470.02.e. of these rules. (3-20-04)

e. Fourth offense. The practitioner's controlled substance registration shall be suspended or revoked, pursuant to Section 37-2718, Idaho Code, for such period as the Board, in its discretion, may determine based on the circumstances, and an administrative fine assessed, pursuant to Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension or revocation of the registration. The notice shall be sent by certified mail, return receipt requested, to the practitioner at the practitioner's registration address. (3-20-04)

f. Offenses subject to discipline under Subsection 470.02 of these rules shall accumulate for each subsequent offense that occurs within six (6) months of the date the practitioner is sent notice of the prior offense. An offense occurring more than six (6) months after the date the practitioner receives notice of any immediately prior offense shall be deemed a first offense. (3-20-04)

g. Prescribing or dispensing controlled substances by a practitioner whose registration has been suspended or revoked hereunder shall be deemed a separate offense of the Board's rules and applicable statute and shall be subject to a separate action by the Board. (3-20-04)

450. REQUIREMENT OF PRESCRIPTION - SCHEDULE V.

04. Dispensing Schedule V Controlled Substances by Individual Practitioner. An individual practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code. (7-1-93)

05. Dispensing Schedule V Controlled Substances by Institutional Practitioner. An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 37-2723, Idaho Code, except for

the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user subject to Section 37-2720, Idaho Code. (7-1-93)

446. REQUIREMENT OF PRESCRIPTION - SCHEDULE III OR IV.

01. Dispensing a Controlled Substance -- Pharmacist. A pharmacist may dispense a controlled substance listed in Schedule III or IV, that is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 37-2722(c), Idaho Code, except for the signature of the prescribing individual practitioner. (7-1-93)

02. Dispensing a Controlled Substance -- Individual Practitioner. An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code. (7-1-93)

03. Dispensing a Controlled Substance -- Institutional Practitioner. An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all of the information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user subject to Section 37-2720, Idaho Code. (7-1-93)

442. REQUIREMENT OF PRESCRIPTION - SCHEDULE II.

01. Pharmacist. A pharmacist may dispense a controlled substance listed in Schedule II, that is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner and on delivery signed by the individual receiving such except as provided in Subsection 442.04 of these rules. (7-1-93)

04. Emergency. In the case of an emergency situation, as defined in Section 37-2722(b), Idaho Code, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner. (7-1-93)

a. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner). (7-1-93)

b. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner. (7-1-93)

c. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory or other good faith effort to ensure his identity, or both. (7-1-93)

d. Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirement of Section 37-2723, Idaho Code, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. (7-1-99)

e. The written prescription may be delivered to the pharmacist in person or by mail; however, if delivered by mail, it must be postmarked within the seven-day period. (7-1-99)

g. The pharmacist shall notify the Board if the prescribing individual practitioner fails to deliver a written prescription to him. Failure of the pharmacist to so notify the Board shall void the prescribing individual practitioner's authority, conferred by this Subsection to dispense without a written prescription. (7-1-93)

454. PRESCRIBING FOR SELF PROHIBITED.

No person shall prescribe, administer, or furnish a controlled substance for himself. (7-1-93)

455. ANTEDATING OR POSTDATING PRESCRIPTION PROHIBITED.

No person shall antedate or postdate a prescription. (7-1-93)

456. FALSE NAME OR ADDRESS PROHIBITED.

No person shall, in connection with the prescribing, furnishing, administering or dispensing of a controlled substance, give a false name or false address.

457. ALTERATION OR ERASURE - FILLING PROHIBITED.

No person shall fill a prescription if it shows evidence of alteration, erasure, or addition by any person other than the person writing it. (7-1-93)

464. FILLING A CONTROLLED SUBSTANCE PRESCRIPTION AND POSITIVE IDENTIFICATION.

01. Filling and Dispensing. No person other than a registered pharmacist under the laws of this state shall be responsible for the filling and dispensing of a prescription for a controlled substance. (4-2-08)

184. UNPROFESSIONAL CONDUCT.

The following acts or practices by a licensed pharmacist or a pharmacy owner declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: (7-1-93)

03. Prescriber Incentives. Allowing a commission or rebate to be paid to a person writing, making, or otherwise ordering a prescription, or providing consultant services at no charge to receive prescription business. (7-1-93)

162. PRESCRIPTION EXPIRATION.

Prescription orders that are legally refillable must have the refill instructions indicated on their face. All prescription orders expire fifteen (15) months after date of issue. For long term medication orders a new prescription must be obtained and a new file number issued. (4-6-05)

