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IDAHO PHARMACY LAWS

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Title 37 Food, Drugs & Oil: Chapter 1 - Idaho Food, Drug & Cosmetic Act
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Title 54 – Professions, Vocations & Businesses: Chapter 17 - Pharmacists
Rules of the Idaho State Board of Pharmacy

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CHAPTER 1
IDAHO FOOD, DRUG AND COSMETIC ACT

37-113.SHORT TITLE. This act may be cited as the Idaho Food, Drug and Cosmetic Act.

[37-113, added 1959, ch. 153, sec. 1, p. 351.]
37-114.DEFINITIONS. For the purpose of this act

(a) The term "board" means the state board of health and welfare and "director" means the director of the department of health and welfare.

(b) The term "person" includes individual, partnership, corporation, and association;

(c) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article;

(d) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals, and (4) articles intended for use as a component of any article specified in clause (1), (2) or (3), but does not include devices or their components, parts or accessories;

(e) The term "device" (except when used in paragraph (k) of this section and in section [sections] 37-115(g), 37-123(f), 37-127(b) and 37-130(c), Idaho Code) means instruments, apparatus and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals;

(f) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (2) articles intended for use as a component of any such articles, except that such term shall not include soap;

(g) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

(h) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article, and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if there be any, of the retail package of such article, or is easily legible through the outside container or wrapper;

(i) The term "immediate container" does not include package liners;

(j) The term "labeling" means all labels and other written, printed or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article;

(k) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or in any

combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual;

(l) The term "advertisement" means all representations disseminated in any manner or by any means other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;

(m) The representation of a drug in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body;

(n) The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions;

(o) The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations;

(p) The provisions of this act regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale, and the sale, dispensing, and giving of any such article and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

(q) The term "federal act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).

[37-114, added 1959, ch. 153, sec. 2, p. 351; am. 1974, ch. 23, sec. 14, p. 633.]

37-115.PROHIBITED ACTS. The following acts and the causing thereof within the state of Idaho are hereby prohibited:

(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

(b) The adulteration or misbranding of any food, drug, device, or cosmetic;

(c) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 37-124 or 37-127;

(e) The dissemination of any false advertisement;

(f) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 37-133;

(g) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the state of Idaho from whom he received in good

faith the food, drug, device, or cosmetic;

(h) The removal or disposal of a detained or embargoed article in violation of section 37-118;

(i) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this act;

(k) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 37-128, or that such drug complies with the provisions of such section.

[37-115, added 1959, ch. 153, sec. 3, p. 351.]

37-116.INJUNCTIONS AUTHORIZED. In addition to the remedies hereinafter provided the director is hereby authorized to apply to the district court for, and such court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of section 37-115, Idaho Code, irrespective of whether or not there exists an adequate remedy at law.

[37-116, added 1959, ch. 153, sec. 4, p. 351; am. 1974, ch. 23, sec. 15, p. 633.]

37-117.VIOLATIONS -- PENALTY -- EXCEPTIONS.

(1) (a) Any person who intentionally adulterates a drug that is held for sale or distribution, or that is to be administered or dispensed, shall be guilty of a felony and shall, upon conviction thereof, be subject to imprisonment for not more than fifteen (15) years or a fine of not more than fifty thousand dollars ($50,000), or both.

(b) Any health care provider who, with knowledge that a drug has been adulterated, permits that drug to be administered or dispensed to a person shall be guilty of a felony and shall, upon conviction thereof, be subject to imprisonment for not more than fifteen (15) years, or a fine of not more than fifty thousand dollars ($50,000), or both. For the purposes of this subsection, the term "health care provider" shall be defined as any person licensed in this state to prescribe, dispense, conduct research with respect to, or administer drugs in the course of professional practice and any unlicensed person, who, as part of such person's employment or profession, provides health care services.

(c) The determination of whether or not a drug has been adulterated shall be made in accordance with the provisions of section 37-126, Idaho Code.

(2) Any person who violates any of the provisions of this act or of rules promulgated by the board of health and welfare thereunder or who interferes with the director of the department of health and welfare or the personnel of the department in the administration of this act shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than six (6) months or a fine of not more than five hundred dollars ($500), or both such imprisonment and fine, but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than one (1) year, or a fine of not more than one thousand dollars ($1000), or both such imprisonment and fine.

(3) No person shall be subject to the penalties of subsection (2) of this section, for having

violated section 37-115 (a) or (c), Idaho Code, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the state of Idaho from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this act, designating this act.

(4) No publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused, on the request of the director to furnish him the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the state of Idaho who causes him to disseminate such advertisement.

[37-117, added 1959, ch. 153, sec. 5, p. 351; am. 1974, ch. 23, sec. 16, p. 633; am. 2002, ch. 231, sec. 1, p. 661.]

37-117A.REPORTING AND DISCLOSURE REQUIREMENTS FOR EMPLOYMENT RELATED ADULTERATION OR MISAPPROPRIATION OF CERTAIN DRUGS. (1) When the employment of a health care provider has been terminated, either voluntarily or involuntarily, for adulteration or misappropriation of controlled substances, as defined in chapter 27, title 37, Idaho Code, the employer shall, within thirty (30) days of the termination, furnish written notice of the termination, described herein as "notice of termination," to the health care provider's professional licensing board of the state of Idaho, which shall include a description of the controlled substance adulteration or misappropriation involved in the termination. An employer who in good faith provides such information shall not be held civilly liable for the disclosure or the consequences of providing the information. There is a rebuttable presumption that an employer is acting in good faith when the employer provides such information. The presumption of good faith is overcome only upon showing by clear and convincing evidence that the employer disclosed the information with actual malice or with deliberate intent to mislead. For the purposes of this section, "actual malice" means knowledge that the information was false or given with reckless disregard of whether the information was false. For the purposes of this section, the term "health care provider" means any person licensed by a professional licensing board of the state of Idaho whose license permits the health care provider to dispense or administer controlled substances. For the purposes of this section, "employer" means a person or entity licensed under chapter 18, title 54, Idaho Code, or chapter 13, title 39, Idaho Code, who employs a health care provider or providers.

(2) A professional licensing board that receives a notice of termination from an employer pursuant to subsection (1) of this section shall maintain the notice of termination for the health care provider. The notice of termination shall be subject to disclosure in accordance with the provisions of subsection (3) of this section.

(3) Any prospective employer of a health care provider shall, before hiring such health care provider, request in writing that the health care provider's professional licensing board furnish the prospective employer any notice of termination maintained by the board with respect to the health care provider. The prospective employer shall maintain the confidentiality of such information and shall not disclose it to any other person or entity without the prior written approval of the health care provider or as required by law, court order or the rules of civil procedure. The professional licensing board shall require, as a condition of furnishing the notice of termination, that the prospective employer file a written request for the health care provider's notice of termination, stating under oath that the request for the notice of termination is made for a bona fide hiring

purpose, that the request is made pursuant to the provisions of this section, and that the prospective employer will not disclose the information to any other person or entity without the prior written approval of the health care provider or as required by law, court order or rules of civil procedure. In the event that the prospective employer discloses the information in the notice of termination to any other person or entity in violation of the provisions of this section, and unless the disclosure is required by law, court order or the rules of civil procedure, the health care provider may pursue a civil cause of action against the prospective employer for a breach of the health care provider's right of privacy. Upon receipt of a request made in accordance with this section for a health care provider's notice of termination, the professional licensing board shall furnish the notice of termination to the prospective employer. The professional licensing board shall not be held liable for the correctness or completeness of the information contained in the notice of termination and shall include a disclaimer statement on all released information, attesting that the information has not been verified by the professional licensing board. An employer who obtains a notice of termination from the appropriate professional licensing board as provided in this section shall not be held civilly liable for hiring or contracting with a health care provider who the employer in good faith believes has been rehabilitated from drug abuse, absent the employer's gross negligence or reckless conduct.

(4) Notices of termination submitted hereunder shall be maintained and available to employers as set forth above for fifteen (15) years from the date of receipt by the professional licensing board.

[37-117A, added 2004, ch. 333, sec. 1, p. 993.]

37-118.TAGGING AND DETENTION OF ARTICLE OR PRODUCT SUSPECTED OF BEING ADULTERATED OR MISBRANDED -- EMBARGO AND CONDEMNATION UNDER CERTAIN CONDITIONS AND BY CERTAIN PROCEDURES. (a) Whenever a duly authorized agent of the director finds or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this act, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

(b) When an article detained or embargoed under subsection (a) of this section has been found by such agent to be adulterated, or misbranded, he shall petition the probate court or district court in the county in whose jurisdiction the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree be destroyed at the expense of the claimant thereof, under the supervision of such agent, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing

under the supervision of an agent of the director. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the director that the article is no longer in violation of this act, and that the expenses of such supervision have been paid.

(d) Whenever the director or any of its authorized agents shall find in any room, building, vehicle of transportation or other structure, any meat, sea food, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the director or its authorized agent, shall forthwith condemn or destroy the same, or in any other manner render the same unsaleable as human food.

(e) Whenever the director or its duly authorized agent shall find, or have probable cause to believe, that any food, drug, device or cosmetic is offered or exposed for sale, or held in possession with intent to distribute or sell, or is intended for distribution or sale in violation of any provision of this act, whether it is in the custody of a common carrier or any other person, the director may affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, in violation of this act, and has been embargoed. Within seven (7) days after an embargo has been placed upon any article, the embargo shall be removed by the director or a summary proceeding for the confiscation of the article shall be instituted by the director. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the director or agent; or after summary proceedings have been instituted, without permission from the court. If the embargo shall be removed by the director or by the court, neither the director nor the state shall be held liable for damages because of such embargo in the event that the court shall find that there was probable cause for the embargo.

(f) Such proceeding shall be by complaint, verified by affidavit, which may be made on information and belief in the name of the director or agent against the article to be confiscated.

(g) The complaint shall contain: (1) a particular description of the article, (2) the name of the place where the article is located, (3) the name of the person in whose possession or custody the article was found, if such name be known to the person making the complaint or can be ascertained by reasonable effort, and (4) a statement as to the manner in which the article is adulterated or misbranded or the characteristics which render its distribution or sale illegal.

(h) Upon the filing of the verified complaint, the court shall issue a warrant directed to the proper officer to seize and take in his possession the article described in the complaint and bring the same before the court who issued the warrant and to summon the person named in the warrant, and any other person who may be found in possession of the article, to appear at the time and place therein specified.

(i) Any such person shall be summoned by service of a copy of the warrant in the same manner as a summons issuing out of the court in which the warrant has been issued.

(j) The hearing upon the complaint shall be at the time and place specified in the warrant, which time shall not be less than five (5) days or more than fifteen (15) days from the date of issuing the warrant, but, if the execution and service of the warrant has been less than three (3) days before the return of the warrant, either party shall be entitled to a reasonable continuance. Upon the hearing the complaint may be amended.

(k) Any person who shall appear and claim the food, drug, device, or cosmetic seized under the warrant shall be required to file a claim in writing.

(l) If, upon the hearing, it shall appear that the article was offered or exposed for sale, or was in possession with intent to distribute or sell, or was intended for distribution or sale, in violation of any provision of this act, it shall be confiscated and disposed of by destruction or sale as the

court may direct, but no such article shall be sold contrary to any provision of this act. The proceeds of any sale, less the legal costs and charges, shall be paid into the state treasury.

[37-118, added 1959, ch. 153, sec. 6, p. 351; am. 1974, ch. 23, sec. 17, p. 633.]
37-119.PROSECUTIONS OF VIOLATIONS -- RIGHT OF PARTY TO NOTICE AND PRESENTATION OF VIEWS PRIOR TO PROSECUTION. It shall be the duty of each county prosecuting attorney to whom the director or his agent reports any punishable violation of this act (including, but not limited to, rules and regulations) to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Before any violation of this act is reported to the county prosecuting attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the director or his designated agent, either orally or in writing, in person, or by attorney, with regard to such contemplated proceeding.

[37-119, added 1959, ch. 153, sec. 7, p. 351; am. 1974, ch. 23, sec. 18, p. 633.]
37-120.REPORT OF MINOR VIOLATIONS. Nothing in this act shall be construed as requiring the director to report for the institution of proceedings under this act, minor violations of this act, whenever the director believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

[37-120, added 1959, ch. 153, sec. 8, p. 351; am. 1974, ch. 23, sec. 19, p. 633.]
37-121.PROMULGATION OF REASONABLE STANDARDS BY BOARD. Whenever in the judgment of the board such action will promote honesty and fair dealing in the interest of consumers, the board shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the federal act.

[37-121, added 1959, ch. 153, sec. 9, p. 351.]
37-122.FOOD DEEMED ADULTERATED. A food shall be deemed to be adulterated--(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 37-125; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or (5) if it is the product of a diseased

animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is.

(c) If it is confectionery and it bears or contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per centum (.4%), harmless natural gum, and pectic; Provided, that this paragraph shall not apply to any confectionery by reason of its containing less than one-half of one per centum (.5%) by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances.

(d) If it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the federal act.

[37-122, added 1959, ch. 153, sec. 10, p. 351.]

37-123.FOOD DEEMED MISBRANDED. A food shall be deemed to be misbranded--

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word, imitation, and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the board.

(f) If any word, statement, or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 37-121, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, in so far as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as--(1) A food for which a standard of quality has been prescribed by regulations as provided by section 37-121 and its quality falls below such standard unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (2) A food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 37-121, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section, unless it bears labeling clearly giving (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each; Provided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the board.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the board determines to be, and by regulations prescribed, as, necessary in order to fully inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; Provided, that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

[37-123, added 1959, ch. 153, sec. 11, p. 351.]

37-124.CONTAMINATION OF FOOD WITH MICROORGANISMS -- PERMIT REGULATIONS -- ACCESS TO FACTORY. (a) Whenever the director finds after investigation that the distribution in Idaho of any class of food may, by reason of contamination with microorganisms during manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, he then, and in such case only, shall prescribe regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the director as provided by such regulations.

(b) The director is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the director shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the director shall have access to any factory or establishment, the operator of which holds a permit from the director for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

[37-124, added 1959, ch. 153, sec. 12, p. 351; am. 1974, ch. 23, sec. 20, p. 633.]

37-125.POISONOUS OR DELETERIOUS SUBSTANCE -- REGULATIONS AS TO USE. Any

poisonous or deleterious substance added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of clause (2) of section 37-122(a); but when such substance is so required or cannot be so avoided, the board shall promulgate regulations limiting the quantity therein or thereon to such extent as the board finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 37-122(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) section 37-122(a). In determining the quantity of such added substance to be tolerated in or on different articles of food, the board shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

[37-125, added 1959, ch. 153, sec. 13, p. 351.]

37-126.DRUGS OR DEVICES DEEMED ADULTERATED. A drug or device shall be deemed to be adulterated:

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under the authority of the federal act.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium or in the absence of or inadequacy of such tests or methods of assay, these prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of a practitioner prescribing the drug for the purpose of administering the drug to a patient.

(c) If it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of the practitioner prescribing the drug for the purpose of administering the drug to a patient.

(d) If it is a drug and any substance has been: (1) mixed or packed therewith so as to reduce its quality or strength; or (2) substituted wholly or in part therefor. Nothing in this subsection shall be deemed to prohibit a change in the strength, quality or purity of a drug, if the change is made by or pursuant to the orders of the practitioner prescribing the drug for the purpose of administering the drug to a patient.

[37-126, added 1959, ch. 153, sec. 14, p. 351; am. 2002, ch. 231, sec. 2, p. 662.]

37-127.DRUGS OR DEVICES DEEMED MISBRANDED. A drug or device shall be deemed to be misbranded--(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the board.

(c) If any word, statement, or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana [marijuana], morphine, opium, paraldehyde, peyete [peyote], or sulphonmethane, or any chemical derivative of such substance, which derivative has been by the board after investigation, found to be, and by regulations under this act, designated as habit forming, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit forming."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two (2) or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acotphenetidin, amidapyrine, anti-pyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis glucosines, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any substances, contained therein: Provided, that to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirements.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that the method of packing may be modified with the consent of the board. Whenever a drug is recognized in both the United States

Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the board to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the board shall by regulations require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the board shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is a drug sold at retail and quantity of aminopyrine, barbituric acid, cinchophen, dinitrophenol, sulfanilamide or their derivatives, or any other drug which has been found by the board to be dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, and so designated by the board in a regulation adopted; unless it is sold on a written prescription signed by a member of the medical, osteopathic, chiropodial, dental, or veterinary profession who is licensed by law to administer such drug, and its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, osteopathic, chiropodial, dental, or veterinary profession.

(l) A drug sold on a written prescription signed by a member of the medical, osteopathic, chiropodial, dental, or veterinary profession (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of this section if--(1) such member of the medical, osteopathic, chiropodial, dental, or veterinary profession is licensed by law to administer such drug, and (2) such drug bears a label containing the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, osteopathic, chiropodial, dental, or veterinary profession.

[37-127, added 1959, ch. 153, sec. 15, p. 351.]

37-128.SALE OF NEW DRUGS -- REGULATIONS AND PROCEDURES. (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has become effective under section 505 of the federal act, or (2) when not subject to the federal act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the director an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drugs and of the articles used as components thereof as the board may require; and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a)(2) shall become effective on the sixtieth (60th) day after the filing thereof, except that if the director finds after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply--(1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs provided the drug is plainly labeled "For investigational use only"; or (2) to a drug sold in this state at any time prior to the enactment of this act or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) to any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U.S.C. 1934 ed. title 42, Chap. 4).

(d) An order refusing to permit an application under this section to become effective may be revoked by the director.

[37-128, added 1959, ch. 153, sec. 16, p. 351; am. 1974, ch. 23, sec. 21, p. 633.]

37-129.COSMETICS DEEMED ADULTERATED. A cosmetic shall be deemed to be adulterated--(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual. Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution--This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the federal act.

[37-129, added 1959, ch. 153, sec. 17, p. 351.]

37-130.COSMETICS DEEMED MISBRANDED. A cosmetic shall be deemed to be misbranded--(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the board.

(c) If any word, statement, or other information required by or under authority of this act to

appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

[37-130, added 1959, ch. 153, sec. 18, p. 351.]

37-131.FALSE ADVERTISING. (a) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this act the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecytitis, diabetes, diptheria [diphtheria], dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, venereal disease, shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, osteopathic, chiropodial, dental, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public-health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices: Provided, that whenever the board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the board may deem necessary in the interests of public health: Provided, that this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

[37-131, added 1959, ch. 153, sec. 19, p. 351.]

37-132.REGULATIONS BY BOARD -- HEARINGS -- NOTICE. (a) The authority to promulgate regulations for the efficient enforcement of this act is hereby vested in the board. The board is hereby authorized to make the regulations promulgated under this act conform, in so far as practicable with those promulgated under the federal act.

(b) Hearings authorized or required by this act shall be conducted by the board or such officer, agent, or employee as the board may designate for the purpose.

(c) Before promulgating any regulations contemplated by section 37-121; 37-123(j); 37-124; 37-127(d), (f), (g), (h), and (k), or 37-131(b), the board shall give appropriate notice of the proposal and of the time and place for a hearing. The regulation so promulgated shall become effective on a date fixed by the board (which date shall not be prior to 30 days after its promulgation). Such regulation may be amended or repealed in the same manner as is provided for its adoption, except that in the case of a regulation amending or repealing any such regulation the board, to such an extent as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.

[37-132, added 1959, ch. 153, sec. 20, p. 351.]

37-133.INSPECTION OF ESTABLISHMENTS -- EXAMINATION OF SPECIMENS -- REPORTS -- RECEIPT FOR SAMPLES. The director or his duly authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose: (1) of inspecting such factory, warehouse, establishment, or vehicle to determine if any of the provisions of this act are being violated, and (2) to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such sample. It shall be the duty of the director to make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this act is being violated.

(a) Upon the completion of any inspection of a factory, warehouse, or other establishment and prior to leaving the premises, the director or his duly authorized agent making the inspection shall give to the owner, operator, or agent in charge, a report in writing setting forth any condition or practice observed by him which in his judgment indicates that any food, drug, device, or cosmetic in the establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substances; or (2) has been prepared, packed, or held in unsanitary condition whereby it may have become contaminated with filth or whereby it may be rendered injurious to health.

(b) If the director or his duly authorized agent making any such inspection of any warehouse, factory, or other establishment has obtained any samples in the process of the inspection, upon completion of the inspection and prior to his leaving the premises, he shall give to the owner, operator, or agent in charge, a receipt describing the samples obtained.

(c) Whenever in the course of any such inspection of the factory, or other establishment where food is manufactured, processed, or packed, the director or his duly authorized agent making the inspection obtains a sample of any such food and if analysis is made of such sample for the purpose of determining whether such food consists in whole or part of any filthy, putrid or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be sent promptly to the owner, operator, or agent in charge.

[37-133, added 1959, ch. 153, sec. 21, p. 351; am. 1974, ch. 23, sec. 22, p. 633.]

37-134.PUBLICATION OF REPORTS BY DIRECTOR -- DISSEMINATION OF INFORMATION. (a) The director may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this act, including the nature of the charge and the disposition thereof.

(b) The director may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the board deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the director from collecting, reporting, and illustrating the results of the investigations of the director.

[37-134, added 1959, ch. 153, sec. 22, p. 351; am. 1974, ch. 23, sec. 23, p. 633.]

CHAPTER 27
UNIFORM CONTROLLED SUBSTANCES

37-2701.DEFINITIONS. As used in this chapter:

(a) "Administer" means the direct application of a controlled substance whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) A practitioner or, in his presence, by his authorized agent; or

(2) The patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(c) "Board" means the state board of pharmacy created in chapter 17, title 54, Idaho Code, or its successor agency.

(d) "Bureau" means the drug enforcement administration, United States department of justice, or its successor agency.

(e) "Controlled substance" means a drug, substance or immediate precursor in schedules I through VI of article II of this chapter.

(f) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance.

(g) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one (1) person to another of a controlled substance, whether or not there is an agency relationship.

(h) "Director" means the director of the Idaho state police.

(i) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(j) "Dispenser" means a practitioner who dispenses.

(k) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(l) "Distributor" means a person who distributes.

(m) "Drug" means (1) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (3) substances, other than food, intended to affect the structure or any function of the body of man or animals; and (4) substances intended for use as a component of any article specified in clause (1), (2), or (3) of this subsection. It does not include devices or their components, parts, or accessories.

(n) "Drug paraphernalia" means all equipment, products and materials of any kind which are used, intended for use, or designed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter. It includes, but is not limited to:

(1) Kits used, intended for use, or designed for use in planting, propagating, cultivating,

growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived;

(2) Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances;

(3) Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance;

(4) Testing equipment used, intended for use, or designed for use in identifying, or in analyzing the strength, effectiveness or purity of controlled substances;

(5) Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances;

(6) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use, or designed for use in cutting controlled substances;

(7) Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;

(8) Blenders, bowls, containers, spoons and mixing devices used, intended for use, or designed for use in compounding controlled substances;

(9) Capsules, balloons, envelopes and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances;

(10) Containers and other objects used, intended for use, or designed for use in storing or concealing controlled substances;

(11) Hypodermic syringes, needles and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body;

(12) Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:

(i) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(ii) Water pipes;

(iii) Carburetion tubes and devices;

(iv) Smoking and carburetion masks;

(v) Roach clips: meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand;

(vi) Miniature cocaine spoons, and cocaine vials;

(vii) Chamber pipes;

(viii) Carburetor pipes;

(ix) Electric pipes;

(x) Air-driven pipes;

(xi) Chillums;

(xii) Bongs;

(xiii) Ice pipes or chillers;

In determining whether an object is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, the following:

1. Statements by an owner or by anyone in control of the object concerning its use;
2. Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance;
3. The proximity of the object, in time and space, to a direct violation of this chapter;
4. The proximity of the object to controlled substances;
5. The existence of any residue of controlled substances on the object;

6. Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he knows, or should reasonably know, intend to use the object to facilitate a violation of this chapter; the innocence of an owner, or of anyone in control of the object, as to a direct violation of this chapter shall not prevent a finding that the object is intended for use, or designed for use as drug paraphernalia;

7. Instructions, oral or written, provided with the object concerning its use;

8. Descriptive materials accompanying the object which explain or depict its use;

9. National and local advertising concerning its use;

10. The manner in which the object is displayed for sale;

11. Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

12. Direct or circumstantial evidence of the ratio of sales of the object(s) to the total sales of the business enterprise;

13. The existence and scope of legitimate uses for the object in the community;

14. Expert testimony concerning its use.

(o) "Financial institution" means any bank, trust company, savings and loan association, savings bank, mutual savings bank, credit union, or loan company under the jurisdiction of the state or under the jurisdiction of an agency of the United States.

(p) "Immediate precursor" means a substance which the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(q) "Isomer" means the optical isomer, except as used in section 37-2705(d), Idaho Code.

(r) "Law enforcement agency" means a governmental unit of one (1) or more persons employed full-time or part-time by the state or a political subdivision of the state for the purpose of preventing and detecting crime and enforcing state laws or local ordinances, employees of which unit are authorized to make arrests for crimes while acting within the scope of their authority.

(s) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, and includes extraction, directly or indirectly, from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance:

(1) By a practitioner as an incident to his administering, dispensing or, as authorized by board rule, distributing of a controlled substance in the course of his professional practice; or

(2) By a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for delivery.

(t) "Marijuana" means all parts of the plant of the genus Cannabis, regardless of species, and whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. It does not include the mature stalks of the plant unless the same are intermixed with prohibited parts thereof, fiber produced from the stalks, oil or cake made from the seeds or the achene of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin extracted therefrom or where the same are intermixed with prohibited parts of such plant, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. Evidence that any plant material or the resin or any derivative thereof, regardless of form, contains any of the chemical substances classified as tetrahydrocannabinols

shall create a presumption that such material is "marijuana" as defined and prohibited herein.

(u) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause 1, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(v) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under section 37-2702, Idaho Code, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(w) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

(x) "Peace officer" means any duly appointed officer or agent of a law enforcement agency, as defined herein, including, but not limited to, a duly appointed investigator or agent of the Idaho state police, an officer or employee of the board of pharmacy, who is authorized by the board to enforce this chapter, an officer of the Idaho state police, a sheriff or deputy sheriff of a county, or a marshal or policeman of any city.

(y) "Person" means individual, corporation, government, or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(z) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(aa) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of his professional practice or research in this state;

(2) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of its professional practice or research in this state.

(bb) "Prescribe" means a direction or authorization permitting an ultimate user to lawfully obtain or be administered controlled substances.

(cc) "Prescriber" means an individual currently licensed, registered or otherwise authorized to prescribe and administer controlled substances in the course of professional practice.

(dd) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(ee) "Simulated controlled substance" means a substance that is not a controlled substance, but which by appearance or representation would lead a reasonable person to believe that the substance is a controlled substance. Appearance includes, but is not limited to, color, shape, size, and markings of the dosage unit. Representation includes, but is not limited to, representations or factors of the following nature:

(1) Statements made by an owner or by anyone else in control of the substance concerning

the nature of the substance, or its use or effect;

(2) Statements made to the recipient that the substance may be resold for inordinate profit; or

(3) Whether the substance is packaged in a manner normally used for illicit controlled substances.

(ff) "State," when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America.

(gg) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

(hh) "Utility" means any person, association, partnership or corporation providing telephone and/or communication services, electricity, natural gas or water to the public.

[37-2701, added 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 1, p. 261; am. 1974, ch. 27, sec. 78, p. 811; am. 1975, ch. 196, sec. 1, p. 545; am. 1980, ch. 388, sec. 1, p. 977; am. 1982, ch. 169, sec. 1, p. 442; am. 1983, ch. 218, sec. 1, p. 599; am. 1989, ch. 266, sec. 1, p. 646; am. 1995, ch. 116, sec. 23, p. 399; am. 1999, ch. 280, sec. 1, p. 696; am. 2000, ch. 469, sec. 84, p. 1528; am. 2010, ch. 118, sec. 2, p. 257; am. 2014, ch. 79, sec. 1, p. 211; am. 2015, ch. 25, sec. 1, p. 30.]

37-2702.AUTHORITY TO CONTROL. (a) The board shall administer the regulatory provisions of this act and may add substances to or delete or reschedule all substances enumerated in the schedules in sections 37-2705, 37-2707, 37-2709, 37-2711, or 37-2713, Idaho Code, pursuant to the procedures of chapter 52, title 67, Idaho Code. In making a determination regarding a substance, the board shall consider the following:

(1) the actual or relative potential for abuse;

(2) the scientific evidence of its pharmacological effect, if known;

(3) the state of current scientific knowledge regarding the substance;

(4) the history and current pattern of abuse;

(5) the scope, duration, and significance of abuse;

(6) the risk to the public health;

(7) the potential of the substance to produce psychic or physiological dependence liability; and

(8) whether the substance is an immediate precursor of a substance already controlled under this article.

(b) After considering the factors enumerated in subsection (a) of this section, the board shall make findings with respect thereto and issue a rule controlling the substance if it finds the substance has a potential for abuse.

(c) If the board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the board, the board shall similarly control the substance under this act after the expiration of thirty (30) days from publication in the Federal Register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that thirty (30) day period, the board objects to inclusion, rescheduling, or

deletion. In that case, the board shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall publish its decision, which shall be final unless altered by statute. Upon publication of objection to inclusion, rescheduling, or deletion under this act by the board, control under this act is stayed until the board publishes its decision.

(e) Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco.

[I.C., sec. 37-2702, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 2, p. 261.]

37-2703.NOMENCLATURE. The controlled substances listed or to be listed in the schedules in sections 37-2705, 37-2707, 37-2709, 37-2711 and 37-2713, Idaho Code, are included by whatever official, common, usual, chemical, or trade-name designated.

[I.C., sec. 37-2703, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2704.SCHEDULE I TESTS. The board shall place a substance in schedule I if it finds that the substance:

(a) Has high potential for abuse; and

(b) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

[I.C., sec. 37-2704, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2705.SCHEDULE I. (a) The controlled substances listed in this section are included in schedule I.

(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-pip-eridinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM);

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl;

(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-pip-eridinyl]-N-phenylpropanamide);

(9) Benzethidine;

(10) Betacetylmethadol;

(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperid-inyl]-N-phenylpropanamide);

(12) Beta-hydroxy-3-methylfentanyl (N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl)-N-phenylpropanamide);

(13) Betameprodine;
(14) Betamethadol;
(15) Betaprodine;
(16) Clonitazene;
(17) Dextromoramide;
(18) Diampromide;
(19) Diethylthiambutene;
(20) Difenoxin;
(21) Dimenoxadol;
(22) Dimepheptanol;
(23) Dimethylthiambutene;
(24) Dioxaphetyl butyrate;
(25) Dipipanone;
(26) Ethylmethylthiambutene;
(27) Etonitazene;
(28) Etoxeridine;
(29) Furethidine;
(30) Hydroxypethidine;
(31) Ketobemidone;
(32) Levomoramide;
(33) Levophenacylmorphan;
(34) 3-Methylfentanyl;
(35) 3-methylthiofentanyl (N-[(3-methyl-1-(2-thienyl)ethyl-4-pip-eridinyl]-N-phenylpropanamide);
(36) Morpheridine;
(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
(38) Noracymethadol;
(39) Norlevorphanol;
(40) Normethadone;
(41) Norpipanone;
(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phen-ethyl)-4-piperidinyl] propanamide);
(43) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);
(44) Phenadoxone;
(45) Phenampromide;
(46) Phenomorphan;
(47) Phenoperidine;
(48) Piritramide;
(49) Proheptazine;
(50) Properidine;
(51) Propiram;
(52) Racemoramide;
(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piper-idinyl]-propanamide);
(54) Tilidine;
(55) Trimeperidine.

(c) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible

within the specific chemical designation:

(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-Oxide;
(6) Cyprenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Drotebanol;
(10) Etorphine (except hydrochloride salt);
(11) Heroin;
(12) Hydromorphinol;
(13) Methyldesorphine;
(14) Methyldihydromorphine;
(15) Morphine methylbromide;
(16) Morphine methylsulfonate;
(17) Morphine-N-Oxide;
(18) Myrophine;
(19) Nicocodeine;
(20) Nicomorphine;
(21) Normorphine;
(22) Pholcodine;
(23) Thebacon.

(d) Hallucinogenic substances. Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):

(1) Dimethoxyphenethylamine, or any compound not specifically excepted or listed in another schedule that can be formed from dimethoxyphenethylamine by replacement of one (1) or more hydrogen atoms with another atom(s), functional group(s) or substructure(s) including, but not limited to, compounds such as DOB, DOC, 2C-B, 25B-NBOMe;

(2) Methoxyamphetamine or any compound not specifically excepted or listed in another schedule that can be formed from methoxyamphetamine by replacement of one (1) or more hydrogen atoms with another atom(s), functional group(s) or substructure(s) including, but not limited to, compounds such as PMA and DOM;

(3) 5-methoxy-3,4-methylenedioxy-amphetamine;

(4) 5-methoxy-N,N-diisopropyltryptamine;

(5) Amphetamine or methamphetamine with a halogen substitution on the benzyl ring, including compounds such as fluorinated amphetamine and fluorinated methamphetamine;

(6) 3,4-methylenedioxy amphetamine;

(7) 3,4-methylenedioxymethamphetamine (MDMA);

(8) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-et-hyl-alpha-methyl-3,4 (methylenedioxy) phenethylamine, and N-et-hyl MDA, MDE, MDEA);

(9) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hyd-roxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, and N-hyd-roxy MDA);

(10) 3,4,5-trimethoxy amphetamine;
(11) 5-methoxy-N,N-dimethyltryptamine (also known as 5-methoxy-3-2[2-(dimethylamino)ethyl]indole and 5-MeO-DMT);
(12) Alpha-ethyltryptamine (some other names: etryptamine, 3-(2-am-inobutyl) indole);
(13) Alpha-methyltryptamine;
(14) Bufotenine;
(15) Diethyltryptamine (DET);
(16) Dimethyltryptamine (DMT);
(17) Ibogaine;
(18) Lysergic acid diethylamide;
(19) Marihuana;
(20) Mescaline;
(21) Parahexyl;
(22) Peyote;
(23) N-ethyl-3-piperidyl benzilate;
(24) N-methyl-3-piperidyl benzilate;
(25) Psilocybin;
(26) Psilocyn;
(27) Tetrahydrocannabinols or synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure such as the following:

i. Tetrahydrocannabinols:

a. Δ^{1} cis or trans tetrahydrocannabinol, and their optical isomers, excluding dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration.

b. Δ^{6} cis or trans tetrahydrocannabinol, and their optical isomers.

c. $\Delta^{3,4}$ cis or trans tetrahydrocannabinol, and its optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)

d. [(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-o1)], also known as 6aR-trans-3-(1,1-dimethylheptyl)-6a,7,10,10a-tetrahydro-1-hydroxy-6,6-dimethyl-6H-dibenzo[b,d]pyran-9-methanol (HU-210) and its geometric isomers (HU211 or dexanabinol).

ii. The following synthetic drugs:

a. Any compound structurally derived from (1H-indole-3-yl)(cycloalkyl, cycloalkenyl, aryl)methanone, or (1H-indole-3-yl)(cycloalkyl, cycloalkenyl, aryl)methane, or (1H-indole-3-yl)(cycloalkyl, cycloalkenyl, aryl)carboxamide by substitution at the nitrogen atoms of the indole ring or carboxamide to any extent, whether or not further substituted in or on the indole ring to any extent, whether or not substituted to any extent in or on the cycloalkyl, cycloalkenyl, aryl ring(s) (substitution in the ring may include, but is not limited to, heteroatoms such as nitrogen, sulfur and oxygen).

b. Any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring to any extent, whether or not further substituted in the pyrrole ring to any extent, whether or not

substituted in the naphthyl ring to any extent.

c. Any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring to any extent, whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent.

d. Any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring to any extent, whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent.

e. Any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring to any extent, whether or not substituted in the cyclohexyl ring to any extent.

f. Any compound structurally derived from 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring to any extent, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent.

g. [2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-napthalenylmethanone (WIN-55,212-2).

h. 3-dimethylheptyl-11-hydroxyhexahydrocannabinol (HU-243).

i. [(6S, 6aR, 9R, 10aR)-9-hydroxy-6-methyl-3-[(2R)-5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl]acetate (CP 50,5561).

(28) Ethylamine analog of phencyclidine:N-ethyl-1-phenylcy-clohexylamine (1-phenylcyclohexyl) ethylamine; N-(1-phenylcy-clohexyl) ethylamine, cyclohexamine, PCE;

(29) Pyrrolidine analog of phencyclidine: 1-(phenylcyclohex-yl) -pyrrolidine, PCPy, PHP;

(30) Thiophene analog of phencyclidine 1-[1-(2-thienyl)-cy-clohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP;

(31) 1-[1-(2-thienyl) cyclohexyl] pyrrolidine another name: TCPy;

(32) Spores or mycelium capable of producing mushrooms that contain psilocybin or psilocin.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Gamma hydroxybutyric acid (some other names include GHB; gam-ma-hydroxybutyrate, 4-hydroxybutyrate; 4-hyroxybutanoic acid; sod-ium oxybate; sodium oxybutyrate);

(2) Flunitrazepam (also known as "R2," "Rohypnol");

(3) Mecloqualone;

(4) Methaqualone.

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex (some other names: aminoxaphen, 2-amino-5-phenyl-2-ox-azoline, or 4,5-dihydro-5-phenyl-2-oxazolamine);

(2) Cathinone (some other names: 2-amino-1-phenol-1-propanone, alpha-

aminopropiophenone, 2-amino-propiophenone and norephedrone);

(3) Substituted cathinones. Any compound, except bupropion or compounds listed under a different schedule, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

i. By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl or halide substituents, whether or not further substituted in the ring system by one (1) or more other univalent substituents;

ii. By substitution at the 3-position with an acyclic alkyl substituent;

iii. By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

(4) Fenethylline;

(5) Methcathinone (some other names: 2-(methyl-amino)-propioph-enone, alpha-(methylamino)-propiophenone, N-methylcathin-one, AL-464, AL-422, AL-463 and UR1423);

(6) (+/-)cis-4-methylaminorex [(+/-)cis-4,5-dihydro-4-meth-yl-5-phenyl-2-oxazolamine];

(7) N-benzylpiperazine (also known as: BZP, 1-benzylpiperazine);

(8) N-ethylamphetamine;

(9) N,N-dimethylamphetamine (also known as: N,N-al-pha-trimethyl-benzeneethanamine).

[37-2705, added 1971, ch. 215, sec. 1, p. 939; am. 1977, ch. 234, sec. 1, p. 698; am. 1980, ch. 160, sec. 1, p. 343; am. 1981, ch. 102, sec. 1, p. 149; am. 1984, ch. 160, sec. 1, p. 390; am. 1985, ch. 25, sec. 1, p. 41; am. 1986, ch. 209, sec. 1, p. 535; am. 1987, ch. 38, sec. 1, p. 61; am. 1988, ch. 190, sec. 1, p. 337; am. 1989, ch. 177, sec. 1, p. 428; am. 1995, ch. 1, sec. 1, p. 3; am. 1996, ch. 36, sec. 1, p. 90; am. 1998, ch. 160, sec. 1, p. 545; am. 2003, ch. 185, sec. 1, p. 500; am. 2004, ch. 302, sec. 1, p. 845; am. 2010, ch. 117, sec. 1, p. 243; am. 2011, ch. 46, sec. 1, p. 105; am. 2011, ch. 47, sec. 1, p. 109; am. 2011, ch. 134, sec. 1, p. 368; am. 2012, ch. 181, sec. 1, p. 472; am. 2013, ch. 253, sec. 1, p. 623; am. 2014, ch. 349, sec. 1, p. 870.]

37-2706.SCHEDULE II TESTS. The board shall place a substance in schedule II if it finds that:

(a) The substance has high potential for abuse;

(b) The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

(c) The abuse of the substance may lead to severe psychic or physical dependence.

[I.C., sec. 37-2706, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2707.SCHEDULE II. (a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, naltrexone and their

respective salts, but including the following:

1. Raw opium;
2. Opium extracts;
3. Opium fluid extracts;
4. Powdered opium;
5. Granulated opium;
6. Tincture of opium;
7. Codeine;
8. Dihydroetorphine;
9. Diprenorphine;
10. Ethylmorphine;
11. Etorphine hydrochloride;
12. Hydrocodone;
13. Hydromorphone;
14. Metopon;
15. Morphine;
16. Oripavine;
17. Oxycodone;
18. Oxymorphone;
19. Tapentadol;
20. Thebaine.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b)(1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but shall not include the following:

1. Decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine; or ecgonine; or
2. [^{123}I]ioflupane.

(5) Benzoylecgonine.

(6) Methylbenzoylecgonine (Cocaine - its salts, optical isomers, and salts of optical isomers).

(7) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy).

(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, unless specifically excepted or unless listed in another schedule:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) Bulk Dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;
(10) Isomethadone;
(11) Levo-alphacetylmethadol (also known as levo-alpha-acetylmet-hadol, levomethadyl acetate, LAAM);
(12) Levomethorphan;
(13) Levorphanol;
(14) Metazocine;
(15) Methadone;
(16) Methadone -- Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
(17) Moramide -- Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl propane-carboxylic acid;
(18) Pethidine (meperidine);
(19) Pethidine -- Intermediate -- A, 4-cyano-1-methyl-4-phenyl-piperidine;
(20) Pethidine -- Intermediate -- B, ethyl-4-phenylpiperid-ine-4-carboxylate;
(21) Pethidine -- Intermediate -- C, 1-methyl-4-phenylpiperid-ine-4-carboxylic acid;
(22) Phenazocine;
(23) Piminodine;
(24) Racemethorphan;
(25) Racemorphan;
(26) Remifentanil;
(27) Sufentanil.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
(2) Lisdexamfetamine;
(3) Methamphetamine, its salts, isomers, and salts of its isomers;
(4) Phenmetrazine and its salts;
(5) Methylphenidate.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;
(2) Glutethimide;
(3) Pentobarbital;
(4) Phencyclidine;
(5) Secobarbital.

(f) Hallucinogenic substances.

(1) Nabilone (another name for nabilone: (+/-)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hy-droxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one) (21 CFR 1308.12 (f)).

(g) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(a) Anthranilic acid;
(b) Ephedrine;
(c) Lead acetate;
(d) Methylamine;
(e) Methyl formamide;
(f) N-methylephedrine;
(g) Phenylacetic acid;
(h) Phenylacetone;
(i) Phenylpropanolamine;
(j) Pseudoephedrine.

Except that any combination or compound containing ephedrine, or any of its salts and isomers, or phenylpropanolamine or its salts and isomers, or pseudoephedrine, or any of its salts and isomers which is prepared for dispensing or over-the-counter distribution is not a controlled substance for the purpose of this section, unless such substance is possessed, delivered, or possessed with intent to deliver to another with the intent to manufacture methamphetamine, amphetamine or any other controlled substance in violation of section 37-2732, Idaho Code. For purposes of this provision, the requirements of the uniform controlled substances act shall not apply to a manufacturer, wholesaler or retailer of over-the-counter products containing the listed substances unless such person possesses, delivers, or possesses with intent to deliver to another the over-the-counter product with intent to manufacture a controlled substance.

(2) Immediate precursors to phencyclidine (PCP):
(a) 1-phenylcyclohexylamine;
(b) 1-piperidinocyclohexanecarbonitrile (PCC).

(3) Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP).

[37-2707, added 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 3, p. 261; am. 1977, ch. 234, sec. 2, p. 701; am. 1980, ch. 160, sec. 2, p. 343; am. 1981, ch. 102, sec. 2, p. 152; am. 1984, ch. 160, sec. 2, p. 393; am. 1985, ch. 25, sec. 2, p. 44; am. 1986, ch. 209, sec. 2, p. 538; am. 1987, ch. 38, sec. 2, p. 64; am. 1988, ch. 190, sec. 2, p. 341; am. 1989, ch. 177, sec. 2, p. 432; am. 1992, ch. 24, sec. 1, p. 72; am. 1995, ch. 1, sec. 2, p. 6; am. 1998, ch. 328, sec. 1, p. 1058; am. 2000, ch. 110, sec. 1, p. 242; am. 2010, ch. 117, sec. 2, p. 246; am. 2011, ch. 134, sec. 2, p. 372; am. 2016, ch. 70, sec. 1, p. 245.]

37-2708.SCHEDULE III TESTS. The board shall place a substance in schedule III if it finds that:

(a) The substance has a potential for abuse less than the substances listed in schedules I and II;

(b) The substance has currently accepted medical use in treatment in the United States; and

(c) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

[I.C., sec. 37-2708, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2709.SCHEDULE III. (a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following

substances having a stimulant effect on the central nervous system, including its salts, isomers, (whether optical or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed as excepted compounds under 21 CFR 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) Depressants. Unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:

i. Amobarbital;

ii. Secobarbital;

iii. Pentobarbital or any salt thereof and one (1) or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing:

i. Amobarbital;

ii. Secobarbital;

iii. Pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof, including, but not limited to:

i. Aprobarbital;

ii. Butabarbital (secbutabarbital);

iii. Butalbital;

iv. Butobarbital (butethal);

v. Talbutal;

vi. Thiamylal;

vii. Thiopental;

viii. Vinbarbital.

(4) Chlorhexadol;

(5) Embutramide;

(6) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal food, drug, and cosmetic act;

(7) Ketamine, its salts, isomers, and salts of isomers-7285. (Some other names for ketamine: (+/-)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone).

(8) Lysergic acid;

(9) Lysergic acid amide;

(10) Methyprylon;

(11) Perampanel, and its salts, isomers and salts of isomers;

(12) Sulfondiethylmethane;

(13) Sulfonethylmethane;
(14) Sulfonmethane;
(15) Tiletamine and zolazepam or any salt thereof.
(d) Nalorphine.
(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule:
(1) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(i) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(ii) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(iii) Not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(iv) Not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more ingredients in recognized therapeutic amounts;

(v) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(vi) Not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(2) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:

(i) Buprenorphine.

(ii) [Reserved].

(f) Anabolic steroids and human growth hormones. Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins and corticosteroids) that promotes muscle growth including any salt, ester or isomer of a drug or substance listed in this paragraph, if that salt, ester or isomer promotes muscle growth.

(1) 13beta-ethyl-17beta-hydroxygon-4-en-3-one;
(2) 17alpha-methyl-3alpha, 17beta-dihydroxy-5alpha-androstane;
(3) 17alpha-methyl-3beta, 17beta-dihydroxy-5alpha-androstane;
(4) 17alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene;
(5) 17alpha-methyl-4-hydroxynandrolone;
(6) 17alpha-methyl-delta1-dihydrotestosterone;
(7) 19-nor-4-androstenediol;
(8) 19-nor-4-androstenedione;
(9) 19-nor-4,9(10)-androstadienedione;
(10) 19-nor-5-androstenediol;
(11) 19-nor-5-androstenedione;
(12) 1-androstenediol;
(13) 1-androstenedione;
(14) 3alpha,17beta-dihydroxy-5alpha-androstane;

(15) 3beta,17beta-dihydroxy-5alpha-androstane;
(16) 4-androstenediol;
(17) 4-androstenedione;
(18) 4-hydroxy-19-nortestosterone;
(19) 4-hydroxytestosterone;
(20) 5-androstenediol;
(21) 5-androstenedione;
(22) Androstenedione;
(23) Bolasterone;
(24) Boldenone;
(25) Boldione;
(26) Calusterone;
(27) Chlorotestosterone (4-chlorotestosterone);
(28) Clostebol;
(29) Dehydrochlormethyltestosterone;
(30) Delta1-dihydrotestosterone;
(31) Desoxymethyltestosterone;
(32) Dihydrotestosterone (4-dihydrotestosterone);
(33) Drostanolone;
(34) Ethylestrenol;
(35) Fluoxymesterone;
(36) Formebulone;
(37) Furazabol;
(38) Human growth hormones;
(39) Mestanolone;
(40) Mesterolone;
(41) Methandienone;
(42) Methandranone;
(43) Methandriol;
(44) Methandrostenolone;
(45) Methasterone (2a, 17a-dimethyl-5a-androstan-17β-ol-3-one);
(46) Methenolone;
(47) Methyldienolone;
(48) Methyltestosterone;
(49) Methyltrienolone;
(50) Mibolerone;
(51) Nandrolone;
(52) Norbolethone;
(53) Norclostebol;
(54) Norethandrolone;
(55) Normethandrolone;
(56) Oxandrolone;
(57) Oxymesterone;
(58) Oxymetholone;
(59) Prostanozol (17β-hydroxy-5a-androstano[3,2-c]pyrazole);
(60) Stanolone;
(61) Stanozolol;

(62) Stenbolone;
(63) Testolactone;
(64) Testosterone;
(65) Testosterone cypionate;
(66) Testosterone enanthate;
(67) Testosterone propionate;
(68) Tetrahydrogestrinone;
(69) Trenbolone.

Anabolic steroids that are expressly intended for administration through implants to cattle or other nonhuman species, and that are approved by the federal Food and Drug Administration for such use, shall not be classified as controlled substances under this act and shall not be governed by its provisions.

In addition to the penalties prescribed in article IV of the uniform controlled substances act, any person shall be guilty of a felony who prescribes, dispenses, supplies, sells, delivers, manufactures or possesses with the intent to prescribe, dispense, supply, sell, deliver or manufacture anabolic steroids or any other human growth hormone for purposes of enhancing performance in an exercise, sport or game or hormonal manipulation intended to increase muscle mass, strength or weight without a medical necessity as determined by a physician.

(g) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in the federal Food and Drug Administration approved product -- 7369. (Some other names for dronabinol: (6aR-trans) -6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran-1-ol or (-)-delta-9-(trans)-tetrahydrocannabinol).

(h) Other substances. Unless specifically excepted, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance, including its salts:

(1) Butorphanol.

(i) The board may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) and (c) of this section from the application of all or any part of this act if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

[37-2709, added 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 4, p. 261; am. 1977, ch. 234, sec. 3, p. 703; am. 1980, ch. 160, sec. 3, p. 345; am. 1982, ch. 91, sec. 1, p. 166; am. 1984, ch. 160, sec. 3, p. 395; am. 1992, ch. 24, sec. 2, p. 75; am. 1996, ch. 36, sec. 2, p. 94; am. 2000, ch. 110, sec. 2, p. 245; am. 2003, ch. 185, sec. 2, p. 503; am. 2006, ch. 203, sec. 1, p. 620; am. 2010, ch. 117, sec. 3, p. 249; am. 2012, ch. 181, sec. 2, p. 477; am. 2014, ch. 33, sec. 1, p. 48; am. 2015, ch. 29, sec. 1, p. 62.]

37-2710.SCHEDULE IV TESTS. The board shall place a substance in schedule IV if it finds that:

(a) The substance has a low potential for abuse relative to substances in schedule III;

(b) The substance has currently accepted medical use in treatment in the United States; and

(c) Abuse of the substance may lead to limited physical dependence or psychological

dependence relative to the substances in schedule III.

[I.C., sec. 37-2710, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2711.SCHEDULE IV. (a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) No more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl- 3-methyl-2-propionoxybutane).

(3) 2- [(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (including tramadol), including its salts, optical and geometric isomers, and salts of isomers.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alfaxalone 5[alpha]-pregnan-3[alpha]-ol-11,20-dione;
(2) Alprazolam;
(3) Barbital;
(4) Bromazepam;
(5) Camazepam;
(6) Carisprodol;
(7) Chloral betaine;
(8) Chloral hydrate;
(9) Chlordiazepoxide;
(10) Clobazam;
(11) Clonazepam;
(12) Clorazepate;
(13) Clotiazepam;
(14) Cloxazolam;
(15) Delorazepam;
(16) Diazepam;
(17) Dichloralphenazone;
(18) Estazolam;
(19) Ethchlorvynol;
(20) Ethinamate;
(21) Ethyl loflazepate;
(22) Fludiazepam;
(23) Flurazepam;
(24) Halazepam;
(25) Haloxazolam;
(26) Ketazolam;
(27) Loprazolam;

(28) Lorazepam;
(29) Lormetazepam;
(30) Mebutamate;
(31) Medazepam;
(32) Meprobamate;
(33) Methohexital;
(34) Methylphenobarbital (mephobarbital);
(35) Midazolam;
(36) Nimetazepam;
(37) Nitrazepam;
(38) Nordiazepam;
(39) Oxazepam;
(40) Oxazolam;
(41) Paraldehyde;
(42) Petrichloral;
(43) Phenobarbital;
(44) Pinazepam;
(45) Prazepam;
(46) Quazepam;
(47) Suvorexant;
(48) Temazepam;
(49) Tetrazepam;
(50) Triazolam;

(51) Zaleplon;
(52) Zolpidem;
(53) Zopiclone.

(d) Fenfluramine -- Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Dexfenfluramine;
(2) Fenfluramine.

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cathine ((+)-norpseudoephedrine);
(2) Diethylpropion;
(3) Fencamfamin;
(4) Fenproporex;
(5) Lorcaserin;
(6) Mazindol;
(7) Mefenorex;
(8) Modafinil;
(9) Pemoline (including organometallic complexes and chelates thereof);

(10) Phentermine;
(11) Pipradrol;
(12) Sibutramine;
(13) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(f) Other substances. Unless specifically excepted, or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine;
(2) Fospropofol.

(g) The board may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection (c) of this section from the application of all or any part of this act if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

[37-2711, added 1971, ch. 215, sec. 1, p. 939; am. 1977, ch. 234, sec. 4, p. 706; am. 1980, ch. 160, sec. 4, p. 347; am. 1981, ch. 102, sec. 3, p. 154; am. 1982, ch. 91, sec. 2, p. 167; am. 1984, ch. 160, sec. 4, p. 397; am. 1986, ch. 209, sec. 3, p. 540; am. 1988, ch. 190, sec. 3, p. 344; am. 1989, ch. 177, sec. 3, p. 435; am. 1989, ch. 197, sec. 1, p. 493; am. 1992, ch. 24, sec. 3, p. 77; am. 1996, ch. 36, sec. 3, p. 97; am. 1999, ch. 67, sec. 1, p. 177; am. 2010, ch. 117, sec. 4, p. 253; am. 2012, ch. 181, sec. 3, p. 481; am. 2014, ch. 33, sec. 2, p. 52; am. 2015, ch. 29, sec. 2, p. 65.]

37-2712.SCHEDULE V TESTS. The board shall place a substance in schedule V if it finds that:

(a) The substance has low potential for abuse relative to the controlled substances listed in schedule IV;

(b) The substance has currently accepted medical use in treatment in the United States; and

(c) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV.

[I.C., sec. 37-2712, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2713.SCHEDULE V. (a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below.

(c) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of

atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligrams difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]-2779;

(2) Lacosamide;

(3) Pregabalin;

(4) Propylhexedrine (except as Benzedrex™ inhaler);

(5) Pyrovalerone.

[I.C., sec. 37-2713, as added by 1971, ch. 215, sec. 1, p. 939; am. 1977, ch. 234, sec. 5, p. 707; am. 1980, ch. 160, sec. 5, p. 348; am. 1984, ch. 160, sec. 5, p. 399; am. 1986, ch. 209, sec. 4, p. 542; am. 1989, ch. 177, sec. 4, p. 437; am. 1990, ch. 29, sec. 1, p. 44; am. 2003, ch. 185, sec. 3, p. 507; am. 2010, ch. 117, sec. 5, p. 254; am. 2012, ch. 181, sec. 4, p. 483.]

37-2713A.SCHEDULE VI. (a) Schedule VI shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section.

(b) Volatile nitrites. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following drugs or their related compounds, congeners or isomers as follows:

(1) Amyl nitrite;

(2) Butyl nitrite;

(3) Isobutyl nitrite;

(4) Isoamyl nitrite;

(5) Isopentyl nitrite.

Except that any combination or compound containing amyl nitrite which is prepared pursuant to a prescription issued by a licensed practitioner is not a controlled substance for the purpose of this section.

[37-2713A, added 1989, ch. 268, sec. 1, p. 654.]

37-2714.REPUBLISHING OF SCHEDULES. The board shall revise and republish the schedules semiannually for two (2) years from the effective date [May 1, 1971] of this act, and thereafter annually.

[I.C., sec. 37-2714, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2715.RULES. The board may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this state.

[I.C., sec. 37-2715, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2716.REGISTRATION REQUIREMENTS. (a) Every person who manufactures, distributes, prescribes, administers, dispenses, or conducts research with any controlled substance within this state shall obtain annually a registration issued by the board in accordance with this chapter and its rules.

(b) Every prescriber, except veterinarians, shall also register with the board to obtain online access to the controlled substances prescriptions database.

(c) Persons registered by the board under this chapter may possess, manufacture, distribute, dispense, prescribe, administer, or conduct research with those substances to the extent authorized by their registration and licensing entity and in conformity with the other provisions of this chapter.

(d) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any person registered pursuant to this chapter, if he is acting in the usual course of his business or employment;

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.

(e) The board may waive by rule the requirement for registration of certain persons if it finds it consistent with the public health and safety.

(f) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, administers, dispenses, or conducts research with controlled substances, except a separate registration is not required under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through IV where the practitioner is already registered under this chapter in another capacity.

(g) Practitioners registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this state upon registering in Idaho and furnishing the board with evidence of the practitioner's federal registration.

(h) The board may inspect the establishment of a registrant or applicant for registration in accordance with this chapter and board rule.

[37-2716, added 1971, ch. 215, sec. 1, p. 939; am. 1974, ch. 27, sec. 79, p. 811; am. 2000, ch. 469, sec. 85, p. 1533; am. 2014, ch. 79, sec. 2, p. 215; am. 2015, ch. 25, sec. 2, p. 35.]

37-2717.REGISTRATION. The board shall register an applicant to manufacture, prescribe, administer, dispense, distribute or conduct research with 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:

(a) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(b) Compliance with applicable state and local law;

(c) Any convictions of the applicant under any federal and state laws relating to any controlled substance;

(d) Past experience in the manufacture, dispensing, prescribing, administering, research or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversions;

(e) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

(f) Restriction, suspension or revocation of the applicant's federal registration; and

(g) Any other factors relevant to and consistent with the public health and safety.

[37-2717, added 1971, ch. 215, sec. 1, p. 939; am. 2015, ch. 25, sec. 3, p. 36.]

37-2718. DISCIPLINE. (a) A registration under section 37-2717, Idaho Code, may be restricted, 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 restricted, suspended or revoked;

(4) Has violated this chapter, any rule of the board promulgated under this act, an order of the board or any federal regulation relating to controlled substances; provided, however, that no restriction, 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 subsection (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) Restriction, 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 the 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 restricts, suspends or revokes a registration, all pertinent controlled substances owned or possessed by the registrant at the time of the restriction or 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 therefor, 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 restricting, 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, prescribe, administer, dispense, or conduct research with 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.

[37-2718, added 1971, ch. 215, sec. 1, p. 939; am. 1981, ch. 102, sec. 4, p. 156; am. 1985, ch. 152, sec. 1, p. 405; am. 2001, ch. 211, sec. 1, p. 835; am. 2015, ch. 25, sec. 4, p. 36.]

37-2719.ORDER TO SHOW CAUSE. (a) Except as set forth in section 37-2718(g), Idaho Code, before denying, restricting, suspending or revoking a registration, or refusing a renewal of registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should be restricted, denied, revoked, or suspended, or why the renewal should be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the board at a time and place not less than thirty (30) days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than thirty (30) days before the expiration of the registration. These proceedings shall be conducted in accordance with chapter 52, title 67, Idaho Code, without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(b) The board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 37-2718, Idaho Code, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction.

(c) In conjunction with a proceeding for denying, restricting, suspending or revoking a registration, or refusing a renewal of registration, and upon a finding of grounds for such denial, restriction, suspension, revocation or refusal to renew, the board may also impose an administrative fine not to exceed two thousand dollars ($2,000) per occurrence and 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.

[37-2719, added 1971, ch. 215, sec. 1, p. 939; am. 2001, ch. 211, sec. 2, p. 836; am. 2015, ch. 25, sec. 5, p. 38.]

37-2720.RECORDS -- DRUG STORAGE -- INVENTORY. Persons registered under this chapter shall keep records, store controlled substances and maintain inventories in conformance with the recordkeeping, storage and inventory requirements of federal law and with any additional rules the board issues.

[37-2720, added 1971, ch. 215, sec. 1, p. 939; am. 2015, ch. 25, sec. 6, p. 38; am. 2016, ch. 74, sec. 1, p. 252.]

37-2721.ORDER FORMS. Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

[I.C., sec. 37-2721, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2722.PRESCRIPTIONS. (a) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

(b) In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 37-2720, Idaho Code. No prescription for a schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under this act or regulation of the bureau or the board, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.

(d) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.

(e) Solely for the purpose of allowing the dispensing of controlled substances pursuant to the prescription of an individual licensed in a jurisdiction other than the state of Idaho, and for no other purpose under this act, with respect to the written or oral prescription of a "practitioner" as required under subsections (a), (b) and (c) of this section, the term "practitioner" shall also include a physician, dentist, veterinarian, scientific investigator or other individual, other than a pharmacy licensed in a jurisdiction other than the state of Idaho, and permitted by such license to dispense, conduct research with respect to or administer the prescribed controlled substance 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 written or oral prescription.

[I.C., sec. 37-2722, as added by 1971, ch. 215, sec. 1, p. 939; am. 2000, ch. 276, sec. 1, p. 898; am. 2001, ch. 178, sec. 1, p. 601.]

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 unless it is in compliance with applicable federal law.

[I.C., sec. 37-2723, as added by 1971, ch. 215, sec. 1, p. 939; am. 1996, ch. 12, sec. 1, p. 31; am. 2011, ch. 133, sec. 1, p. 367.]

37-2724.USE IN HOSPITAL -- FORM OF ORDER -- RECORD -- NURSING HOME, EXTENDED CARE FACILITY. An order for schedule II substance for use by a patient in a county or licensed hospital, or in a licensed nursing home or extended care facility employing a

unit dose distribution system, shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name, strength and dosage schedule of the drug ordered. A direct copy of this order will be furnished within seventy-two (72) hours to the pharmacist supplying the medication. The record of said orders and the administration record shall be maintained as a record in the hospital, nursing home or extended care facility for a minimum of three (3) years and shall be available for inspection by all inspectors of the board.

[37-2724, added I.C., sec. 37-2724, as added by 1971, ch. 215, sec. 1, p. 939; am. 1976, ch. 108, sec. 1, p. 432; am. 1997, ch. 18, sec. 1, p. 28; am. 2001, ch. 178, sec. 2, p. 602.]

37-2725.PRESCRIPTION REQUIRED -- PRESCRIPTION BLANKS -- POSSESSION -- TRANSFERENCE -- CONTENTS. (1) A prescription shall be required for all scheduled drugs. Paper 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.

(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 contain 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 paper 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 or drugs lost or stolen must be immediately reported to the board.

[37-2725, added 2001, ch. 178, sec. 4, p. 602; am. 2002, ch. 367, sec. 1, p. 1035; am. 2011, ch. 133, sec. 2, p. 367.]

37-2726.FILING PRESCRIPTIONS -- DATABASE. (1) All controlled substances dispensed for humans shall be filed with the board electronically in a format established by the board or by other method as required by board rule. The board may require the filing of other prescriptions by board rule. The board shall establish by rule the information to be submitted pursuant to the purposes of this section and the purposes set forth in section 37-2730A, Idaho Code.

(2) The board shall create, operate and maintain a controlled substances prescriptions database containing the information submitted pursuant to subsection (1) of this section, to be used for the purposes and subject to the terms, conditions and immunities described in section 37-2730A, Idaho Code. The database information must be made available only to the following:

(a) Authorized individuals employed by Idaho's boards or other states' licensing entities charged with the licensing and discipline of practitioners;

(b) Peace officers employed by federal, state and local law enforcement agencies engaged as a specified duty of their employment in enforcing law regulating controlled substances;

(c) Authorized individuals under the direction of the department of health and welfare for the purpose of monitoring and enforcing that department's responsibilities under the public health, medicare and medicaid laws;

(d) A practitioner, licensed in Idaho or another state, having authority to prescribe controlled substances, or a delegate under the practitioner's supervision, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance;

(e) A pharmacist, licensed in Idaho or another state, having authority to dispense controlled substances, or a delegate under the pharmacist's supervision, to the extent the information relates specifically to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance, or providing pharmaceutical care as defined in the Idaho pharmacy act;

(f) An individual who is the recipient of a dispensed controlled substance entered into the database may access records that pertain to that individual, upon the production of positive identification, or that individual's designee upon production of a notarized release of information by that individual;

(g) Upon a lawful order issued by the presiding judge in a court of competent jurisdiction for the release of prescription monitoring program records of a named individual;

(h) Prosecuting attorneys, deputy prosecuting attorneys and special prosecutors of a county or city and special assistant attorneys general from the office of the attorney general engaged in enforcing law regulating controlled substances; and

(i) A medical examiner or coroner who is an officer of or employed by a state or local government, for determining a cause of death or for performing other duties authorized by law.

(3) The board shall require prescribers, except veterinarians, to annually register with the board to obtain online access to the controlled substances prescriptions database.

(4) The board must maintain records on the information disclosed from the database, including:

(a) The identification of each individual who requests or receives information from the database and who that individual represents;

(b) The information provided to each such individual; and

(c) The date and time the information is requested or provided.

(5) The board shall promulgate rules to ensure that only authorized individuals have access to the database.

(6) The board shall limit to four (4) the number of delegates that a practitioner or pharmacist may permit to access the database under the practitioner or pharmacist's supervision.

(7) Any person who knowingly misrepresents to the board that he is a person entitled under subsection (2) of this section to receive information from the controlled substances prescriptions database under the conditions therein provided, and who receives information from the controlled

substances prescriptions database resulting from that misrepresentation, shall be guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six (6) months, or by a fine not to exceed two thousand dollars ($2,000), or both. The foregoing criminal penalty is in addition to, and not in lieu of, any other civil or administrative penalty or sanction authorized by law.

(8) Any person in possession, whether lawfully or unlawfully, of information from the controlled substances prescriptions database which identifies an individual patient and who knowingly discloses such information to a person not authorized to receive or use such information under any state or federal law, rule or regulation; the lawful order of a court of competent jurisdiction; or written authorization of the individual patient shall be guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six (6) months, or by a fine not to exceed two thousand dollars ($2,000), or both. The foregoing criminal penalty is in addition to, and not in lieu of, any other civil or administrative penalty or sanction authorized by law. The provisions of this subsection shall not apply to disclosure of individual patient information by the patient himself. The provisions of this subsection shall not apply to disclosure of information by a prosecuting attorney, deputy prosecuting attorney or special prosecutor of a county or city or by a special assistant attorney general from the office of the attorney general in the course of a criminal proceeding, whether preconviction or postconviction.

(9) Any person with access to the board's online prescription monitoring program pursuant to a board issued user account, login name and password who intentionally shares or recklessly fails to safeguard his user account, login name and password, resulting in another person not authorized to receive or use such information under the provisions of any state or federal law, rule or regulation obtaining information from the controlled substances prescriptions database, shall be guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six (6) months or by a fine not to exceed two thousand dollars ($2,000), or both. The foregoing criminal penalty is in addition to, and not in lieu of, any other civil or administrative penalty or sanction authorized by law.

(10) The board may, at its discretion, block access to certain controlled substances prescriptions database data if the board has reason to believe that access to the data is or may be used illegally.

(11) All costs associated with recording and submitting data as required in this section are assumed by the dispensing practitioner recording and submitting the data.

(12) For purposes of this section, "delegate" means a nurse, medical or office assistant, or registered pharmacy technician who is designated by a supervising practitioner or pharmacist to access the database according to the provisions of this section and who must register with the state board of pharmacy for such access.

[37-2726, added 2001, ch. 178, sec. 5, p. 603; am. 2006, ch. 175, sec. 2, p. 538; am. 2008, ch. 129, sec. 1, p. 362; am. 2012, ch. 185, sec. 1, p. 489; am. 2012, ch. 198, sec. 1, p. 531; am. 2014, ch. 32, sec. 1, p. 46; am. 2014, ch. 79, sec. 3, p. 216; am. 2015, ch. 27, sec. 1, p. 42; am. 2016, ch. 72, sec. 1, p. 249; am. 2016, ch. 82, sec. 1, p. 262.]

37-2727.CONTROLLED SUBSTANCES IN NARCOTIC TREATMENT PROGRAMS. (1) At a facility with a controlled substance registration certificate issued by the United States department of justice, drug enforcement administration, for the operation of a narcotic treatment program, a nurse licensed under chapter 14, title 54, Idaho Code, may, pursuant to a valid order of a physician licensed under chapter 18, title 54, Idaho Code:

(a) Prepare and administer to a patient at that facility a controlled substance whether or not a practitioner is present; and

(b) Deliver at that facility to a patient for subsequent use by the patient off-site, take-home doses of a controlled substance, provided that:

(i) The patient is entitled to receive take-home doses of the controlled substance;

(ii) The take-home doses delivered by the nurse to the patient were obtained at the facility by the nurse from a locked storage area suitable to prevent unauthorized access and to ensure a proper environment for preservation of the drugs within such area; and

(iii) The take-home doses were prepared pursuant to a valid order of the physician by a pharmacist licensed under chapter 17, title 54, Idaho Code, and were delivered by the pharmacist to the locked storage area at the facility in a suitable container appropriately labeled for subsequent delivery by the nurse to the patient and for subsequent use by the patient entitled to receive the take-home doses of the controlled substance.

(2) A nurse acting under the authority of this section is exempt from the registration requirements imposed by this chapter.

[37-2727, added 2007, ch. 250, sec. 1, p. 735.]

37-2730A.PRESCRIPTION TRACKING PROGRAM. (1) The board shall maintain a program to track the prescriptions for controlled substances that are filed with the board under section 37-2726, Idaho Code, for the purpose of assisting in identifying illegal activity related to the dispensing of controlled substances and for the purpose of assisting the board in providing information to patients, practitioners and pharmacists to assist in avoiding inappropriate use of controlled substances. The tracking program and any data created thereby shall be administered by the board.

(2) The board shall use the information obtained through the tracking program in identifying activity it reasonably suspects may be in violation of this chapter or medical assistance law. The board shall report this information to the individuals and persons set forth in section 37-2726(2), Idaho Code. The board may release unsolicited information to pharmacists and practitioners when the release of information may be of assistance in preventing or avoiding inappropriate use of controlled substances. The board may provide the appropriate law enforcement agency, medicaid or medicare agency or licensing board with the relevant information in the board's possession, including information obtained from the tracking program, for further investigation, or other appropriate law enforcement or administrative enforcement use.

(3) Information, which does not identify individual patients, practitioners or dispensing pharmacists or pharmacies, may be released by the board for educational, research or public information purposes.

(4) Nothing herein shall prevent a pharmacist or practitioner from furnishing another pharmacist or practitioner information obtained pursuant to and in compliance with this chapter.

(5) Unless there is shown malice or criminal intent or gross negligence or reckless, willful and wanton conduct as defined in section 6-904C, Idaho Code, the state of Idaho, the board, any other state agency, or any person, or entity in proper possession of information as herein provided shall not be subject to any liability or action for money damages or other legal or equitable relief by reason of any of the following:

(a) The furnishing of information under the conditions herein provided;

(b) The receiving and use of, or reliance on, such information;

(c) The fact that any such information was not furnished; or

(d) The fact that such information was factually incorrect or was released by the board to the wrong person or entity.

(6) The board may apply for any available grants and accept any gifts, grants or donations to assist in developing and maintaining the program required by this section.

[37-2730A, added 2000, ch. 194, sec. 1, p. 480; am. 2001, ch. 178, sec. 6, p. 603; am. 2006, ch. 175, sec. 3, p. 539; am. 2012, ch. 198, sec. 2, p. 533; am. 2013, ch. 6, sec. 1, p. 14.]

37-2731.INFORMATION REQUIRED ON LABEL. (a) The practitioner dispensing a controlled substance listed in schedule II shall affix to the package a label showing date of dispensing, the dispenser's name and address, the serial number of the prescription if applicable, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) The practitioner dispensing controlled substances listed in schedule III or IV shall affix to the package a label showing the dispenser's name and address, the serial number if applicable, and date of initial dispensing, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(c) The practitioner dispensing a controlled substance listed in schedule V pursuant to a prescription shall affix to the package a label showing the dispenser's name and address, the serial number if applicable, and the date of dispensing, the name of the patient, the name of the practitioner issuing the prescription, the directions for use and cautionary statements, if any, contained in such prescription as required by law.

[I.C., sec. 37-2731, as added by Acts 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 5, p. 261.]

37-2732.PROHIBITED ACTS A -- PENALTIES. (a) Except as authorized by this chapter, it is unlawful for any person to manufacture or deliver, or possess with intent to manufacture or deliver, a controlled substance.

(1) Any person who violates this subsection with respect to:

(A) A controlled substance classified in schedule I which is a narcotic drug or a controlled substance classified in schedule II, except as provided for in section 37-2732B(a)(3), Idaho Code, is guilty of a felony and upon conviction may be imprisoned for a term of years not to exceed life imprisonment, or fined not more than twenty-five thousand dollars ($25,000), or both;

(B) Any other controlled substance which is a nonnarcotic drug classified in schedule I, or a controlled substance classified in schedule III, is guilty of a felony and upon conviction may be imprisoned for not more than five (5) years, fined not more than fifteen thousand dollars ($15,000), or both;

(C) A substance classified in schedule IV, is guilty of a felony and upon conviction may be imprisoned for not more than three (3) years, fined not more than ten thousand dollars ($10,000), or both;

(D) A substance classified in schedules V and VI, is guilty of a misdemeanor and upon conviction may be imprisoned for not more than one (1) year, fined not more

than five thousand dollars ($5,000), or both.

(b) Except as authorized by this chapter, it is unlawful for any person to create, deliver, or possess with intent to deliver, a counterfeit substance.

(1) Any person who violates this subsection with respect to:

(A) A counterfeit substance classified in schedule I which is a narcotic drug, or a counterfeit substance classified in schedule II, is guilty of a felony and upon conviction may be imprisoned for not more than fifteen (15) years, fined not more than twenty-five thousand dollars ($25,000), or both;

(B) Any other counterfeit substance classified in schedule I which is a nonnarcotic drug contained in schedule I or a counterfeit substance contained in schedule III, is guilty of a felony and upon conviction may be imprisoned for not more than five (5) years, fined not more than fifteen thousand dollars ($15,000), or both;

(C) A counterfeit substance classified in schedule IV, is guilty of a felony and upon conviction may be imprisoned for not more than three (3) years, fined not more than ten thousand dollars ($10,000), or both;

(D) A counterfeit substance classified in schedules V and VI or a noncontrolled counterfeit substance, is guilty of a misdemeanor and upon conviction may be imprisoned for not more than one (1) year, fined not more than five thousand dollars ($5,000), or both.

(c) It is unlawful for any person to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by this chapter.

(1) Any person who violates this subsection and has in his possession a controlled substance classified in schedule I which is a narcotic drug or a controlled substance classified in schedule II, is guilty of a felony and upon conviction may be imprisoned for not more than seven (7) years, or fined not more than fifteen thousand dollars ($15,000), or both.

(2) Any person who violates this subsection and has in his possession lysergic acid diethylamide is guilty of a felony and upon conviction may be imprisoned for not more than three (3) years, or fined not more than five thousand dollars ($5,000), or both.

(3) Any person who violates this subsection and has in his possession a controlled substance which is a nonnarcotic drug classified in schedule I except lysergic acid diethylamide, or a controlled substance classified in schedules III, IV, V and VI is guilty of a misdemeanor and upon conviction thereof may be imprisoned for not more than one (1) year, or fined not more than one thousand dollars ($1,000), or both.

(d) It shall be unlawful for any person to be present at or on premises of any place where he knows illegal controlled substances are being manufactured or cultivated, or are being held for distribution, transportation, delivery, administration, use, or to be given away. A violation of this section shall deem those persons guilty of a misdemeanor and upon conviction shall be punished by a fine of not more than three hundred dollars ($300) and not more than ninety (90) days in the county jail, or both.

(e) If any person is found to possess marijuana, which for the purposes of this subsection shall be restricted to all parts of the plants of the genus Cannabis, including the extract or any preparation of cannabis which contains tetrahydrocannabinol, in an amount greater than three (3) ounces net weight, it shall be a felony and upon conviction may be imprisoned for not more than five (5) years, or fined not more than ten thousand dollars ($10,000), or both.

(f) If two (2) or more persons conspire to commit any offense defined in this act, said persons shall be punishable by a fine or imprisonment, or both, which may not exceed the maximum

punishment prescribed for the offense, the commission of which was the object of the conspiracy.

(g) (1) It is unlawful for any person to manufacture or distribute a "simulated controlled substance," or to possess with intent to distribute, a "simulated controlled substance." Any person who violates this subsection shall, upon conviction, be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than one thousand dollars ($1,000) and not more than one (1) year in the county jail, or both.

(2) It is unlawful for any person to possess a "simulated controlled substance." Any person who violates this subsection shall, upon conviction, be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than three hundred dollars ($300) and not more than six (6) months in the county jail, or both.

(h) It is unlawful for any person to cause to be placed in any newspaper, magazine, handbill, or other publication, or to post or distribute in any public place, any advertisement or solicitation offering for sale simulated controlled substances. Any person who violates this subsection is guilty of a misdemeanor and shall be punished in the same manner as prescribed in subsection (g) of this section.

(i) No civil or criminal liability shall be imposed by virtue of this chapter on any person registered under the Uniform Controlled Substances Act who manufactures, distributes, or possesses an imitation controlled substance for use as a placebo or other use by a registered practitioner, as defined in section 37-2701(aa), Idaho Code, in the course of professional practice or research.

(j) No prosecution under this chapter shall be dismissed solely by reason of the fact that the dosage units were contained in a bottle or other container with a label accurately describing the ingredients of the imitation controlled substance dosage units. The good faith of the defendant shall be an issue of fact for the trier of fact.

(k) Upon conviction of a felony or misdemeanor violation under this chapter or upon conviction of a felony pursuant to the "racketeering act," section 18-7804, Idaho Code, or the money laundering and illegal investment provisions of section 18-8201, Idaho Code, the court may order restitution for costs incurred by law enforcement agencies in investigating the violation. Law enforcement agencies shall include, but not be limited to, the Idaho state police, county and city law enforcement agencies, the office of the attorney general and county and city prosecuting attorney offices. Costs shall include, but not be limited to, those incurred for the purchase of evidence, travel and per diem for law enforcement officers and witnesses throughout the course of the investigation, hearings and trials, and any other investigative or prosecution expenses actually incurred, including regular salaries of employees. In the case of reimbursement to the Idaho state police, those moneys shall be paid to the Idaho state police for deposit into the drug and driving while under the influence enforcement donation fund created in section 57-816, Idaho Code. In the case of reimbursement to the office of the attorney general, those moneys shall be paid to the general fund. A conviction for the purposes of this section means that the person has pled guilty or has been found guilty, notwithstanding the form of the judgment(s) or withheld judgment(s).

[37-2732, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 6, p. 261; am. 1972, ch. 409, sec. 1, p. 1195; am. 1974, ch. 242, sec. 1, p. 1606; am. 1977, ch. 185, sec. 1, p. 515; am. 1982, ch. 169, sec. 2, p. 447; am. 1983, ch. 218, sec. 2, p. 605; am. 1984, ch. 200, sec. 1, p. 490; am. 1986, ch. 286, sec. 1, p. 709; am. 1989, ch. 268, sec. 2, p. 654; am. 1992, ch. 20, sec. 1, p. 64; am. 1993, ch. 105, sec. 1, p. 266; am. 1999, ch. 143, sec. 1, p. 407; am. 2000, ch. 469, sec. 86, p. 1533; am. 2004, ch. 242, sec. 1, p. 705; am. 2009, ch. 108, sec. 3, p. 348; am. 2010, ch. 118,

sec. 3, p. 262.]

37-2732A.SACRAMENTAL USE OF PEYOTE PERMITTED. The criminal sanctions provided in this chapter do not apply to that plant of the genus Lophophora Williamii commonly known as peyote when such controlled substance is transported, delivered or possessed to be used as the sacrament in religious rites of a bona fide native American religious ceremony conducted by a bona fide religious organization; provided, that this exemption shall apply only to persons of native American descent who are members or eligible for membership in a federally recognized Indian tribe. Use of peyote as a sacrament in religious rites shall be restricted to Indian reservations as defined in subsection (2) of section 63-3622Z, Idaho Code. A person transporting, possessing or distributing peyote in this state for religious rites shall have on their person a tribal enrollment card, a card identifying the person as a native American church member and a permit issued by a bona fide religious organization authorizing the transportation, possession and distribution of peyote for religious rites.

[37-2732A, added 1991, ch. 125, sec. 1, p. 279.]

37-2732B.TRAFFICKING -- MANDATORY SENTENCES. (a) Except as authorized in this chapter, and notwithstanding the provisions of section 37-2732, Idaho Code:

(1) Any person who knowingly manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, one (1) pound of marijuana or more, or twenty-five (25) marijuana plants or more, as defined in section 37-2701, Idaho Code, is guilty of a felony, which felony shall be known as "trafficking in marijuana." If the quantity of marijuana involved:

(A) Is one (1) pound or more, but less than five (5) pounds, or consists of twenty-five (25) marijuana plants or more but fewer than fifty (50) marijuana plants, regardless of the size or weight of the plants, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of one (1) year and fined not less than five thousand dollars ($5,000);

(B) Is five (5) pounds or more, but less than twenty-five (25) pounds, or consists of fifty (50) marijuana plants or more but fewer than one hundred (100) marijuana plants, regardless of the size or weight of the plants, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of three (3) years and fined not less than ten thousand dollars ($10,000);

(C) Is twenty-five (25) pounds or more, or consists of one hundred (100) marijuana plants or more, regardless of the size or weight of the plants, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of five (5) years and fined not less than fifteen thousand dollars ($15,000).

(D) The maximum number of years of imprisonment for trafficking in marijuana shall be fifteen (15) years, and the maximum fine shall be fifty thousand dollars ($50,000).

(E) For the purposes of this section, the weight of the marijuana is its weight when seized or as determined as soon as practicable after seizure, unless the provisions of subsection (c) of this section apply.

(2) Any person who knowingly manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, twenty-eight (28) grams or more of cocaine or of any mixture or substance containing a detectable amount of cocaine is guilty of a felony, which felony shall be known as "trafficking in cocaine." If the quantity involved:

(A) Is twenty-eight (28) grams or more, but less than two hundred (200) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of three (3) years and fined not less than ten thousand dollars ($10,000);

(B) Is two hundred (200) grams or more, but less than four hundred (400) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of five (5) years and fined not less than fifteen thousand dollars ($15,000);

(C) Is four hundred (400) grams or more, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of ten (10) years and fined not less than twenty-five thousand dollars ($25,000).

(D) The maximum number of years of imprisonment for trafficking in cocaine shall be life, and the maximum fine shall be one hundred thousand dollars ($100,000).

(3) Any person who knowingly manufactures or attempts to manufacture methamphetamine and/or amphetamine is guilty of a felony which shall be known as "trafficking in methamphetamine and/or amphetamine by manufacturing." Any person convicted of trafficking in methamphetamine and/or amphetamine by attempted manufacturing shall be sentenced to a mandatory minimum fixed term of imprisonment of two (2) years and not to exceed fifteen (15) years imprisonment and fined not less than ten thousand dollars ($10,000). Any person convicted of trafficking in methamphetamine and/or amphetamine by manufacturing shall be sentenced to a mandatory minimum fixed term of imprisonment of five (5) years and not to exceed life imprisonment and fined not less than twenty-five thousand dollars ($25,000). The maximum number of years of imprisonment for trafficking in methamphetamine and/or amphetamine by manufacturing shall be life, and the maximum fine shall be one hundred thousand dollars ($100,000).

(4) Any person who knowingly delivers, or brings into this state, or who is knowingly in actual or constructive possession of, twenty-eight (28) grams or more of methamphetamine or amphetamine or of any mixture or substance containing a detectable amount of methamphetamine or amphetamine is guilty of a felony, which felony shall be known as "trafficking in methamphetamine or amphetamine." If the quantity involved:

(A) Is twenty-eight (28) grams or more, but less than two hundred (200) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of three (3) years and fined not less than ten thousand dollars ($10,000);

(B) Is two hundred (200) grams or more, but less than four hundred (400) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of five (5) years and fined not less than fifteen thousand dollars ($15,000);

(C) Is four hundred (400) grams or more, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of ten (10) years and fined not less than twenty-five thousand dollars ($25,000).

(D) The maximum number of years of imprisonment for trafficking in methamphetamine or amphetamine shall be life, and the maximum fine shall be one hundred thousand dollars ($100,000).