163. EMERGENCY PRESCRIPTION REFILL. In an emergency a pharmacist may refill a prescription for a patient if the prescribing practitioner is not available for authorization and, in the professional judgment of the pharmacist, the prescription should be refilled. Only sufficient medication may be furnished for the emergency period and the practitioner must be contacted as soon as possible for further refill instructions. (7-1-93)

443. REFILLING PRESCRIPTIONS.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. (7-1-93)

458. EXPIRATION DATE: SCHEDULE II PRESCRIPTION DRUG ORDER.

No Schedule II prescription drug order shall be filled more than ninety (90) days after the date the order was written. (5-8-09)

447. REFILLING OF PRESCRIPTION.

No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six (6) months after the date on which the prescription was issued, and no such prescription authorized to be refilled may be refilled more than five (5) times. (7-1-93)

03. New Prescription Required for Additional Quantities. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new and separate prescription, as provided in Section 37-2722, Idaho Code. (7-1-93)

444. PARTIAL FILLING OF PRESCRIPTIONS.

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and a notation is made of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). (7-1-93)

01. Remaining Portion of Prescription. The remaining portion of the prescription may be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner.(7-1-93)

02. Supplying Further Quantity. No further quantity may be supplied after the seventy-two (72) hour period without a new prescription. (7-1-93)

03. Partial Quantities. A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." (7-1-99)

b. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date, unless sooner terminated by the discontinuance of medication. (7-1-99)

160. PRESCRIPTION TRANSFER.

A pharmacist may transfer prescription order information for the purpose of filling or refilling a prescription only if the information is communicated orally directly from pharmacist to pharmacist. Such oral information can be communicated by a student pharmacist, under the direct supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. In the alternative, the transferring pharmacist may transfer the prescription order information by facsimile transmission to the receiving pharmacist. In the case of a facsimile transmission, the transmission shall be signed by the transferring pharmacist. (3-29-10)

01. Transferring Prescriptions for Controlled Substances. A prescription for a controlled substance may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer. (7-1-93)

180. DIFFERENTIAL HOURS.07. Oral Prescriptions. An oral prescription may not be accepted if the pharmacist is not present unless the prescription is taken on a recording that must inform the caller of the times the pharmacy is open. (7-1-93)

251. PHARMACY TECHNICIANS.

c. Only a registered pharmacist may do any of the following (which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a licensed pharmacist's professional judgment): (4-5-00)

i. Receive a new prescription order verbally from a prescriber or other person authorized by law. (4-5-00)

iii. Consult with the prescriber concerning any necessary clarification regarding a patient and his prescription. (4-5-00)

v. Perform professional consultation with any prescriber, nurse or other health care professional. (7-1-93)

187. PROHIBITED ACTS - DRUG PRODUCT SUBSTITUTION.

02. Substitution Prohibition Exception. Substitutions are allowed only in situations requiring compliance with a formulary or drug list prepared by: (5-8-09)

a. The pharmacy and therapeutics committee of a hospital and agreed to by the staff physicians of the hospital. (5-8-09)

b. The quality assessments and assurance committee of a skilled nursing facility, consisting of the director of nursing services, a physician designated by the facility, and at least three (3) other members of the facility's staff. For purposes of this rule, a "skilled nursing facility" means an institutional facility, or a distinct part of an institutional facility, which is primarily engaged in providing daily skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for injured, disabled or sick persons.

188. DRUG PRODUCT SELECTION.

Drug product selection is allowed only between bioequivalent products. (7-1-93)

01. Method of Drug Product Selection. For non-Medicaid patients a brand must be dispensed only if the prescriber has indicated "BRAND ONLY" by checking the appropriate box on the face of the prescription. (4-11-06)

03. Consumer's Right of Refusal. The consumer shall have the right to refuse generic equivalents when product selection has been allowed by the practitioner. (7-1-93)

04. Labeling. Unless the prescriber indicates "Do not label," the pharmacist shall label the prescription with the brand name dispensed or, if filled with a generic, the name of the drug and the manufacturer. In addition, he must indicate the same information on the face of the prescription. (7-1-93)

05. Definition of Drug Product Selection. Drug product selection is the act of selecting either the brand or a therapeutically-equivalent generic drug product and is permitted in the state of Idaho. (7-1-93)

ADMINISTERING

TITLE 54 PROFESSIONS, VOCATIONS, AND BUSINESSES CHAPTER 17 PHARMACISTS 54-

1721. UNLAWFUL PRACTICE (1)

It shall be unlawful for any person to engage in the practice of pharmacy unless licensed to so practice under the provisions of this act; provided, however, physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this state may deliver and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by statute of this state.