(5) Any person who knowingly manufactures, delivers, brings into this state, or who is knowingly in actual or constructive possession of the below-specified quantities of any of the following immediate precursors to methamphetamine or amphetamine (namely ephedrine, methylamine, methyl formamide, phenylacetic acid, phenylacetone, or pseudoephedrine) as defined in section 37-2707(g)(1), Idaho Code, or any compound, mixture or preparation which contains a detectable quantity of these substances, is guilty of a felony which shall be known as "trafficking in immediate precursors of methamphetamine

or amphetamine." If the quantity:

(A) Of ephedrine is five hundred (500) grams or more;

(B) Of methylamine is one-half (1/2) pint or more;

(C) Of methyl formamide is one-quarter (1/4) pint or more;

(D) Of phenylacetic acid is five hundred (500) grams or more;

(E) Of phenylacetone is four hundred (400) grams or more;

(F) Of pseudoephedrine is five hundred (500) grams or more;

such person shall be sentenced to a mandatory minimum fixed term of imprisonment of ten (10) years and fined not less than twenty-five thousand dollars ($25,000). The maximum number of years of imprisonment for trafficking in immediate precursors of methamphetamine or amphetamine in the quantities specified in paragraphs (A) through (F) of this subsection (5) shall be life, and the maximum fine shall be one hundred thousand dollars ($100,000). If the quantity of pseudoephedrine is twenty-five (25) grams or more, but less than five hundred (500) grams, such person shall be sentenced to a term of imprisonment of up to ten (10) years and fined not more than twenty-five thousand dollars ($25,000).

(6) Any person who knowingly manufactures, delivers or brings into this state, or who is knowingly in actual or constructive possession of, two (2) grams or more of heroin or any salt, isomer, or salt of an isomer thereof, or two (2) grams or more of any mixture or substance containing a detectable amount of any such substance is guilty of a felony, which felony shall be known as "trafficking in heroin." If the quantity involved:

(A) Is two (2) grams or more, but less than seven (7) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of three (3) years and fined not less than ten thousand dollars ($10,000);

(B) Is seven (7) grams or more, but less than twenty-eight (28) grams, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of ten (10) years and fined not less than fifteen thousand dollars ($15,000);

(C) Is twenty-eight (28) grams or more, such person shall be sentenced to a mandatory minimum fixed term of imprisonment of fifteen (15) years and fined not less than twenty-five thousand dollars ($25,000).

(D) The maximum number of years of imprisonment for trafficking in heroin shall be life, and the maximum fine shall be one hundred thousand dollars ($100,000).

(7) A second conviction for any trafficking offense as defined in subsection (a) of this section shall result in a mandatory minimum fixed term that is twice that otherwise required under this section.

(8) Notwithstanding any other provision of law, with respect to any person who is found to have violated the provisions of this section, adjudication of guilt or the imposition or execution of sentence shall not be suspended, deferred, or withheld, nor shall such person be eligible for parole prior to serving the mandatory minimum fixed term of imprisonment prescribed in this section. Further, the court shall not retain jurisdiction.

(b) Any person who agrees, conspires, combines or confederates with another person or solicits another person to commit any act prohibited in subsection (a) of this section is guilty of a felony and is punishable as if he had actually committed such prohibited act.

(c) For the purposes of subsections (a) and (b) of this section the weight of the controlled substance as represented by the person selling or delivering it is determinative if the weight as represented is greater than the actual weight of the controlled substance.

[37-2732B, added 1992, ch. 336, sec. 1, p. 1005; am. 1995, ch. 58, sec. 1, p. 129; am. 1995, ch. 103, sec. 1, p. 331; am. 1998, ch. 168, sec. 1, p. 563; am. 1999, ch. 143, sec. 2, p. 410; am. 2002, ch. 186, sec. 1, p. 537; am. 2006, ch. 245, sec. 1, p. 749.]

37-2732C.USING OR BEING UNDER THE INFLUENCE -- PENALTIES. (a) Except as authorized in this chapter, it is unlawful for any person on a public roadway, on a public conveyance, on public property or on private property open to the public, to use or be under the influence of any controlled substance specified in subsection (b), (c), (d), (e) and (f) of section 37-2705, Idaho Code, or subsection (b), (c) and (d) of section 37-2707, Idaho Code, or subsection (c)(6) of section 37-2709, Idaho Code, or any narcotic drug classified in schedule III, IV or V, except when administered by or under the direction of a person licensed by the state to dispense, prescribe, or administer controlled substances. It shall be the burden of the defense to show that it comes within this exception.

(b) Any person convicted of violating the provisions of subsection (a) of this section is guilty of a misdemeanor and is punishable by imprisonment in a county jail for not more than six (6) months, or by a fine not exceeding one thousand dollars ($1,000) or by both.

(c) Any person who is convicted of violating subsection (a) of this section, when the offense occurred within five (5) years of that person being convicted of two (2) or more separate violations of that subsection and who refuses to complete a licensed drug rehabilitation program offered by the court pursuant to subsection (d) shall be punished by imprisonment in the county jail for a mandatory minimum period of time of not less than one hundred twenty (120) days, nor more than one (1) year. The court may not reduce the mandatory minimum period of incarceration provided in this subsection.

(d) The court may, when it would be in the interest of justice, permit any person convicted of a violation of subsection (a) of this section, punishable under subsection (b) or (c) of this section, to complete a licensed drug rehabilitation program in lieu of part or all of the imprisonment in the county jail. As a condition of sentencing, the court may require the offender to pay all or a portion of the drug rehabilitation program. In order to alleviate jail overcrowding and to provide recidivist offenders with a reasonable opportunity to seek rehabilitation pursuant to this subsection, counties are encouraged to include provisions to augment licensed drug rehabilitation programs in their substance abuse proposals and applications submitted to the state for federal and state drug abuse funds.

(e) Notwithstanding subsection (a), (b) or (c) of this section, or any other provision of law to the contrary, any person who is unlawfully under the influence of cocaine, cocaine base, methamphetamine, heroin, or phencyclidine while in the immediate personal possession of a loaded, operable firearm is guilty of a public offense and is punishable by imprisonment in the county jail or the state prison for not more than one (1) year. As used in this subsection, "immediate possession" includes, but is not limited to, the interior passenger compartment of a motor vehicle.

(f) Every person who violates subsection (e) of this section is punishable upon the second and each subsequent conviction by imprisonment in the state prison for a period of time not in excess of four (4) years.

(g) In addition to any fine assessed under this section and notwithstanding the provisions of section 19-4705, Idaho Code, the court may, upon conviction, assess an additional cost to the defendant in the way of restitution, an amount not to exceed two hundred dollars ($200) to the arresting and/or prosecuting agency or entity. These funds shall be remitted to the appropriate fund to offset the expense of toxicology testing.

[37-2732C, added 1996, ch. 261, sec. 1, p. 858; am. 2003, ch. 185, sec. 4, p. 507; am. 2010, ch. 117, sec. 6, p. 255.]

37-2733.PROHIBITED ACTS B -- PENALTIES. (a) It is unlawful for any person:

(1) Who is subject to article III of this act to distribute or dispense a controlled substance in violation of section 37-2722, Idaho Code;

(2) Who is a registrant, to manufacture a controlled substance not authorized by his registration, or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person;

(3) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this act;

(4) To refuse an entry into any premises for any inspection authorized by this act; or

(5) Knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place, which is resorted to by persons using controlled substances in violation of this act for the purpose of using these substances, or which is used for keeping or selling them in violation of this act.

(b) Any person who violates this section is guilty of a misdemeanor and upon conviction may be imprisoned for not more than one (1) year, fined not more than twenty-five thousand dollars ($25,000), or both.

[I.C., sec. 37-2733, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 409, sec. 2, p. 1195.]

37-2734.PROHIBITED ACTS C -- PENALTIES. (a) It is unlawful for any person knowingly or intentionally:

(1) to distribute as a registrant a controlled substance classified in schedules I or II, except pursuant to an order form as required by section 37-2721, Idaho Code;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(b) Any person who violates this section is guilty of a felony and upon conviction may be imprisoned for not more than four (4) years, or fined not more than thirty thousand dollars ($30,000), or both.

[I.C., sec. 37-2734, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 7, p. 261; am. 1972, ch. 409, sec. 3, p. 1195.]

37-2734A.PROHIBITED ACTS D -- PENALTIES. (1) It is unlawful for any person to use, or to possess with intent to use, drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store,

contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance.

(2) It is unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing, or under circumstances where one reasonably should know, that the purpose of the advertisement, in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia.

(3) Any person who is in violation of the provisions of subsections (1) and/or (2) of this section is guilty of a misdemeanor and upon conviction may be imprisoned for not more than one (1) year, fined not more than one thousand dollars ($1,000), or both.

[37-2734A, added 1980, ch. 388, sec. 2, p. 982; am. 1990, ch. 311, sec. 1, p. 851.]

37-2734B.PROHIBITED ACTS E -- PENALTIES. It is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver, drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance. Any person who is in violation of this section is guilty of a felony and upon conviction may be imprisoned for not more than nine (9) years, fined not more than thirty thousand dollars ($30,000), or both.

[37-2734B, added 1980, ch. 388, sec. 3, p. 983.]

37-2734C.PROHIBITED ACTS F -- PENALTIES. (1) A person is guilty of the crime of unlawful storage of anhydrous ammonia in a container that:

(a) Is not approved by the United States department of transportation to hold anhydrous ammonia; or

(b) Was not constructed to meet state and federal industrial health and safety standards for holding anhydrous ammonia.

(2) Violation of this section is a felony.

(3) This section does not apply to public employees or private contractors authorized to clean up and dispose of hazardous waste or toxic substances pursuant to the provisions of chapter 22, title 49, Idaho Code.

(4) Any damages arising out of the unlawful possession of, storage of, or tampering with anhydrous ammonia equipment shall be the sole responsibility of the person or persons unlawfully possessing, storing or tampering with the anhydrous ammonia. In no case shall liability for damages arising out of the unlawful possession of, storage of, or tampering with anhydrous ammonia or anhydrous ammonia equipment extend to the lawful owner, installer, maintainer, designer, manufacturer, possessor or seller of the anhydrous ammonia or anhydrous ammonia equipment, unless such damages arise out of the acts or omissions of the owner, installer, maintainer, designer, manufacturer, possessor or seller that constitute negligent misconduct to abide by the laws regarding anhydrous ammonia possession and storage.

[37-2734C, added 2002, ch. 257, sec. 3, p. 748.]

37-2735.PENALTIES UNDER OTHER LAWS. Any penalty imposed for violation of this act is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise

authorized by law.

[I.C., sec. 37-2735, as added by 1971, ch. 215, sec. 1, p. 939.]
37-2735A.DRUG HOTLINE FEE. In addition to any other penalties, a person convicted of a violation of this chapter shall be subject to an additional fine of ten dollars ($10.00) to be deposited in the drug and driving while under the influence enforcement donation fund, as set forth in section 57-816, Idaho Code, to be used for the purposes designated in that section.

[37-2735A, added 2006, ch. 113, sec. 1, p. 308; am. 2009, ch. 108, sec. 4, p. 350.]
37-2736.BAR TO PROSECUTION. If a violation of this act is a violation of a federal law or the law of another state, a conviction or acquittal under federal law or the law of another state for the same act is a bar to prosecution in this state.

[I.C., sec. 37-2736, as added by 1971, ch. 215, sec. 1, p. 939.]
37-2737.DISTRIBUTION TO PERSONS UNDER AGE 18. Any person eighteen (18) years of age or over who violates section 37-2732(a), Idaho Code, by distributing any nonnarcotic drug classified in schedule I, or any controlled substance classified in schedule III, IV, V, or VI, to a person under eighteen (18) years of age who is at least three (3) years his junior is punishable by the fine authorized by section 37-2732(a)(1)(B), (C) or (D), Idaho Code, by a term of imprisonment of up to twice that authorized by section 37-2732(a)(1)(B), (C) or (D), Idaho Code, or by both.

[I.C., sec. 37-2737, as added by 1971, ch. 215, sec. 1, p. 939; am. 1990, ch. 268, sec. 2, p. 757.]
37-2737A.MANUFACTURE OR DELIVERY OF CONTROLLED SUBSTANCE WHERE CHILDREN ARE PRESENT. (1) Except as authorized in this chapter, it is unlawful for any person to manufacture or deliver, or possess with the intent to manufacture or deliver, a controlled substance as defined in schedules I, II, III and IV in this chapter, upon the same premises where a child under the age of eighteen (18) years is present.

(2) As used in this section, "premises" means any:

(a) Motor vehicle or vessel;

(b) Dwelling or rental unit including, but not limited to, apartment, townhouse, condominium, mobile home, manufactured home, motel room or hotel room;

(c) Dwelling house, its curtilage and any other outbuildings.

(3) Except as provided in subsection (4) of this section, a person who violates the provisions of this section shall be guilty of a felony and upon conviction may be imprisoned for a term not to exceed five (5) years, fined not more than five thousand dollars ($5,000), or be both so imprisoned and fined.

(4) A person who violates the provisions of this section by manufacturing or delivering, or possessing with the intent to manufacture or deliver, methamphetamine or amphetamine in quantities as specified in section 37-2732B(a)(4), Idaho Code, shall be guilty of a felony and upon conviction may be imprisoned for a term of up to ten (10) years, fined not more than twenty-five thousand dollars ($25,000), or be both so imprisoned and fined.

(5) Any fine imposed under the provisions of this section shall be in addition to the fine imposed for any other offense, and any term of imprisonment shall be consecutive to any term imposed for any other offense, regardless of whether the violation of the provisions of this section and any of the other offenses have arisen from the same act or transaction.

[37-2737A, added 1991, ch. 275, sec. 1, p. 712; am. 2006, ch. 76, sec. 1, p. 234.]

37-2738.SENTENCING CRITERIA IN DRUG CASES. (1) Any person who pleads guilty to, is found guilty of or has a judgment of conviction entered upon a violation of the provisions of subsection (a), (b), (c) or (e) of section 37-2732, Idaho Code, shall be sentenced according to the criteria set forth herein.

(2) Prior to sentencing for a violation enumerated in subsection (1) of this section, the defendant shall undergo, at his own expense (or at county expense through the procedures set forth in chapters 34 and 35, title 31, Idaho Code), a substance abuse evaluation at a facility approved by the Idaho department of health and welfare. Provided however, if the defendant has no prior or pending charges under the provisions of subsection (a), (b), (c) or (e) of section 37-2732, Idaho Code, and the court does not have any reason to believe that the defendant regularly abuses drugs and is in need of treatment, the court may, in its discretion, waive the evaluation with respect to sentencing for a violation of subsection (b), (c)(3), or (e) of section 37-2732, Idaho Code, and proceed to sentence the defendant. The court may also, in its discretion, waive the requirement of a substance abuse evaluation with respect to a defendant's violation of the provisions of subsection (a), (b), (c) or (e) of section 37-2732, Idaho Code, and proceed to sentence the defendant if the court has a presentence investigation report, substance abuse assessment, criminogenic risk assessment, or similar assessment which has evaluated the defendant's need for substance abuse treatment conducted within twelve (12) months preceding the date of the defendant's sentencing.

(3) In the event a substance abuse evaluation indicates the need for substance abuse treatment, the evaluation shall recommend an appropriate treatment program, together with the estimated costs thereof, and recommendations for other suitable alternative treatment programs, together with the estimated costs thereof. The person shall request that a copy of the completed evaluation be forwarded to the court. The court shall take the evaluation into consideration to determine an appropriate sentence. If a copy of the completed evaluation has not been provided to the court, the court may proceed to sentence the defendant; however, in such event it shall be presumed that substance abuse treatment is needed unless it is shown by a preponderance of evidence that treatment is not required. If the defendant has not made a good faith effort to provide the completed copy of the evaluation to the court, the court may consider the failure of the defendant to provide or report an aggravating circumstance in determining an appropriate sentence. If treatment is ordered, the person or facility performing the evaluation shall not be the person or facility that provides the treatment, unless this requirement is waived by the sentencing court, and with the exception of federally recognized Indian tribes or federal military installations where diagnoses and treatment are appropriate and available. Nothing herein contained shall preclude the use of funds authorized pursuant to the provisions of chapter 3, title 39, Idaho Code, for court ordered substance abuse treatment for indigent defendants.

(4) When sentencing an individual for the crimes enumerated in subsection (1) of this section, the court shall not enter a withheld judgment unless it finds by a preponderance of the evidence that:

(a) The defendant has no prior finding of guilt for any felony, any violation of chapter

80, title 18, Idaho Code, or subsection (a), (b), (c) or (e) of section 37-2732, Idaho Code, whatsoever; and

(b) The sentencing court has an abiding conviction that the defendant will successfully complete the terms of probation; and

(c) The defendant has satisfactorily cooperated with law enforcement authorities in the prosecution of drug related crimes of which the defendant has previously had involvement.

The requirements for the granting of a withheld judgment pursuant to this subsection shall not apply to a defendant who has been admitted to a problem solving court program approved by the drug court and mental health court coordinating committee and is participating in, or about to begin participating in, such a program, or who participated in such a problem solving court program in connection with the pending case and who successfully graduated from such a program prior to sentencing.

(5) Any person who pleads guilty to or is found guilty of a violation of the provisions of the Idaho Code identified in subsection (1) of this section shall, when granted a probationary period of any sort whatsoever, be required by the court to complete a period of not less than one hundred (100) hours of community service work.

[37-2738, added 1989, ch. 174, sec. 2, p. 423; am. 2003, ch. 285, sec. 1, p. 770; am. 2004, ch. 22, sec. 1, p. 24; am. 2016, ch. 161, sec. 1, p. 444.]

37-2739.SECOND OR SUBSEQUENT OFFENSES. (a) Any person convicted of a second or subsequent offense under this act, who is not subject to a fixed minimum term under section 37-2739B, Idaho Code, may be imprisoned for a term up to twice the term otherwise authorized, fined an amount up to twice that otherwise authorized, or both.

(b) For purposes of this section, an offense is considered a second or subsequent offense, if, prior to his conviction of the offense, the offender has at any time been convicted under this act or under any statute of the United States or of any state relating to narcotic drugs, marijuana, depressant, stimulant, or hallucinogenic drugs.

[I.C., sec. 37-2739, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 8, p. 261; am. 1990, ch. 268, sec. 3, p. 757.]

37-2739A.MANDATORY MINIMUM PENALTY. Any person who is convicted of violating the felony provisions of section 37-2732(a), Idaho Code, by distributing controlled substances to another person, who is not subject to a fixed minimum term under section 37-2739B, Idaho Code, and who has previously been convicted within the past ten (10) years in a court of the United States, any state or a political subdivision of one or more felony offenses of dealing, selling or trafficking in controlled substances on an occasion or occasions different from the felony violation of section 37-2732(a), Idaho Code, and which offense or offenses were punishable in such court by imprisonment in excess of one (1) year, shall be sentenced to the custody of the state board of correction for a mandatory minimum period of time of not less than three (3) years or for such greater period as the court may impose up to a maximum of life imprisonment. The mandatory minimum period of three (3) years incarceration shall not be reduced and shall run consecutively to any other sentence imposed by the court.

[37-2739A, added 1981, ch. 88, sec. 1, p. 122; am. 1990, ch. 268, sec. 4, p. 757.]

37-2739B.FIXED MINIMUM SENTENCES IN DRUG CASES. (a) The legislature intends to allow fixed minimum sentences for certain aggravating factors found in cases brought under the uniform controlled substances act. The legislature hereby finds and declares that trafficking in controlled substances in the state of Idaho is a primary contributor to a societal problem that causes loss of life, personal injury and theft of property, and exacts a tremendous toll on the citizens of this state. To afford better protection to our citizens from those who traffic in controlled substances, the fixed minimum sentencing contained in subsections (b) and (c) of this section is enacted. By enacting fixed minimum sentences, the legislature does not seek to limit a court's power to impose a greater sentence pursuant to section 19-2513, Idaho Code.

(b) Any person who is found guilty of violating the provisions of section 37-2732(a)(1)(A), Idaho Code, or of any attempt or conspiracy to commit such a crime, may be sentenced to a fixed minimum term of confinement to the custody of the state board of correction, which term shall be at least five (5) years and may extend to life, for each of the following aggravating factors found by the trier of fact:

(1) That the defendant has previously been found guilty of or convicted of a violation of section 37-2732(a)(1)(A), Idaho Code, or of an attempt or conspiracy to commit such a crime, or an offense committed in another jurisdiction which, if committed in this jurisdiction, would be punishable as a violation of section 37-2732(a)(1)(A), Idaho Code, or as an attempt or conspiracy to commit such an offense.

(2) That the violation occurred on or within one thousand (1,000) feet of the property of any public or private primary or secondary school, or in those portions of any building, park, stadium or other structure or grounds which were, at the time of the violation, being used for an activity sponsored by or through such a school.

(3) That the violation consisted of the delivery or attempted delivery of a controlled substance to a minor child under the age of eighteen (18) years.

(c) The fixed minimum terms provided in this section may be imposed where the aggravating factors are separately charged in the information or indictment and admitted by the accused or found to be true by the trier of fact at the trial of the substantive crime; provided, however, that the prosecutor shall give notice to the defendant of intent to seek a fixed penalty at least fourteen (14) days prior to trial. During a fixed minimum term of confinement imposed under this section, the offender shall not be eligible for parole or discharge or credit or reduction of sentence for good conduct except for meritorious service. Each fixed minimum term imposed shall be served consecutively to the others, and consecutively to any minimum term of confinement imposed for the substantive offense.

(d) Any person who is found guilty of violating the provisions of section 37-2732(a)(1)(A), Idaho Code, or of any attempt or conspiracy to commit such a crime, and who is sentenced to serve at least one (1) minimum term of confinement under this section, may be fined an amount up to twice that otherwise provided for the substantive offense.

[37-2739B, added 1990, ch. 268, sec. 1, p. 756.]

37-2740.POWERS OF ENFORCEMENT PERSONNEL. (a) Any peace officer, as defined by this act, may:

(1) Carry firearms in the performance of his official duties;

(2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state;

(3) Make arrests without warrant for any offense under this act committed in his presence,

or if he has probable cause to believe that the person to be arrested has committed or is committing a violation of this act which may constitute a felony or a misdemeanor;

(4) Make seizures of property pursuant to this act.

(b) The director of the Idaho state police shall administer the state-level program of Idaho to suppress the unlawful traffic and abuse of controlled substances and shall have the authority to appoint and commission agents to enforce the provisions of this act.

(c) All duly authorized peace officers while investigating offenses under this act in the performance of their official duties, and any person working under their immediate direction, supervision, or instruction, provided such person shall not deviate from the lawful direction of the peace officer, are immune from prosecution under this act.

[I.C., sec. 37-2740, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 9, p. 261; am. 1974, ch. 27, sec. 80, p. 811; am. 2000, ch. 469, sec. 87, p. 1536.]

37-2741.ADMINISTRATIVE INSPECTIONS AND WARRANTS. (a) Issuance and execution of administrative inspection warrants shall be as follows:

(1) A magistrate, within his jurisdiction, and upon proper oath or affirmation showing probable cause, may issue warrants for the purpose of conducting administrative inspections authorized by this act or rules hereunder, and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this act or rules hereunder, sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant;

(2) A warrant shall issue only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any. The warrant shall:

(A) State the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof;

(B) Be directed to a person authorized by section 37-2740, Idaho Code, to execute it;

(C) Command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified;

(D) Identify the item or types of property to be seized, if any;

(E) Direct that it be served during normal business hours and designate the judge or magistrate to whom it shall be returned;

(3) A warrant issued pursuant to this section must be executed and returned within ten (10) days of its date unless, upon a showing of a need for additional time, the court orders otherwise. If property is seized pursuant to a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one (1) credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the

applicant for the warrant;

(4) The judge or magistrate who has issued a warrant shall attach thereto a copy of the return and all papers returnable in connection therewith and file them with the clerk of the court in the county in which the inspection was made.

(b) The board may make administrative inspections of controlled premises in accordance with the following provisions:

(1) For purposes of this section only, "controlled premises" means:

(A) Places where persons registered or exempted from registration requirements under this act are required to keep records; and

(B) Places including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this act are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled substance.

(2) When authorized by an administrative inspection warrant issued pursuant to subsection (a) of this section an officer or employee designated by the board, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.

(3) When authorized by an administrative inspection warrant, an officer or employee designated by the board may:

(A) Inspect and copy records required by this act to be kept;

(B) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in subsection (b)(5) of this section, all other things therein, including records, files, papers, processes, controls, and facilities bearing on violation of this act; and

(C) Inventory any stock of any controlled substance therein and obtain samples thereof;

(4) This section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with chapter 52, title 67, Idaho Code, nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:

(A) If the owner, operator, or agent in charge of the controlled premises consents;

(B) In situations presenting imminent danger to health or safety;

(C) In situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(D) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(E) In all other situations in which a warrant is not constitutionally required;

(5) An inspection authorized by this section shall not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

[I.C., sec. 37-2741, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2741A.UTILITY RECORDS -- INSPECTION AND COPYING -- WRONGFUL DISCLOSURE. (a) Upon request of the attorney general or prosecuting attorney, a subpoena for the production of records of a utility may be signed and issued by a magistrate judge if there is reasonable articulable suspicion that a violation of the provisions of section 37-2732, 37-

2732B, 37-2733, 37-2734 or 37-2734A, Idaho Code, has occurred or is occurring and that the records sought will materially aid in the investigation of such activity or appear reasonably calculated to lead to the discovery of information that will do so. The subpoena shall be served on the utility as in civil actions. The court may, upon motion timely made and in any event before the time specified for compliance with the subpoena, condition compliance upon advancement by the attorney general or prosecuting attorney of the reasonable costs of producing the records specified in the subpoena.

(b) A response to a subpoena issued under this section is sufficient if a copy or printout, duly authenticated by an authorized representative of the utility as a true and correct copy or printout of its records, is provided, unless otherwise provided in the subpoena for good cause shown.

(c) Except as provided in this subsection, a utility served with a subpoena under this section may disclose to the customer the fact that a subpoena seeking records relating to the customer has been served. A magistrate judge may order that the attorney general, prosecuting attorney or utility refrain from disclosing the fact that a subpoena has been served.

(d) A utility shall be reimbursed in an amount set by the court for reasonable costs incurred in providing information pursuant to the provisions of this section.

(e) The provisions of this section do not preclude the use of other legally authorized means of obtaining records, nor preclude the assertion of any legally recognized privileges or the right to seek a protective order where appropriate.

(f) Disclosure by the attorney general, county prosecuting attorney, or any peace officer or other person designated by the attorney general or the county prosecuting attorney, of information obtained under this section, except in the proper discharge of official duties, is punishable as a misdemeanor.

(g) Upon filing of any civil or criminal action, the nondisclosure requirements of any subpoena or order under this section shall terminate, and the attorney general or prosecuting attorney filing the action shall provide copies to the defendant of all subpoenas or other orders issued under this section.

(h) A good faith reliance on a court order by a utility shall constitute a complete defense to any civil or criminal action brought against such utility under the laws of this state.

(i) The term "utility," as used herein, shall mean every corporation, association, company, partnership, sole proprietorship, business entity, person, or any municipal corporation, mutual nonprofit or cooperative corporation which provides water, gas or electrical services to members of the public, for compensation, within the state of Idaho.

(j) If an action is not filed within two (2) years and the investigation is no longer active, records obtained pursuant to this section shall be destroyed by the attorney general or prosecuting attorney.

[37-2741A, added 1989, ch. 266, sec. 2, p. 652; am. 1991, ch. 218, sec. 1, p. 522; am. 1994, ch. 358, sec. 1, p. 1126.]

37-2742.INJUNCTIONS. (a) The district courts have jurisdiction to restrain or enjoin violations of this act.

(b) The defendant may demand trial by jury for an alleged violation of an injunction or restraining order under this section.

[I.C., sec. 37-2742, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2743.COOPERATIVE ARRANGEMENTS. (a) The director of the Idaho state police shall cooperate with federal and other state agencies in discharging his responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he may:

(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;

(2) Coordinate and cooperate in training programs concerning controlled substance law enforcement at local and state levels;

(3) Cooperate with the bureau by establishing a centralized unit to accept, catalogue, file, and collect statistics, including records of drug dependent persons and other controlled substance law offenders within the state, and make the information available for federal, state and local law enforcement purposes. The name or identity of a patient or research subject whose identity could not be obtained under subsection (c) of this section shall be subject to disclosure according to chapter 1, title 74, Idaho Code;

(4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substance may be extracted;

(5) Enter into agreements with other states to coordinate and facilitate the enforcement of this act; and

(6) Require law enforcement agencies to report such information regarding traffic in controlled substances and abuse of controlled substances as he deems necessary to enforce this act. Such reports shall be on forms supplied by the director of the Idaho state police and shall include, but not be limited to, the following information: Names, ages, sex, race, and residences of individuals involved in violations of this act; the contraband confiscated, showing the kind, location, quantity, date, and place where seized; the circumstances surrounding the arrests and a report of the disposition of charges.

(b) Results, information, and evidence received from the bureau relating to the regulatory functions of this act, including results of inspections and investigations conducted by the bureau may be relied and acted upon by the board in the exercise of its regulatory functions under this act.

(c) A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the director, nor may he be compelled in any state or local civil, criminal, administrative, legislative or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential and as such the name or identity of the patient or research subject is subject to disclosure according to chapter 1, title 74, Idaho Code.

[37-2743, added 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 10, p. 261; am. 1974, ch. 27, sec. 81, p. 811; am. 1990, ch. 213, sec. 32, p. 507; am. 2000, ch. 469, sec. 88, p. 1537; am. 2015, ch. 141, sec. 80, p. 438.]

37-2744.FORFEITURES. (a) The following are subject to forfeiture:

(1) All controlled substances which have been manufactured, distributed, dispensed, acquired, possessed or held in violation of this act or with respect to which there has been any act by any person in violation of this act;

(2) All raw materials, products and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substances or counterfeit substances in violation of this act;

(3) All property which is used, or intended for use, as a container for property described in

paragraph (1) or (2) of this section;

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or intended for use, to transport, or in any manner to facilitate the transportation, delivery, receipt, possession or concealment, for the purpose of distribution or receipt of property described in paragraph (1) or (2) of this section, but:

(A) No conveyance used by any person as a common carrier in the transaction of business as a common carrier is subject to forfeiture under this section unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this act;

(B) No conveyance is subject to forfeiture under this section if the owner establishes that he could not have known in the exercise of reasonable diligence that the conveyance was being used, had been used, was intended to be used or had been intended to be used in any manner described in subsection (a)(4) of this section;

(C) A forfeiture of a conveyance encumbered by a bona fide security interest is subject to the interest of the secured party if the security interest was created without any knowledge or reason to believe that the conveyance was being used, had been used, was intended to be used, or had been intended to be used for the purpose alleged.

(5) All books, records, and research products and materials, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this act.

(6) (A) All moneys, currency, negotiable instruments, securities or other items easily liquidated for cash, such as, but not limited to, jewelry, stocks and bonds, or other property described in paragraphs (2) and (3) hereof, found in close proximity to property described in paragraph (1), (2), (3), (5), (7) or (8) of subsection (a) of this section or which has been used or intended for use in connection with the illegal manufacture, distribution, dispensing or possession of property described in paragraph (1), (2), (3), (5), (7) or (8) of subsection (a) of this section;

(B) Items described in paragraph (6)(A) of this subsection or other things of value furnished or intended to be furnished by any person in exchange for a contraband controlled substance in violation of this chapter, all proceeds, including items of property traceable to such an exchange, and all moneys or other things of value used or intended to be used to facilitate any violation of this chapter, except that no property shall be forfeited under this paragraph to the extent of the interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without the knowledge or consent of that owner.

(7) All drug paraphernalia as defined by section 37-2701, Idaho Code.

(8) All simulated controlled substances, which are used or intended for use in violation of this chapter.

(9) All weapons, or firearms, which are used in any manner to facilitate a violation of the provisions of this chapter.

(b) Property subject to forfeiture under this chapter may be seized by the director, or any peace officer of this state, upon process issued by any district court, or magistrate's division thereof, having jurisdiction over the property. Seizure without process may be made if:

(1) The seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) The property subject to seizure has been the subject of a prior judgment in favor of the state in a criminal racketeering or civil forfeiture proceeding based upon a violation of this chapter;

(3) Probable cause exists to believe that the property is directly or indirectly dangerous to health or safety; or

(4) Probable cause exists to believe that the property was used or is intended to be used in violation of this chapter.

(c) In the event of seizure pursuant to subsection (b) of this section, proceedings under subsection (d) of this section shall be instituted promptly.

(1) When property is seized under this section, the director or the peace officer who seized the property may:

(A) Place the property under seal;

(B) Remove the property to a place designated by it; or

(C) Take custody of the property and remove it to an appropriate location for disposition in accordance with law.

(2) The peace officer who seized the property shall within five (5) days notify the director of such seizure.

(3) In the event of seizure pursuant to subsection (b) of this section, proceedings under subsection (d) of this section shall be instituted within thirty (30) days by the director or appropriate prosecuting attorney.

(d) Property taken or detained under this section shall not be subject to replevin, but is deemed to be in the custody of the director, or appropriate prosecuting attorney, subject only to the orders and decrees of the district court, or magistrate's division thereof, having jurisdiction over the forfeiture proceedings. Forfeiture proceedings shall be civil actions against the property subject to forfeiture and the standard of proof shall be preponderance of the evidence.

(1) All property described in paragraphs (1), (7) and (8) of subsection (a) of this section shall be deemed contraband and shall be summarily forfeited to the state. Controlled substances which are seized or come into possession of the state, the owners of which are unknown, shall be deemed contraband and shall be summarily forfeited to the state.

(2) When property described in paragraphs (2), (3), (4), (5) and (6) of subsection (a) of this section is seized pursuant to this section, forfeiture proceedings shall be filed in the office of the clerk of the district court for the county wherein such property is seized. The procedure governing such proceedings shall be the same as that prescribed for civil proceedings by the Idaho rules of civil procedure. The court shall order the property forfeited to the director, or appropriate prosecuting attorney, if he determines that such property was used, or intended for use, in violation of this chapter, or, in the case of items described in paragraph (6)(A) of subsection (a), was found in close proximity to property described in paragraph (1), (2), (3), (5), (7) or (8) of subsection (a) of this section.

(3) When conveyances, including aircraft, vehicles, or vessels are seized pursuant to this section a complaint instituting forfeiture proceedings shall be filed in the office of the clerk of the district court for the county wherein such conveyance is seized.

(A) Notice of forfeiture proceedings shall be given each owner or party in interest who has a right, title, or interest which in the case of a conveyance shall be determined by the record in the Idaho transportation department or a similar department of another state if the records are maintained in that state, by serving a copy of the complaint and summons according to one (1) of the following methods:

(I) Upon each owner or party in interest by mailing a copy of the complaint and summons by certified mail to the address as given upon the records of the appropriate department.

(II) Upon each owner or party in interest whose name and address is known,

by mailing a copy of the notice by registered mail to the last known address.

(B) Within twenty (20) days after the mailing or publication of the notice, the owner of the conveyance or claimant may file a verified answer and claim to the property described in the complaint instituting forfeiture proceedings.

(C) If at the end of twenty (20) days after the notice has been mailed there is no verified answer on file, the court shall hear evidence upon the fact of the unlawful use, or intent to use, and shall order the property forfeited to the director, or appropriate prosecuting attorney, if such fact is proved.

(D) If a verified answer is filed, the forfeiture proceeding shall be set for hearing before the court without a jury on a day not less than thirty (30) days therefrom; and the proceeding shall have priority over other civil cases.

(I) At the hearing any owner who has a verified answer on file may show by competent evidence that the conveyance was not used or intended to be used in any manner described in subsection (a)(4) of this section.

(II) At the hearing any owner who has a verified answer on file may show by competent evidence that his interest in the conveyance is not subject to forfeiture because he could not have known in the exercise of reasonable diligence that the conveyance was being used, had been used, was intended to be used or had been intended to be used in any manner described in subsection (a)(4) of this section.

(III) If the court finds that the property was not used or was not intended to be used in violation of this act, or is not subject to forfeiture under this act, the court shall order the property released to the owner as his right, title, or interest appears on records in the appropriate department as of the seizure.

(IV) An owner, co-owner or claimant of any right, title, or interest in the conveyance may prove that his right, title, or interest, whether under a lien, mortgage, conditional sales contract or otherwise, was created without any knowledge or reason to believe that the conveyance was being used, had been used, was intended to be used, or had been intended to be used for the purpose alleged;

(i) In the event of such proof, the court shall order the conveyance released to the bona fide or innocent owner, purchaser, lienholder, mortgagee, or conditional sales vendor. The court may order payment of all costs incurred by the state or law enforcement agency as a result of such seizure.

(ii) If the amount due to such person is less than the value of the conveyance, the conveyance may be sold at public auction by the director or appropriate prosecuting attorney. The director, or appropriate prosecuting attorney, shall publish a notice of the sale by at least one (1) publication in a newspaper published and circulated in the city, community or locality where the sale is to take place at least one (1) week prior to sale of the conveyance. The proceeds from such sale shall be distributed as follows in the order indicated:

1. To the bona fide or innocent owner, purchaser, conditional sales vendor, lienholder or mortgagee of the conveyance, if any, up to the value of his interest in the conveyance.
2. The balance, if any, in the following order:

A. To the director, or appropriate prosecuting attorney, for all expenditures made or incurred by it in connection with the sale, including expenditure for any necessary repairs, storage, or transportation of the conveyance, and for all expenditures made or incurred by him in connection with the forfeiture proceedings including, but not limited to, expenditures for witnesses' fees, reporters' fees, transcripts, printing, traveling and investigation.

B. To the law enforcement agency of this state which seized the conveyance for all expenditures for traveling, investigation, storage and other expenses made or incurred after the seizure and in connection with the forfeiture of any conveyance seized under this act.

C. The remainder, if any, to the director for credit to the drug and driving while under the influence enforcement donation fund or to the appropriate prosecuting attorney for credit to the local drug enforcement donation fund, or its equivalent.

(iii) In any case, the director, or appropriate prosecuting attorney, may, within thirty (30) days after judgment, pay the balance due to the bona fide lienholder, mortgagee or conditional sales vendor and thereby purchase the conveyance for use to enforce this act.

(e) When property is forfeited under this section, or is received from a federal enforcement agency, the director, or appropriate prosecuting attorney, may:

(1) Retain it for official use;

(2) Sell that which is not required to be destroyed by law and which is not harmful to the public.

The director, or appropriate prosecuting attorney, shall publish a notice of the sale by at least one (1) publication in a newspaper published and circulated in the city, community or locality where the sale is to take place at least one (1) week prior to sale of the property. The proceeds from such sale shall be distributed as follows in the order indicated:

(A) To the director, or prosecuting attorney on behalf of the county or city law enforcement agency, for all expenditures made or incurred in connection with the sale, including expenditure for any necessary repairs, maintenance, storage or transportation, and for all expenditures made or incurred in connection with the forfeiture proceedings including, but not limited to, expenditures for witnesses' fees, reporters' fees, transcripts, printing, traveling and investigation.

(B) To the law enforcement agency of this state which seized the property for all expenditures for traveling, investigation, storage and other expenses made or incurred after the seizure and in connection with the forfeiture of any property seized under this act.

(C) The remainder, if any, to the director for credit to the drug and driving while under the influence enforcement donation fund or to the appropriate prosecuting attorney for credit to the local agency's drug enforcement donation fund; or

(3) Take custody of the property and remove it for disposition in accordance with law.

(f) (1) The director or any peace officer of this state seizing any of the property described in

paragraphs (1) and (2) of subsection (a) of this section shall cause a written inventory to be made and maintain custody of the same until all legal actions have been exhausted unless such property has been placed in lawful custody of a court or state or federal law enforcement agency. After all legal actions have been exhausted with respect to such property, the property shall be surrendered by the court, law enforcement agency, or person having custody of the same to the director to be destroyed pursuant to paragraph (2) of this subsection. The property shall be accompanied with a written inventory on forms furnished by the director.

(2) All property described in paragraphs (1) and (2) of subsection (a) which is seized or surrendered under the provisions of this act may be destroyed after all legal actions have been exhausted. The destruction shall be done under the supervision of the Idaho state police by a representative of the office of the director and a representative of the state board of pharmacy. An official record listing the property destroyed and the location of destruction shall be kept on file at the office of the director. Except, however, that the director of the Idaho state police or his designee may authorize the destruction of drug or nondrug evidence, or store those items at government expense when, in the opinion of the director or his designee, it is not reasonable to remove or transport such items from the location of the seizure for destruction. In such case, a representative sample will be removed and preserved for evidentiary purposes and, when practicable, destroyed as otherwise is in accordance with this chapter. On-site destruction of such items shall be witnessed by at least two (2) persons, one (1) of whom shall be the director or his designee who shall make a record of the destruction.

(g) Species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this act, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the state.

(h) The failure, upon demand by the director, or his duly authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, constitutes authority for the seizure and forfeiture of the plants.

(i) The director shall have the authority to enter upon any land or into any dwelling pursuant to a search warrant, to cut, harvest, carry off or destroy such plants described in subsection (g) of this section.

[37-2744, added 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 11, p. 261; am. 1972, ch. 409, sec. 4, p. 1195; am. 1974, ch. 27, sec. 82, p. 811; am. 1980, ch. 388, sec. 4, p. 983; am. 1982, ch. 265, sec. 1, p. 680; am. 1983, ch. 218, sec. 3, p. 607; am. 1986, ch. 286, sec. 2, p. 712; am. 1988, ch. 47, sec. 3, p. 58; am. 1990, ch. 239, sec. 1, p. 676; am. 1990, ch. 312, sec. 1, p. 852; am. 1992, ch. 174, sec. 1, p. 546; am. 1994, ch. 285, sec. 1, p. 894; am. 1994, ch. 286, sec. 1, p. 900; am. 1999, ch. 218, sec. 1, p. 578; am. 2000, ch. 469, sec. 89, p. 1538; am. 2009, ch. 108, sec. 5, p. 350; am. 2014, ch. 78, sec. 1, p. 205.]

37-2744A.REAL PROPERTY SUBJECT TO FORFEITURE. (a) Any real property, including any interest therein and any appurtenances thereto or improvements thereon, which is used in any manner or part, to commit or to facilitate the commission of a violation of the provisions of this chapter punishable by more than one (1) year of imprisonment, shall be subject to forfeiture under the provisions of this section.

(b) Property subject to forfeiture under the provisions of this section may be seized by the director upon determining that a parcel of property is subject to forfeiture, by filing a notice of forfeiture with the recorder of the county in which the property or any part thereof is situated. The

notice must contain a legal description of the property sought to be forfeited; provided, however, that in the event the property sought to be forfeited is part of a greater parcel, the director may, for the purposes of this notice, use the legal description of the greater parcel. The director shall also send by certified mail a copy of the notice of forfeiture to any persons holding a recorded interest or of whose interest the director has actual knowledge. The director shall post a similar copy of the notice conspicuously upon the property and publish a copy thereof once a week for three (3) consecutive weeks immediately following the seizure in a newspaper published in the county. The owner or party in lawful possession of the property sought to be forfeited may retain possession and use thereof and may collect and keep income from the property while the forfeiture proceedings are pending.

(c) In the event of a seizure pursuant to subsection (a) of this section, a complaint instituting forfeiture proceedings under subsection (d) of this section shall be filed in the district court in the county in which the real property is situated within ninety (90) days of the date of seizure. The complaint shall be served in the same manner as other complaints subject to the Idaho rules of civil procedure on all persons having an interest in the real property sought to be forfeited.

(d) Real property sought to be forfeited under the provisions of this section shall not be subject to an action for detainer or any other collateral action, but is deemed to be in the custody of the director subject only to the orders and decrees of the district court having jurisdiction over the forfeiture proceedings. Forfeiture proceedings shall be civil proceedings in which the burden of proof shall be on the director to prove by a preponderance of the evidence that the property sought to be forfeited is subject to forfeiture. Upon being satisfied that an owner or claimant as defined in paragraph (4) of this subsection should not be subjected to forfeiture because that person had no knowledge or reason to believe that the real property was being used or had been used for the purposes alleged by the department, the director shall release the property to the owner or other claimant. The procedure applicable to such cases shall be the same as that prescribed by the Idaho rules of civil procedure. Following service the director may, where appropriate, seek default judgment pursuant to the Idaho rules of civil procedure. If an answer is filed the court shall proceed to set the case for hearing before the court without a jury.

(1) Following the hearing, if the court finds that the property is subject to forfeiture pursuant to subsection (a) of this section the court shall order the property forfeited to the director and title shall vest as of the date of the original seizure.

(2) Following the hearing, if the court finds that the property is not subject to forfeiture pursuant to subsection (a) of this section, the court shall order the property released to the owner or owners thereof.

(3) Any owner who has an answer on file may show by competent evidence that his interest in the property sought to be forfeited is not subject to forfeiture because he could not have known in the exercise of reasonable diligence that the real property was being used, or had been used in any manner in violation of the provisions of this section. If the court finds that the property was not used in violation of the provisions of this section or is not subject to forfeiture under the provisions of this section, the court shall order the property released to the owner.

(4) An owner, co-owner or claimant of any right, title or interest in the real property sought to be forfeited may prove that his right, title or interest, whether under a lien, mortgage, or otherwise, was created without any knowledge or reason to believe that the real property was being used or had been used for the purposes alleged by the department;

(A) In the event of such proof, the court shall order the real property released to the innocent owner, purchaser, lienholder or mortgagee.

(B) If the amount due to such person is less than the value of the real property, the real property may be sold in a commercially reasonable manner by the director. The proceeds from such sale shall be distributed as follows in the order indicated:

(i) To the innocent owner, purchaser or mortgagee of the real property, if any, up to the value of his interest in the real property.

(ii) The balance, if any, in the following order:

1. To the director for all expenditures made or incurred by the department in connection with the sale, including expenditure for any necessary repairs or maintenance of the real property, and for all expenditures made or incurred by the department in connection with the forfeiture proceedings including, but not limited to, expenditures for witnesses' fees, reporters' fees, transcripts, printing, travel, investigation, title company fees and insurance premiums.

2. The remainder, if any, to the director for credit to the drug enforcement donation account.

(C) In any case, the director may, within thirty (30) days after judgment, pay the balance due to the innocent owner, purchaser, lienholder or mortgagee and thereby purchase the real property for use in the enforcement of this act.

(e) In issuing any order under the provisions of this section, the court shall make a determination that the property, or a portion thereof, was actually used in violation of the provisions of this act. The size of the property forfeited shall not be unfairly disproportionate to the size of the property actually used in violation of the provisions of this section.

(f) When property is forfeited under the provisions of this section the director may:

(1) Retain it for official use; or

(2) Sell the property in a commercially reasonable manner. The proceeds shall be distributed by the director as follows:

(A) To reimburse for all expenditures made or incurred in connection with the sale, including expenditures for any necessary repairs or maintenance, and for all expenditures made or incurred in connection with the forfeiture proceedings including, but not limited to, expenditures for attorneys' fees, title company fees, insurance premiums, recording costs, witnesses' fees, reporters' fees, transcripts, printing, travel and investigation.

(B) The remainder, if any, shall be credited to the drug enforcement donation account.

(3) Recommend to the court that the property, or proceeds thereof, be forfeited in whole or in part to a city or county, the law enforcement agency of which participated in the events leading to the seizure of the property or proceeds. Property distributed pursuant to this recommendation shall be used by the city or county for purposes consistent with the provisions of this chapter.

[37-2744A, added 1989, ch. 341, sec. 2, p. 863; am. 1994, ch. 395, sec. 1, p. 1251.]

37-2744B.AUTHORIZATION TO RECEIVE AND ADMINISTER FEDERAL FORFEITURES AND PRIVATE DONATIONS. The director of the Idaho state police is authorized to receive and dispose of any real or personal property which has been seized by a federal drug enforcement agency, or any donations from private citizens, the proceeds of which shall be placed in the drug and driving while under the influence enforcement donation fund created in section 57-816,

[(37-2744B) 1986, ch. 286, sec. 3, p. 718; am. and redesignated 1989, ch. 341, sec. 1, p. 862; am. 2000, ch. 469, sec. 90, p. 1544; am. 2010, ch. 79, sec. 13, p. 142.]

37-2745.BURDEN OF PROOF -- LIABILITIES. (a) It is not necessary for the state to negate any exemption or exception in this act in any complaint, information, indictment or other pleading or in any trial, hearing, or other proceeding under the provisions of this act. The burden of proof of any exemption or exception is upon the person claiming it.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration, valid prescription, or order form issued under the provisions of this act, he is presumed not to be the holder of the registration, valid prescription or form. The burden of proof is upon him to rebut the presumption.

(c) In all prosecutions under the provisions of this act involving the analysis of a controlled substance or a sample thereof, a certified copy of the analytical report with the notarized signature of the bureau chief of the Idaho forensic laboratory and the criminalist who conducted the analysis shall be accepted as prima facie evidence of the results of the analytical findings.

(d) Notwithstanding any statute or rule to the contrary, the defendant may subpoena the criminalist to testify at the preliminary hearing and trial of the issue at no cost to the defendant.

(e) No liability is imposed under the provisions of this act upon any authorized state, county or municipal officer, engaged in the lawful performance of his duties.

[I.C., sec. 37-2745, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 12, p. 261; am. 1993, ch. 158, sec. 1, p. 408.]

37-2746.JUDICIAL REVIEW. All final determinations, findings and conclusions of the board under this act are final and conclusive decisions of the matters involved. Any person aggrieved by the decision may obtain review of the decision in the district court of the county where the aggrieved person resides. Findings of fact by the board, if supported by substantial evidence, are conclusive.

[I.C., sec. 37-2746, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2747.EDUCATION AND RESEARCH. (a) The director or his authorized agent shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs he may:

(1) Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations;

(2) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances;

(3) Consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(4) Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances;

(5) Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat them; and

(6) Assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of controlled substances.

(b) The director shall encourage research on misuse and abuse of controlled substances. In connection with the research, and in furtherance of the enforcement of this act, he may:

(1) Establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse;

(2) Make studies and undertake programs of research to:

(A) Develop new or improved approaches, techniques, systems, equipment and devices to strengthen the enforcement of this act;

(B) Determine patterns of misuse and abuse of controlled substances and the social effects thereof; and

(C) Improve methods for preventing, predicting, understanding and dealing with the misuse and abuse of controlled substances; and

(3) Enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of controlled substances.

(c) The director may enter into contracts for educational and research activities without performance bonds.

(d) The director may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

(e) The director may authorize the possession and distribution of controlled substances by persons lawfully engaged in education and research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

[I.C., sec. 37-2747, as added by 1971, ch. 215, sec. 1, p. 939; am. 1972, ch. 133, sec. 13, p. 261; am. 1974, ch. 27, sec. 83, p. 811.]

37-2748.PENDING PROCEEDINGS. (a) Prosecution for any violation of law occurring prior to the effective date of this act is not affected or abated by this act. If the offense being prosecuted is similar to one set out in article IV of this act, then the penalties under article IV apply if they are less than those under prior law.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of this act are not affected by this act.

(c) All administrative proceedings pending under prior laws which are superseded by this act shall be continued and brought to a final determination in accord with the laws and rules in effect prior to the effective date of this act. Any substance controlled under prior law which is not listed within schedules I through V, is automatically controlled without further proceedings and shall be listed in the appropriate schedule.

(d) The board shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dispensing of any controlled substance prior to the effective date of this act and who are registered or licensed by the state.

(e) This act applies to violations of law, seizures and forfeiture, injunctive proceedings, administrative proceedings and investigations which occur following its effective date.

[I.C., sec. 37-2748, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2749.CONTINUATION OF RULES. Any orders and rules promulgated under any law affected by this act and in effect on the effective date of this act and not in conflict with it continue in effect until modified, superseded or repealed.

[I.C., sec. 37-2749, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2750.UNIFORMITY OF INTERPRETATION. This act shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this act among those states which enact it.

[I.C., sec. 37-2750, as added by 1971, ch. 215, sec. 1, p. 939.]

37-2751.SHORT TITLE. This act may be cited as the "Uniform Controlled Substances Act."

[I.C., sec. 37-2751, as added by 1971, ch. 215, sec. 1, p. 939.]

CHAPTER 32

LEGEND DRUG CODE IMPRINT

37-3201.DEFINITIONS. As used in this chapter:

(1) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both;

(2) "Distributor" means a person who distributes for resale a drug in solid dosage form under his own label even though he is not the actual manufacturer of the drug;

(3) "Solid dosage form" means capsules or tablets intended for oral use;

(4) "Legend drug" means any drug defined by section 54-1705(37), Idaho Code.

[37-3201, added 1981, ch. 41, sec. 1, p. 63; am. 2002, ch. 26, sec. 3, p. 33; am. 2002, ch. 69, sec. 1, p. 155; am. 2006, ch. 290, sec. 3, p. 894; am. 2009, ch. 244, sec. 1, p. 748; am. 2011, ch. 135, sec. 1, p. 375; am. 2013, ch. 28, sec. 1, p. 52; am. 2013, ch. 270, sec. 4, p. 705; am. 2014, ch. 146, sec. 6, p. 400; am. 2015, ch. 28, sec. 11, p. 59.]

37-3202.CODE IMPRINT REQUIRED. No legend drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.

[37-3202, added 1981, ch. 41, sec. 1, p. 63.]

37-3203.LIST OF LEGEND DRUGS PROVIDED. All manufacturers and distributors of legend drugs in solid dosage form shall, upon request, provide to the board of pharmacy a listing of all such legend drugs identifying by code imprint the manufacturer and the specific type of drug. Such listing shall at all times be kept current by all manufacturers and distributors subject to this chapter.

[37-3203, added 1981, ch. 41, sec. 1, p. 63.]

37-3204.EXEMPTIONS MAY BE PERMITTED. The board of pharmacy may grant exemptions from the requirements of this chapter upon application by any drug manufacturer or distributor showing size, physical characteristics, or other unique characteristics which render the application of a code imprint to a legend drug subject to this chapter impractical or impossible. Any such exemption granted by the board shall be included by the manufacturer or distributor in the listing required by section 37-3203, Idaho Code, describing the physical characteristics and type of drug to which the exemption relates.

[37-3204, added 1981, ch. 41, sec. 1, p. 63.]

37-3205.SEIZURE. All legend drugs in solid dosage form that are possessed, distributed, sold or offered for sale in violation of the provisions of this chapter shall be deemed contraband and shall be seized by the board of pharmacy and summarily forfeited to the state.

[37-3205, added 1981, ch. 41, sec. 1, p. 63.]

CHAPTER 33
RETAIL SALES OF PSEUDOEPHEDRINE PRODUCTS

37-3301.DEFINITIONS. As used in this chapter:

(1) "Pseudoephedrine product" means any compound, mixture or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers.

(2) "Retailer" means any person, other than a wholesaler, who sells or offers for sale or distributes at retail pseudoephedrine products, irrespective of the quantity or amount or the amount of sales of such pseudoephedrine products.

[37-3301, added 2006, ch. 95, sec. 1, p. 269.]

37-3302.SALES OF PSEUDOEPHEDRINE PRODUCTS. A retailer shall ensure that:

(1) Pseudoephedrine products offered for sale are located either in an area where the public is not permitted or inside a locked display case; and

(2) All distributions of pseudoephedrine products are conducted by an employee of the retailer. No pseudoephedrine products shall be dispensed by a self-service system of any kind.

[37-3302, added 2006, ch. 95, sec. 1, p. 269.]

37-3303.LIMITATIONS ON SALES AND PURCHASES. (1) It shall be unlawful for any retailer to knowingly sell, transfer or otherwise furnish in a single day a pseudoephedrine product or products containing more than a base amount of three and six-tenths (3.6) grams of pseudoephedrine.

(2) It shall be unlawful for any person to knowingly purchase from a retailer more than the daily sales limit of a pseudoephedrine product or products containing a base amount of three and six-tenths (3.6) grams per purchaser or more than a base amount of nine (9) grams of pseudoephedrine in a single thirty (30) day period, regardless of the number of transactions.

(3) The retailer shall not sell the pseudoephedrine product unless the purchaser presents a photographic identification card issued by a state or by the federal government.

(4) (a) A retailer shall, before completing a sale under the provisions of this section, submit the required information to the electronic sales tracking system established under section 37-3303A, Idaho Code, as long as such a system is available without charge to the retailer for accessing the system. The retailer may not complete the sale if the system generates a stop sale alert, except as permitted in section 37-3303A, Idaho Code.

(b) If a retailer selling a nonprescription pseudoephedrine product experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, he or she shall make available for inspection by any law enforcement officer or board inspector during normal business hours the logbook required by the federal combat methamphetamine epidemic act of 2005 until such time as he or she is able to comply with the electronic sales tracking requirement.

(c) A retailer selling a nonprescription pseudoephedrine product may seek an exemption from submitting transactions to the electronic sales tracking system in writing to the board of pharmacy stating the reasons for the exemption. The board may grant an exemption for good cause shown, but in no event shall a granted exemption exceed one hundred eighty

(180) days. The board may grant multiple exemptions for any retailer if the good cause shown indicates significant hardship for compliance with this section. A retailer that receives an exemption shall make available for inspection by any law enforcement officer or board inspector during normal business hours the logbook required by the federal combat methamphetamine epidemic act of 2005. For purposes of this subsection, "good cause" includes, but is not limited to, situations where the installation of the necessary equipment to access the system is unavailable or cost prohibitive to the retailer.

(d) A retailer may withdraw from participating in the electronic sales tracking system if the system is no longer being furnished without charge for accessing the system. A retailer who withdraws from the electronic sales tracking system is subject to the same requirements as a retailer who has been granted an exemption under subsection (c) of this section.

(e) For the purposes of subsection (4) of this section and section 37-3303A, Idaho Code:

(i) "Charge for accessing the system" means charges relating to:

1. Access to the web-based electronic sales tracking software;
2. Training; and
3. Technical support to integrate to point of sale vendors, if necessary.

(ii) "Charge for accessing the system" does not include:

1. Charges relating to required internet access;
2. Optional hardware that a pharmacy may choose to purchase for work flow purposes; or
3. Other equipment.

[37-3303, added 2006, ch. 95, sec. 1, p. 269; am. 2012, ch. 303, sec. 1, p. 841.]

37-3303A.ELECTRONIC TRACKING SYSTEM. (1) The board of pharmacy shall implement a real-time electronic sales tracking system to monitor the nonprescription sale of pseudoephedrine products in this state provided that such system is available to the state without charge for accessing the system to the state or retailers. If a real-time electronic sales tracking system is not available to the state without charge for accessing the system to the state or retailers, the board of pharmacy shall not be required to create such a system.

(2) The records submitted to the tracking system shall include the following:

(a) The purchaser's name and address;

(b) The purchaser's signature, either on a written form or stored electronically in the tracking system, attesting to the validity of all information provided;

(c) The type of photographic identification presented pursuant to section 37-3303, Idaho Code;

(d) The number and issuing government entity of the photographic identification presented;

(e) The date and time of sale; and

(f) The name and quantity of the product sold.

(3) The records submitted to the tracking system are for the confidential use of the retailer who submitted such records, except that:

(a) The records must be produced in court when lawfully required;

(b) The records must be open for inspection by the board of pharmacy; and

(c) The records must be available to any general or limited authority Idaho peace officer to enforce the provisions of this chapter or to federal law enforcement officers.

(4) The electronic sales tracking system shall be capable of generating a stop sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser

violating the quantity limits in section 37-3303, Idaho Code. The system shall contain an override function for use by a dispenser of pseudoephedrine products. Each instance in which the override function is utilized shall be logged by the system.

(5) The board of pharmacy shall have the authority to adopt rules necessary to implement and enforce the provisions of this section and section 37-3303, Idaho Code.

(6) A retailer participating in the electronic sales tracking system:

(a) Is not liable for civil damages resulting from any act or omission in carrying out the requirements of this section or section 37-3303, Idaho Code, other than an act or omission constituting gross negligence or willful or wanton misconduct; and

(b) Is not liable for civil damages resulting from a data breach that was proximately caused by a failure on the part of the electronic sales tracking system to take reasonable care through the use of industry standard levels of encryption to guard against unauthorized access to account information that is in the possession or control of the system.

[37-3303A, added 2012, ch. 303, sec. 2, p. 842.]

37-3304.PENALTIES. A person who knowingly violates any provision of this chapter shall be guilty of a misdemeanor.

[37-3304, added 2006, ch. 95, sec. 1, p. 269.]

37-3305.PREEMPTION. The provisions of this chapter shall be construed to preempt more stringent regulation of retail sales of pseudoephedrine products by any county, city or other political subdivision.

[37-3305, added 2006, ch. 95, sec. 1, p. 270.]

37-3306.APPLICATION. The provisions of this chapter shall not apply to a pseudoephedrine product dispensed pursuant to a valid prescription unless otherwise provided by law.

[37-3306, added 2006, ch. 95, sec. 1, p. 270.]

CHAPTER 17

PHARMACISTS

54-1701.SHORT TITLE. This chapter shall be known as the "Idaho Pharmacy Act."

[54-1701, added 1979, ch. 131, sec. 3, p. 404.; am. 2013, ch. 28, sec. 2, p. 52.]

54-1702.LEGISLATIVE DECLARATION. The practice of pharmacy in the state of Idaho is declared a professional practice affecting the health, safety and welfare of the public and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, merits and receives the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in or into the state of Idaho. This chapter shall be liberally construed to carry out these objects and purposes.

[54-1702, added 1979, ch. 131, sec. 3, p. 404.; am. 2013, ch. 28, sec. 3, p. 52.]

54-1703.STATEMENT OF PURPOSE. It is the purpose of this act to promote, preserve and protect the health, safety and welfare of the public by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

[54-1703, added 1979, ch. 131, sec. 3, p. 404.]

54-1704.PRACTICE OF PHARMACY. "Practice of pharmacy" means:

(1) The interpretation, evaluation and dispensing of prescription drug orders;

(2) Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related research;

(3) The provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care;

(4) The responsibility for:

(a) Compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager or distributor of nonprescription drugs and commercially packaged legend drugs and devices;

(b) Proper and safe storage of drugs and devices, and maintenance of proper records for them; and

(c) The offering or performing of those acts, services, operations or transactions necessary to the conduct, operation, management and control of pharmacy;

(5) The prescribing of:

(a) Dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;

(b) Agents for active immunization when prescribed for susceptible persons six (6) years of

age or older for the protection from communicable disease;

(c) Opioid antagonists pursuant to section 54-1733B, Idaho Code; and

(d) Epinephrine auto-injectors pursuant to sections 54-1733C and 54-1733D, Idaho Code.

[54-1704, added 1979, ch. 131, sec. 3, p. 404; am. 1992, ch. 179, sec. 1, p. 565; am. 1993, ch. 49, sec. 1, p. 126.; am. 2009, ch. 244, sec. 2, p. 748; am. 2011, ch. 264, sec. 1, p. 709; am. 2013, ch. 28, sec. 4, p. 52; am. 2015, ch. 88, sec. 1, p. 217; am. 2016, ch. 62, sec. 1, p. 198; am. 2016, ch. 264, sec. 1, p. 693.]

54-1705.DEFINITIONS. In this chapter:

(1) "Board of pharmacy" or "board" means the Idaho state board of pharmacy.

(2) "Central drug outlet" means a resident or nonresident pharmacy, drug outlet, or business entity employing or contracting pharmacists to perform centralized pharmacy services.

(3) "Central pharmacist" means a pharmacist performing centralized pharmacy services.

(4) "Centralized pharmacy services" means the processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations.

(5) "Compounding" means the practice in which a pharmacist, a prescriber, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

(6) "Counseling" or "counsel" means the effective communication by the pharmacist of information as set out in this chapter, to the patient or caregiver, in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices. Specific areas of counseling shall include, but are not limited to:

(a) Name and strength and description of the drug;

(b) Route of administration, dosage, dosage form, continuity of therapy and refill information;

(c) Special directions and precautions for preparation, administration, storage and use by the patient as deemed necessary by the pharmacist;

(d) Side effects or adverse effects and interactions and therapeutic contraindications that may be encountered, including their avoidance, which may interfere with the proper use of the drug or device as was intended by the prescriber, and the action required if they occur;

(e) Techniques for self-monitoring drug therapy; and

(f) Action to be taken in the event of a missed dose.

(7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one (1) person to another, whether or not for a consideration.

(8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article including any component part or accessory which is:

(a) Recognized in the official United States Pharmacopoeia or official National Formulary, other drug compendia or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Intended to affect the structure or any function of the body of man or other animal, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(9) "Dispense" or "dispensing" means the preparation and delivery of a drug pursuant to a lawful prescription drug order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription.

(10) "Distribute" means the delivery of a drug other than by administering or dispensing.

(11) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

(12) "Drug order" means a prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes as defined in rules. Unless specifically differentiated, state law applicable to a prescription drug order is also applicable to a drug order.

(13) "Drug outlets" means all resident or nonresident pharmacies, business entities and other facilities where employees or personnel are engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, delivering, distributing or manufacturing of drugs or devices in or into Idaho.

(14) "Extern" means a bona fide student enrolled in an approved school or college of pharmacy who has not received his first professional degree in pharmacy.

(15) "Externship" means a structured practical experience program in pharmacy administered by a school or college of pharmacy.

(16) "Institutional facility" means a facility for which its primary purpose is to provide a physical environment for patients to obtain health care services and in which patients spend a majority of their time, as may be further defined by board rules.

(17) "Intern" means any person who has completed a course of study at an approved school or college of pharmacy, received the first professional degree in pharmacy and is registered with the board as a pharmacist intern. Interns must register with the board prior to commencement of an internship program.

(18) "Internship" means a postgraduate practical experience program under the supervision of a preceptor.

(19) "Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

(20) "Labeling" means the process of preparing and affixing of a label to any drug container, exclusive however of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law.

(21) "Limited service outlet" means a resident or nonresident facility or business entity that is subject to registration by the board, pursuant to section 54-1729, Idaho Code, and has employees or personnel engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, delivering, distributing or manufacturing of drugs or devices but is not

a retail pharmacy, institutional facility, manufacturer, wholesaler, veterinary drug outlet, nonresident central drug outlet or mail service pharmacy.

(22) "Mail service pharmacy" means a nonresident pharmacy that ships, mails or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law.

(23) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for his own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a pharmacist or practitioner as an incident to his administering, dispensing or, as authorized by board rule, distributing of a drug in the course of his professional practice; or

(b) By a practitioner or by his authorization under his supervision for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

(24) "Manufacturer" means a person who by compounding, cultivating, harvesting, mixing or other process, produces or prepares legend drugs, and includes persons who prepare such drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process, or who packages or repackages such drugs, but does not include pharmacists or practitioners in the practice of their profession.

(25) "Nonprescription drugs" means medicines or drugs which may be sold without a prescription drug order and which are prepackaged for use by the consumer and labeled in accordance with state and federal law.

(26) "Nonresident" means a person or business entity located in the District of Columbia or a state other than Idaho that practices pharmacy including, but not limited to, pharmaceutical care services into Idaho.

(27) "Outsourcing facility" means a facility that is registered by the United States food and drug administration pursuant to 21 U.S.C. section 353b and either registered or endorsed by the board.

(28) "Person" means an individual, corporation, partnership, association or any other legal entity.

(29) "Pharmaceutical care" means drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board.

(30) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist registered by this state who is located in another state or the District of Columbia and is engaged in the practice of pharmacy into Idaho, unless exempted.

(31) "Pharmacist-in-charge" (PIC) means a pharmacist whose qualifications, responsibilities and reporting requirements are defined in rule.

(32) "Pharmacy" means any facility, department or other place where prescription drug orders are filled or compounded and prescriptions are sold, dispensed, offered or displayed for sale, which has, as its principal purpose, the dispensing of drug and health supplies intended for the general health, welfare and safety of the public.

(33) "Practitioner" means a person licensed in this state and permitted by such license to

dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

(34) "Precursor" means a substance, other than a legend drug, which is an immediate chemical intermediate that can be processed or synthesized into a legend drug, and is used or produced primarily for use in the manufacture of a legend drug by persons other than persons licensed to manufacture such legend drugs by the Idaho board of pharmacy, registered by the state board of health and welfare, or licensed to practice pharmacy by the Idaho board of pharmacy.

(35) "Preceptor" means a pharmacist licensed and in good standing who supervises the internship or externship training of a registered student pharmacist. The preceptor shall be actively engaged in the practice of pharmacy on a full-time employment basis.

(36) "Prescriber" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

(37) "Prescription drug or legend drug" means a drug that 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 drug order only or is restricted to use by practitioners only.

(38) "Prescription drug order" means a valid order of a practitioner for a drug or device for an ultimate user of the drug or device.

(39) "Prospective drug review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription drug order for:

(i) Known allergies;

(ii) Rational therapy contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

(b) Evaluation of the prescription drug order for duplication of therapy.

(c) Evaluation of the prescription drug order for interactions:

(i) Drug-drug;

(ii) Drug-food; and

(iii) Drug-disease.

(d) Evaluation of the prescription drug order for proper utilization:

(i) Over or under utilization; and

(ii) Abuse/misuse.

(40) "Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records or other written indicia, documents or objects which are used in any way in connection with the purchase, sale or handling of any drug or device.

(41) "Sale" means every sale and includes:

(a) Manufacturing, processing, transporting, handling, packaging or any other production, preparation or repackaging;

(b) Exposure, offer, or any other proffer;

(c) Holding, storing or any other possession;

(d) Dispensing, giving, delivering or any other supplying; and

(e) Applying, administering or any other usage.

(42) "Ultimate user" means a person who lawfully possesses a drug for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

(43) "Wholesaler" means a person who in the usual course of business lawfully distributes drugs or devices in or into Idaho to persons other than the ultimate user.

[54-1705, added 1979, ch. 131, sec. 3, p. 404; am. 1989, ch. 193, sec. 14, p. 483; am. 1992, ch. 179, sec. 2, p. 565; am. 1993, ch. 49, sec. 2, p. 126; am. 2000, ch. 103, sec. 1, p. 228; am. 2000, ch. 274, sec. 132, p. 866; am. 2002, ch. 26, sec. 1, p. 29; am. 2006, ch. 290, sec. 1, p. 888; am. 2008, ch. 51, sec. 1, p. 124; am. 2009, ch. 244, sec. 3, p. 749; am. 2011, ch. 135, sec. 2, p. 375; am. 2013, ch. 28, sec. 5, p. 53; am. 2013, ch. 270, sec. 1, p. 698; am. 2014, ch. 146, sec. 2, p. 392; am. 2015, ch. 28, sec. 1, p. 44.]

54-1706.STATE BOARD OF PHARMACY ESTABLISHED. There is hereby established in the department of self-governing agencies a state board of pharmacy whose responsibilities shall be to enforce the provisions of this act. The board shall have all of the duties, powers and authority specifically granted by and necessary to the enforcement of this act, as well as such other duties, powers and authority as it may be granted from time to time by appropriate statute.

[54-1706, added 1979, ch. 131, sec. 3, p. 408.]

54-1707.MEMBERSHIP. The board of pharmacy shall consist of five (5) members. One (1) member shall be a representative of the public, and four (4) members shall be licensed pharmacists who possess the qualifications specified in section 54-1708, Idaho Code. The board of pharmacy shall have diverse pharmacy practice experience, with at least one (1) member having substantial experience in retail pharmacy and at least one (1) member having substantial experience in hospital pharmacy.

[54-1707, added 1979, ch. 131, sec. 3, p. 408.; am. 2013, ch. 65, sec. 1, p. 161.]

54-1708.QUALIFICATIONS OF BOARD MEMBERS. (1) The public member of the board of pharmacy shall be a resident of the state of Idaho who has attained the age of majority and shall not be nor shall he ever have been a member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, or a person who has or has had a material financial interest in providing pharmacy service or any other activity directly related to the practice of pharmacy.

(2) The pharmacist members of the board of pharmacy shall at the time of their appointment and at all times thereafter:

(a) Be residents of the state of Idaho;

(b) Be licensed and in good standing to engage in the practice of pharmacy in the state of Idaho;

(c) Be engaged in the practice of pharmacy in the state of Idaho;

(d) Have five (5) years of experience in the practice of pharmacy in the state of Idaho after licensure.

[54-1708, added 1979, ch. 131, sec. 3, p. 408.]

54-1709.APPOINTMENT OF BOARD MEMBERS -- NOTICE OF VACANCY -- NOMINEES. Prior to the expiration of the regular term of a member of the board or upon the occurrence of declaration of a vacancy in the membership of the board, the governor shall appoint a qualified person to fill the vacancy. The governor may consider recommendations for appointment to the board from the Idaho state pharmacy association and from any individual residing in this state.

[54-1709, added 1979, ch. 131, sec. 3, p. 409; am. 1997, ch. 22, sec. 1, p. 32; am. 2016, ch. 340, sec. 20, p. 943.]

54-1710.TERMS OF OFFICE. (1) Except as provided in subsection (2) of this section, members of the board of pharmacy shall be appointed for a term of five (5) years, except that members of the board who are appointed to fill vacancies which occur prior to the expiration of a former member's full term shall serve the unexpired portion of such term.

(2) The terms of the members of the board shall be staggered, so that the terms of no more than one (1) member shall expire in any year.

(3) No member of the board shall serve more than (2) consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this section.

(4) An appointee to a full term on the board shall be appointed by the governor as provided in section 54-1709, Idaho Code, and be effective on July 1 of the year of appointment. Appointees to unexpired portions of full terms shall become members of the board upon appointment.

[54-1710, added 1979, ch. 131, sec. 3, p. 409.; am. 2016, ch. 71, sec. 1, p. 248.]

54-1711.VACANCIES. Any vacancy which occurs in the membership of the board for any reason, including expiration of term, removal, resignation, death, disability or disqualification, shall be filled by the governor in the manner prescribed in section 54-1709, Idaho Code. The governor shall fill vacancies which occur by expiration of full terms within thirty (30) days prior to each date of expiration, and shall fill vacancies which occur for any other reason within sixty (60) days after such vacancy occurs.

[54-1711, added 1979, ch. 131, sec. 3, p. 409.]

54-1712.REMOVAL OF BOARD MEMBERS. All board members shall serve at the pleasure of the governor.

[54-1712, added 1979, ch. 131, sec. 3, p. 410; am. 2016, ch. 340, sec. 21, p. 943.]

54-1713.ORGANIZATION OF THE BOARD. (1) The board of pharmacy shall elect from its members a chairman and such other officers as it deems appropriate and necessary to the conduct of its business. The chairman of the board of pharmacy shall preside at all meetings of the board and shall be responsible for the performance of all of the duties and functions of the board required or permitted by this chapter. Each additional officer elected by the board shall perform those duties normally associated with his position and such other duties assigned to him from time to time by the board.

(2) Officers elected by the board shall serve terms of one (1) year commencing with the day of their election, and ending upon election of their successors.

(3) The board shall employ a person who shall be an ex officio member of the board without vote to serve as a full-time employee of the board in the position of executive director. The executive director shall be responsible for the performance of the regular administrative functions of the board and such other duties as the board may direct.

[54-1713, added 1979, ch. 131, sec. 3, p. 410.; am. 2016, ch. 71, sec. 2, p. 248; am. 2016, ch. 341, sec. 3, p. 967.]

54-1714.COMPENSATION OF BOARD MEMBERS. (1) Each member of the board of pharmacy shall be compensated as provided by section 59-509(p), Idaho Code, for each day on which the member is engaged in performance of the official duties of the board, and reimbursement for all expenses incurred in connection with the discharge of such official duties.

(2) The executive director of the board of pharmacy shall be a nonclassified officer and shall receive, as compensation, an annual salary payable on regular pay periods, the amount of which shall be determined by the board, and reimbursement for all expenses incurred in connection with performance of his official duties.

[54-1714, added 1979, ch. 131, sec. 3, p. 410; am. 1980, ch. 247, sec. 63, p. 627; am. 1982, ch. 260, sec. 1, p. 671; am. 1996, ch. 237, sec. 2, p. 767; am. 2016, ch. 71, sec. 3, p. 249.]

54-1715.MEETINGS OF THE BOARD. (1) The board of pharmacy shall meet at least once every six (6) months to transact its business. One such meeting held during each fiscal year of the state shall be designated as the annual meeting and shall be for the purpose of electing officers and for the reorganization of the board. The board shall meet at such additional times as it may determine. Such additional meetings may be called by the chairman of the board or by three (3) of the members of the board.

(2) The board shall meet at such place as it may from time to time determine. The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.

(3) Notice of all meetings of the board shall be given in the manner and pursuant to requirements prescribed by the state's applicable statutes, rules and regulations.

(4) A majority of the members of the board shall constitute a quorum for the conduct of a board meeting and, except where a greater number is required by the act, or by any rule or regulation of the board, all actions of the board shall be by a majority of a quorum.

(5) All meetings and hearings of the board shall be conducted in compliance with the provisions of chapter 2, title 74, Idaho Code.

[54-1715, added 1979, ch. 131, sec. 3, p. 410.; am. 2015, ch. 141, sec. 139, p. 485.]

54-1716.EMPLOYEES. (1) The board of pharmacy may, in its discretion, employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of board business and to the fulfillment of the board's responsibilities as defined by this act.

(2) The employees of the board other than the executive director and the board's chief controlled substance investigator under chapter 27, title 37, Idaho Code, shall be classified employees and shall receive, as compensation, an annual salary payable on regular pay periods, the amount of which shall be determined by the personnel commission classification and

compensation plan set forth in section 67-5309, Idaho Code, and reimbursement for all expenses incurred in connection with performance of their official duties.

[54-1716, added 1979, ch. 131, sec. 3, p. 411; am. 2000, ch. 353, sec. 1, p. 1187.]

54-1717.RULES AND REGULATIONS. The board of pharmacy shall make, adopt, amend and repeal such rules and regulations as may be deemed necessary by the board, from time to time, for the proper administration and enforcement of this act. Such rules and regulations shall be promulgated in accordance with the procedures specified in Chapter 52, Title 67, Idaho Code, the administrative procedures act.

[54-1717, added 1979, ch. 131, sec. 3, p. 411.]

54-1718.LICENSURE AND DISCIPLINE. (1) The board of pharmacy shall be responsible for the control and regulation of the practice of pharmacy in this state including, but not limited to, the following:

(a) The licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy under the provisions of this chapter;

(b) The renewal of licenses to engage in the practice of pharmacy;

(c) The determination and issuance of standards for recognition and approval of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, and the specification and enforcement of requirements for practical training, including internship;

(d) The enforcement of the provisions of this chapter relating to the conduct or competence of pharmacists practicing in this state, and the suspension, revocation or restriction of licenses to practice pharmacy;

(e) The regulation of the training, qualifications and employment of pharmacy interns.

(2) The board of pharmacy shall require the following applicants to submit to a fingerprint-based criminal history check of the Idaho central criminal history database and the federal bureau of investigation criminal history database:

(a) Original applicants for licensure or registration;

(b) Applicants for reinstatement of a license or registration that has been suspended or revoked; and

(c) Applicants for reinstatement of a license or registration that has lapsed for a period of time that is more than one (1) year.

Each applicant shall submit a completed ten (10) finger fingerprint card or scan to the board of pharmacy at the time of application and shall pay the cost of the criminal history check.

[54-1718, added 1979, ch. 131, sec. 3, p. 411.; am. 2010, ch. 63, sec. 1, p. 112; am. 2015, ch. 36, sec. 1, p. 75.]

54-1719.MEDICATIONS -- DRUGS -- DEVICES -- OTHER MATERIALS. The board of pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The regulation of the sale at retail and the dispensing of medications, drugs, devices and other materials, including the method of dispensing in institutional facilities, and including the right to seize such drugs, devices and other materials found to be detrimental to the public health

and welfare by the board after appropriate hearing as required under the administrative procedure act;

(2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, dispensing and distribution of such medications, drugs, devices and other materials within the practice of pharmacy;

(3) The control of the purity and quality of such medications, drugs, devices and other materials within the practice of pharmacy;

(4) The issuance and renewal of certificates of registration of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs.

[54-1719, added 1979, ch. 131, sec. 3, p. 412; am. 1990, ch. 144, sec. 1, p. 324.; am. 2013, ch. 270, sec. 2, p. 702.]

54-1720.OTHER DUTIES -- POWERS -- AUTHORITY. The board of pharmacy shall have such other duties, powers, and authority as may be necessary to the enforcement of this chapter and to the enforcement of board rules made pursuant thereto, which shall include, but are not limited to, the following:

(1) The board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board.

(2) In addition to any statutory requirements, the board may require such surety bonds as it deems necessary to guarantee the performance and discharge of the duties of any officer or employee receiving and disbursing funds.

(3) The executive director of the board shall keep the seal of the board and shall affix it only in such manner as may be prescribed by the board.

(4) On or before the 60th day after the last day of each state fiscal year, the board shall submit to the governor a report summarizing its proceedings and activities during that fiscal year, together with a report of all moneys received and disbursed by the board. Such reports or comprehensive summaries or abstracts thereof, as determined by the board shall be made available to the public.

(5) (a) The board shall determine the fees to be collected for:

(i) Examinations and reexaminations, which fee shall not exceed two hundred fifty dollars ($250);

(ii) The issuance of licenses, which fee shall not exceed two hundred fifty dollars ($250);

(iii) The issuance and renewal of certificates of registration, which fee shall not exceed one hundred dollars ($100), except the fee for nonresident registrations shall not exceed five hundred dollars ($500) for initial registration and two hundred fifty dollars ($250) thereafter for annual renewals.

(b) All fees or fines which shall be paid under the provisions of this chapter shall be paid over by the board to the treasurer of the state of Idaho, and shall be held by the state treasurer in the pharmacy account, which shall be paid out by the state treasurer upon warrant drawn by the state controller against said account. The state controller is hereby authorized, upon presentation of the proper vouchers of claims against the state, approved by the said board and the state board of examiners, as provided by law, to draw his warrant upon said account.

(6) The board may receive and expend moneys in addition to its annual appropriations, from

parties other than the state, provided:

(a) Such moneys are awarded for the pursuit of a specific objective which the board is authorized to accomplish by this chapter, or which the board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(b) Such moneys are expended for the pursuit of the objective for which they are awarded;

(c) Activities connected with or occasioned by the expenditures of such moneys do not interfere with or impair the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's powers as specified by this chapter;

(d) Such moneys are kept in a separate, special state account; and

(e) Periodic reports are made to the administrator, division of financial management, concerning the board's receipt and expenditure of such moneys.

(7) The board shall assign to each drug outlet under its jurisdiction a uniform state number.

(8) The board or its authorized representatives shall also have power to investigate and gather evidence concerning alleged violations of the provisions of this chapter or of the rules of the board.

(9) (a) Notwithstanding anything in this chapter to the contrary, whenever a duly authorized representative of the board finds or has probable cause to believe that any drug, or device is adulterated or misbranded within the meaning of the Idaho food, drug and cosmetic act, he shall affix to such drug or device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated or misbranded, has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board, its agent or the court. No person shall remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission from the court.

(b) When a drug or device detained or embargoed under paragraph (a) of this subsection (9) has been declared by such representative to be adulterated or misbranded, the board shall, as soon as practical thereafter, petition the judge of the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated or misbranded, the board shall direct the immediate removal of the tag or other marking.

(c) If the court finds the detained or embargoed drug or device is adulterated or misbranded, such drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage and other proper expense shall be borne by the owner of such drug or device. When the adulteration or misbranding can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner thereof for such labeling or processing under the supervision of a board representative. Expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid.

(d) It is the duty of the attorney general to whom the board reports any violation of this subsection to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subsection (9) shall be construed to require the board to report violations whenever the board believes the public's

interest will be adequately served in the circumstances by a suitable written notice or warning.

(10) Except as otherwise provided to the contrary, the board shall exercise all of its duties, powers and authority in accordance with the administrative procedure act.

(11) (a) For the purpose of any proceedings held before the board as authorized by law, including the refusal, nonrenewal, revocation or suspension of licenses, registrations or certifications authorized by this chapter, or the imposition of fines or reprimands on persons holding such licenses, certification or registrations, the board may subpoena witnesses and compel their attendance, and may also at such time require the production of books, papers, documents or other memoranda. In any such proceeding before the board, any member of the board, or its designee, may administer oaths or affirmations to witnesses so appearing.

(b) If any person shall refuse to obey a subpoena so issued, or refuse to testify or produce any books, papers or documents called for by said subpoena, the board may make application to the district court of the county in which the proceeding is held, for an order of the court requiring the person to appear before the court, and to show cause why the person should not be compelled to testify, to produce such books, papers, memoranda or other documents required by the subpoena, or otherwise comply with its terms. The application shall set forth the action theretofore taken by the board to compel the attendance of the witness, the circumstances surrounding the failure of the witness to attend or otherwise comply with the subpoena, together with a brief statement of the reasons why compliance with the subpoena is necessary to the proceeding before the board.