256. ADMINISTRATION OF DRUGS.

01. Administration of Drugs. Drugs shall be administered at an institutional facility, only upon the orders, including chart orders, of those members of the medical staff who have been granted clinical privileges, or who are authorized members of the house staff, by authorized licensed facility personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable law and rules, and in accordance with usual and customary standards of good medical practice. (5-8-09)

02. Self-Administration of Drugs by Patients. Self-administration of drugs by patients shall be permitted only when specifically authorized by the treating or ordering physician and only if the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient. (7-1-93)

259. INVESTIGATIONAL DRUGS.

Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal physician-investigator or his authorized clinician with prior approval of the appropriate committee of the institutional facility. (7-1-93)

01. Administration of Investigational Drugs. Nurses may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the clinician of the pharmacy. (7-1-93)

DISPOSAL OF RX & NON-RX DRUGS

Federal Guidelines For Drug Disposal- Office of National Drug Control Policy October 2009

(a) Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA's website.

(b) To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community.

(c) If a drug take-back or collection program is not available:

1. Take your prescription drugs out of their original containers.
2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
5. Place the sealed container with the mixture, and the empty drug containers, in the trash.

495. CONTROLLED SUBSTANCE DISPOSAL.

Any person in possession of a controlled substance and desiring or required to dispose of the substance may request the assistance of the executive director of the Board in disposing of such substances. (7-1-93)

01. If Reports Required by Registrant for Disposal of Controlled Substance. If the person is a registrant required to make reports, pursuant to Section 37-2720, Idaho Code, he shall list the controlled substance or substances that he desires to dispose of on IBP Form 15 in quadruplicate and submit three copies to the Board. (7-1-93)

156. PHARMACIES.

05. Return of Drugs or Other Items. In the interest of public health, drugs, medicines, sickroom supplies, devices, and items of personal hygiene shall not be accepted for return by any pharmacist or pharmacy after such drugs, medicines, sickroom supplies, devices, and items of personal hygiene have been taken from the premises where sold, distributed, or dispensed, except that medications for in-patients of residential or assisted living facilities, licensed skilled nursing care facilities, and hospitals may be returned to the dispensing pharmacy for credit if the medications are liquid medications that have been supplied in manufacturer sealed containers and remain unopened, or the medications are in unopened "unit dose" packaging. In addition, the conditions set forth in Paragraph 156.05.b. of these rules must be satisfied: (3-20-04)

a. Unit dose is defined as medications packaged in individual, sealed doses with tamper-evident packaging (for example, single unit of use, blister packaging, unused injectable vials, and ampules). (3-20-04)

b. The following conditions must be satisfied: (3-20-04)