(c) Upon the failure of a person to appear before the court at the time and place designated by it, the court may enter an order without further proceedings requiring the person to comply with the subpoena. Any person failing or refusing to obey such order of the court shall be punished for contempt of court as in other cases provided.

[54-1720, added 1979, ch. 131, sec. 3, p. 412; am. 1980, ch. 354, sec. 1, p. 915; am. 1985, ch. 152, sec. 2, p. 406; am. 1994, ch. 180, sec. 100, p. 491; am. 1994, ch. 348, sec. 1, p. 1104.; am. 2013, ch. 28, sec. 6, p. 57.]

54-1721.UNLAWFUL PRACTICE. (1) It shall be unlawful for any person or business entity to engage in the practice of pharmacy including, but not limited to, pharmaceutical care services in or into Idaho unless licensed or registered to so practice under the provisions of this chapter, except as provided herein:

(a) 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; and

(b) Nonresident pharmacists practicing pharmacy into Idaho who are employed by and practicing for an Idaho registered nonresident mail service pharmacy.

(2) Notwithstanding the provisions of subsection (1) of this section and any statute or rule to the contrary, persons who hold a valid and current license to practice practical or professional nursing in this state pursuant to sections 54-1407, 54-1408 and 54-1418, Idaho Code, and who are employed by one (1) of the public health districts established under section 39-408, Idaho Code, shall be permitted to engage in the labeling and delivery of refills of the following prepackaged items when such items have been prescribed to a patient by a licensed physician, licensed physician's assistant or licensed advanced practice nurse:

(a) Prenatal vitamins;

(b) Contraceptive drugs approved by the United States food and drug administration;

(c) Antiviral drugs approved by the United States centers for disease control and prevention for treatment of sexually transmitted infection; and

(d) Drugs approved by the United States centers for disease control and prevention for treatment of active and latent tuberculosis.

(3) It shall be unlawful for any person, not legally licensed or registered as a pharmacist, to take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import.

(4) Any person who shall be found to have unlawfully engaged in the practice of pharmacy shall be subject to a fine not to exceed three thousand dollars ($3,000) for each offense. Each such violation of this chapter or the rules promulgated hereunder pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this state.

[54-1721, added 1979, ch. 131, sec. 3, p. 415.; am. 2010, ch. 346, sec. 1, p. 904; am. 2013, ch. 28, sec. 7, p. 59.]

54-1722.QUALIFICATIONS FOR LICENSURE BY EXAMINATION. (1) To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:

(a) Have submitted a written application in the form prescribed by the board of pharmacy.

(b) Have attained the age of majority.

(c) Be of good moral character and temperate habits.

(d) Have graduated and received the first professional undergraduate degree from a school or college of pharmacy which has been approved by the board of pharmacy.

(e) Have completed an internship or other program which has been approved by the board of pharmacy, or demonstrated to the board's satisfaction experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board.

(f) Have successfully passed an examination given by the board of pharmacy.

(g) Paid the fees specified by the board of pharmacy for examination and issuance of license.

(2) Examinations.

(a) The examination for licensure required under section 54-1722(1)(f), Idaho Code, shall be given by the board at least two (2) times during each fiscal year of the state. The board shall determine the content and subject matter of each examination, the place, time and date of administration of the examination, and those persons who shall have successfully passed the examination.

(b) The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ and cooperate with any organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed such an examination.

(3) Internship and other training programs.

(a) All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the board shall determine.

(b) The board shall establish standards for internship or any other program necessary to qualify an applicant for the licensure examination and shall also determine the necessary

qualifications of any preceptors used in any internship or other program.

(4) Any applicant who is a graduate of a school or college of pharmacy located outside the United States, the degree program of which has not been approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, may be considered to have satisfied the degree requirements of subsection (1)(d) of this section by verification to the board of his academic record and his graduation and by meeting any other requirements as the board may establish from time to time. The board may require the applicant successfully pass an examination given or approved by the board to establish proficiency in english and an equivalency of education with qualified graduates of a degree program specified in subsection (1)(d) of this section as a prerequisite of taking the licensure examination as provided in subsection (1)(f) of this section.

[54-1722, added 1979, ch. 131, sec. 3, p. 415; am. 1985, ch. 49, sec. 1, p. 99.]

54-1723.QUALIFICATIONS FOR LICENSURE BY RECIPROCITY. (1) To obtain a license as a pharmacist by reciprocity, an applicant for licensure shall:

(a) Have submitted a written application in the form prescribed by the board of pharmacy.

(b) Have attained the age of majority.

(c) Have good moral character and temperate habits.

(d) Have possessed at the time of initial licensure as a pharmacist such other qualifications necessary to have been eligible for licensure at that time in this state.

(e) Have engaged in the practice of pharmacy for a period of at least one (1) year or have met the internship requirements of this state within the one (1) year immediately previous to the date of such application.

(f) Have presented to the board proof of initial licensure by examination and proof that such license and any other license or licenses granted to the applicant by any other state or states have not been suspended, revoked, canceled or otherwise restricted for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.

(g) Have paid the fees specified by the board of pharmacy for issuance of a license.

(2) Eligibility. No applicant shall be eligible for licensure by reciprocity unless the state in which the applicant was initially licensed as a pharmacist also grants reciprocal licensure to pharmacists duly licensed by examination in this state, under like circumstances and conditions.

(3) Temporary reciprocity license.

(a) In conjunction with an application for a license as a pharmacist by reciprocity, the applicant may be granted a temporary license as a pharmacist upon compliance with the following terms and conditions:

(i) The applicant has filed a complete application for licensure by reciprocity and paid all fees for such application, which fees shall not be refundable upon grant of a temporary license;

(ii) The applicant has passed the state jurisprudence examination with a score of not less than seventy-five (75);

(iii) The applicant submits photocopies of all current licenses to practice pharmacy in any other states or jurisdictions;

(iv) The applicant provides documentation of any and all actions taken against any of the applicant's licenses to practice pharmacy by any other state or jurisdiction, and any such action does not otherwise render the applicant ineligible for licensure by

reciprocity in Idaho;

(v) The applicant submits evidence that the applicant has lawfully practiced pharmacy in the United States or its territories for the preceding twelve (12) months prior to filing of the application;

(vi) The applicant submits evidence that the applicant has completed all continuing education requirements of the applicant's active licenses for the three (3) calendar years preceding the application; and

(vii) The applicant executes a sworn statement that all of the documents, evidence and statements of the applicant submitted to the board in conjunction with the application for licensure by reciprocity and the request for temporary licensure are true and correct, and that the applicant has fully disclosed all information required for licensure by reciprocity and for temporary licensure.

(b) Upon completion of the above requirements to the satisfaction of the executive director, the applicant may be granted a temporary license by reciprocity for a period of not more than sixteen (16) consecutive weeks as follows:

(i) The temporary license shall not be renewable nor may the applicant reapply for temporary licensure for a period of one (1) year after lapse of a temporary license;

(ii) The temporary license shall lapse automatically upon the grant or denial of a license by reciprocity upon subsections (1) and (2) of this section;

(iii) The temporary license shall not include acting as a pharmacist-in-charge or as a preceptor or supervising interns or externs;

(iv) The temporary license shall be subject to discipline in the same manner as a full license, and shall also be subject to immediate suspension by the executive director upon reasonable evidence that the applicant has not fulfilled the requirements for such temporary license or that the documents, evidence and statement of the applicant submitted to the board are not true and correct, or that the applicant's disclosures required by this section are not complete. Suspension of a temporary license by the executive director shall be immediate subject only to reinstatement upon appeal by the applicant to the board at its next scheduled meeting; and

(v) In the event the temporary license lapses without the contemporaneous grant of full licensure by reciprocity, or the temporary license is suspended by the executive director, then all privileges allowed under the temporary license, including those relating to any controlled substance registration granted under the temporary license, shall also cease.

[54-1723, added 1979, ch. 131, sec. 3, p. 416; am. 2005, ch. 218, sec. 1, p. 693.]

54-1723A.REGISTRATION TO ENGAGE IN THE PRACTICE OF PHARMACY INTO IDAHO. (1) To obtain a registration to practice as a pharmacist into the state of Idaho, the applicant shall:

(a) Be licensed and in good standing in the state from which the applicant practices pharmacy;

(b) Submit a written application in the form prescribed by the board;

(c) Pay the fee(s) specified by the board for the issuance of the registration; and

(d) Comply with all other requirements of the board.

(2) A successful applicant for registration under this section shall be subject to the disciplinary provisions of section 54-1726, Idaho Code, the penalty provisions of section 54-

1728, Idaho Code, and the rules of the board.

(3) A successful applicant for registration under this section shall comply with the board's laws and rules of this state unless compliance would violate the laws or rules in the state in which the registrant is located, except as follows:

(a) A technician shall not exceed the practice limitations for technicians in Idaho;

(b) A pharmacist shall only substitute drug products in accordance with Idaho law;

(c) A pharmacist shall only select drug products in accordance with Idaho law; and

(d) A pharmacist shall not exceed the pharmacy staffing ratio, as defined in rule.

(4) Renewal shall be required annually and submitted to the board no later than the thirtieth day of June. The board shall specify by rule the procedures to be followed and the fees to be paid for renewal of registration.

[54-1723A, added 2009, ch. 244, sec. 4, p. 752; am. 2010, ch. 116, sec. 1, p. 242; am. 2013, ch. 28, sec. 8, p. 60; am. 2014, ch. 34, sec. 1, p. 54.]

54-1724.RENEWAL OF LICENSES. (1) Each pharmacist shall apply for license renewal annually no later than the thirtieth day of June. The board shall renew the license of each pharmacist who is qualified to engage in the practice of pharmacy.

(2) The board shall specify by rule or regulation the procedures to be followed and the fees to be paid for renewal of licenses.

[54-1724, added 1979, ch. 131, sec. 3, p. 416.; am. 2010, ch. 116, sec. 2, p. 242.]

54-1725.CONTINUING PHARMACY EDUCATION. (1) The legislature makes the following findings and declarations:

(a) Because of the continuous introduction of new therapeutic and diagnostic agents and the changing concepts in the delivery of health-care services in the practice of pharmacy, it is essential that a pharmacist undertake a continuing education program in order to maintain his professional competency and improve his professional skills; and

(b) To assure the continued competency of the pharmacist and to maintain uniform qualifications for registration and licensure in the profession for the protection of the health and welfare of its citizens, the legislature of this state deems it in the public interest to adopt a continuing professional education program.

(2) Commencing July 1, 1980, no annual renewal license shall be issued to a pharmacist until such pharmacist shall have submitted proof to the board that he has satisfactorily completed an accredited program of continuing professional education during the previous year to help assure his continued competence to engage in the practice of pharmacy. The board shall from time to time determine the amount of continuing education to be required.

(3) The board shall adopt rules and regulations necessary to carry out the stated objectives and purposes and to enforce the provisions of this section, which shall include the methods of determining accredited programs, any fees and such other rules and regulations consistent with this section as the board shall determine.

(4) The board may grant to a pharmacist who meets all of the necessary requirements for renewal of licensure, except the continuing education requirements, alternate methods of obtaining continuing education through home-study courses, correspondence courses, audiovisual aids, or other such programs, examination or the like, substantially equivalent in scope and content to the continuing professional education programs regularly scheduled; provided, however, only those

pharmacists shall be eligible for the alternative programs who, upon written application to the board and for good cause shown, demonstrate that they are unable to attend a sufficient number of regularly scheduled continuing professional education programs for licensure. This section and all rules and regulations promulgated hereunder shall be uniformly applied by the board.

[54-1725, added 1979, ch. 131, sec. 3, p. 417.]

54-1726.GROUNDS FOR DISCIPLINE. (1) The board of pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the license or registration of any person, pursuant to the procedures set forth in chapter 52, title 67, Idaho Code, upon one (1) or more of the following grounds:

(a) Unprofessional conduct as that term is defined by the rules of the board;

(b) Incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public;

(c) Being found guilty, convicted or having received a withheld judgment or suspended sentence by a court of competent jurisdiction in this state or any other state of one (1) or more of the following:

(i) Any felony;

(ii) Any act involving moral turpitude, gross immorality or which is related to the qualifications, functions or duties of a licensee; or

(iii) Violations of the pharmacy or drug laws of this state or rules pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government;

(d) Fraud or intentional misrepresentation by a licensee in securing the issuance or renewal of a license.

(e) Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license, or falsely using the title of pharmacist.

(f) Being found by the board to be in violation of any of the provisions of this chapter, chapter 27, title 37, Idaho Code, or rules adopted pursuant to either chapter.

(2) Nonresident licensees and registrants shall be held accountable to the board for violations by its agents and employees and subject to the same grounds for discipline and penalties for their actions as set forth herein.

[54-1726, added 1979, ch. 131, sec. 3, p. 417; am. 1985, ch. 152, sec. 3, p. 409; am. 1988, ch. 12, sec. 1, p. 15; am. 1993, ch. 216, sec. 70, p. 650.; am. 2013, ch. 28, sec. 9, p. 61.]

54-1727.CONFIDENTIALITY OF PRESCRIPTIONS AND PATIENT INFORMATION. (1) All prescriptions, drug orders, records or any other prescription information that specifically identifies an individual patient shall be held in the strictest confidence. No person in possession of such information shall release the information, unless requested as follows:

(a) By the board, or its representatives, acting in their official capacity;

(b) By the patient, or the patient's designee, regarding the patient's own records;

(c) By the practitioner, or the practitioner's designee, who issued the prescription;

(d) By other licensed health care professionals who are responsible for the direct and acute care of the patient;

(e) By agents of the department of health and welfare when acting in their official capacity with reference to issues related to the practice of pharmacy (written requests by authorized agents of the department requesting such information are required);

(f) By agents of any board whose practitioners have prescriptive authority, when the board is enforcing laws governing that practitioner;

(g) By an agency of government charged with the responsibility for providing medical care for the patient (written requests by authorized agents of the agency requesting such information are required);

(h) By the federal food and drug administration (FDA), for purposes relating to monitoring of adverse drug events in compliance with the requirements of federal law, rules or regulations adopted by the federal food and drug administration;

(i) By the patient's authorized insurance benefit provider or health plan providing health care coverage or pharmacy benefits to the patient.

(j) Nothing in this section shall be construed to prohibit consultations between health care professionals who are involved in the diagnosis, care and treatment of the patient.

(k) Nothing in this section shall prohibit insurance companies and health plans from sharing patient specific information with law enforcement authorities or any of the entities identified in subsections (1)(a) through (i) of this section, in cases of suspected fraud and substance abuse.

(l) Nothing in this section shall prohibit disclosure of patient specific information to law enforcement authorities pursuant to a search warrant, subpoena, or other court order.

(2) Nothing in this section shall prevent the pharmacist or others from providing aggregate or other data, which does not identify the patient to qualified researchers, including pharmaceutical manufacturers, for purposes of clinical, pharmacoepidemiological, or pharmacoeconomic research.

(3) Any person who has knowledge by virtue of his office or occupation of any prescription drug order, record, or pharmacy related information that specifically identifies an individual patient shall not divulge such information except as authorized in subsections (1) and (2) of this section. Any person or entity to whom information is divulged pursuant to subsection (1) of this section shall not divulge such information except in compliance with this section.

(4) Nothing in this section shall limit the authority of the board or its representatives from inspecting the records of pharmacies or pharmacists or the authority of any other board with licensees who have prescriptive authority from performing any other duty or authority of that board, nor shall this section limit a court of competent jurisdiction from ordering the release or disclosure of such records upon a showing of just cause after such review or hearing as the court deems necessary and proper. This section shall not limit the authority of any other board or agency to inspect records of persons it regulates, notwithstanding that the records may contain information protected by the provisions of this section.

(5) In addition to all other penalties as provided by law, any person or entity found by the board to be in violation of the provisions of this section shall be subject to an administrative penalty not to exceed three thousand dollars ($3,000) for each violation.

(6) No person shall be liable, nor shall a cause of action exist, for any loss or damage based upon the proper good faith release of records pursuant to the provisions of subsection (1) or (2) of this section.

[54-1727, added 2000, ch. 189, sec. 1, p. 465; am. 2007, ch. 140, sec. 1, p. 405.]

54-1728.PENALTIES AND REINSTATEMENT. (1) Upon the finding of the existence of grounds for discipline of any person or business entity holding a license or registration, seeking a license or registration, or a renewal license or registration under the provisions of this chapter, the board of pharmacy may impose one (1) or more of the following penalties:

(a) Suspension of the offender's license or registration for a term to be determined by the board;

(b) Revocation of the offender's license or registration;

(c) Restriction of the offender's license or registration to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board;

(d) Refusal to renew offender's license or registration;

(e) Placement of the offender on probation and supervision by the board for a period to be determined by the board;

(f) Imposition of an administrative fine not to exceed two thousand dollars ($2,000) plus 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.

(2) The board may take any action against a nonresident licensee or registrant that the board can take against a resident licensee or registrant for violation of the laws of this state or the state in which it resides.

(3) The board may report any violation by a nonresident licensee or registrant, or its agent or employee, of the laws and rules of this state, the state in which it resides or the United States to any appropriate state or federal regulatory or licensing agency including, but not limited to, the regulatory agency of the state in which the nonresident licensee or registrant is a resident.

(4) The board may elect to not initiate an administrative action under Idaho law against a nonresident licensee or registrant upon report of a violation of law or rule of this state if the licensee's or registrant's home state commences an action for the violation complained of; provided however, that the board may elect to initiate an administrative action if the home state action is unreasonably delayed or the home state otherwise fails to take appropriate action for the reported violation.

(5) The suspension, revocation, restriction or other action taken against a licensee or registrant by a state licensing board with authority over a licensee's or registrant's professional license or registration or by the drug enforcement administration may result in the board's issuance of an order likewise suspending, revoking, restricting or otherwise affecting the license or registration in this state, without further proceeding, but subject to the effect of any modification or reversal by the issuing state or the drug enforcement administration.

(6) Any person whose license to practice pharmacy in this state has been suspended, revoked or restricted pursuant to this chapter, or any drug outlet whose certificate of registration has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right, at reasonable intervals, to petition the board for reinstatement of such license. Such petition shall be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may in its discretion grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications.

(7) Nothing herein shall be construed as barring criminal prosecutions for violations of the act where such violations are deemed as criminal offenses in other statutes of this state or of the United States.

(8) All final decisions by the board shall be subject to judicial review pursuant to the procedures of the administrative procedure act.

[54-1728, added 1979, ch. 131, sec. 3, p. 419; am. 1985, ch. 152, sec. 4, p. 409; am. 1995,

ch. 42, sec. 1, p. 63.; am. 2013, ch. 28, sec. 10, p. 62.]

54-1729.REGISTRATION AND LICENSURE OF FACILITIES. (1) All drug or device outlets doing business in or into Idaho shall:

(a) If a nonresident, be licensed or registered and in good standing in the applicant's state of residence;

(b) Submit a written application in the form prescribed by the board;

(c) Pay the fee or fees specified by the board for the issuance of the registration or license; and

(d) Have a PIC or director who is licensed or registered by the board, except manufacturers, wholesalers, veterinary drug outlets and limited service outlets without a pharmacy.

(2) Each drug or device outlet shall apply for a certificate of registration or a license in one (1) of the following classifications:

(a) Retail pharmacy;

(b) Institutional facility;

(c) Manufacturer;

(d) Wholesaler;

(e) Veterinary drug outlet;

(f) Nonresident central drug outlet;

(g) Mail service pharmacy;

(h) Limited service outlet.

(3) The board shall establish by rule under the powers granted to it under sections 54-1718 and 54-1719, Idaho Code, the criteria which each outlet, that has employees or personnel engaged in the practice of pharmacy, must meet to qualify for registration or licensure in each classification designated in subsection (2) of this section. The board may issue various types of certificates with varying restrictions to such outlets designated in subsection (2) of this section where the board deems it necessary by reason of the type of outlet requesting a certificate.

(4) It shall be lawful for an outlet registered or licensed under this section to sell and distribute nonprescription drugs. Outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule will be adopted by the board under this chapter which shall require the sale of nonprescription drugs by a pharmacist or under the supervision of a pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

(5) If the regulatory board or licensing authority of the state in which a nonresident outlet is located fails or refuses to conduct an inspection or fails to obtain records or reports required by the board, upon reasonable notice to the nonresident outlet, the board may conduct an inspection. Nonresident outlets shall also pay the actual costs of the out-of-state inspection of the outlet, including the transportation, lodging and related expenses of the board's inspector.

(6) A successful applicant for registration under the provisions of this section shall be subject to the disciplinary provisions of section 54-1726, Idaho Code, the penalty provisions of section 54-1728, Idaho Code, and the rules of the board.

(7) A successful applicant for registration under the provisions of this section shall comply with the board's laws and rules of this state unless compliance would violate the laws or rules in the state in which the registrant is located, except as follows:

(a) A technician shall not exceed the practice limitations for technicians in Idaho;

(b) A pharmacist shall only substitute drug products in accordance with the board's laws and rules;

(c) A pharmacist shall only select drug products in accordance with the board's laws and rules; and

(d) A pharmacy shall not exceed the pharmacy staffing ratio as defined in rule.

(8) Renewal shall be required annually and submitted to the board no later than June 30. The board shall specify by rule the procedures to be followed and the fees to be paid for renewal of registration or licensure.

[54-1729, added 1979, ch. 131, sec. 3, p. 420; am. 1985, ch. 21, sec. 1, p. 33.; am. 2009, ch. 244, sec. 5, p. 753; am. 2011, ch. 135, sec. 3, p. 379; am. 2013, ch. 28, sec. 11, p. 63; am. 2014, ch. 34, sec. 2, p. 55.]

54-1730.DRUG OUTLET APPLICATION PROCEDURES. (1) The board shall specify by rule the registration procedures to be followed including, but not limited to, specification of forms for use in applying for such certificates of registration and times, places and fees for filing such application; provided however, the annual fee for an original or renewal certificate shall not exceed one hundred dollars ($100), except the fee for nonresident pharmacies or outlets shall not exceed five hundred dollars ($500) for initial registration and two hundred fifty dollars ($250) thereafter for annual renewals.

(2) Applications for certificates of registration shall include the following information about the proposed outlet:

(a) Ownership;

(b) Location;

(c) Identity of pharmacist licensed or registered to practice in the state, who shall be the pharmacist in charge of the outlet, where one (1) is required by this chapter, and such further information as the board may deem necessary.

(3) Certificates of registration issued by the board pursuant to this chapter shall not be transferable or assignable.

(4) The board shall specify by rule minimum standards for the professional responsibility in the conduct of any outlet that has employees or personnel engaged in the practice of pharmacy. The board is specifically authorized to require that the portion of the facility to which such certificate of registration applies be operated only under the direct supervision of no less than one (1) pharmacist licensed to practice in this state and not otherwise, and to provide such other special requirements as deemed necessary.

[54-1730, added 1979, ch. 131, sec. 3, p. 420.; am. 2013, ch. 28, sec. 12, p. 64.]

54-1731.NOTIFICATIONS. (1) All registered drug outlets shall report to the board of pharmacy the occurrence of any of the following changes:

(a) Permanent closing;

(b) Change of ownership, management, location or pharmacist in charge;

(c) Any and all other matters and occurrences as the board may require by rules and regulations.

(2) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the board.

[54-1731, added 1979, ch. 131, sec. 3, p. 421.]

54-1732.VIOLATIONS AND PENALTIES. (1) No drug outlet designated in section 54-1729, Idaho Code, shall be operated until a certificate of registration has been issued to said facility by the board. Upon the finding of a violation of this subsection, the board may impose one (1) or more of the penalties enumerated in section 54-1728, Idaho Code.

(2) Reinstatement of a certificate that has been suspended, revoked or restricted by the board may be granted in accordance with the procedures specified in section 54-1728(6), Idaho Code.

(3) The following acts, or the failure to act, and the causing of any such act or failure are unlawful:

(a) The sale, delivery or administration of any prescription drug or legend drug, except an opioid antagonist pursuant to section 54-1733B, Idaho Code, or an epinephrine auto-injector pursuant to sections 54-1733C and 54-1733D, Idaho Code, unless:

(i) Such legend drug is dispensed or delivered by a pharmacist upon an original prescription, drug order or prescription drug order by a practitioner in good faith in the course of his practice. Any person violating the provisions of this subparagraph shall be guilty of a felony, and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years, or punished by a fine of not more than five thousand dollars ($5,000) or by both such fine and imprisonment.

(ii) In the case of a legend drug dispensed by a pharmacist or prescriber, there is a label affixed to the immediate container in which such drug is dispensed. Any person violating this subparagraph shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than five hundred dollars ($500). Nothing in this subparagraph prohibits a practitioner from delivering professional samples of legend drugs in their original containers in the course of his practice when oral directions for use are given at the time of such delivery.

(b) The refilling of any prescription or drug order for a legend drug except as designated on the prescription or drug order, or by the authorization of the practitioner. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars ($1,000) or by both such fine and incarceration.

(c) The possession or use of a legend drug or a precursor, except an opioid antagonist pursuant to section 54-1733B, Idaho Code, or an epinephrine auto-injector pursuant to sections 54-1733C and 54-1733D, Idaho Code, by any person unless such person obtains such drug on the prescription or drug order of a practitioner. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars ($1,000) or by both such fine and incarceration.

(d) The wholesale distribution of drugs or devices by a pharmacy except for:

(i) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(ii) The sale of minimal quantities of prescription drugs to practitioners for office use.

(iii) The sale of a prescription drug for emergency medical reasons, but never to a wholesale distributor.

(iv) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees or a colicensed product, but never to a wholesale distributor.

(e) The failure to keep records as required by the board. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars ($1,000) or by both such fine and incarceration.

(f) The refusal to make available and to accord full opportunity to check any record, as required by the board. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars ($1,000) or by both such fine and incarceration.

(g) It is unlawful to:

(i) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by fraud, deceit, misrepresentation or subterfuge; by the forgery or alteration of a prescription, drug order, or of any written order; by the concealment of a material fact; or by the use of a false name or the giving of a false address.

(ii) Communicate information to a physician in an effort unlawfully to procure a legend drug, or unlawfully to procure the administration of any such drug. Any such communication shall not be deemed a privileged communication.

(iii) Intentionally make a false statement in any prescription, drug order, order, report or record required by this chapter.

(iv) For the purpose of obtaining a legend drug to falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian or other person.

(v) Make or utter any false or forged prescription or false drug order or forged written order.

(vi) Affix any false or forged label to a package or receptacle containing legend drugs. This subparagraph does not apply to law enforcement agencies or their representatives while engaged in enforcing state and federal drug laws.

(vii) Wholesale or retail any prescription or legend drug to any person in this state not entitled by law to deliver such drug to another.

Every violation of paragraph (g)(i) through (vi) of this subsection shall be a misdemeanor, and any person convicted thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or fined not more than one thousand dollars ($1,000), or punished by both such fine and imprisonment. Any person violating paragraph (g)(vii) of this subsection is guilty of a felony and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years, or punished by a fine of not more than five thousand dollars ($5,000), or by both such fine and imprisonment.

(4) Provided however, that a veterinarian may dispense or deliver a legend drug prescribed for an animal upon the prescription, drug order, or prescription drug order of another veterinarian. The label shall be affixed pursuant to subsection (3)(a)(ii) of this section, and penalties for violations of the provisions of this subsection shall be as provided in this section for like violations by a pharmacist.

(5) The ultimate user of a legend drug who has lawfully obtained such legend drug may

deliver, without being registered, the legend drug to another person for the purpose of disposal of the legend drug if the person receiving the legend drug for purposes of disposal is authorized under a state or federal law or regulation to engage in such activity.

[54-1732, added 1979, ch. 131, sec. 3, p. 421; am. 1985, ch. 43, sec. 1, p. 91; am. 2010, ch. 113, sec. 1, p. 231; am. 2013, ch. 28, sec. 13, p. 65; am. 2014, ch. 146, sec. 3, p. 396; am. 2015, ch. 28, sec. 2, p. 48; am. 2015, ch. 88, sec. 2, p. 218; am. 2016, ch. 264, sec. 2, p. 694.]

54-1733.VALIDITY OF PRESCRIPTION DRUG ORDERS. (1) A prescription drug order for a legend drug is valid only if it is issued by a prescriber 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.

(2) A prescriber who is otherwise authorized to perform any of the activities listed in this section may prescribe or perform any of the following activities for a patient with whom the prescriber does not have a prescriber-patient relationship under the following circumstances:

(a) Writing initial admission orders for a newly hospitalized patient;

(b) Writing a prescription drug order for a patient of another prescriber for whom the prescriber is taking call;

(c) Writing a prescription drug order for a patient examined by a physician assistant, advanced practice registered nurse or other licensed practitioner with whom the prescriber has a supervisory or collaborative relationship;

(d) Writing a prescription drug order for a medication on a short-term basis for a new patient prior to the patient's first appointment;

(e) Writing a prescription for an opioid antagonist pursuant to section 54-1733B, Idaho Code;

(f) In emergency situations where the life or health of the patient is in imminent danger;

(g) In emergencies that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;

(h) Epinephrine auto-injectors in the name of a school pursuant to section 33-520A, Idaho Code, or an authorized entity pursuant to section 54-1733C, Idaho Code; and

(i) If a prescriber makes a diagnosis of a sexually transmitted disease in a patient, the prescriber may prescribe or dispense antibiotics to the infected patient's named sexual partner or partners for treatment of the sexually transmitted disease as recommended by the most current centers for disease control and prevention (CDC) guidelines.

(3) Treatment, including issuing a prescription drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.

(4) A prescription drug order shall only be issued by a prescriber including a prescriber who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to prescribe legend drugs in the course of his professional practice so long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription drug order.

(5) The following acts shall be unlawful:

(a) To knowingly issue an invalid prescription drug order for a legend drug;

(b) To knowingly dispense a legend drug pursuant to an invalid prescription drug order; or

(c) To prescribe drugs to individuals without a prescriber-patient relationship, unless

excepted in this section.

Such acts shall constitute unprofessional conduct and the prescriber or dispenser shall be subject to discipline according to the provisions of the Idaho Code chapter pursuant to which the prescriber or dispenser is licensed, certified or registered.

[54-1733, added 1979, ch. 131, sec. 3, p. 423; am. 1985, ch. 43, sec. 2, p. 93; am. 2000, ch. 276, sec. 2, p. 899; am. 2006, ch. 117, sec. 1, p. 330; am. 2006, ch. 290, sec. 2, p. 893; am. 2007, ch. 90, sec. 25, p. 262; am. 2007, ch. 245, sec. 1, p. 722; am. 2010, ch. 112, sec. 1, p. 229; am. 2011, ch. 135, sec. 4, p. 380; am. 2012, ch. 163, sec. 1, p. 442; am. 2014, ch. 146, sec. 4, p. 398; am. 2015, ch. 26, sec. 1, p. 39; am. 2015, ch. 88, sec. 3, p. 219; am. 2016, ch. 264, sec. 3, p. 696.]

54-1733A.TRANSMISSION OF PRESCRIPTION DRUG ORDERS. (1) A valid prescription drug order may be transmitted to a licensed pharmacy by the following means:

(a) By delivery of the original signed written prescription drug order;

(b) Electronically by the prescriber or prescriber's agent in compliance with the uniform electronic transactions act, chapter 50, title 28, Idaho Code;

(c) Electronically by a licensed practical or professional nurse in an institutional facility for a patient of that facility via a secure, interoperable information technology system that exchanges data accurately, effectively and in compliance with applicable laws;

(d) Verbally by the prescriber, prescriber's agent, or a licensed practical or professional nurse for a patient of an institutional facility or for a hospice patient; and

(e) Via facsimile by a prescriber, prescriber's agent, institutional facility or hospice agent, provided that if the order was initially received verbally, the transmitted document shall include the name of the prescriber, the name of the licensed practical or professional nurse who received and transcribed the order and the name of the person who faxed the order.

(2) In the event that there are no refills remaining on an existing prescription drug order and the pharmacist requests a new prescription drug order from the prescriber, the prescriber's agent, after obtaining prescriber authorization, may sign and return the request via facsimile so long as:

(a) The request is generated from the pharmacy;

(b) The request is for medication that the patient is currently taking;

(c) There are no changes to the type of drug, its strength or directions for the continuation of therapy;

(d) The prescriber's agent's transmission is received via facsimile from the prescriber's office; and

(e) The request, which is subsequently transmitted back to the requesting pharmacy by the prescriber's agent, contains all components of a valid prescription drug order.

[54-1733A, added 2015, ch. 26, sec. 2, p. 41.]

54-1733B.OPIOID ANTAGONISTS. (1) Notwithstanding any other provision of law, any prescriber or pharmacist acting in good faith and exercising reasonable care may prescribe an opioid antagonist to:

(a) A person at risk of experiencing an opiate-related overdose;

(b) A person in a position to assist a person at risk of experiencing an opiate-related overdose;

(c) A person who, in the course of his official duties or business, may encounter a person experiencing an opiate-related overdose; or

(d) A person who in the opinion of the prescriber or pharmacist has valid reason to be in the possession of an opioid antagonist.

(2) Notwithstanding any other provision of law, any person acting in good faith and exercising reasonable care may administer an opioid antagonist to another person who appears to be experiencing an opiate-related overdose. As soon as possible, the administering person shall contact emergency medical services.

(3) Any person who prescribes or administers an opioid antagonist pursuant to subsection (1) or (2) of this section shall not be liable in a civil or administrative action or subject to criminal prosecution for such acts.

(4) The department of health and welfare in cooperation with the office of drug policy shall create and maintain an online education program for laypersons and the general public on matters pertaining to opiate-related overdoses, including:

(a) How to recognize symptoms or indications of an opiate-related overdose;

(b) How to store, administer and dispose of an opioid antagonist;

(c) Emergency procedures in the event of an opiate-related overdose; and

(d) Other information deemed pertinent by the department of health and welfare and the office of drug policy.

(5) As used in this section, "opioid antagonist" means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal food and drug administration for the treatment of drug overdose.

[54-1733B, added 2015, ch. 88, sec. 4, p. 221.]

54-1733C.EPINEPHRINE AUTO-INJECTORS -- EMERGENCY ADMINISTRATION. Notwithstanding any provision of law to the contrary:

(1) A health care practitioner, including a pharmacist, may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists and other health care practitioners may dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.

(2) An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use. Following administration, the administering person shall contact emergency medical services as soon as possible.

(3) An employee or agent of an authorized entity or other individual who has completed the training required by subsection (4) of this section may use an epinephrine auto-injector prescribed pursuant to subsection (1) of this section to:

(a) Provide an epinephrine auto-injector to any individual whom the employee, agent or other individual believes in good faith to be experiencing anaphylaxis, or the parent, guardian or caregiver of such an individual, for immediate administration, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy; or

(b) Administer an epinephrine auto-injector to any individual whom the employee, agent or other individual believes in good faith to be experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(4) An employee, agent or other individual described in subsection (2) or (3) of this section

must complete a biennial anaphylaxis training program. Such training shall be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment. Training may be conducted online or in person, and at a minimum shall cover:

(a) How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis;

(b) Standards and procedures for the storage, administration and disposal of an epinephrine auto-injector; and

(c) Emergency follow-up procedures.

The entity that conducts training shall issue a document of completion to each person who successfully completes the anaphylaxis training program.

(5) Nurses, pharmacists or other health care practitioners may act pursuant to subsection (3) of this section without completing the training required by subsection (4) of this section.

(6) The following shall not be liable for any injuries or related damages that result from any act or omission taken pursuant to this section:

(a) An authorized entity that possesses and makes available epinephrine auto-injectors, and the employees, agents or other individuals associated with such entity;

(b) A pharmacist or other health care practitioner who prescribes or dispenses epinephrine auto-injectors to an authorized entity; and

(c) An individual or entity that conducts the training required by subsection (4) of this section.

This provision of immunity does not apply to acts or omissions constituting gross negligence. The administration of an epinephrine auto-injector in accordance with this section is not the practice of medicine or any other profession that otherwise requires licensure. This section does not eliminate, limit or reduce any other immunity or defense that may be available under state law, including that provided under section 5-330, Idaho Code.

(7) An entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector outside of this state if the entity:

(a) Would not have been liable for such injuries or related damages had the provision or administration occurred within this state; or

(b) Is not liable for such injuries or related damages under the law of the state in which such provision or administration occurred.

(8) An authorized entity that possesses and makes available epinephrine auto-injectors shall take effort to remove outdated product and dispose of it properly.

(9) As used in this section:

(a) "Administer" means the direct application of an epinephrine auto-injector to the body of an individual.

(b) "Authorized entity" means any entity or organization, other than a school pursuant to section 33-520A, Idaho Code, in connection with or at which allergens capable of causing anaphylaxis may be present including, but not limited to, recreation camps, colleges and universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment and sports arenas.

(c) "Epinephrine auto-injector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(d) "Health care practitioner" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

(e) "Provide" means to supply one (1) or more epinephrine auto-injectors to an individual.

[54-1733C, added 2016, ch. 264, sec. 4, p. 697.]

54-1733D.EPINEPHRINE AUTO-INJECTORS -- PRESCRIPTION AND ADMINISTRATION. Notwithstanding any other provision of law, any prescriber or pharmacist acting in good faith and exercising reasonable care may prescribe an epinephrine auto-injector to:

(1) A person at risk of experiencing anaphylaxis;

(2) A person in a position to assist a person at risk of experiencing anaphylaxis;

(3) A person who, in the course of the person's official duties or business, may encounter a person experiencing anaphylaxis; and

(4) A person who, in the opinion of the prescriber or pharmacist, has a valid reason to be in possession of an epinephrine auto-injector.

[54-1733D, added 2016, ch. 264, sec. 5, p. 699.]

54-1734. POSSESSION OF LEGEND DRUGS. (1) The following persons or their agents or employees may possess legend drugs for use in the usual and lawful course of their business or practice or in the performance of their lawful official duties, without a valid prescription drug order:

(a) Pharmacists;

(b) Prescribers;

(c) Researchers who are prohibited from further distribution;

(d) Hospitals and other institutional facilities;

(e) Manufacturers and wholesalers;

(f) Common carriers solely in the usual course of business of transporting prescription drugs;

(g) Schools or other authorized entities possessing stock supplies of epinephrine auto-injectors pursuant to section 33-520A or 54-1733C, Idaho Code, upon presenting proof that the authorized entity has at least one (1) individual who has completed the training requirement of section 33-520A(5)(b) or 54-1733C(4), Idaho Code;

(h) Persons, agencies and organizations possessing opioid antagonists pursuant to section 54-1733B, Idaho Code;

(i) Midwives licensed pursuant to section 54-5507, Idaho Code, limited to formulary drugs consistent with rules promulgated by the Idaho board of midwifery; and

(j) Home health nurses or agencies, or hospice agencies possessing emergency kits pursuant to rules of the board.

(2) Veterinary drug outlets or their agents or employees may possess legend drugs, excluding controlled substances, for use in the usual and lawful course of their business or practice or in the performance of their lawful official duties, without a valid prescription drug order.

[54-1734, added 1979, ch. 131, sec. 3, p. 423; am. 1985, ch. 21, sec. 2, p. 34; am. 2010, ch. 64, sec. 1, p. 113; am. 2014, ch. 146, sec. 5, p. 400; am. 2015, ch. 28, sec. 3, p. 50; am. 2015, ch. 88, sec. 5, p. 222; am. 2016, ch. 73, sec. 1, p. 251; am. 2016, ch. 264, sec. 6, p. 699.]

54-1735. PATIENT MEDICATION RECORDS. In order to effectively counsel patients, the pharmacist shall make a reasonable effort to obtain, record and maintain significant patient information including, but not limited to:

(1) Name, address, telephone number;

(2) Date of birth (age), gender;

(3) Medical history:
    (a) Disease state(s);
    (b) Allergies/drug reactions; and
    (c) Current list of medications and devices;
(4) Pharmacist comments.

[54-1735, added 1979, ch. 131, sec. 3, p. 424; am. 1992, ch. 179, sec. 3, p. 569.; am. 2015, ch. 28, sec. 4, p. 51.]

54-1736.DECLARATION OF COMMON NUISANCE. Any store, shop, warehouse, dwelling house, apartment, building, vehicle, boat, aircraft, or any place whatever, which is used by any person for the purpose of unlawfully using any legend drug, or which is used for the unlawful keeping or selling of the same, is a common nuisance. No person shall keep, or maintain such a common nuisance, nor frequent or visit such place knowing it to be used for any said purposes.

[54-1736, added 1979, ch. 131, sec. 3, p. 424.]

54-1737.BURDEN OF PROOF. (a) In any complaint, information, affidavit or indictment, and in any action or proceeding brought for the enforcement of any provision of this chapter, proviso, or exemption contained in this chapter, the burden of proof is upon the party claiming any such exception, excuse, proviso or exemption.

(b) Anyone wholesaling or retailing prescription or legend drugs shall bear the burden of ascertaining that the receiver of such drugs is entitled by law to administer, dispense or deliver such drugs and proof that one has sold such drugs at wholesale or retail to an unauthorized person shall be prima facie evidence of illegality.

[57-1737, added 1979, ch. 131, sec. 3, p. 424.]

54-1738.PROOF THAT A DRUG IS A PRESCRIPTION DRUG OR LEGEND DRUG. The following shall constitute prima facie evidence in any criminal or civil proceeding in this state that a drug is a prescription drug or legend drug:

(1) In the case of a drug for which a new drug application was submitted to the United States food and drug administration, the affidavit of an officer having legal custody of the official records of the United States food and drug administration stating that such record show that the new drug application was approved, setting forth the date of approval, and further stating that the records show that proposed labeling for the drug which includes the legend "Caution: federal law prohibits dispensing without prescription" was approved. The affidavit shall be accompanied by a certificate that such officer has the custody.

(2) In the case of a drug for which the United States food and drug administration does not require an approved new drug application as a condition for marketing the drug, the affidavit of an officer having legal custody of the official records of the United States food and drug administration stating that such records reflect that the drug meets the criteria of federal law to be regarded as a prescription drug and is required to bear the regend [legend] "Caution: federal law prohibits dispensing without prescription." The affidavit shall be accompanied by a certificate that such officer has the custody.

(3) In the case of drug designated a prescription drug by action of the state board of pharmacy, independently of federal law, the affidavit of an officer having legal custody of the

records of the state board of pharmacy stating that such records show that the drug has been denominated a prescription drug, to which shall be attached a copy of the official document evidencing such action. The affidavit shall be accompanied by a certificate that such officer has the custody.

(4) This section does not prevent proof that a drug is a prescription or legend drug by any method authorizied [authorized] by any applicable state [statute], rule of procedure or rule of evidence.

[54-1738, added 1979, ch. 131, sec. 3, p. 424.]

54-1739.PROSPECTIVE DRUG REVIEW AND COUNSELING. (1) Before dispensing any prescription, a pharmacist shall complete a prospective drug review as defined in section 54–1705, Idaho Code.

(2) Before dispensing a prescription for a new medication, or when otherwise deemed necessary or appropriate, a pharmacist shall counsel the patient or caregiver. In addition to the counseling requirements provided in section 54–1705, Idaho Code, counseling shall include such supplemental written materials as required by law or as are customary in that practice setting. For refills or renewed prescriptions, a pharmacist or a technician shall extend an offer to counsel the patient or caregiver. If such offer is accepted, a pharmacist shall provide such counseling as necessary or appropriate in the professional judgment of the pharmacist. All counseling and offers to counsel shall be face to face with the patient or caregiver when possible, but if not possible, then a reasonable effort shall be made to contact the patient or caregiver. Nothing in this section shall require a pharmacist to provide counseling when a patient or caregiver refuses such counseling or when counseling is otherwise impossible. Patient counseling shall not be required for inpatients of a hospital or institutional facility when licensed health care professionals administer the medication.

(3) This section shall apply to all registered and licensed pharmacies, including mail service pharmacies. In cases of prescriber dispensing, the prescriber shall perform the prospective drug review and counseling consistent with the provisions of this section.

[54-1739, added 2011, ch. 263, sec. 2, p. 708.]

54-1751.SHORT TITLE. Sections 54-1751 through 54-1759, Idaho Code, shall be known and may be cited as the "Idaho Wholesale Drug Distribution Act."

[54-1751, added 2007, ch. 319, sec. 1, p. 949.]

54-1752.DEFINITIONS. As used in sections 54-1751 through 54-1759, Idaho Code:

(1) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control.

(2) "Colicensed partner or product" means an instance where two (2) or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the federal food and drug administration's implementation of the prescription drug marketing act.

(3) "Manufacturer" means a person, including a colicensed partner or affiliate of that person, who prepares, derives, manufactures, produces or repackages a drug or is licensed or approved by the federal food and drug administration to engage in the manufacture of drugs.

(4) "Person" means an individual, corporation, business entity, government, governmental subdivision or agency, partnership, business trust, association or any other legal entity.

(5) "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances, subject to section 503(b) of the federal food, drug and cosmetic act.

(6) "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing product to the patient.

(7) "Reverse distributor" means a drug outlet that receives nonsaleable prescription drugs from persons or their agents, who may lawfully possess prescription drugs without being issued a valid prescription drug order, and processes for credit or disposes of such prescription drugs.

(8) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 CFR 203.23.

(b) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription.

(c) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse or take legal ownership of the prescription drug.

(d) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, mis-picked, returned or recalled prescription drugs to the original manufacturer, original wholesaler, or third party returns processor, including a reverse distributor.

[54-1752, added 2007, ch. 319, sec. 1, p. 949; am. 2009, ch. 105, sec. 1, p. 320; am. 2009, ch. 143, sec. 7, p. 430; am. 2011, ch. 144, sec. 1, p. 405; am. 2013, ch. 270, sec. 3, p. 702; am. 2014, ch. 34, sec. 3, p. 56; am. 2015, ch. 28, sec. 5, p. 51.]

54-1753.WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENT -- MINIMUM REQUIREMENTS FOR LICENSURE. (1) Every business entity that engages in the wholesale distribution of prescription drugs in or into Idaho must be licensed by the board as a wholesale distributor except:

(a) Manufacturers distributing their own federal food and drug administration approved drugs and devices including distribution of prescription drug samples by manufacturer's representatives and intracompany sales, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity or any transfer between colicensees of a colicensed product, unless particular requirements are deemed necessary and appropriate following rulemaking.

(b) An entity that donates prescription drugs, when conducted in accordance with sections 54-1760 through 54-1765, Idaho Code.

(c) A pharmacy distributing in accordance with section 54-1732, Idaho Code.

(d) Persons selling, purchasing, distributing, trading or transferring a prescription drug for emergency medical reasons.

(2) The board shall require the following minimum information from each wholesale distributor applying for a license under subsection (1) of this section:

(a) The name, full business address and telephone number of the licensee;
(b) All trade or business names used by the licensee;
(c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
(d) The type of ownership or operation, i.e., partnership, corporation, or sole proprietorship;
(e) The name of each person who is an owner or an operator of the licensee;
(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;
(g) The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to paragraph (h) of this subsection for such individual;
(h) Each individual required by paragraph (g) of this subsection to provide a personal information statement and fingerprints shall provide the following information to the board:
(i) The individual's places of residence for the past seven (7) years;
(ii) The individual's date and place of birth;
(iii) The individual's occupations, positions of employment and offices held during the past seven (7) years;
(iv) The principal business and address of any business, corporation or other organization in which each such office of the individual was held or in which each such occupation or position of employment was carried on;
(v) Whether the individual has been, during the past seven (7) years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;
(vi) Whether, during the past seven (7) years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control or distribution of prescription drugs or criminal violations, together with details concerning any such event;
(vii) A description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, distributed or stored pharmaceutical products, and any lawsuits in which such businesses were named as a party and in which the individual was also a named party in the same lawsuit or, regardless of whether the individual was a named party, in which the individual testified as a witness at trial or in a deposition;
(viii) A description of any felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen (15) days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and
(ix) A photograph of the individual taken in the previous year.

(3) The information required pursuant to subsection (2) of this section shall be provided under oath.

(4) The board shall not issue a wholesale distributor license to an applicant, unless the board:
(a) Conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (2)(a) of this section or approves an inspection report that evidences equivalent standards to those in Idaho; and

(b) Determines that the designated representative meets the following qualifications:

(i) Is at least twenty-one (21) years of age;

(ii) Has been employed full time for at least three (3) years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(v) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized including, but not limited to, sick leave and vacation leave;

(vi) Is serving in the capacity of a designated representative for only one (1) applicant at a time, except where more than one (1) licensed wholesale distributor is colocated in the same facility and such wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code;

(vii) Does not have any convictions under any federal, state or local law relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(viii) Does not have any felony convictions under federal, state or local law.

(5) All applicant-designated representatives shall submit to a fingerprint-based criminal history check of the Idaho central criminal history database and the federal bureau of investigation criminal history database. Each applicant shall submit a completed ten (10) finger fingerprint card or scan to the board of pharmacy at the time of application and shall pay the cost of the criminal history check.

(6) If a wholesale distributor distributes prescription drugs in or into Idaho from more than one (1) facility, the wholesale distributor shall obtain a license for each facility.

(7) A wholesale distributor shall have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, or orders of unusual frequency.

(8) The designated representative identified pursuant to subsection (2)(g) of this section must receive and complete continuing training in applicable federal law and the law of this state governing wholesale distribution of prescription drugs.

(9) The board may adopt rules to approve an accreditation body to evaluate a wholesaler's operations to determine compliance with professional standards and any other applicable laws, and to perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesaler.

[54-1753, added 2007, ch. 319, sec. 1, p. 952; am. 2008, ch. 190, sec. 1, p. 595; am. 2015, ch. 28, sec. 6, p. 55.]

54-1754.RESTRICTIONS ON TRANSACTIONS. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled or otherwise nonsaleable pharmaceutical product shall be distributed by the receiving wholesale distributor only to either

the original manufacturer or third party returns processor, including a reverse distributor. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(2) A wholesale distributor shall not engage in the wholesale distribution of prescription drugs that are purchased from pharmacies or practitioners or from wholesale distributors that purchase them from pharmacies or practitioners.

(3) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate state licensing agency to manufacture, distribute, dispense, conduct research or independently administer such prescription drugs. A manufacturer or wholesale distributor shall furnish a scheduled controlled substance listed in section 37-2705, 37-2707, 37-2709, 37-2711 or 37-2713, Idaho Code, only to a person who has been issued a valid controlled substance registration by the United States drug enforcement administration and the Idaho board of pharmacy, unless exempted by state or federal law.

(4) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(a) The identity and authorization of the recipient is properly established; and

(b) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(5) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(6) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person's credit to establish an account for the purchase of prescription drugs from any person other than the owner(s) of record, the chief executive officer or the chief financial officer listed on the license of a person legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

[54-1754, added 2007, ch. 319, sec. 1, p. 955; am. 2014, ch. 34, sec. 4, p. 59; am. 2015, ch. 28, sec. 7, p. 57.]

54-1757.DISCIPLINE -- GROUNDS -- PENALTIES. (1) Upon a finding that a wholesale distributor is in violation of any provision of this chapter or of this act, or such rules or standards of conduct and practice as may be adopted by the board, and in accordance with the provisions of chapter 52, title 67, Idaho Code, the board may impose any one (1) or more of the penalties provided for in section 54-1728, Idaho Code.

(2) Imposition of a penalty by the board or other action against a wholesale distributor by the board as set forth in this act shall not be construed as barring other civil, administrative or criminal proceedings or prosecutions or entry of any available penalty or sanction as authorized by law.

[54-1757, added 2007, ch. 319, sec. 1, p. 957.]

54-1758.PROHIBITED ACTS. (1) It shall be unlawful for a person to knowingly perform, or cause the performance of, or aid and abet any of the following acts in this state:

(a) Failure to obtain a license when a license is required by this chapter;

(b) Operate as a wholesale distributor without a valid license when a license is required by this chapter;

(c) Purchase from or otherwise receive, return or exchange a prescription drug from a pharmacy or chain pharmacy warehouse, other than in compliance with section 54-1754(1), Idaho Code;

(d) When a state license is required pursuant to section 54-1754(3), Idaho Code, sell, distribute, transfer or otherwise furnish a prescription drug to a person who is not authorized under the law of the jurisdiction in which the person received the prescription drug to receive the prescription drug;

(e) Failure to deliver prescription drugs to specified premises, as required by section 54-1754(4), Idaho Code;

(f) Acceptance of payment or credit for the purchase of prescription drugs, other than in compliance with section 54-1754(6), Idaho Code;

(g) Provide the board or any of its representatives or any federal official with false or fraudulent records or make false or fraudulent statements regarding any matter within the provisions of this chapter;

(h) Obtain, or attempt to obtain, a prescription drug by fraud, deceit or misrepresentation or engage in misrepresentation or fraud in the distribution of a prescription drug;

(i) Manufacture, repackage, sell, transfer, deliver, hold or offer for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or otherwise has been rendered unfit for distribution;

(j) Adulterate, misbrand or counterfeit any prescription drug;

(k) Receive any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;

(l) Deliver or proffer delivery of, for pay or otherwise, any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;

(m) Alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of a prescription drug or commit any other act with respect to a prescription drug that results in the prescription drug being misbranded; or

(n) Sell, deliver, transfer or offer to sell to a person not authorized under law to receive the return or exchange of a prescription drug, a prescription drug that has expired, been damaged or recalled by either the original manufacturer, a third party returns processor or a reverse distributor.

(2) The acts prohibited in subsection (1) of this section do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, who obtains or attempts to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

[54-1758, added 2007, ch. 319, sec. 1, p. 958; am. 2015, ch. 28, sec. 8, p. 58.]

54-1759.PENALTIES. (1) Any person who commits any act prohibited by section 54-1758(1)(a) through (f), Idaho Code, is guilty of a misdemeanor, which is punishable by not more

than one (1) year of imprisonment, or by a fine not exceeding five thousand dollars ($5,000), or both.

(2) Any person who commits any act prohibited by section 54-1758(1)(g) through (n), Idaho Code, is guilty of a felony, which is punishable by imprisonment for a term of not less than five (5) years and not more than twenty (20) years, or by a fine not exceeding five hundred thousand dollars ($500,000), or both.

(3) Any person who, with the intent to commit any of the acts prohibited by section 54-1758(1)(g) through (n), Idaho Code, commits any act prohibited by section 54-1758(1)(a) through (f), Idaho Code, is guilty of a felony, which is punishable by imprisonment for a term of not less than five (5) years and not more than twenty (20) years, or by a fine not exceeding five hundred thousand dollars ($500,000), or both.

(4) Any criminal penalty imposed on a person who commits any act prohibited by section 54-1758, Idaho Code, is in addition to, and not in lieu of, any other civil or administrative penalty or sanction authorized by law.

[54-1759, added 2007, ch. 319, sec. 1, p. 959; am. 2015, ch. 28, sec. 12, p. 60.]

54-1760.SHORT TITLE. Sections 54-1760 through 54-1765, Idaho Code, shall be known and may be cited as the "Idaho Legend Drug Donation Act."

[54-1760, added 2009, ch. 143, sec. 1, p. 428.]

54-1761.DEFINITIONS. As used in sections 54-1760 through 54-1765, Idaho Code:

(1) "Legend drug" has the same meaning as provided in section 54-1705(37), Idaho Code.

(2) "Medically indigent" means any person who is in need of a legend drug and who is not eligible for medicaid or medicare, who cannot afford private prescription drug insurance or who does not have income and other resources available sufficient to pay for the legend drug.

(3) "Patient assistance program" means a program in which pharmaceutical manufacturers provide financial or medication assistance to low-income or medically indigent individuals.

(4) "Qualifying charitable clinic or center" means a community health center as defined in section 39-3203, Idaho Code, and means a free medical clinic as defined in section 39-7702, Idaho Code, acting in consultation with a pharmacist licensed in the state of Idaho; or a designated regional behavioral health center as identified in chapter 31, title 39, Idaho Code; or a state charitable institution as defined in chapter 1, title 66, Idaho Code, acting in consultation with a pharmacist, physician, physician assistant or advanced practice professional nurse with prescriptive authority licensed in the state of Idaho.

[54-1761, added 2009, ch. 143, sec. 2, p. 428; am. 2010, ch. 79, sec. 19, p. 146; am. 2010, ch. 348, sec. 1, p. 909; am. 2011, ch. 135, sec. 5, p. 381; am. 2013, ch. 28, sec. 15, p. 67; am. 2013, ch. 270, sec. 5, p. 706; am. 2014, ch. 146, sec. 7, p. 401; am. 2015, ch. 28, sec. 13, p. 60; am. 2016, ch. 81, sec. 1, p. 259.]

54-1762.IDAHO LEGEND DRUG DONATION ACT. (1) The board of pharmacy shall establish and implement a program through which legend drugs may be transferred from a qualified donor that elects to participate in the program for the purpose of distribution to a qualifying charitable clinic or center for donation to qualifying medically indigent patients.

(2) A qualifying charitable clinic or center shall establish procedures consistent with the

Idaho legend drug donation act and rules promulgated thereunder.

(3) The acceptance and distribution of legend drugs for use in the program shall be subject to the following requirements:

(a) Donated drugs shall be in the manufacturer's original, sealed and tamper evident packaging, including drugs packaged in single unit doses when the outside packaging is open and the single unit dose packaging is intact, except for patient assistance program medications as described in subsection (8) of this section, which must be originally received by the qualifying designated regional behavioral health center or qualifying state charitable institution and remain under the control and storage of such center or institution. Drugs that have been previously dispensed by a pharmacy in unit dose packaging may be donated provided that the packaging is sealed, tamper evident and properly labeled.

(b) Only drugs that bear a clear and verifiable lot number and expiration date may be accepted and dispensed. However, drugs that bear an expiration date that is less than three (3) months from the date the drug is donated shall not be accepted and dispensed.

(c) Drugs and other substances provided in schedules II through V of article II, chapter 27, title 37, Idaho Code, shall not be accepted and shall not be dispensed.

(d) A drug shall not be accepted or dispensed if the person accepting or dispensing the drug has reason to believe that the drug has been adulterated.

(4) The following entities that are licensed or registered in the state of Idaho are qualified donors and may donate legend drugs to a qualifying charitable clinic or center:

(a) Pharmacies;

(b) Hospitals and nursing homes;

(c) Drug manufacturers;

(d) Wholesale distributors; and

(e) Prescriber drug outlets.

(5) The following entities may accept legend drugs:

(a) A qualifying charitable clinic's or center's pharmacy;

(b) A qualifying charitable clinic or center in consultation with a pharmacist licensed in the state of Idaho; or

(c) A qualifying charitable clinic or center designated as a regional behavioral health center or a state charitable institution acting in consultation with a pharmacist, physician, physician assistant or advanced practice professional nurse with prescriptive authority licensed in the state of Idaho.

(6) Any qualifying charitable clinic or center that participates in the program may dispense drugs donated under the Idaho legend drug donation act to persons who are medically indigent residents of the state of Idaho.

(7) Any qualifying charitable clinic or center dispensing legend drugs shall:

(a) Comply with the provisions of the Idaho legend drug donation act and all rules promulgated thereunder;

(b) Comply with all applicable federal and state laws related to the storage and distribution of drugs;

(c) Inspect all drugs prior to dispensing to determine that such drugs have not been adulterated; and

(d) Dispense drugs only pursuant to a valid prescription.

(8) A qualifying charitable clinic or center designated as a regional behavioral health center or state charitable institution may accept unused patient assistance program medications as donations for use and may dispense these medications if:

(a) The unused patient assistance program medication has remained under the control of the designated regional behavioral health center or state charitable institution;

(b) The storage of the medication complies with all applicable federal and state laws; and

(c) At least one (1) of the following applies:

(i) The original recipient of the patient assistance program medication no longer has a valid prescription order for the medication;

(ii) The patient assistance program medication was not picked up for the use of the original recipient; or

(iii) The original recipient of the patient assistance program medication is no longer receiving services from the regional behavioral health center or state charitable institution.

(9) Participation in the program is voluntary and nothing in the Idaho legend drug donation act shall require any person or entity to participate in the program.

(10) Nothing in the Idaho legend drug donation act shall prohibit or restrict the return of unused prescription drugs to the Idaho medicaid program pursuant to rules promulgated by the Idaho department of health and welfare.

[54-1762, added 2009, ch. 143, sec. 3, p. 428; am. 2010, ch. 348, sec. 2, p. 909; am. 2016, ch. 81, sec. 2, p. 260.]

54-1763.BOARD DUTIES AND POWERS. (1) The board of pharmacy shall adopt rules necessary for the donation of legend drugs to qualifying charitable clinics or centers by nursing homes, including:

(a) Standards and procedures for the transfer, acceptance and safe storage of donated drugs;

(b) Standards and procedures for inspecting donated drugs to ensure that the drugs are in compliance with the provisions of the Idaho legend drug donation act and all federal and state product integrity standards and regulations;

(c) Standards and procedures for the distribution of donated drugs to a qualifying charitable clinic or center;

(d) Standards and procedures for the dispensing of donated drugs to qualifying medically indigent patients; and

(e) Any other standards and procedures the board deems appropriate or necessary to implement or enforce the provisions of the Idaho legend drug donation act.

(2) The board shall provide technical assistance to participants in the program.

[54-1763, added 2009, ch. 143, sec. 4, p. 429; am. 2010, ch. 348, sec. 3, p. 910.]

54-1764.IMMUNITY FROM LIABILITY. Any entity that lawfully and voluntarily participates by donating, accepting, distributing or dispensing legend drugs under the Idaho legend drug donation act shall be immune from liability for any civil action arising out of the provision of such action. This section shall not extend immunity to the participating entity for any acts constituting intentional, willful or grossly negligent conduct or to acts by a participating entity that are outside the scope of practice authorized by the entity's licensure, certification or registration.

[54-1764, added 2009, ch. 143, sec. 5, p. 430.]

54-1765.EXEMPT FROM THE IDAHO WHOLESALE DRUG DISTRIBUTION ACT. Any person or entity lawfully donating, accepting, distributing or dispensing legend drugs under the Idaho legend drug donation act shall be exempt from the provisions of the Idaho wholesale drug distribution act as provided in sections 54-1751 through 54-1759, Idaho Code.

[54-1765, added 2009, ch. 143, sec. 6, p. 430.]

54-1769.COMMUNICATION REGARDING BIOLOGICAL PRODUCTS. **[EFFECTIVE UNTIL JULY 1, 2026]** (1) A pharmacist who dispenses a biological product according to board rule shall communicate to the prescriber the name and manufacturer of the drug within five (5) business days following the dispensing of the biological product. Communication shall occur via an entry in an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system or a pharmacy record that can be accessed electronically by the prescriber. Entry into an electronic records system as described in this subsection shall be considered notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that the communication shall not be required when:

(a) There is no interchangeable biological product approved by the federal food and drug administration for the product prescribed;

(b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

(c) The pharmacist or the pharmacist's designee has already communicated to the prescriber the specific product to be provided to the patient, including the name and manufacturer of the product, prior to dispensing; and that product is the product that is actually dispensed.

(2) Nothing in this section shall delay the dispensing of a valid prescription for a biological product.

(3) For purposes of this section:

(a) "Biological product" shall have the same meaning as in 42 U.S.C. 262(i).

(b) "Interchangeable biological product" means a biological product that the federal food and drug administration has licensed and determined meets the standards for interchangeability set forth in 42 U.S.C. 262(k)(4) or has been deemed therapeutically equivalent by the federal food and drug administration in the latest edition of or supplement to the publication "Approved Drug Products with Therapeutic Equivalence Evaluations."

[54-1769, added 2016, ch. 197, sec. 1, p. 553.]

54-1770.NOTIFICATION OF DRUG PRODUCT SELECTION FOR EPILEPSY AND SEIZURE DRUGS. (1) In this section:

(a) "Anti-epileptic drug" means:

(i) A drug used for the treatment of epilepsy; or

(ii) A drug used to treat or prevent seizures.

(b) "Drug product selection" means the selection of a therapeutically equivalent drug, including a generic version for the prescribed brand, a branded version for the prescribed generic, a generic version by one (1) manufacturer for a generic version by a different manufacturer.

(c) "Epilepsy" means a neurological condition characterized by recurrent seizures.

(d) "Seizure" means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain.

(2) When a prescriber has specified that a drug is prescribed for the treatment of epilepsy or seizures, pharmacy personnel who perform drug product selections shall:

(a) Notify the prescriber of such drug product selection via facsimile, telephone message or any other appropriate means to the prescriber's place of business; and

(b) Provide the patient or the patient's representative with notification of the selection.

(3) Nothing in this section shall delay the dispensing of a valid prescription for an anti-epileptic drug.

[54-1770, added 2010, ch. 277, sec. 1, p. 717.]

54-1771.SEVERABILITY. The provisions of this chapter are hereby declared to be severable and if any provision of this chapter or the application of such provision to any person or circumstance is declared invalid for any reason, such declaration shall not affect the validity of remaining portions of this chapter.

[54-1771, added 2011, ch. 263, sec. 5, p. 709.]

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IDAPA 27
TITLE 01
CHAPTER 01

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

Subchapter A -- Standard Provisions
(Rules 0 through 9 -- 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. (3-21-12)

001. TITLE AND SCOPE.

01. Title. The title of this chapter is "Rules of the Idaho State Board of Pharmacy," IDAPA 27, Title 01, Chapter 01. (3-21-12)

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to: (3-21-12)

a. Regulate and control the manufacture, distribution, and dispensing of controlled substances within or into the state, pursuant to the Uniform Controlled Substances Act, Section 37-2715, Idaho Code; (3-21-12)

b. Regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Section 54-1718, Idaho Code; and (3-21-12)

c. Carry out its duties in regard to drugs, devices and other materials used in the diagnosis, mitigation and treatment, or prevention of injury, illness, and disease, pursuant to Section 54-1719, Idaho Code, or in regard to professionals or other individuals licensed or registered by the Board or otherwise engaged in conduct subject to regulation under these Acts. (3-21-12)

002. WRITTEN INTERPRETATIONS.
Written interpretations, explanatory comments that accompanied a notice of proposed rulemaking, comments submitted in a rulemaking process, or written statements that the Board may have or prepare that pertain to the interpretation of the rules of this chapter may be obtained through submission of a public records request pursuant to Title 74, Chapter 1, Idaho Code. (3-21-12)

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. (3-21-12)

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. (3-21-12)

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. (3-21-12)

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into these rules. (3-21-12)

005. BOARD OFFICE INFORMATION.

01. Street Address. The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (3-21-12)

02. Mailing Address. The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (3-21-12)

03. Telephone Number. The telephone number is (208) 334-2356. (3-21-12)

04. Fax Number. The fax number is (208) 334-3536. (3-21-12)

05. Electronic Address. The website address is http://bop.idaho.gov. (3-21-12)

06. Office Hours. The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (3-21-12)

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 74, Chapiter, Idaho Code. (3-21-12)

007. OFFICIAL BOARD JOURNAL.
The official journal of the Board is the Idaho Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website and copies may be obtained from the Board office. 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. (3-21-12)

008. MAINTENANCE, RETENTION, AND INSPECTION OF RECORDS.

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 as required and retained in a readily retrievable form and location for at least three (3) years. (3-21-12)

02. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (3-21-12)

009. POLICIES AND PROCEDURES.
Policies and procedures required by this chapter must be written and maintained onsite or immediately retrievable in electronic form, operationally implemented and enforced, and updated or revised as necessary to maintain compliance with these rules. (3-21-12)

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

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

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

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

04. ADS -- Automated Dispensing and Storage. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

05. Biological Product. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (4-11-15)

06. Biosimilar. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (4-11-15)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24. **DME**. Durable medical equipment. (3-21-12)

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

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

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

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

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

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

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

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

33. **Floor Stock**. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

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

35. **Hazardous Drug**. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: (3-25-16)

a. Carcinogenicity; (3-25-16)

b. Teratogenicity or developmental toxicity; (3-25-16)

c. Reproductive toxicity in humans; (3-25-16)

d. Organ toxicity at low doses in humans or animals; (3-25-16)

e. Genotoxicity; or (3-25-16)

f. New drugs that mimic existing hazardous drugs in structure or toxicity. (3-25-16)

36. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

37. **Hospital System**. A hospital or hospitals and at least one (1) on-site institutional pharmacy under

common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

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

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

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

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

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

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

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

41. **Interchangeable Biosimilar**. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (4-11-15)

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. **LTCF -- Long-Term Care Facility**. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. **Mail Service Pharmacy**. A nonresident pharmacy that ships, mails, or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law. (7-1-13)

03. **MPJE**. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

04. **MTM -- Medication Therapy Management**. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

05. **NABP**. National Association of Boards of Pharmacy. (3-21-12)

06. **NAPLEX**. North American Pharmacists Licensure Examination. (3-21-12)

07. **NDC**. National Drug Code. (3-21-12)

08. **Non-Institutional Pharmacy**. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

09. **Outsourcing Drug Outlet**. A drug outlet that is registered by the United States Food and Drug Administration pursuant to 21 U.S.C. Section 353b and either registered or endorsed by the Board. (4-6-15)

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

11. **Pharmaceutical Care Services**. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Except as permitted pursuant to a collaborative practice agreement, nothing in these rules allows a pharmacist, beyond what is statutorily allowed, to engage in the unlicensed practice of medicine or to diagnose, prescribe, or conduct physical examinations. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (4-4-13)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; (3-25-16)

m. Ordering and interpreting laboratory tests; and (3-25-16)

n. Other services as allowed by law. (3-21-12)

12. **Pharmacist Extern**. A person enrolled in an accredited school or college of pharmacy who is

pursuing a professional degree in pharmacy. (4-4-13)

13. **Pharmacist Intern**. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

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

15. **PHI -- Protected Health Information**. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)

16. **PIC**. Pharmacist-in-charge. (3-21-12)

17. **PMP**. Prescription Monitoring Program. (3-21-12)

18. **Prepackaging**. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)

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

20. **Prescriber Drug Outlet**. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

21. **Purple Book**. The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. (4-11-15)

22. **Readily Retrievable**. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

23. **Reconstitution**. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. (3-25-16)

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

25. **Remote Dispensing Site**. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

26. **Remote Office Location**. A secured area that is restricted to authorized personnel, adequately protects private health information, and shares a secure common electronic file or a private, encrypted connection with a pharmacy, from which a pharmacist who is contracted or employed by a central drug outlet performs centralized pharmacy services. (7-1-13)

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

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

29. **R.N**. Registered nurse. (3-21-12)

012. DEFINITIONS AND ABBREVIATIONS (S -- Z).

01. **Sample**. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (3-21-12)

02. **Secured Pharmacy**. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-21-12)

03. **Skilled Nursing Facility**. An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (3-21-12)

04. **Student Pharmacist**. A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. (3-21-12)

05. **Technician**. Unless specifically differentiated, a term inclusive of pharmacy technician, certified pharmacy technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (3-21-12)

06. **Telepharmacy**. The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (3-21-12)

07. **Therapeutic Equivalent Drugs**. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). (4-4-13)

08. **Unit Dose**. Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (3-21-12)

09. **USP**. United States Pharmacopeia. (3-21-12)

10. **USP-NF**. United State Pharmacopeia-National Formulary. (3-21-12)

11. **USP 795**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 795. (3-25-16)

12. **USP 797**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 797. (3-25-16)

13. **VAWD -- Verified Accredited Wholesale Distributor**. An accreditation program for wholesale distributors offered through NABP. (3-21-12)

14. **VDO -- Veterinary Drug Outlet**. A registered establishment that employs a qualified VDT to distribute prescription veterinary drugs pursuant to lawful orders of a veterinarian. (3-21-12)

15. VDT -- Veterinary Drug Technician. A non-pharmacist qualified by registration with the Board to distribute prescription veterinary drugs in a VDO. (3-21-12)

16. Veterinary Drug Order. A lawful order by a veterinarian issued pursuant to the establishment of a veterinarian-patient-client relationship as recognized by the American Veterinary Medical Association. (3-21-12)

17. VIS. Vaccine Information Statement. (3-21-12)

013. WAIVERS OR VARIANCES.

01. Criteria. The Board may grant or deny, in whole or in part, a waiver of, or variance from, specified Board rules based on consideration of the following: (3-21-12)

a. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; (3-21-12)

b. The waiver or variance requested would not allow conduct specifically prohibited by, or otherwise contrary to, state or federal law; and (4-4-13)

c. The granting of the waiver or variance is consistent with the Board's mandate to promote, preserve, and protect public health, safety, and welfare. (4-4-13)

02. Content and Filing of a Waiver or Variance Petition. A petition for waiver or variance must be submitted in writing and must include at least the following: (3-21-12)

a. The name, address, and telephone number of the petitioner; (3-21-12)

b. A specific reference to the rule or rules from which a waiver or variance is requested; (3-21-12)

c. A statement detailing the waiver or variance requested, including the precise scope and duration; (3-21-12)

d. The name, address, and telephone number of any public agency or political subdivision that also regulates the activity in question or that might be affected by the granting of the waiver or variance; and (3-21-12)

e. The name, address, and telephone number of any known person who would be adversely affected by the granting of the waiver or variance. (3-21-12)

f. A description of how the waiver or variance, if granted, will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. (4-4-13)

03. Additional Information. Prior to granting or denying the waiver or variance, the executive director may request additional information from the petitioner and may require the petitioner to appear before the Board at an upcoming Board meeting. (3-21-12)

04. Granting or Denying the Petition for Waiver or Variance. The decision to grant or deny the petition for waiver or variance will be at the discretion of the Board or, pursuant to Board authorization, its executive director based upon consideration of relevant factors. (3-21-12)

05. Prohibited Requests. A waiver or variance request that is contrary to federal law or Idaho Code or that seeks to delay or cancel an administrative deadline will not be considered or granted by the Board. (3-21-12)

06. Conditions. Waivers or variances may be granted subject to binding conditions, limitations, or restrictions determined necessary to protect the public health, safety, and welfare. (3-21-12)

07. Time Period of Waiver or Variance. Waivers or variances may be granted on a permanent or temporary basis. Temporary waivers or variances have no automatic renewal, but may be renewed if the Board finds that sufficient grounds to allow the waiver or variance continue to exist. (3-21-12)

08. Cancellation or Modification of a Waiver or Variance. A waiver or variance granted by the Board may be cancelled or modified if the Board finds any of the following: (3-21-12)

a. The petitioner or other person who was the subject of the waiver or variance withheld or misrepresented material facts; (3-21-12)

b. The alternative means for ensuring adequate protection of public health, safety, or welfare are demonstrated to be insufficient after issuance of the waiver or variance; or (3-21-12)

c. The subject of the waiver or variance has failed to comply with the prescribed conditions, limitations, or restrictions of the waiver or variance. (3-21-12)

09. Violations. Violation of a condition, restriction, or limitation of a waiver or variance will be deemed a violation of the particular rule or rules for which the waiver or variance was granted. (3-21-12)

014. BOARD-RECOGNIZED EXAMINATIONS, CERTIFICATIONS, AND PROGRAMS.
A specific reference in these rules to a named examination or examining body, certification or certifying body, or other item or program indicates the Board's review and determination that the referenced item or entity meets the Board's objectives or desired criteria and has thus been granted Board recognition. Nevertheless, a specific reference in these rules is not intended to, and does not, indicate exclusivity, and alternative equivalents may also be accepted upon prior Board consideration and approval. (3-21-12)

015. BOARD INSPECTIONS AND INVESTIGATIONS.

01. Inspections. Prior to the commencement of business, if required, and thereafter at reasonable times, in a reasonable manner, to the extent authorized by law, and upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (3-21-12)

02. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, one (1) follow-up inspection may be performed by the Board at no cost. Additional follow-up inspections will be at the expense of the drug outlet. Charges for additional inspections will be actual travel and personnel costs incurred in the inspection and must be paid within ninety (90) days of inspection. (3-21-12)

03. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. The licensee or registrant must retain a copy of the inspection report issued by the inspector or investigator in an immediately retrievable manner. (3-21-12)

04. Investigations. Licensees or registrants must also fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, to gather information pertinent to a complaint received by the Board, or to enforce disciplinary actions. (3-21-12)

05. Prosecution of Violations -- Reporting Discretion Reserved. The executive director will report violations of law to proper prosecuting authorities as required by law or otherwise ordered by the Board. These rules should not be construed as requiring the Board, through its executive director, to report violations for the initiation of formal proceedings when not required by law and if the Board believes, under the circumstances, that public interest will be adequately served through administrative disciplinary processes. (3-21-12)

016. BOARD OF PHARMACY LICENSURE AND REGISTRATION.
The Board is responsible for the control and regulation of the practice of pharmacy in or into the state of Idaho, which includes the licensure or registration of professional, supportive, and ancillary personnel who engage in or support the

practice. The Board is also responsible for the control, regulation, and registration of persons or drug outlets that manufacture, distribute, or dispense controlled substances within or into the state. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions, except that the Board may suspend such requirements for the duration of a national, state or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, for individuals engaged in the scope of practice for which they are licensed in another state. (3-25-16)

01. Pharmacy Practice Act Licenses and Registrations. The Board will issue or renew a license or a certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act and any additional criteria specified by these rules for the license or registration classification. Licenses and certificates of registration issued pursuant to Title 54, Chapter 17, Idaho Code, expire annually on June 30 unless an alternate expiration term or date is specifically stated in these rules. (3-21-12)

02. Idaho Controlled Substances Act Registrations. The Board will issue or renew controlled substance registrations upon application and determination that the applicant has satisfied the requirements of the Idaho Controlled Substances Act and any additional criteria specified by state or federal law applicable to applicants that manufacture, distribute, or dispense, or conduct research with, controlled substances. Registrations issued pursuant to Title 37, Chapter 27, Idaho Code, must be renewed annually by June 30 for pharmacists and by December 31 for all other registrants. (4-4-13)

a. Unless a wholesaler, an applicant for an Idaho controlled substance registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances and, unless a pharmacist or certified euthanasia technician, a valid federal DEA registration. If a required license or registration is cancelled or otherwise invalidated by the issuing agency, the Idaho controlled substance registration will be correspondingly cancelled. (3-21-12)

b. A registrant engaging in more than one (1) group of independent activities, as defined by federal law, must obtain a separate Idaho controlled substance registration for each group of activities if not exempted from separate DEA registration by federal law. (3-21-12)

017. LICENSURE AND REGISTRATION: APPLICATION AND RENEWAL.

01. Board Forms. Initial licensure and registration applications, annual renewal applications, and other forms used for licensure, registration, or other purposes must be in such form as designated by the Board. (3-21-12)

02. Incomplete Applications. Information requested on the application or other form must be provided and submitted to the Board office with the applicable fee or the submission will be considered incomplete and will not be processed. (3-21-12)

03. On-Time Annual Renewal Application. Licenses and registrations must be renewed annually to remain valid. Applications for renewal must be completed and submitted to the Board office prior to the license or registration expiration. Timely submission of the renewal application is the responsibility of each licensee or registrant. (3-21-12)

04. Late Application. Failure to submit a renewal application prior to the expiration date will cause the license or registration to lapse and will result in the assessment of a late fee and possible disciplinary action. A lapsed license or registration is invalid until renewal is approved by the Board and if not renewed within thirty (30) days after its expiration will require reinstatement. (3-21-12)

05. Exemption. New licenses and registrations issued ten (10) weeks or less prior to the renewal due date are exempt from the renewal requirements that year only. (3-21-12)

06. Reporting Information Changes. Changes to required information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change. (3-21-12)

018. LICENSE AND REGISTRATION: REINSTATEMENT.
The Board may, at its discretion, consider reinstatement of a license or registration upon receipt of a written petition and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested. (3-21-12)

01. Satisfactory Evidence. If applicable, reinstatement applicants must also provide satisfactory evidence of completion of continuing education requirements and compliance with any direct orders of the Board. (3-21-12)

02. Additional Requirements. A pharmacist reinstatement applicant must provide evidence of completion of a minimum of thirty (30) CPE hours within the twenty-four (24) months prior to reinstatement application and may be required to appear before the Board. The Board may also, at its discretion, impose additional requirements on a pharmacist reinstatement applicant who has not practiced as a pharmacist for the preceding twelve (12) months or longer that may include taking and passing an examination, completion of forty (40) intern hours for each year away from the practice of pharmacy, completion of additional CPE hours, or other requirements determined necessary to acquire or demonstrate professional competency. (4-4-13)

019. LICENSE AND REGISTRATION: INSPECTION.
Licenses and registrations issued under the Idaho Pharmacy and the Uniform Controlled Substances Acts must be immediately retrievable at the licensed or registered location or at the drug outlet where the licensee or registrant is employed. (4-4-13)

01. Application Pending. Pending receipt of the current registration or license from the Board, the confirmation of successful submission of an online application must be printed. (4-4-13)

02. Temporary Locations. A licensee or registrant engaged in professional practice at a temporary or alternate location or in training must be able to produce written proof of licensure or registration immediately upon request. (3-21-12)

020. BOARD FEES.

01. Fee Determination and Collection. Pursuant to the authority and limitations established by Sections 37-2715 and 54-1720(5)(a), Idaho Code, the Board has determined and will collect fees for the issuance, annual renewal, or required reinstatement of licenses and certificates of registration to persons and drug outlets engaged in acts or practices regulated by the Board. The Board may also charge reasonable fees for specified administrative services or publications. (3-21-12)

02. Time and Method of Payment. Fees are due and must be paid by cash, credit card, or by personal, certified, or cashier's check or money order payable to the "Idaho State Board of Pharmacy" at the time of application, submission, or request. Fees are nonrefundable and will not be prorated. (3-21-12)

03. Fee For Dishonored Payment. A reasonable administrative fee may be charged for a dishonored check or other form of payment. If a license or registration application has been approved or renewed by the Board and payment is subsequently dishonored, the approval or renewal is immediately cancelled on the basis of the submission of an incomplete application. The board may require subsequent payments to be made by cashier's check, money order, or other form of guaranteed funds. (3-21-12)

04. Overpayment of Fees. "Overpayment" refers to the payment of any fee in excess of the required amount. Refunds issued will be reduced by a reasonable processing fee. (3-21-12)

05. Fee Exemption for Controlled Substance Registrations. Persons or drug outlets exempt pursuant to federal law from fee requirements applicable to controlled substance registrations issued by the DEA are also exempt from fees applicable to controlled substance registrations issued by the Board. (3-21-12)

021. FEE SCHEDULE.

01. Licenses -- Professionals. (3-21-12)

a. Original pharmacist license: one hundred dollars ($100). (3-21-12)

b. Licensure by reciprocity: two hundred fifty dollars ($250). (3-21-12)

c. Pharmacist license annual renewal. (3-21-12)

i. Active: ninety dollars ($90). (3-21-12)

ii. Inactive: fifty dollars ($50). (3-21-12)

d. Late payment processing: fifty dollars ($50). (3-21-12)

e. License reinstatement fee: seventy-five dollars ($75). (3-21-12)

02. Certificates of Registration -- Professionals. (3-21-12)

a. Pharmacist registration or annual renewal: two hundred fifty dollars ($250). (7-1-13)

b. Pharmacist intern - registration or annual renewal: fifty dollars ($50). (3-21-12)

c. Pharmacist extern registration and annual renewal: fifty dollars ($50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. (3-21-12)

d. Technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

e. Veterinary drug technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

f. Registration reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

03. Certificates of Registration and Licensure - Facilities. (3-21-12)

a. Retail pharmacy - registration or annual renewal: one hundred dollars ($100). (3-21-12)

b. Institutional facility - registration or annual renewal. (3-21-12)

i. Hospital pharmacy: one hundred dollars ($100). (3-21-12)

ii. Nursing home: thirty-five dollars ($35). (3-21-12)

c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars ($100). (3-21-12)

d. Wholesaler. (3-21-12)

i. License or annual renewal: one hundred thirty dollars ($130); or (3-21-12)

ii. Registration or annual renewal: one hundred dollars ($100). (3-21-12)

e. Veterinary drug outlet - registration or annual renewal: one hundred dollars ($100). (3-21-12)

f. Nonresident central drug outlet. (7-1-13)

i. Initial license: five hundred dollars ($500). (7-1-13)

ii. License annual renewal: two hundred fifty dollars ($250). (7-1-13)

g. Mail service pharmacy. (3-21-12)

i. Initial license: five hundred dollars ($500). (3-21-12)

ii. License annual renewal: two hundred fifty dollars ($250). (3-21-12)

h. Limited service outlet - registration or annual renewal. (3-21-12)

i. Limited service outlet, if not listed: one hundred dollars ($100). (3-21-12)

ii. Sterile product pharmacy: one hundred dollars ($100). (4-4-13)

iii. Remote dispensing pharmacy: one hundred dollars ($100). (3-21-12)

iv. Facility operating a narcotic treatment program: one hundred dollars ($100). (3-21-12)

v. Durable medical equipment outlet: fifty dollars ($50). (3-21-12)

vi. Prescriber drug outlet: thirty five dollars ($35). (3-21-12)

vii. Outsourcing facilities: (4-6-15)