- i. The medications must be returned with tamper-evident packaging intact and with no evidence of tampering. (3-20-04)
- ii. In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity. (4-5-00)
- iii. Policies and procedures are followed for the appropriate storage and handling of medications at the facility and for the transfer, receipt, and security of medications returned to the dispensing pharmacy. (4-5-00)
- iv. A system is in place to track restocking and reuse to allow medications to be recalled if required. (4-5-00)
- v. No controlled substance may be returned except those delivered by unit dose on a daily delivery system. (4-5-00)
- vi. If the drug is prepackaged by the pharmacy, each prepackaged container must be labeled in accordance with the following (For purpose of this rule, any change from the original manufacturer's packaging prior to delivery of the medication to the hospital or the facility shall be considered prepackaged): (3-20-04)
 - (1) Name and strength of the medication; (3-20-04)
 - (2) A suitable expiration date that shall not be later than the expiration date on the original manufacturer's container or one (1) year from the date the drug is prepackaged (If a medication that was prepackaged and delivered to the hospital or facility is thereafter returned to the pharmacy and subsequently prepackaged again, the expiration date hereunder shall not be later than the expiration date used when the medication was initially prepackaged.); (3-20-04)
 - (3) The date the medication was prepackaged; (3-20-04)
 - (4) The manufacturer's lot number, expiration date, and identity; and (3-20-04)
 - (5) The identity of the pharmacist responsible for the prepackaging. (3-20-04)
- c. If the information required under Subparagraphs 156.05.b.vi.(4) and 156.05.b.vi.(5) of these rules is maintained in the internal records of the pharmacy, those requirements may be omitted from the labeling. The labeling requirements of Subparagraph 156.05.b.vi. of these rules shall apply in addition to the labeling requirements under Section 159 of these rules. (3-20-04)
- d. Medications that have been outside the custody and control of the hospital or facility for any reason are not eligible for return. To be considered as having been in the custody and control of the hospital or facility, the medications must have been delivered by the dispensing pharmacy directly to the hospital or facility or to an agent thereof who is authorized and qualified to accept delivery, and the medications must then be held by the hospital or facility in an area suitable for storing medications and not accessible to patients. Once a medication has passed from the hospital or facility storage area to the patient or to the patient's designee for any reason, the medication is no longer eligible for return. (3-20-04)
- e. Medications otherwise eligible for return under this rule by virtue of their packaging but that have become ineligible for return for any reason must be marked as follows: (3-20-04)
 - i. Medications released for self-administration by the patient or for administration outside the hospital or facility premises or otherwise released to be taken outside the custody and control of the hospital or facility shall first be clearly marked and identified "Not Eligible For Return"; however, the foregoing requirement for marking shall not apply to the daily dose of medication released to a patient on the day such dose is to be administered if the hospital or facility does not allow the medication to be returned to the same medication storage area as medications eligible for return. (3-20-04)
 - ii. Medications that are received by the hospital or facility from the patient or the patient's representative, and not directly from the dispensing pharmacy, and that are to be stored in the same storage area as medications which are eligible for return, shall first be clearly marked and identified "Not Eligible for Return." (3-20-04)
 - iii. In the event medications otherwise eligible for return under this rule by virtue of their packaging are discovered to be ineligible for return because they have been outside the custody and control of the hospital or facility, or for any other reason, such medications shall be clearly marked and identified "Not Eligible for Return" immediately upon discovery if they are to remain stored in the same storage area as medications that are eligible for return. (3-20-04)
- f. Each pharmacy and its pharmacist-in-charge shall be responsible for consulting with each hospital or facility from which the pharmacy will accept returns under Section 156 of these rules to ensure that the

hospital or facility has an employee who is trained and knowledgeable in the proper storage, use, and administration of medications at the hospital or facility and to ensure that the hospital or facility has in place and enforces written protocols that will ensure compliance with the conditions necessary to allow returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval thereof, on file in the pharmacy and produce them for Board inspectors upon request. (3-20-04)

g. Each pharmacy and its pharmacist-in-charge that will be accepting returns under Section 156 of these rules shall establish written protocols for the pharmacy that will ensure compliance with Section 156 for all returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval thereof, on file in the pharmacy and produce them for Board inspectors upon request. (3-20-04)

06. Damaged Drugs. To sell, offer for sale, barter, or give away drugs damaged by fire, water, or any other means that might affect the potency of the drug is prohibited without first obtaining the written approval of the Board. (7-1-93)

07. Dangerous Drugs. Legend drugs, controlled substances, or other limited sale items must be stored in accordance with United States Pharmacopoeia/National Formulary requirements in the prescription area (where prescriptions are compounded, dispensed or filled) and in a manner as to limit access to licensed pharmacists or authorized personnel of that area only. Failure to comply with this requirement shall be *prima facie* evidence of unprofessional conduct. (7-1-93)

LEGEND DRUG DONATION ACT

380. LEGEND DRUG DONATION – STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. In order to be eligible for donation, drugs must meet the following criteria: (3-29-10)

a. The drug name, strength, lot number, and expiration date must appear on the drug package or label. (3-29-10)

b. Donated drugs must be approved by the federal Food and Drug Administration and: (3-29-10) i. Be in the original unit dose packaging; or (3-29-10) ii. Be oral or parenteral drugs in sealed single-dose containers approved by the federal Food and Drug Administration; or (3-29-10) iii. Be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or (3-29-10) iv. Be parenteral drugs in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn. (3-29-10)

c. Donated drugs must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug wholesaler or manufacturer. (3-29-10)

d. Donated drugs must not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia. (3-29-10)

e. Donated drugs must not be the subject of federal Food and Drug Administration restricted drug distribution programs including, but not limited to, thalidomide and lenalidomide. (3-29-10)