(1) Initial nonresident registration: five hundred dollars ($500). (4-6-15)

(2) Initial resident registration: two hundred fifty dollars ($250). (4-6-15)

(3) Registration annual renewal: two hundred fifty dollars ($250). (4-6-15)

i. Analytical or research lab -- registration or annual renewal: forty dollars ($40). (3-21-12)

j. Retail non-pharmacy outlets. (3-24-16)

i. Retail store registration or annual renewal: thirty-five dollars ($35). (3-24-16)

ii. "V" (Vending machines): ten dollars ($10) per machine. (3-21-12)

k. Supplemental facility registrations or annual renewals. (3-21-12)

i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration required for one (1) or more hoods: no charge. (3-21-12)

ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)

l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

04. Controlled Substance Registration. (3-21-12)

a. Controlled substance - registration or annual renewal: sixty dollars ($60). (3-21-12)

b. Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars ($100). (3-21-12)

c. Controlled substance registration reinstatement: seventy-five dollars ($75). (3-21-12)

05. Administrative Services and Publications. (3-21-12)

a. Experiential hours certification: twenty-five dollars ($25). (3-21-12)

b. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). (3-21-12)

c. Duplicate registration or license card: ten dollars ($10). (3-21-12)

d. Commercial lists. (3-21-12)

i. Except for Subparagraph 021.05.d.ii. below, any registrant or licensee lists: fifty dollars ($50). (3-24-16)

ii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). (3-21-12)

e. Official Idaho Register: fifteen dollars ($15). (3-21-12)

f. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). (3-21-12)

g. Hearing transcript: five dollars ($5) per page. (3-21-12)

022. -- 028. (RESERVED)

029. PHARMACIST LICENSE OR REGISTRATION.

01. Practice in Idaho. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws. (7-1-13)

02. Practice Into Idaho. Unless statutorily exempted, all pharmacists practicing pharmacy into the state of Idaho must be licensed or registered as follows: (7-1-13)

a. The following pharmacists must be licensed to provide centralized pharmacy services into Idaho: (7-1-13)

i. Pharmacists engaged in the independent practice of pharmacy across state lines as defined by the Pharmacist Independent Practice Rule. (7-1-13)

ii. Pharmacists practicing from a central drug outlet that is not a pharmacy. (7-1-13)

iii. Pharmacists practicing from a remote office location. (3-20-14)

b. The following pharmacists not licensed in Idaho must be registered to practice pharmacy into Idaho. (7-1-13)

i. The PIC or director of a nonresident central drug outlet or mail service pharmacy. (7-1-13)

ii. Pharmacists practicing from a pharmacy or its COE. (7-1-13)

Subchapter B -- Professional and Drug Outlet Licensure and Registration Provisions
(Rules 30 Through 99 -- Professional And Drug Outlet Licensure and Registration Provisions)

030. PHARMACIST LICENSURE BY EXAMINATION: ACCREDITED SCHOOL OR COLLEGE OF PHARMACY GRADUATES.

To be considered for licensure, a graduate of an accredited school or college of pharmacy within the United States must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, and submit to the Board an application for licensure by examination. (3-21-12)

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

01. Licensure Submission Requirements. To be considered for licensure, a graduate of a school or college of pharmacy located outside of the United States must submit an application for licensure by examination, certification of completion of a minimum of seventeen hundred forty (1740) experiential hours, and; (3-24-16)

a. Certification by the FPGEC; or (4-11-15)

b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. (4-11-15)

02. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

032. PHARMACIST LICENSURE EXAMINATIONS.
Qualified applicants may sit for and to obtain licensure must pass the NAPLEX and the MPJE in accordance with NABP standards. (3-21-12)

033. PHARMACIST LICENSURE BY RECIPROCITY.
An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and this rule to obtain an Idaho license. The Board will issue a reciprocal license only to a pharmacist licensed in good standing in another state at the time of application and issuance of the Idaho license. (3-21-12)

01. Transfer Application. The applicant must submit a preliminary application for licensure transfer through NABP. (3-21-12)

02. MPJE. The applicant must pass the Idaho-based MPJE. (3-21-12)

03. Intern Hours. An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may also be required to complete up to forty (40) intern hours for each year away from the practice of pharmacy. (3-21-12)

034. PHARMACIST INACTIVE STATUS LICENSE.

01. Required Criteria. Upon Board approval, an inactive status pharmacist license may be issued if an applicant: (3-21-12)

a. Is a pharmacist in the state of Idaho licensed in good standing; (3-21-12)

b. Is unable or unwilling to practice pharmacy due to physical limitations or changes in circumstance; and (3-21-12)

c. Has submitted the required application. (3-21-12)

02. Exemptions and Restrictions. Inactive status licensees are exempt from CPE requirements and are prohibited from engaging in the practice of pharmacy while on inactive status. (3-21-12)

03. Return to Active Status. If an inactive status licensee wishes to return to active status, the licensee must comply with the reinstatement requirements of these rules. (4-4-13)

035. PHARMACIST REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered to practice pharmacy into Idaho an applicant must submit an application in the manner and form prescribed by the Board including, but not limited to: (7-1-13)

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (7-1-13)

02. Facility License Information. The license or registration number of the facility for which the

applicant will be practicing. (3-20-14)

036. STUDENT PHARMACIST REGISTRATION.

01. Registration Requirements. (4-4-13)

a. To be approved for and maintain registration as a pharmacist extern, the applicant must currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy. (4-4-13)

b. To be approved for and maintain registration as a pharmacist intern, the applicant must be: (4-4-13)

i. A graduate of an accredited school or college of pharmacy within the United States or; (4-4-13)

ii. A graduate of a school or college of pharmacy located outside the United States and obtain certification by the FPGEC. (4-4-13)

02. Renewal. (4-4-13)

a. A pharmacist extern registration must be renewed annually by July 15; however, the renewal fee will be waived for the duration of the student's enrollment in the school or college of pharmacy and until July 15 following graduation. (4-4-13)

b. A pharmacist intern registration must be renewed annually by June 30. (4-4-13)

03. Cancellation of Registration. Failure to maintain the requirements for student pharmacist registration will result in the cancellation of registration. (4-4-13)

037. -- 039. (RESERVED)

040. CERTIFIED PHARMACY TECHNICIAN REGISTRATION.
To be approved for registration as a certified pharmacy technician, a person must satisfy the following requirements: (3-21-12)

01. Age. Be at least eighteen (18) years of age unless a waiver is granted by the Board's executive director; (3-21-12)

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma unless a waiver is granted by the Board's executive director; (3-21-12)

03. Personal Characteristics. Be of good moral character and temperate habits; and (3-21-12)

04. Certification. Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the National Healthcare Association, or their successors unless qualified for a continuous employment exemption. (3-24-16)

05. Cancellation of Registration. Failure to maintain the certification requirements for certified pharmacy technician registration may result in cancellation of the registration. (3-24-16)

041. TECHNICIAN-IN-TRAINING REGISTRATION.
A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a technician and obtains and maintains employment as a technician-in-training. (4-4-13)

01. Duties. Upon registration, a technician-in-training may perform any of the duties allowed by statute or rule to be delegated to a registered technician under the supervision of a pharmacist. (3-21-12)

02. Renewal. The registration of a technician-in-training must be renewed by June 30 annually, however a technician-in-training may only renew a technician-in-training registration twice. (4-11-15)

03. Registration Expiration. Upon the final expiration of a technician-in-training registration, a person must satisfy the technician certification and registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (3-21-12)

04. Cancellation of Registration. Failure to maintain employment will result in the cancellation of the registration. (4-4-13)

042. PHARMACY TECHNICIAN CERTIFICATION: CONTINUOUS EMPLOYMENT EXEMPTION.
A technician registered with the Board and employed as a technician on June 30, 2009, is not required to obtain or maintain certification as a condition of registration renewal after June 30, 2009, as long as the registrant remains continuously employed as a technician by the same employer. If a registrant that qualifies for this exemption disrupts continuous employment as a technician with one employer, the technician registration will become invalid. The person must thereafter satisfy the certified pharmacy technician registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (4-4-13)

043. -- 044. (RESERVED)

045. VETERINARY DRUG TECHNICIAN REGISTRATION.
A person must have a valid, active Board registration to be employed as, or perform the duties of, a VDT. To qualify for registration as a VDT, a person must: (3-21-12)

01. Age. Be at least eighteen (18) years of age; (3-21-12)

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma; and (3-21-12)

03. Examination. Score at least seventy-five percent (75%) on a Board examination designed to measure knowledge of these rules. (3-21-12)

046. -- 049. (RESERVED)

050. CPE: PROGRAM CRITERIA.

01. Board Approval of CPE Programs. The Board recognizes CPE program accreditation by ACPE and CME. CPE programs not accredited by either ACPE or CME must be approved by the Board. A sponsoring organization, presenter or continuing education coordinator may apply to the Board for accreditation of a CPE program. An application must be submitted twenty-one (21) days in advance of the program and must include: (3-20-14)

a. The name of the sponsoring organization, if applicable; (3-20-14)

b. The title of the program offered; (3-20-14)

c. The learning objectives and a description of the subject matter; (3-20-14)

d. The method and materials for assessing the learning objectives; (3-20-14)

e. The method of evaluating satisfactory completion of the program; (3-20-14)

f. The dates, time schedule, number of clock hours and location of the program; and (3-20-14)

g. The names and curriculum vitae or resume of instructors or other persons responsible for the delivery and content of the program; and (3-20-14)

h. A copy of the materials to be offered to the participants and the program to be presented (electronic or hard copy), if applicable. (3-20-14)

02. Postgraduate Education. A CPE program must consist of postgraduate education in one or more of the following general areas: (3-21-12)

a. The socioeconomic and legal aspects of health care; (3-21-12)

b. The properties and actions of drugs and dosage forms; or (3-21-12)

c. The etiology, characteristics, and therapeutics of a disease state. (3-21-12)

03. Evidence of Satisfactory Completion. A CPE program must provide evidence of satisfactory completion by participants. (3-21-12)

04. Qualified Instruction. The program presenter must be qualified in the subject matter by education or experience. (3-21-12)

051. CPE: INSTRUCTION CREDITS.

01. Pharmacists. A pharmacist, whose primary responsibility is not the education of health professionals, who leads, instructs, or lectures to groups of nurses, physicians, pharmacists, or others on pharmacy-related topics in organized CPE or in-service programs will be granted CPE credit for time expended during actual presentation upon the provision of adequate documentation to the Board. (3-21-12)

02. Educators. A pharmacist whose primary responsibility is the education of health professionals will be granted CPE credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses, or others on pharmacy-related topics outside his formal course responsibilities in a learning institution. (3-21-12)

052. CPE: REQUIREMENTS.
Each pharmacist applicant for license renewal must annually complete fifteen (15) CPE hours. (4-4-13)

01. ACPE or CME. At a minimum, twelve (12) of the CPE hours obtained must be all or a combination of ACPE or CME accredited programs. ACPE accredited activities must have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. (3-20-14)

02. Pharmacy Law. One (1) of the CPE hours obtained must address federal, state or local law effecting the practice of pharmacy. (3-20-14)

03. Board Approved. A maximum of three (3) of the CPE hours obtained may be Board-approved programs not accredited through ACPE or CME. (3-20-14)

04. Live Attendance. Three (3) of the CPE hours obtained must be by attendance at live or synchronous online CPE programs. (4-4-13)

05. Immunizer Qualification. To maintain qualification to administer immunizations, a minimum of one (1) of the ACPE-approved CPE hours must be related to vaccines, immunizations, or their administration. (4-4-13)

06. Sterile Compounding Requirement. To engage in the practice of sterile compounding a minimum of one (1) of the CPE hours must be ACPE accredited and related to the practice of sterile compounding. (3-20-14)

07. Carryover of Certain Unused Units. CPE hours accrued during June of a licensing period may be carried over into the next licensing period to the extent that a pharmacist's total CPE hours for the current licensing period exceed the total CPEs hours required by these rules. (4-4-13)

08. New Pharmacist Exemption. Recent pharmacist graduates applying for the first license renewal are not required to complete or certify the annual CPE requirements. (3-21-12)

09. Requirements for Dual Licenses. (3-20-14)

a. An Idaho-licensed pharmacist residing in another state must meet Idaho CPE requirements to be granted an Idaho license renewal. (3-20-14)

b. CPE programs attended by an Idaho-licensed pharmacist for purposes of satisfying licensing requirements of another state must be accredited by either ACPE or CME or must be approved by the Board to also be recognized for purposes of renewal of the pharmacist's Idaho license. (3-20-14)

053. -- 059. (RESERVED)

060. DRUG OUTLET LICENSURE AND REGISTRATION.
A license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. (3-21-12)

01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location and the drug outlet may not open for business prior to satisfactory completion of the opening inspection, if required. (3-21-12)

02. Licenses and Registrations Transferability. (3-25-16)

a. Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place, except in the event of a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. (3-25-16)

b. Temporary Pharmacy Facilities and Mobile Pharmacies. To provide pharmacy services during a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy: (3-25-16)

i. Is under the control and management of the pharmacist-in-charge, director, or designated supervising pharmacist; (3-25-16)

ii. Is located within the declared disaster area or is intended for affected populations; (3-25-16)

iii. Notifies the Board of its proposed location; (3-25-16)

iv. Is properly secured to prevent theft and diversion of drugs; (3-25-16)

v. Maintains records in accordance with laws and rules of the state; and (3-25-16)

vi. Ceases the provision of services with the termination of the declared emergency, or as otherwise authorized by the Board. (3-25-16)

03. Nonresident Drug Outlet. The Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. (7-1-13)

061. -- 069. (RESERVED)

070. LIMITED SERVICE OUTLET REGISTRATION.
Pursuant to Section 54-1729(3), certificates of registration may be limited, conditioned, or restricted based upon the outlet type and the specialized or limited products or services provided. Examples of limited service outlet registrations include, but are not limited to: sterile product, nuclear, remote dispensing, cognitive service, and COE pharmacies and DME outlets. (3-21-12)

01. Required Waivers. An applicant for a limited service outlet registration must submit a registration application and a request for waiver of applicable Board rules that are unfeasible or impractical for the specialized or limited products or services offered, if any. (3-21-12)

02. Compliance Standards. A limited service outlet registration will be subject to continuous compliance with any required policies and procedures, applicable law, any of these rules applicable to the practice setting unless specifically waived in writing by the Board, and any limitations, conditions, or restrictions established by the Board. (3-21-12)

03. Inspection and Review. If required, policies and procedures must be available for review and approval during the initial inspection and thereafter retained on the outlet premises. (3-21-12)

071. REMOTE DISPENSING SITE REGISTRATION.

01. Remote Dispensing Site Registration. A limited service outlet registration must be obtained by a remote dispensing site prior to participating in the practice of telepharmacy. (3-21-12)

02. Supplemental Registration Application Requirements. Prior to construction, an applicant for registration of a remote dispensing site must submit and obtain Board approval of a registration application. The application must include: (3-21-12)

a. An attached description of the telepharmacy communication, electronic recordkeeping, and ADS systems; (3-21-12)

b. The operating specifications; and (3-21-12)

c. An accurate scale drawing of the facility that illustrates: (3-21-12)

i. The layout and location of the systems; (3-21-12)

ii. The location of a patient counseling area; and (3-21-12)

iii. All access points to the electronic recordkeeping system and the ADS system. (3-21-12)

072. STERILE PRODUCT DRUG OUTLET REGISTRATION.
A separate registration that requires an onsite Board inspection must be obtained prior to engaging in sterile product preparation. (3-21-12)

01. Floor Plan Approval. Floor plans for construction of a new sterile product preparation area must be submitted along with the registration application and must be approved by the Board prior to commencement of construction. (3-21-12)

02. Hood or Aseptic Environment Control Device Registration. A drug outlet engaged in sterile product preparation must obtain a single registration for one or more hood or aseptic environmental control devices. (3-21-12)

073. NONRESIDENT CENTRAL DRUG OUTLET AND MAIL SERVICE PHARMACY REGISTRATION.

A nonresident central drug outlet or mail service pharmacy must be registered with the Board in order for its employee or contract pharmacist to practice pharmacy into Idaho. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: (7-1-13)

01. **Executive Summary**. An executive summary describing the centralized pharmacy services to be performed; (7-1-13)

02. **PIC or Director**. Identity of a pharmacist licensed to practice pharmacy in the state of domicile, who shall be the PIC or director of the nonresident central drug outlet or mail service pharmacy. (7-1-13)

074. OUTSOURCING FACILITY REGISTRATION.

An outsourcing facility must be registered with the Board in order to distribute compounded drug product for human use in or into Idaho. (4-6-15)

01. **Application**. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: (4-6-15)

a. A copy of a valid FDA registration as an outsourcing facility as required by 21 U.S.C. Section 353b; (4-6-15)

b. Identity of a pharmacist licensed or registered in Idaho who is designated the PIC of the outsourcing facility; and (4-6-15)

c. An inspection report indicating compliance with applicable state and federal law. (4-6-15)

02. **Coincidental Activity**. An outsourcing facility applicant currently registered by the Board as a pharmacy or mail service pharmacy will be considered for an outsourcing facility registration with a supplemental pharmacy or mail service pharmacy registration at no additional fee. Exemption from registration fees does not excuse compliance with all laws and rules pertaining to pharmacies and mail service pharmacies. (4-6-15)

075. -- 079. (RESERVED)

080. WHOLESALER LICENSURE AND REGISTRATION.

01. **Wholesaler Licensure**. In addition to the information required pursuant to Section 54-1753, Idaho Code, the following information must be provided under oath by each applicant for wholesaler licensure as part of the initial licensing procedure and for each renewal. (3-21-12)

a. The name of the owner and operator of the applicant, including: (3-21-12)

i. If a person, the name of the person; (3-21-12)

ii. If a partnership, the name of each partner, and the name of the partnership; (3-21-12)

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any; or (3-21-12)

iv. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. (3-21-12)

b. Any felony conviction or any conviction of the applicant relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-21-12)

c. Any discipline of the applicant by a regulatory agency in any state for violating any law relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-21-12)

02. **Wholesaler Licensure -- Other Eligibility Factors**. The Board will consider at least the following

factors in determining the applicant's eligibility for licensure as a wholesaler: (3-21-12)

a. The qualifications of the wholesaler's designated representative; (3-21-12)

b. Any convictions of the applicant, including those relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances; (3-21-12)

c. The applicant's past experience in the manufacture or distribution of drugs, including controlled substances; (3-21-12)

d. The provision by the applicant of false or fraudulent material in an application made in connection with drug manufacturing or distribution; (3-21-12)

e. Suspension or revocation by a local, state, or federal government of a registration or license currently or previously held by the applicant for the manufacture or distribution of drugs, including controlled substances; (3-21-12)

f. Compliance with licensing requirements under previously granted licenses, if any; and (3-21-12)

g. Compliance with the requirements to maintain and make available to the state licensing authority or to local, state, or federal law enforcement officials those records required to be maintained by wholesale drug distributors. (3-21-12)

03. Controlled Substance Registration. All wholesalers distributing controlled substances must register with both the Board and the DEA. (3-21-12)

04. VAWD Accreditation. The Board will recognize a wholesaler's VAWD accreditation by NABP for purposes of reciprocity and satisfying the new drug outlet inspection requirements of these rules. (3-21-12)

05. Wholesaler Registration. Except when licensed pursuant to the Idaho Wholesale Drug Distribution Act and these rules, a wholesaler that engages in wholesale distribution of DME supplies, prescription medical devices, or non-prescription drugs in or into Idaho must be registered by the Board. (3-21-12)

081. -- 089. (RESERVED)

090. MANUFACTURER REGISTRATION.
A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing. Non-resident manufacturers that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident must be registered by the Board as a mail service pharmacy. (7-1-13)

091. -- 099. (RESERVED)

Subchapter C -- General Practice Standards
(Rules 100 through 299 -- General Practice Standards)

100. ELECTRONIC RECORDKEEPING SYSTEM.
Unless specifically exempted by these rules, an electronic recordkeeping system must be used to establish and store patient medication records and prescription drug order, refill, and transfer information. (3-21-12)

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. (3-21-12)

02. Immediately Retrievable Refill Data. The electronic recordkeeping system must have functionality that allows required 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. (3-21-12)

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 pharmacists responsible for the accuracy of these processes. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited. (3-21-12)

04. System Security. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (3-21-12)

a. Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and (3-21-12)

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. (3-21-12)

05. System Downtime. Pharmacies may use handwritten records or another auxiliary procedure for documentation of refills of prescription drug orders in the event the system becomes inoperative while the pharmacy is open that ensures: (3-21-12)

a. Refills are authorized by the original prescription drug order; (3-21-12)

b. If a controlled substance, the maximum number of refills is not exceeded; and (3-21-12)

c. The required data is retained for entry into the system within ninety-six (96) hours after the electronic recordkeeping system is restored. (3-21-12)

d. Nothing in Subsection 100.05 precludes a pharmacist from exercising professional judgment in the issuance of an emergency prescription refill, pursuant to these rules, for the benefit of a patient's health or safety. (3-21-12)

06. System Backup and Recovery. The drug outlet must implement routine system backup, maintenance, and recovery procedures to protect its data and provide reasonable continuity of service in the event of human error, power failure, system malfunction, accident, or catastrophe resulting in the loss, destruction, or corruption of data. (3-21-12)

07. Board Approval. The Board reserves the right to approve and revoke approval of the use of an electronic recordkeeping system. (3-21-12)

08. Exemption. Recordkeeping systems in use as of the effective date of this rule may continue to be used as long as the information required by these rules for an electronic recordkeeping system is collected and retained in an immediately retrievable manner for a minimum of fifteen (15) months. (3-21-12)

101. ELECTRONIC RECORDKEEPING SYSTEM: PATIENT MEDICATION RECORDS.
A patient medication record must be created and maintained for each patient who has a prescription drug order filled or refilled, and a reasonable effort must be made to obtain and record in it the following: (3-21-12)

01. Patient Personal Information. The patient's name, address, telephone number, date of birth (or age), and gender; (3-21-12)

02. Prospective Drug Review Information. Information relevant to a prospective drug review; (3-21-12)

03. Prescriber-Provided Information. Relevant information provided by the prescriber; and (3-21-12)

04. Other Information. Any other information that the pharmacist deems appropriate. (3-21-12)

102. ELECTRONIC RECORDKEEPING SYSTEM: PRESCRIPTION DRUG ORDER INFORMATION.

01. Original Prescription Drug Order Information. For each original prescription drug order, the information entered into the electronic recordkeeping system must include at least the following: (3-21-12)

a. The serial number, if any; (3-21-12)

b. The date of issuance; (3-21-12)

c. The date filled; (3-21-12)

d. The identity of each individual involved in or, alternatively, the pharmacist ultimately responsible for its processing, filling, or dispensing; (3-21-12)

e. The drug name, strength, dosage form, quantity prescribed (and quantity dispensed if different from the quantity prescribed); (3-21-12)

f. The directions for use; (3-21-12)

g. The total number of refills authorized by the prescriber, if applicable; (3-21-12)

h. The name of the prescriber; and (3-21-12)

i. For controlled substances, the prescriber's address and DEA registration number. (3-21-12)

02. Prescription Drug Order Refill Information. For each prescription drug order refill, at least the following information must be added to the original prescription drug order information in the electronic recordkeeping system: (3-21-12)

a. The date of dispensing of each refill; (3-21-12)

b. The quantity dispensed; (3-21-12)

c. Unless dispensed in a hospital, the identification of the dispensing pharmacist for each refill; and (3-21-12)

d. The total number of refills dispensed to date. (3-21-12)

03. Refill Verification of Controlled Substances. Written verification of the accuracy of the refill information entered into the electronic recordkeeping system for controlled substances must be provided by pharmacists utilizing the system. Verification must be documented in a bound log book or separate file in which each pharmacist involved in the dispensing of controlled substance refills signs a statement attesting to the fact that the refill information entered into the electronic recordkeeping system each day has been reviewed and is correct as shown. (3-21-12)

103. -- 104. (RESERVED)

105. PATIENT COUNSELING DOCUMENTATION.
Documentation must be created and retained sufficient to evidence compliance with the offer to counsel and counseling requirements of the Idaho Pharmacy Act. (3-21-12)

106. -- 109. (RESERVED)

110. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its authenticity and validity.

(3-21-12)

01. **Invalid Prescription Drug Orders**. A prescription drug order is invalid if not issued: (3-21-12)

a. In good faith; (3-21-12)

b. For a legitimate medical purpose; (3-21-12)

c. By a licensed prescriber; (3-21-12)

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; (3-21-12)

e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; and (4-4-13)

f. In the form and including the elements required by law. (3-21-12)

02. **Antedating or Postdating**. A prescription drug order is invalid if antedated or postdated.(3-21-12)

03. **Tampering**. A prescription drug order is invalid if it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. (3-21-12)

04. **Prescriber Self-Use**. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (3-21-12)

05. **Family Members**. A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession. (3-21-12)

111. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.
A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for a drug order, must include at least the following: (3-21-12)

01. **Patient's Name**. The patient's name and: (3-21-12)

a. If for a controlled substance, the patient's full name and address; and (3-21-12)

b. If for an animal, the species. (3-21-12)

02. **Date**. The date issued. (3-21-12)

03. **Drug Information**. The drug name, strength, quantity, and if for a controlled substance, the dosage form. (3-21-12)

04. **Directions**. The directions for use. (3-21-12)

05. **Prescriber Information**. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (3-21-12)

06. **Signature**. If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, or if statutorily allowed, the prescriber's agent's signature, and if electronic, the prescriber's electronic signature. (3-20-14)

112. DRUG ORDER: MINIMUM REQUIREMENTS.
A drug order must comply with applicable requirements of federal law and must include at least the following: (3-21-12)

01. **Patient's Name**. The patient's name. (3-21-12)

02. **Date**. The date issued. (3-21-12)

03. **Drug Information**. The drug name, strength, and route of administration. (3-21-12)

04. **Directions**. The directions for use. (3-21-12)

05. **Prescriber Information**. The name of the prescriber. (3-21-12)

06. **Signature**. If written, the signature of the prescriber or if statutorily allowed, the prescriber's agent. (3-20-14)

113. PRESCRIPTION DRUG ORDER: CONTROLLED SUBSTANCES.

01. **Schedule II Faxed Prescription Drug Order Documentation**. A Schedule II prescription must not be dispensed pursuant to a faxed prescription drug order, with the faxed copy serving as the original, except as follows: (3-21-12)

a. To be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion; (3-21-12)

b. For a resident of an LTCF; and (3-21-12)

c. For a patient enrolled in a hospice care program, if so indicated on the prescription drug order. (3-21-12)

02. **Schedule II 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-day supply of a Schedule II controlled substance if the prescriber provides written instructions on each prescription drug order indicating the earliest date on which a pharmacy may fill each prescription, except instructions may be omitted from the first prescription drug order if it is to be filled immediately. (3-21-12)

114. PRESCRIPTION DRUG ORDER: PARTIAL FILLING.

01. **Partial Filling of Schedule II Prescriptions**. A Schedule II controlled substance prescription drug order may be partially filled and dispensed if the pharmacist is unable to supply the full quantity ordered. (3-21-12)

a. The remaining portion of the prescription drug order may be filled if within seventy-two (72) hours of the first partial filling. If the remaining portion is not or cannot be filled within seventy-two (72) hours, the pharmacist must notify the prescriber. (3-21-12)

b. Additional quantities must not be dispensed beyond seventy-two (72) hours without a new prescription drug order. (3-21-12)

02. **Partial Filling of Schedule II Prescriptions for LTCF or Terminally Ill Patients**. A Schedule II controlled substance prescription drug order for a patient in an LTCF or for a patient with a documented terminal illness may be filled in partial quantities and individual dosage units. The pharmacist must record that the patient is either "terminally ill" or an "LTCF patient." (3-21-12)

03. **Schedule II Partial-Fill Documentation**. For each partially filled prescription drug order, the following information must be recorded: (3-21-12)

a. The date; (3-21-12)

b. The quantity dispensed; (3-21-12)

c. The remaining quantity authorized for dispensing; and (3-21-12)

d. The identification of the dispensing pharmacist. (3-21-12)

04. Partial Filling of Schedule III, IV, and V Prescriptions. The partial filling of a prescription drug order for a controlled substance listed in Schedules III, IV, or V is permissible if: (3-21-12)

a. Each partial fill is recorded in the same manner as a refill; (3-21-12)

b. The total quantity dispensed in partial fillings does not exceed the total quantity prescribed; and (3-21-12)

c. Dispensing does not occur after six (6) months from the date on which the prescription drug order was issued. (3-21-12)

115. PRESCRIPTION DRUG ORDER: TRANSFERS.

01. Communicating Prescription Drug Order Transfers. Except prescription drug orders for Schedule II controlled substances, a pharmacist may transfer prescription drug order information for the purpose of filling or refilling if the information is communicated from pharmacist to pharmacist verbally, electronically, or via fax. (3-21-12)

a. Prescription drug order information may also be communicated verbally by a student pharmacist, under the supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. (3-21-12)

b. If transferring by fax transmission, the transfer document used must be signed by the transferring pharmacist. (3-21-12)

02. Documentation Required of the Transferring Pharmacy. The pharmacist transferring prescription drug order information must void or otherwise indicate that the original prescription drug order has been transferred and record the following information: (3-21-12)

a. The name of the transferring pharmacist; (3-21-12)

b. The name of the receiving pharmacist; (3-21-12)

c. The name of the receiving pharmacy; (3-21-12)

d. The date of the transfer; (3-21-12)

e. The number of authorized refills available; and (3-21-12)

f. If written for a controlled substance, the address and DEA registration number of the receiving pharmacy. (3-21-12)

03. Documentation Required of the Receiving Pharmacy. The pharmacist receiving a transferred prescription drug order must document that the prescription drug order is a “transfer” and record the following information: (3-21-12)

a. The name of the receiving pharmacist; (3-21-12)

b. The name of the transferring pharmacist; (3-21-12)

c. The name of the transferring pharmacy; (3-21-12)

d. The date of issuance of the original prescription drug order; (3-21-12)

e. The number of refills authorized by the original prescription drug order; (3-21-12)

f. The number of authorized refills available; and (3-21-12)

g. If written for a controlled substance: (3-21-12)

i. The dates and locations of the original dispensing and previous refills; and (3-21-12)

ii. The name, address, DEA registration number, and the serial number assigned to the prescription by the transferring pharmacy and any additional pharmacy that filled the prescription, if applicable. (4-4-13)

04. Electronic Prescription Drug Order Transfers. For electronic prescription drug orders that are transferred electronically, the transferring pharmacist must provide all of the information required to be recorded by the receiving pharmacist in addition to the original electronic prescription data. The receiving pharmacist must create an electronic record for the prescription drug order that includes the receiving pharmacist's name and all of the information transferred with the prescription. (3-21-12)

05. Pharmacies Using Common Electronic Files. Pharmacies may establish and use a common electronic file to maintain required dispensing information. (3-21-12)

a. Pharmacies using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other pharmacies sharing the common electronic file. (3-21-12)

b. Common electronic files must contain complete and accurate records of each prescription and refill dispensed. (3-21-12)

06. Transferring Prescription Drug Orders for Controlled Substances. A prescription drug order for a controlled substance listed in Schedules III, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. (3-21-12)

07. Transferring Prescription Drug Order Refills. Prescription drug orders for non-controlled substances may be transferred more than one (1) time if there are refills remaining and other legal requirements are satisfied. (3-21-12)

116. PRESCRIPTION DRUG ORDER: REFILLS.

01. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal laws and only as specifically authorized by the prescriber. (3-21-12)

a. A pharmacist, utilizing his best professional judgment, may dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills. (3-21-12)

b. Refills exceeding those authorized by the prescriber on the original prescription drug order may only be authorized through issuance of a new and separate prescription drug order. (3-21-12)

02. Emergency Prescription Refills. A pharmacist may refill a prescription for a patient when: (3-25-16)

a. The prescriber is not available for authorization if, in the professional judgment of the pharmacist, a situation exists that threatens the health or safety of the patient should the prescription not be refilled. Only sufficient medication may be provided, consistent with the dosage instructions, to maintain the prescribed treatment until, at the earliest possible opportunity, the issuing or an alternative prescriber is contacted for further renewal instructions. (3-25-16)

b. Upon the declaration of a national, state, or local emergency by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, a pharmacist may dispense a refill of a prescription drug to an affected patient, not to exceed a thirty (30)-day supply if, in the pharmacist's professional judgment, the prescription drug is essential to the patient's health or continuation of therapy. (3-25-16)

117. PRESCRIPTION DRUG ORDER: EXPIRATION.
A prescription drug order expires no later than fifteen (15) months after its date of issue. (3-21-12)

01. Schedule II Prescription Drug Orders. 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. (3-21-12)

02. Schedule III, IV, and V Prescription Drug Orders. 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. (3-21-12)

118. PRESCRIPTION DRUG ORDER: PRESCRIBER CHANGE OF STATUS.

01. Change of Status. A prescription drug order is invalid after a period reasonably necessary to allow the patient to maintain continuity of care, which must not exceed ninety (90) days, from the date the pharmacist learns of a change of status that precludes a continued prescriber-patient relationship such as death, incapacity, suspension or revocation of the prescriber's license, or permanent relocation. (3-21-12)

02. Patient Notification. A pharmacist who becomes aware of a prescriber's change of status that precludes a continued patient-prescriber relationship must advise the patient of the resultant change to the status of the prescription drug order, advise the patient that a new prescriber will be required, and unless otherwise prohibited by law, provide a sufficient amount of prescribed drug to allow for continuity of care for a period that considers the healthcare needs of the patient but does not exceed ninety (90) days. (3-21-12)

119. PRESCRIPTION DRUG ORDER: RETENTION, INSPECTION, AND COPYING.

01. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner, in the paper or electronic form issued, and must be made available for inspection by the issuing prescriber upon request. (3-21-12)

02. Prescription Drug Order Copies. A copy of a prescription drug order may only be provided as allowed or required by law, and the copy must be marked across its face: "Copy for Information Only. Not to be Filled." (3-21-12)

120. VETERINARY DRUG ORDERS.

01. Veterinary Drug Order Forms. Veterinary drug orders for prescription drugs must be written or documented by a veterinarian licensed to practice veterinary medicine in this or any state sharing an Idaho border on an official, numbered, three (3) part drug order form available through the Idaho Department of Agriculture. For purposes of this rule, the top copy of the official order form is considered the original order, the middle copy (the first duplicate) is "copy one (1)" and the bottom copy (the second duplicate) is "copy two (2)." (3-21-12)

02. Veterinary Drug Order Handling. Copy two (2) of a veterinary drug order must be retained by the prescribing veterinarian. The original and copy one (1) of a veterinary drug order must be presented to a VDO for product preparation and for completion and handling by a VDT as follows: (3-21-12)

a. The VDT must complete the bottom portion of the veterinary drug order with the date filled, the serial number assigned, and the VDT's signature. The serial number must also appear on the copy one (1) that accompanies the order. (3-21-12)

b. Upon completion, the VDT must file the original and attach the copy one (1) to the prepared order. (3-21-12)

03. Veterinary Drug Order -- Required Information. A veterinary drug order must include at least the following information: (3-21-12)

a. The client's name and address; (3-21-12)

b. The animal species; (3-21-12)

c. The date issued; (3-21-12)

d. The name, strength, and quantity of product; (3-21-12)

e. The product instructions or directions for use and any applicable cautionary statements; and (3-21-12)

f. The name, license number, and signature of the prescribing veterinarian. (3-21-12)

04. Verbal Veterinary Drug Orders. Verbal veterinary drug orders must be issued directly by a prescribing veterinarian, received directly by a VDT, and are subject to the following additional requirements: (3-21-12)

a. The verbal order must be promptly reduced to writing on an official, unnumbered, three (3) part telephone drug order form available through the Idaho Department of Agriculture. (3-21-12)

b. If the issuing veterinarian is unknown by the VDT, the VDT must make a reasonable effort to determine the validity of the order. (3-21-12)

c. The verbal order must be otherwise handled and processed as required for written orders. (3-21-12)

d. Written confirmation of the verbal order must be documented on the original of an official, numbered order form, signed by the prescribing veterinarian, and provided to the VDO within seven (7) days. Upon receipt, the VDT must attach the original, verbal order to the original, official, numbered order. (3-21-12)

05. Veterinary Drug Order Processing. Veterinary drug orders must be processed exactly as written and never for more than the original quantity indicated by the prescribing veterinarian. (3-21-12)

a. Refilling or reprocessing of veterinary drug orders is prohibited. (3-21-12)

b. For a split shipment, the VDT must indicate on the back of the original order the date, quantity, and initials of the person supplying the partial order. The remaining quantity must be delivered within ninety (90) days. (3-21-12)

c. Substitution is prohibited. Supplying a different brand or product, including a generic, is prohibited. (3-21-12)

d. Only original manufacturers' containers bearing the entire label intact may be delivered (no partial containers). (3-21-12)

e. Compounding by a VDT is prohibited. (3-21-12)

121. -- 129. (RESERVED)

130. DRUG PRODUCT: SUBSTITUTION.
Drug product substitutions are allowed only as follows: (4-4-13)

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

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

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

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (4-11-15)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (4-11-15)

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and (4-11-15)

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (4-11-15)

131. DRUG PRODUCT: SELECTION.
Drug product selection is allowed only between therapeutic equivalent drugs. (3-21-12)

01. Brand Name Drug Dispensing. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug selection is permitted. (4-4-13)

02. Documentation. If a generic is selected by a non-institutional pharmacy, the name of the drug and the manufacturer or the NDC number must be documented in the patient medication record. (4-4-13)

132. -- 134. (RESERVED)

135. DRUG PRODUCT: FLAVORING.
A flavoring agent may be added to a drug product at the discretion of a pharmacist or upon request by the prescriber, the patient, or the patient's agent. (3-21-12)

136. -- 139. (RESERVED)

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

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business). (3-21-12)

02. Serial Number. The serial number. (4-4-13)

03. Date. The date the prescription is filled. (3-21-12)

04. Prescriber. The name of the prescriber. (3-21-12)

05. Name. (4-11-15)

a. If a person, the name of the patient; (4-11-15)

b. If an animal, the name and species of the patient; or (4-11-15)

c. If a school for epinephrine auto-injectors pursuant to Section 33-520A, Idaho Code, the name of the school. (4-11-15)

06. Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name). (3-21-12)

07. Quantity. The quantity of item dispensed. (3-21-12)

08. Directions. The directions for use. (3-21-12)

09. Cautionary Information. Cautionary information as required or deemed appropriate for proper use and patient safety. (3-21-12)

10. Expiration. An expiration date that is the lesser of: (3-21-12)

a. One (1) year from the date of dispensing; (3-21-12)

b. The manufacturer's original expiration date; (3-21-12)

c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)

d. A shorter period if warranted. (3-21-12)

11. Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable. (4-11-15)

12. Warning. The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed," except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. (4-11-15)

13. Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. (4-11-15)

141. INSTITUTIONAL FACILITY: DRUG LABELING.

01. Labeling for Patient Use While in the Facility. 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: (3-21-12)

a. The date filled; (3-21-12)

b. The name of the patient; (3-21-12)

c. The name and strength of the drug; (3-21-12)

d. The quantity of item dispensed; (3-21-12)

e. The directions for use, including the route of administration; (3-21-12)

f. Cautionary information as required or deemed appropriate for proper use and patient safety; (3-21-12)

g. The expiration or beyond use date, if appropriate; and (3-21-12)

h. The initials or other unique identifier of the dispensing pharmacist. (3-21-12)

02. Labeling for Patient Use Outside of the Facility. A drug dispensed for patient use outside of the facility must be labeled pursuant to the standard prescription drug labeling requirements. (3-21-12)

142. PARENTERAL ADMIXTURE LABELING.
If one 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: (3-21-12)

01. Ingredient Information. The name, amount, strength, and if applicable, the concentration of the drug additive and the base solution or diluent; (3-21-12)

02. Date and Time. The date and time of the addition, or alternatively, the beyond use date and time; (3-21-12)

03. Identification. The initials or other unique identifier of the pharmacist or preparing prescriber responsible for its accuracy; (4-4-13)

04. Prescribed Administration Regimen. The rate or appropriate route of administration or both, as applicable; and (3-21-12)

05. Special Instructions. Any special handling, storage, or device-specific instructions. (3-21-12)

143. PREPACKAGED PRODUCT LABELING.
The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label with at least the following information: (3-21-12)

01. Drug Name and Strength. The name and strength of the drug; (3-21-12)

02. Expiration Date. An expiration date that is the lesser of: (3-21-12)

a. The manufacturer's original expiration date; (3-21-12)

b. One (1) year from the date the drug is prepackaged; or (3-21-12)

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.); (3-21-12)

03. Conditional Information. If not maintained in the records of the pharmacy, the manufacturer's name and lot number and the identity of the pharmacist responsible for the prepackaging. (3-21-12)

144. LABELING OF DISTRIBUTED COMPOUNDED DRUG PRODUCT.
Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription drug order, solely as permitted for outsourcing facilities and pharmacies herein, must be labeled with the following information: (4-11-15)

01. Drug Name. The name of each drug included. (4-11-15)

02. Strength or Concentration. The strength or concentration of each drug included. (4-11-15)

03. Base or Diluents. If a sterile compounded drug product, the name and concentration of the base or diluents. (4-11-15)

04. Administration. If applicable, the dosage form or route of administration. (4-11-15)

05. Quantity. The total quantity of the drug product. (4-11-15)

06. Date. The expiration or beyond use date. (4-11-15)

07. Compounder Identifier. The initials or unique identifier of the compounder responsible for the accuracy of the drug product. (4-11-15)

08. Resale. If: (4-11-15)

a. A pharmacy that is distributing, the statement: "not for further dispensing or distribution;" and (4-11-15)

b. An outsourcing facility, the statement: "not for resale." (4-11-15)

09. Instructions, Cautions, and Warnings. Handling, storage or drug specific instructions, cautionary information, and warnings as required or deemed appropriate for proper use and patient safety. (4-11-15)

145. PRESCRIPTION DRUG PACKAGING.
Prescription drugs must be dispensed in packaging materials that preserve the integrity, cleanliness, and potency of commercially available and compounded drug products. (3-21-12)