02. Donation Standards. (3-29-10)

a. A licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority at the qualifying charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. (3-29-10)

b. Donating nursing homes may only donate drugs that appear on the qualifying charitable clinic or center's formulary. (3-29-10)

c. A licensed pharmacist, nurse, physician, or physician assistant from the donating nursing home must sign and date a manifest before delivery of the donated drugs to the qualifying charitable clinic or center that:

i. Certifies that the donated drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and the United States Pharmacopoeia standards; (3-29-10) ii. Certifies that the donated drugs have been continuously under control of a health

care professional and have never been in the custody of a patient or other individual; (3-29-10) iii. Certifies that the donating nursing home has only donated drugs on the qualifying charitable clinic or center's formulary; (3-29-10) iv. Certifies that the donating nursing home has complied with the provisions of these rules; (3-29-10) v. Certifies that the patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the donating nursing home; (3-29-10) vi. Lists the name of the donating nursing home and the name of the receiving qualifying charitable clinic or center; and (3-29-10) vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug to be donated. (3-29-10)

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. (3-29-10)

03. Receipt of Donated Drugs. Donated drugs may be received at a qualifying charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel. (3-29-10)

04. Verification of Received Drugs. (3-29-10)

a. Receipt of each donated drug must be verified against each manifest by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel. (3-29-10)

b. In the event that the identifying patient information is not removed by the donating entity, the information must be removed or redacted at the charitable clinic or center. (3-29-10)

c. Before donated drugs are placed with a qualified charitable clinic or center's regular stock, a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must: (3-29-10) i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the donated drugs meet the criteria in Subsection 380.01 of these rules; (3-29-10) ii. Verify that the name and strength noted on the label of each unit of the donated drug is correct; and (3-29-10) iii. Determine that the donated drugs are not adulterated or misbranded and that they are safe to dispense. (3-29-10)

d. Improperly donated drugs that do not meet criteria in Subsections 380.01 through 380.03 of these rules must be destroyed, and documentation of such destruction must be maintained within a destruction record. (3-29-10)

05. Storage of Donated Drugs. (3-29-10)

a. Drug storage must have proper environmental controls to assure the integrity of the drug in accordance with the drug manufacturer's recommendations and United States Pharmacopoeia standards. (3-29-10)

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 drugs has been labeled to show that the drugs were obtained through a nursing home. (3-29-10)

c. Donated drugs with packaging that has not been labeled to show that the drugs were obtained through a nursing home must be kept in an area that is separately designated from the qualifying charitable clinic or center's regular stock of drugs. (3-29-10)

d. The space in which drugs are stored must be secured at all times and accessible only to pharmacists, physicians, physician assistants, dentists, optometrists, advanced practice professional nurses with prescriptive authority, and authorized clinic personnel. (3-29-10)

06. Dispensing Donated Drugs to Medically Indigent Patients. (3-29-10)

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions must not be re-dispensed to indigent patients and must be destroyed. Documentation of such destruction must be maintained within a destruction record. (3-29-10)

b. A licensed pharmacist, physician, physician assistant, dentist, optometrist, or an advanced practice professional nurse with prescriptive authority working at a qualifying charitable clinic or center who re-dispenses donated drugs to any patient must: (3-29-10) i. Utilize a proper and appropriate container; (3-29-10) ii. Place a label on the container that conforms to provisions of these rules; and (3-29-10) iii. Initial the prescription label. (3-29-10)

- c. The re-dispensed drug must be assigned the same expiration date as is on the original package. (3-29-10)
- d. A charitable clinic or center must maintain dispensing records for each donated drug dispensed. (3-29-10)
- e. Licensed pharmacists, physicians, physician assistants, dentists, optometrists, and advanced practice professional nurses with prescriptive authority dispensing donated drugs are required to provide patient counseling. (3-29-10)

07. Miscellaneous. (3-29-10)

- a. Authorized clinic personnel means an individual who is: (3-29-10) i. Under the general supervision of a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority; and (3-29-10) ii. Named in writing by the qualifying charitable clinic or center's medical director or consultant pharmacist. (3-29-10)
- b. The qualifying charitable clinic or center must maintain a list of the names of authorized clinic personnel, their individual duties, and a summary of their qualifications. (3-29-10)
- c. Physician assistant has the same definition as in Section 54-1803, Idaho Code. (3-29-10)
- d. Qualifying charitable clinics or centers receiving donated drugs must develop policies and procedures to assure that authorized clinic personnel will comply with applicable federal, state, and local laws. (3-29-10)
- e. Drugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. (3-29-10)
- f. Nothing in these rules precludes a qualifying charitable clinic or center from charging an indigent patient a dispensing fee. (3-29-10)

08. Record Keeping Requirements. (3-29-10)

- a. Donating nursing homes must maintain all manifests in a readily retrievable fashion for at least two (2) years. (3-29-10)
- b. Qualifying charitable clinics or centers must maintain destruction records, dispensing records, and manifests in a readily retrievable fashion for at least two (2) years. (3-29-10)