146. REPACKAGING.
A pharmacy may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: (4-11-15)

01. Unit Dose. The drugs are repackaged into unit dose packaging. (4-11-15)

02. Pharmacist Verification. The repackaging pharmacist verifies: (4-11-15)

a. The identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within; and (4-11-15)

b. The validity and accuracy of the original prescription drug order. (4-11-15)

03. Adulterated Drugs. In the repackaging pharmacist's best professional judgment, the drug has not been adulterated. (4-11-15)

04. Intermingled Drugs. The drugs are never intermingled with the repackaging pharmacy's regular stock. (4-11-15)

05. Time for Repackaging. The pharmacy repackages the entire amount that was delivered to it for repackaging no later than three (3) days after receipt. (4-11-15)

06. Date of Repackaging. The date of repackaging is less than one (1) year from the original date of dispensing and the original expiration date is also used on the repackaged drug's label. (4-11-15)

07. Labeling. The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes: (4-11-15)

a. The original dispensed prescription's serial number; (4-11-15)

b. The name, address, and phone number of the original dispensing pharmacy; and (4-11-15)

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. (4-11-15)

08. Record. The repackaging pharmacy makes a record of: (4-11-15)

a. All required components of the standard prescription drug labeling rule; (4-11-15)

b. The original dispensing pharmacy's name, address, and phone number; (4-11-15)

c. The original dispensed prescription's serial number; and (4-11-15)

d. The name of the pharmacist responsible for compliance with this rule. (4-11-15)

09. Policy and Procedures. The repackaging pharmacy develops policy and procedures to ensure compliance with this rule. (4-11-15)

147. -- 199. (RESERVED)

200. 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. (3-21-12)

01. Positive Identification Presumed. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: (3-21-12)

a. The controlled substance will be paid for, in whole or in part, by an insurer; or (3-21-12)

b. The patient is being treated at an institutional facility or is housed in a correctional facility.(4-4-13)

c. The filled prescription is delivered to the patient's residence either by mail, common carrier, or an employee of the pharmacy. (4-4-13)

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a pharmacy or prescriber drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: (3-21-12)

a. The recipient's name (if other than the patient); (3-21-12)

b. A notation indicating that the recipient was known to the staff member; and (3-21-12)

c. The identity of the staff member making the personal identification. (3-21-12)

03. Acceptable Identification. The identification presented must include an unaltered photograph and signature and acceptable forms include: (3-20-14)

a. A valid U.S. state or U.S. military driver's license or identification card; (3-20-14)

b. A Western Hemisphere Travel Initiative (WHTI) compliant document (i.e., Enhanced Driver's License (EDL) or Nexus Air Card); (3-20-14)

c. A valid passport; and (3-20-14)

d. A U.S. passport card (PASS Card). (3-20-14)

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and must include: (3-21-12)

a. A copy of the identification presented; or (3-21-12)

b. A record that includes: (3-21-12)

i. The recipient's name; (3-21-12)

ii. A notation of the type of identification presented; (3-21-12)

iii. The government entity that issued the identification; and (3-20-14)

iv. The unique identification number. (3-20-14)

201. CONTROLLED SUBSTANCES: SCHEDULE II EMERGENCY DISPENSING.
In an emergency situation, as defined, a pharmacist may dispense a Schedule II controlled substance in accordance with a verbal prescription drug order issued by a prescriber. (3-21-12)

01. Emergency Situation Defined. For purposes of this rule, an emergency situation is one in which the prescriber determines: (3-21-12)

a. That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; (3-21-12)

b. That no appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance; and (3-21-12)

c. That it is not reasonably possible for the prescriber to provide a written prescription drug order prior to the dispensing. (3-21-12)

02. Limited Quantity. The quantity prescribed and dispensed must be limited to the amount adequate to treat the patient during the emergency situation. (3-21-12)

03. Verbal Prescription Drug Order. The verbal prescription drug order must be immediately reduced to writing by the pharmacist and must include all required prescription drug order information except the signature of the prescriber. (3-21-12)

04. Paper Prescription Drug Order. Within seven (7) days after issuing an emergency verbal prescription drug order, the prescriber must provide a written prescription drug order for the emergency quantity prescribed. (3-21-12)

a. The prescription drug order must conform to the requirements for a written prescription drug order and also have written on its face "Authorization for Emergency Dispensing" and the date the verbal prescription drug order was issued. (3-21-12)

b. A paper prescription drug order may be delivered by mail if postmarked within the seven-day period. (3-21-12)

05. Verbal Order Attachment or Annotation. Either a paper prescription drug order must be attached to the documented emergency verbal prescription drug order or an electronic prescription drug order must be annotated by a pharmacist with the original authorization and date of the verbal order. (3-21-12)

06. Board Notification. The pharmacist must notify the Board if the prescriber fails to provide a written prescription drug order within the seven-day period. (3-21-12)

202. CONTROLLED SUBSTANCES: NON-PRESCRIPTION DISPENSING.
A Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted or restricted by these rules. (3-21-12)

01. Dispensing by a Technician Prohibited. Technicians are prohibited from dispensing a non-prescription controlled substance even if under the direct supervision of a pharmacist, but may transact the sale and deliver the product after the pharmacist has fulfilled his professional and legal responsibilities. (3-21-12)

02. Restricted Quantity. No more than four (4) ounces of liquid containing a maximum of two hundred (200) milligrams of codeine per one hundred (100) milliliters or per one hundred (100) grams may be distributed at retail to the same purchaser in any forty-eight (48) hour period. (3-20-14)

03. Purchaser's Age. A purchaser of a non-prescription controlled substance must be at least eighteen (18) years of age. (3-21-12)

04. Identification Required for Purchase. The pharmacist must obtain positive identification as required by these rules that, if appropriate, includes proof of age of the purchaser of a non-prescription Schedule V controlled substance. (3-21-12)

05. Bound Record Book and Patient Signature Required. A bound record book must be used to document sales of non-prescription Schedule V controlled substances and must record the following: (3-21-12)

a. The name and address of the purchaser; (3-21-12)

b. The name and quantity of the controlled substance purchased; (3-21-12)

c. The date of the purchase; (3-21-12)

d. The name or initials of the pharmacist who dispensed the substance to the purchaser; and (3-21-12)

e. The signature of the purchaser. (3-21-12)

203. CONTROLLED SUBSTANCES: PRESCRIBER RESTRICTIONS.
Prescribing, administering, dispensing, or delivering a controlled substance for oneself or, when contrary to the prescriber's scope of practice or prescriptive authority, to an immediate family member is prohibited. (3-21-12)

204. CONTROLLED SUBSTANCES: PMP.
Specified data on controlled substances must be reported weekly, or more often as required by the Board, by all pharmacies holding a DEA retail pharmacy registration that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. (4-4-13)

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

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

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

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

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

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

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

205. CONTROLLED SUBSTANCES: CURRENT, COMPLETE, AND ACCURATE RECORDS.
Each controlled substance registrant must maintain a current, complete, and accurate record of each substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed, or otherwise disposed of by the registrant, except that a registrant is not required by this rule to maintain a perpetual inventory. (3-21-12)

206. CONTROLLED SUBSTANCES: INVENTORIES.

01. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually no later than seven (7) days after the date of the prior year's inventory in a form and manner that satisfies the inventory requirements of federal law. (4-11-15)

02. Separate Inventories for Each Location. A separate controlled substances inventory must be taken and retained at each registered location. (3-21-12)

03. Inventory on PIC or Director Change. A complete controlled substance inventory must be conducted in the event of a change of PIC or director on or by the first day of employment of the incoming PIC or director. (4-4-13)

04. Inventory After Discovery of Theft or Loss. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. (3-21-12)

05. 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. (3-21-12)

06. Annual Inventory Compliance. Complete inventories otherwise conducted may also be considered in complying with the annual inventory requirement. (4-11-15)

207. CONTROLLED SUBSTANCES: INVENTORIES AND RECORDS MAINTENANCE.
Each controlled substance registrant must maintain inventories and records of controlled substances as follows: (3-21-12)

01. Inventories and Records for Schedules I and II. Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other records of the registrant. (3-21-12)

02. Inventories and Records for Schedules III, IV, and V. Inventories and records of controlled substances listed in Schedules III, IV, and V must be maintained separately from all other records or in a manner that the information required is readily retrievable. (3-21-12)

03. Controlled Substance Prescription Drug Orders. Each registered pharmacy must maintain prescription drug orders for controlled substances listed in Schedules II through V as follows: (3-21-12)

a. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file. (3-21-12)

b. 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. (3-21-12)

c. 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 filed. (3-21-12)

04. Central Records Storage. Financial and shipping records including invoices, but excluding controlled substance order forms and inventories, may be retained at a central location if the registrant has provided DEA notification of central recordkeeping as required by federal law. (3-21-12)

05. 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. (3-21-12)

208. CONTROLLED SUBSTANCES --THEFT OR LOSS REPORTING.
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. (3-21-12)

209. CONTROLLED SUBSTANCES: PRESCRIBER DISCIPLINE.
A prescriber who issues a prescription drug order for a controlled substance that does not comply with the requirements of Section 37-2725, Idaho Code, is subject to discipline by the Board as follows: (3-21-12)

01. Discipline of First Offense. A letter with a copy of the prescription drug order or orders issued in noncompliance with the law will be sent to the prescriber at the registered address. The letter will describe the offense and the basis for required action. A copy of the letter and its attachments will be sent to the prescriber's licensing board. The prescriber will have thirty (30) days from the date postmarked on the letter to comply with the requirements of Section 37-2725, Idaho Code. If the prescriber fails to comply within thirty (30) days, the prescriber's licensing board will be notified of the failure to comply and requested to initiate corrective or disciplinary action within thirty (30) days and to immediately notify the Board if action is taken. If not so notified, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

02. Discipline of Second Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended for a period of one (1) week and an administrative fine assessed equal to the prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension proceedings will be mailed to the prescriber at the registered address. To avoid the suspension action, the prescriber may submit to the Board a written explanation and plan of correction, including details of how the prescriber will avoid future offenses, and payment of one hundred dollars ($100) within thirty (30) days of the date postmarked on the notice. If the prescriber fails to comply with the requirements of this rule and Section 37-2725, Idaho Code, within thirty (30) days, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

03. Discipline of Third Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended for a period of thirty (30) days and an administrative fine assessed equal to the prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension proceedings will be mailed to the prescriber at the registered address. To avoid the suspension action, the prescriber may submit to the Board a written explanation and plan of correction, including details of how the prescriber will avoid future offenses, and a payment of five hundred dollars ($500) within thirty (30) days of the date postmarked on the notice. If the prescriber fails to comply with the requirements of this rule and Section 37-2725, Idaho Code, within thirty (30) days, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

04. Discipline of Fourth Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended or revoked, as the Board may determine based on the circumstances, and an administrative fine assessed equal to the prosecution and administrative costs of bringing the suspension or revocation action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension or revocation proceedings will be mailed to the prescriber at the registered address. (3-21-12)

05. Cumulative Discipline. Offenses subject to discipline under this rule will accumulate for each subsequent offense that occurs within six (6) months of the date the prescriber is sent notice of the prior offense. An offense occurring more than six (6) months after the date the prescriber receives notice of any immediately prior offense will be deemed a first offense. (3-21-12)

06. Separate Offense. Prescribing or dispensing controlled substances by a prescriber whose registration has been suspended or revoked pursuant to this rule will be deemed a separate offense. (3-21-12)

210. CONTROLLED SUBSTANCE STORAGE.
Controlled substances must be stored as follows: (3-24-16)

01. Schedule I. Controlled substances listed in Schedule I must be stored in a securely locked, substantially constructed cabinet. (3-24-16)

02. Schedules II, III, IV and, V. Controlled substances listed in Schedules II, III, IV, and V must be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances, in whole or in part, throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. (3-24-16)

211. -- 219. (RESERVED)

220. EPHEDRINE PRESCRIPTION DRUG PRODUCTS.

01. Designated Prescription Drugs. The Board includes preparations containing ephedrine or salts of ephedrine as designated prescription drugs. (3-21-12)

02. Qualified Product Exemption. A qualified product that meets the following criteria is exempt from designation as a prescription drug: (3-21-12)

a. A product containing a formula with a ratio of twelve and one-half (12.5) milligrams ephedrine to two hundred (200) milligrams guaifenesin or twenty-five (25) milligrams ephedrine to four hundred (400) milligrams guaifenesin, not exceeding a maximum of twenty-five (25) milligrams of ephedrine per tablet, capsule, or dose, and in addition to the formula, may include only inert or inactive ingredients or substance; and (3-21-12)

b. A hemorrhoidal ointment containing not more than two tenths percent (0.2%) ephedrine sulfate and suppositories not exceeding four (4) milligrams ephedrine sulfate per suppository. (3-21-12)

03. Disqualified Product Exemption. An ephedrine-containing product that is an immediate precursor to amphetamine or methamphetamine and considered a Schedule II controlled substance pursuant to Section 37-2707(g), Idaho Code, is disqualified from the prescription drug exemption provided by this rule even if otherwise qualified. (3-21-12)

221. -- 229. (RESERVED)

230. INVESTIGATIONAL DRUGS.
Investigational drugs must be properly labeled and administered only under the supervision of a principal physician-investigator or an authorized clinician. (3-21-12)

231. -- 238. (RESERVED)

239. COMPOUNDING DRUG PRODUCTS.
Any compounding that is not permitted herein is considered manufacturing. (4-11-15)

01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: (4-11-15)

a. Compound positron emission tomography drugs; (4-11-15)

b. Radiopharmaceutics; (4-11-15)

c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; (3-25-16)

d. The addition of a flavoring agent to a drug product; and (3-25-16)

e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. (3-25-16)

02. General Compounding Standards. (4-11-15)

a. Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. (4-11-15)

b. Certificate of Analysis. Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a CO must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is required on the COA: (4-11-15)

i. Product name; (4-11-15)

ii. Lot number; (4-11-15)

iii. Expiration date; and (4-11-15)

iv. Assay. (4-11-15)

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (4-11-15)

d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction. (4-11-15)

03. Prohibited Compounding. Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited. (4-11-15)

04. Limited Compounding. (4-11-15)

a. Triad Relationship. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order. (4-11-15)

b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if: (4-11-15)

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (4-11-15)

ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (4-11-15)

c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product. (4-11-15)

05. Drug Compounding Controls. (4-11-15)

a. Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the

USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: (4-11-15)

i. Appropriate packaging, handling, transport, and storage requirements; (4-11-15)

ii. Accuracy and precision of calculations, measurements, and weighing; (4-11-15)

iii. Determining ingredient identity, quality, and purity; (4-11-15)

iv. Labeling accuracy and completeness; (4-11-15)

v. Beyond use dating; (4-11-15)

vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (4-11-15)

vii. Maintaining environmental quality control; and (4-11-15)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (4-11-15)

b. Accuracy. Components including, but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate. The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label. (4-11-15)

c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: (4-11-15)

i. Production date; (4-11-15)

ii. Beyond use date; (4-11-15)

iii. List and quantity of each ingredient; (4-11-15)

iv. Internal control or serial number; and (4-11-15)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (4-11-15)

240. STERILE PRODUCT PREPARATION.

01. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products, these rules apply to all persons, including any business entity, engaged in the practice of sterile compounding and sterile prepackaging in or into Idaho. (4-11-15)

02. Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug product must be sterilized when prepared in the following dosage forms: (4-11-15)

a. Aqueous bronchial and nasal inhalations, except sprays intended to treat bronchial mucosa only; (4-11-15)

b. Baths and soaks for live organs and tissues; (4-11-15)

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (4-11-15)

c. Irrigations for wounds and body cavities; (4-11-15)

d. Ophthalmic drops and ointments; and (4-11-15)

e. Tissue implants. (4-11-15)

03. Compounder Responsibilities. Compounders and sterile prepackagers are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter; (4-11-15)

a. Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows; (4-11-15)

i. Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile products shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; (4-11-15)

ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (4-11-15)

iii. Opened single-dose ampules shall not be stored for any time period; and (4-11-15)

iv. Multiple-dose containers (for example, vials) that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer; (4-11-15)

b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial endotoxins; (4-11-15)

c. Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared. (4-11-15)

04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. (3-21-12)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated. (4-11-15)

b. Filters must be inspected and replaced in accordance with the manufacturer's recommendations. (4-11-15)

05. Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following: (3-21-12)

a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC or director can provide aseptic isolator manufacturer's written documentation that any component of

garbing is not required; (4-11-15)

b. A sink with hot and cold water in close proximity to the hood; (3-21-12)

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; and (4-11-15)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet. (4-11-15)

06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: (3-21-12)

a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (4-11-15)

b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (4-11-15)

c. Audits appropriate for the risk of contamination for the particular sterile product including: (4-11-15)

i. Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing; (4-11-15)

ii. Periodic hand hygiene and garbing competency; (4-11-15)

iii. Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager; (4-11-15)

iv. Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including: (4-11-15)

(1) Total particle counts; (4-11-15)

(2) Viable air sampling; (4-11-15)

(3) Gloved fingertip sampling; (4-11-15)

(4) Surface sampling; (4-11-15)

v. Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, etc.) before dispensing or distributing; (4-11-15)

d. Temperature, logged daily; (4-11-15)

e. Beyond use date and accuracy testing, when appropriate; and (4-11-15)

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (4-11-15)

07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including: (4-11-15)

a. Antiseptic hand cleansing; (4-11-15)

b. Disinfection of non-sterile compounding surfaces; (4-11-15)

c. Selecting and appropriately donning protective garb; (4-11-15)

d. Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients; (4-11-15)

e. Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; (4-11-15)

f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product; and (4-11-15)

g. Inspecting for quality standards before dispensing or distributing. (4-11-15)

241. HAZARDOUS DRUGS PREPARATION.
In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products and Sterile Product Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: (4-11-15)

01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. (4-11-15)

02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. (4-11-15)

a. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; (4-11-15)

b. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. (4-11-15)

c. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: (4-11-15)

i. The hazardous drugs in use will not volatilize while they are being handled; or (4-11-15)

ii. The PIC or Director can provide manufacturer written documentation attesting to the safety of such ventilation. (4-11-15)

03. Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs. (4-11-15)

04. Labeling. Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills. (4-11-15)

05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. (4-11-15)

06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit does or unit-of-use packaging. (4-11-15)

07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste. (4-11-15)

08. **Training**. Ensure that personnel working with hazardous drugs are trained in: (4-11-15)

a. Hygiene; (4-11-15)

b. Garbing; (4-11-15)

c. Receipt; (4-11-15)

d. Storage; (4-11-15)

e. Handling; (4-11-15)

f. Transporting; (4-11-15)

g. Compounding; (4-11-15)

h. Spill control; (4-11-15)

i. Clean up; (4-11-15)

j. Disposal; (4-11-15)

k. Dispensing; (4-11-15)

l. Medical surveillance; and (4-11-15)

m. Environmental quality and control. (4-11-15)

09. **Policy and Procedures Manual**. Maintain a policy and procedures manual to ensure compliance with this rule. (4-11-15)

242. -- 259. (RESERVED)

260. DRUG PRODUCT STORAGE.
Drugs must be stored in accordance with USP-NF requirements in an area maintained and secured appropriately to safeguard product integrity and protect against product theft or diversion. (4-4-13)

261. EXPIRED, ADULTERATED, DAMAGED, OR CONTAMINATED DRUGS.

01. **Removal and Isolation of Damaged Drugs Required**. Expired, deteriorated, adulterated, damaged, or contaminated drugs must be removed from stock and isolated for return, reclamation, or destruction. (3-21-12)

02. **Sale or Distribution of Damaged Drugs Prohibited**. Dispensing, delivering, or placing in saleable stock damaged or contaminated drugs is prohibited without first obtaining written Board approval. (3-21-12)

03. **Adulterated Drug Reporting Required**. A licensee or registrant must report to the Board any adulteration of a prescription drug. (3-21-12)

262. RESTRICTED RETURN OF DRUGS OR DEVICES.
Once removed from the premises from which it was dispensed, a drug or prescription device must only be accepted for return under the conditions permitted by this rule or pursuant to the Legend Drug Donation Act and rules. (3-21-12)

01. **Qualifying Returns**. Unless dispensed in any manner inconsistent with the prescriber's instructions and returned for quarantine for destruction purposes only, a drug or prescription device that has been

received from or delivered to the patient or the patient's representative is ineligible for return. Drugs or devices that may qualify for return include: (3-21-12)

a. Those intended for inpatients of an institutional facility that have been maintained in the custody and control of the institutional facility or dispensing pharmacy; and (3-21-12)

b. That are liquid or in unit dose or unit-of-use packaging and, if a controlled substance, returned from a hospital daily delivery system; and (3-21-12)

c. Those for which the following conditions are satisfied: (3-21-12)

i. The drug was delivered by the dispensing pharmacy directly to the institutional facility or its authorized agent and subsequently stored in a suitable drug storage area that is inaccessible to patients; (3-21-12)

ii. The drug is returned in an unopened manufacturer-sealed container or with other tamper-evident packaging intact; (3-21-12)

iii. In the professional judgment of the pharmacist, the safety and efficacy of the drug has not been compromised; and (3-21-12)

iv. A system is in place to track the restocked drug for purposes of a recall. (3-21-12)

02. Marking Ineligible Returns. Drugs or devices otherwise eligible for return that are or will become ineligible for any reason must be clearly marked "Not Eligible for Return" prior to leaving the institutional facility or upon discovery and before storing in an area with other eligible returns. (3-21-12)

03. Consulting Pharmacy and PIC Responsibilities. The pharmacy and its PIC are responsible for: (4-4-13)

a. Consulting with an institutional facility from which returns will be accepted; (4-4-13)

b. Ensuring that the institutional facility has an employee trained and knowledgeable in the proper storage, use, and administration of drugs and devices; (4-4-13)

c. Reviewing, approving, and enforcing written protocols that will ensure compliance with the conditions necessary to allow returns; and (4-4-13)

d. Storing a copy of the protocols, as well as the written approval thereof, in an immediately retrievable fashion. (4-4-13)

263. CONTROLLED SUBSTANCE DISPOSAL.
A controlled substance registrant must dispose of expired, excess, or unwanted controlled substances through the services of a DEA-registered reverse distributor or by another method permitted by federal law. (3-21-12)

264. (RESERVED)

265. LEGEND DRUG DONATION -- STANDARDS AND PROCEDURES.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

04. Verification of Received Drugs. (3-21-12)

a. Each donated drug must be verified against the donation manifest by an individual authorized to

receive the drugs. (3-21-12)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

07. Miscellaneous. (3-21-12)

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

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

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

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

266. -- 289. (RESERVED)

290. ADS SYSTEMS: MINIMUM STANDARDS.
This rule establishes the minimum standards for the use of an ADS system to dispense and store drugs and devices. (3-21-12)

01. System Registration and Approved Utilization Locations. One or more ADS systems may be utilized by the following drug outlets if registered as required by the Board: (3-21-12)

a. In a pharmacy, remote dispensing site, or other ambulatory healthcare setting where utilization of the ADS system is under the adequate personal or electronic supervision of a pharmacist, as defined by these rules; (3-21-12)

b. In a prescriber drug outlet; and (3-21-12)

c. In an institutional facility. (3-21-12)

02. Multiple System Documentation. At least the following documentation must be maintained for each ADS system by the supervising pharmacy or prescriber drug outlet utilizing multiple ADS systems: (3-21-12)

a. The manufacturer's name and model of the ADS system; (3-21-12)

b. The state and, if applicable, federal ADS system registrations; and (3-21-12)

c. The name, address, and specific location where the ADS system is operational. (3-21-12)

03. System Access, Monitoring, and Control. Access to the ADS system must be monitored and controlled as follows: (3-21-12)

a. Proper identification controls, including electronic passwords or other coded identification, must be utilized and access control must be limited and authorized by the prescriber, PIC, director or their authorized designee; (4-4-13)

b. The prescriber, PIC, or director must be able to stop or change access at any time; (3-21-12)

c. The prescriber, PIC, or director must maintain a current and immediately retrievable list of persons who have access and the limits of that access; (3-21-12)

d. Review of user access reports must be conducted periodically to ensure that access by persons no longer employed has been appropriately disabled; and (3-21-12)

e. Access for maintenance or repair must be pre-approved by the prescriber, PIC, or director and must

be performed under the continuous supervision of a person with appropriate access authorization. (3-21-12)

04. System Security and Patient Confidentiality. The ADS system must have adequate system security and safeguards to prevent and detect unauthorized access or use, maintain the integrity of patient records and prescription drug orders, and protect patient privacy. (3-21-12)

05. System Filling, Stocking, Replenishing. The filling, stocking, or replenishing of drugs into the ADS system must be accomplished by a pharmacist, technician, prescriber, nurse or authorized prescriber drug outlet personnel. Timely pharmacist or prescriber verification of the accuracy of the filling, stocking, or replenishing of the ADS system must occur through a manual process, bar coding, or other electronic technology used for item identification. (4-4-13)

06. Stocked Drug Documentation. The ADS system must be able to generate a record on demand of drugs filled into the system that includes at least: (3-21-12)

a. The date; (3-21-12)

b. The drug name; (3-21-12)

c. The dosage form; (3-21-12)

d. The strength; (3-21-12)

e. The quantity; (3-21-12)

f. The drug expiration; (3-21-12)

g. The identity of the ADS system; and (3-21-12)

h. The name or initials of the authorized individual filling the ADS system and, if applicable, the verifying pharmacist or prescriber. (3-21-12)

07. System Access and Transaction Documentation. The ADS system must automatically document transactions and other events involving access to system contents that is immediately retrievable in written or electronic form and includes at least the following: (3-21-12)

a. The identity of the system and, if applicable, the component accessed; (3-21-12)

b. The name or other identification (e.g., electronic signature or unique identifier) of the person conducting the transaction; (3-21-12)

c. The type of transaction; (3-21-12)

d. The date and time of transaction; (3-21-12)

e. The name, strength, dosage form, and quantity of the drug or description of the medical device accessed; and (3-21-12)

f. If applicable, the name of the patient for whom the drug was ordered. (3-21-12)

08. ADS System Used for Tablets or Capsules. The lot number of each drug contained in an ADS system used to store in bulk and to count tablets or capsules for dispensing must be retained in an immediately retrievable manner or posted on the device. (3-21-12)

09. Prepackaged Bulk Drug Cartridges or Containers. If the ADS system uses removable cartridges or containers to hold bulk drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by an FDA-approved repackager that is licensed as a wholesaler.

The prepackaged cartridges or containers may be sent to a remote dispensing site to be loaded into the ADS system by a pharmacist or a technician if: (3-21-12)

a. A pharmacist has verified the proper filling and labeling of the cartridge or container; (3-21-12)

b. The individual cartridges or containers are transported to the ADS system in a secure, tamper-evident container; and (3-21-12)

c. The ADS system utilizes technologies to ensure that the cartridges or containers are accurately loaded. (3-21-12)

10. Temperature Sensitive Drugs. Products that are temperature sensitive must not be provided unless the system is able to maintain required storage conditions. (4-4-13)

291. ADS SYSTEMS: SELF-SERVICE SYSTEMS.
The use of self-service ADS systems must comply with the ADS system minimum standards and the requirements of this rule. (4-4-13)

01. System Requirements. (4-4-13)

a. The system must only be operational: (4-4-13)

i. During the operating hours of the pharmacy, or prescriber drug outlet respectively; or (4-4-13)

ii. In a hospital's emergency room if no pharmacist is on duty in the community. (4-4-13)

b. The system must be substantially constructed, utilize adequate security, and be: (4-4-13)

i. Physically attached or immediately adjacent to the interior of the pharmacy in a manner that access to areas used to stock the device are only accessible through the pharmacy; or (4-4-13)

ii. Located within the hospital's emergency room or prescriber drug outlet. (4-4-13)

02. Dispensing Restrictions. (4-4-13)

a. Products requiring additional preparation for patient use must be dispensed by the system directly to a prescriber or registered nurse for subsequent preparation and not dispensed directly to the patient. (4-4-13)

b. A pharmacy system may only dispense drugs or devices that have been previously dispensed to the patient. (4-4-13)

c. Controlled substances are prohibited in a pharmacy or prescriber drug outlet system. (4-4-13)

d. Drugs must be prepackaged for use in hospital emergency room systems and no more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (4-4-13)

e. Hospital emergency room systems must only dispense to hospital emergency room patients. (4-4-13)

f. Hospital emergency room systems vouchers or their equivalent must expire within twenty-four (24) hours. (4-4-13)

03. Counseling. (4-4-13)

a. When dispensed via a system in a prescriber drug outlet or a hospital's emergency room, a patient

must receive counseling prior to receiving drugs or devices that have not been previously dispensed to the patient. (4-4-13)

b. Refilled or renewed drugs dispensed via a system must include written notification of how counseling may be obtained. (4-4-13)

04. Packaging and Labeling. Drugs dispensed via a system must be compliant with the standard prescription drug labeling rule, the prescription drug packaging rule, and other pertinent rules. (4-4-13)

292. ADS SYSTEMS: INSTITUTIONAL FACILITIES.
Institutional facilities utilizing one or more ADS systems must ensure compliance with the ADS system minimum standards and the requirements of this rule. (4-4-13)

01. Product Packaging and Labeling. Except as provided herein, drugs stored in the ADS system must be contained in the manufacturers' sealed, original packages or in prepackaged unit-of-use containers (e.g., unit dose tablet/capsule, tube of ointment, inhaler, etc.) and must be labeled as required by these rules. Exceptions to these packaging requirements include: (3-21-12)

a. Injectable drugs stored in a multi-dose vial (e.g., heparin) from which the drug may be withdrawn into a syringe or other delivery device for single patient use; or (3-21-12)

b. OTC products stored in a manufacturers' sealed, multi-dose container (e.g., antacids, analgesics) from which the drug may be withdrawn and placed into an appropriate container for single patient use. (3-21-12)

02. Pharmacist Review. A pharmacist must review the drug order prior to any removal from the system of a drug intended for immediate patient administration except if: (3-21-12)

a. The system is being used as an after-hours cabinet for drug dispensing in the absence of a pharmacist; (3-21-12)

b. The system is being used in place of an emergency kit; (3-21-12)

c. The system is being used to provide access to emergency drugs and only a quantity sufficient is removed to meet the immediate need of the patient; (3-21-12)

d. The drug is a subsequent dose from a previously reviewed drug order; or (4-4-13)

e. The prescriber controls the drug administration process in procedural areas. (4-4-13)

03. Drug Returns. The ADS system, except a self-service system used in a hospital's emergency room, must provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system. A drug removed from a system but not administered to a patient may be returned as follows if unopened, sealed, intact and stored in compliance with the drug product storage rule to: (4-4-13)

a. The pharmacy, immediately; (4-4-13)

b. The ADS system for immediate reuse by authorized personnel in hospitals utilizing bar code scanning technology at the bedside or the ADS system; (4-4-13)

c. The ADS return bin, until: (4-4-13)

i. Returned to the pharmacy; or (4-4-13)

ii. Returned to the ADS system; or (4-4-13)

d. An alternative, secure storage area until return to the pharmacy or the ADS is feasible only if the drug: (4-4-13)

i. Is too large or bulky to be inserted into the system's return bin; (4-4-13)

ii. Requires refrigeration; or (4-4-13)

iii. Requires immediate accessibility for limited critical patient care. (4-4-13)

04. Wasted Controlled Substances. If wasted before completing the transaction, the system must provide a mechanism for accounting for wasted controlled substances. Waste documentation must include at least the following: (4-4-13)

a. Date and time of transaction; (3-21-12)

b. Patient name and location; (3-21-12)

c. Drug and dose; (3-21-12)

d. Wasted amount; (3-21-12)

e. Authorized user identification; and (4-4-13)

f. Witness identification. (4-4-13)

05. Supervising Pharmacy Identification. If used in a nursing home, the ADS system must be clearly marked with the name, address, and phone number of the supervising pharmacy and pharmacist-in-charge. (3-21-12)

293. VENDING MACHINES.
Only non-prescription medical supplies and drugs that are unrestricted for over-the-counter sale may be stored and sold in vending machines which are subject to inspection by the Board upon reasonable notice. (4-4-13)

294. -- 299. (RESERVED)

Subchapter D -- Professional Practice Standards
(Rules 300 through 599 -- Professional Practice Standards)

300. PIC: QUALIFICATIONS.
A pharmacist may neither be designated nor function as the PIC of a pharmacy unless the designee spends a substantial part of the designee's working time each month at the pharmacy in which designated as the PIC. (3-21-12)

301. PIC: RESPONSIBILITIES.
The PIC is responsible for the management, and must maintain full and complete control, of every part of the pharmacy and its regulated operations. (3-21-12)

302. PIC: REPORTING REQUIREMENTS.

01. PIC Change. Both an outgoing and incoming PIC must report to the Board a change in a PIC designation within ten (10) days of the change. (3-21-12)

02. Annual Personnel Report. Coinciding with the annual renewal of the drug outlet registration, the PIC must annually report on the renewal application the names of the designated PIC, each employee pharmacist and technician, and each student pharmacist currently training in the pharmacy. (3-21-12)

03. Employment Changes. Changes in employment of pharmacists, technicians, or student pharmacists must be reported to the Board by the PIC within ten (10) days of the change. (3-21-12)

303. PHARMACIST: ASSIGNMENT OF FUNCTIONS.

01. Assignment to Licensed or Registered Persons Only. A pharmacist must neither delegate to, nor permit performance by, a person other than a pharmacist, student pharmacist, or technician any function related to pharmacy operations. (3-21-12)

02. Assignment of Functions to a Technician. A pharmacist may assign to and allow performance by a technician only those functions performed in pharmacy operations that meet the following criteria: (3-21-12)

a. The function is routine; (3-21-12)

b. The function is one for which the technician is adequately trained; (3-21-12)

c. The function is performed under a pharmacist's supervision; and (3-21-12)

d. The function does not require the use of a pharmacist's professional judgment. (3-21-12)

03. Pharmacist Supervision. If a student pharmacist or a technician performs one (1) or more functions in connection with pharmacy operations, the student pharmacist or technician must be under the supervision of a pharmacist who, in addition to the pharmacy and the PIC, is responsible for every element of the filled prescription. (3-21-12)

304. -- 309. (RESERVED)

310. COLLABORATIVE PHARMACY PRACTICE AND STATEWIDE PROTOCOL AGREEMENTS.

01. Collaborative Agreement. Pharmacists or pharmacies and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. (3-25-16)

a. Agreement Elements. The collaborative pharmacy practice agreement must include: (3-21-12)

i. Identification of the parties to the agreement; (3-21-12)

ii. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; (3-21-12)

iii. The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; (3-21-12)

iv. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; (3-21-12)

v. A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; (3-21-12)

vi. A provision allowing any party to cancel the agreement by written notification; (3-21-12)

vii. An effective date; and (3-21-12)

viii. Signatures of the parties to the agreement and dates of signing. (3-21-12)

ix. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (3-21-12)

b. Board Review. The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. (3-21-12)

c. Agreement Review. The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. (3-21-12)

d. Documentation of Pharmacist Activities. The patient care provided pursuant to the agreement must be documented in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. (3-25-16)

02. Statewide Protocol Agreement. A pharmacist may perform DTM or other patient care services according to a statewide protocol agreement issued by the director of the Idaho Department of Health and Welfare, in conjunction with the Board, for the purpose of improving public health. The protocol agreement must include: (3-25-16)

a. An effective date range; (3-25-16)

b. The geographical portion of the state where the protocol agreement is to be effective; and(3-25-16)

c. The drug name, class, or category and protocol, formulary or clinical guidelines that describe or limit a pharmacist's authority to perform DTM or other patient care services. (3-25-16)

311. -- 319. (RESERVED)

320. PHARMACIST: INDEPENDENT PRACTICE.
An Idaho-licensed pharmacist may provide pharmaceutical care services and MTM outside of a drug outlet or institutional facility, including into Idaho, if the following conditions are met, however nothing herein shall be construed to excuse compliance with the rules governing centralized pharmacy services when applicable: (7-1-13)

01. Access to Relevant Information. The pharmacist has access to prescription drug order records, patient profiles, or other relevant medical information and appropriately reviews the information; (3-21-12)

02. Information Protected from Unauthorized Use. Access to the information required by these rules is protected from unauthorized access and use; and (3-21-12)

03. Records Maintained in Electronic Recordkeeping System. The pharmacist maintains the records or other patient-specific information created, collected, or used in an electronic recordkeeping system that complies with the requirements of these rules. (3-21-12)

321. -- 329. (RESERVED)

330. PHARMACIST: ADMINISTERED IMMUNIZATIONS.

01. Patient Eligibility. A pharmacist may administer an immunization to a healthy patient without immunization contraindications pursuant to the latest recommendations by the CDC or other qualified government authority or to any patient pursuant to a prescription drug order issued by another prescriber. (3-21-12)

02. Pharmacist Qualifications. To qualify to administer immunizations, a pharmacist must first: (3-21-12)

a. Successfully complete an ACPE-accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the CDC's Advisory Committee on Immunization Practices and includes at least the following: (3-21-12)

i. Basic immunology, vaccine, and immunization protection; (3-21-12)

ii. Diseases that may be prevented by vaccination or immunization; (3-21-12)

iii. Current recommended immunization schedules; (3-21-12)

iv. Vaccine and immunization storage and management; (3-21-12)

v. Informed consent; (3-21-12)

vi. Physiology and techniques for administration of immunizations; (3-21-12)

vii. Pre-immunization and post-immunization assessment and counseling; (3-21-12)

viii. Immunization reporting and records management; and (3-21-12)

ix. Identification response, documentation, and reporting of adverse events. (3-21-12)

b. Hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program that includes cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training and requires a hands-on skills assessment by an authorized instructor. (3-21-12)

03. Maintaining Qualification. To maintain qualification to administer immunizations, a pharmacist must annually complete a minimum of one (1) CPE hour of ACPE-approved CPE related to vaccines, immunizations, or their administration, which may also be applied to the general CPE requirements of these rules. (4-4-13)

04. Student Pharmacist Administration. A pharmacist may not delegate authority to administer immunizations; however, a student pharmacist who has satisfied the qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. (3-21-12)

05. Waste Disposal. An immunizing pharmacist must properly dispose of used or contaminated supplies. (3-21-12)

06. Required Reports. An immunizing pharmacist must report: (3-21-12)

a. Adverse events to the healthcare provider identified by the patient, if any, and to the Vaccine Adverse Event Reporting System (VAERS); and (3-21-12)

b. Administration of immunizations to the Idaho Immunization Reminder Information System (IRIS), as required. (3-21-12)

07. Required Resources. A pharmacist must have a current copy of, or on-site access to, the CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases. (3-21-12)

08. Vaccine Information Statements. A corresponding, current CDC-issued VIS must be provided to the patient or the patient's representative for each administered immunization. (3-21-12)

09. Recordkeeping. For each administered immunization, the following information must be collected and maintained in the patient profile: (3-21-12)

a. The patient's name, address, date of birth, and known allergies; (3-21-12)

b. The date of administration; (3-21-12)

c. The product name, manufacturer, dose, lot number, and expiration date of the vaccine; (3-21-12)

d. Documentation identifying the VIS provided; (3-21-12)

e. The site and route of administration and, if applicable, the dose in a series (e.g. one (1) of three (3)); (3-21-12)

f. The name of the patient's healthcare provider, if any; (3-21-12)

g. The name of the immunizing pharmacist and of the student pharmacist, if any; (3-21-12)

h. Adverse events observed or reported, if any, and documentation including at least the dates of any subsequent required reporting; and (3-21-12)

i. Completed informed consent forms. (3-21-12)

10. Emergencies. (3-21-12)

a. An immunizing pharmacist must maintain an immediately retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. At a minimum, the kit must include: (4-11-15)

i. Intramuscular diphenhydramine; (4-11-15)

ii. Oral diphenhydramine; (4-11-15)

iii. Appropriate needles and syringes for injection; (4-11-15)

iv. Alcohol; and (4-11-15)

v. At least one (1) of the following: (4-11-15)

(1) Auto-inject epinephrine; (4-11-15)

(2) A vial of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14); or (4-11-15)

(3) An ampule of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14) and filter needles. (4-11-15)

b. An immunizing pharmacist may initiate and administer epinephrine, intramuscular diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association. (4-11-15)

331. -- 339. (RESERVED)

340. NONRESIDENT PHARMACIST PRACTICE STANDARDS.
An Idaho licensed or registered nonresident pharmacist practicing pharmacy into Idaho must comply with the Board's rules and laws of this state unless compliance would violate the laws or rules in the state in which the registrant is located, except as follows: (4-11-15)

01. Pharmacy Technician. A pharmacist must not allow a technician to exceed the practice limitations for a technician in Idaho. (4-11-15)

02. Drug Product Substitution. A pharmacist must only substitute drug products in accordance with Idaho law. (4-11-15)

03. Drug Product Selection. A pharmacist must only select drug products in accordance with Idaho law. (4-11-15)

04. Staffing Ratio. A pharmacist must not exceed the pharmacy staffing ratio, as defined in rule. (4-11-15)

341. -- 359. (RESERVED)

360. STUDENT PHARMACIST: UTILIZATION AND PRACTICE LIMITATIONS.

01. **Activities**. A student pharmacist may engage in the practice activities of a pharmacist if: (3-21-12)

a. The activity is not specifically required to be performed only by a pharmacist; (3-21-12)

b. The activity is commensurate with the education and skill of the student pharmacist and performed under the supervision of a pharmacist; (3-21-12)

c. Any activity of a compounding, dispensing, or interpretive nature is checked by a pharmacist; and (3-21-12)

d. Any recording activity that requires the initial or signature of a pharmacist is countersigned by a pharmacist. (3-21-12)

02. **Unlawful Acceptance of Assignment**. A student pharmacist must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the student pharmacist is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

03. **Identification of Student Pharmacists**. (3-21-12)

a. Each student pharmacist must be identified by a clearly visible name badge designating the individual as a student pharmacist. The name badge must contain the individual's printed first name and the title of student pharmacist, pharmacist intern, pharmacist extern, or another title that conveys the same meaning. (3-21-12)

b. Student pharmacists must identify themselves as a student pharmacist, pharmacist intern, or pharmacist extern on any phone calls initiated or received while on duty. (3-21-12)

361. -- 399. (RESERVED)

400. TECHNICIAN -- UTILIZATION AND PRACTICE LIMITATIONS.

01. **Unlawful Acceptance of Assignment**. A technician must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the technician is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

02. **Unlawful Performance**. A technician must not perform tasks or functions connected with pharmacy operations that: (3-21-12)

a. Are not routine; (3-21-12)

b. The technician is not adequately trained to perform; (3-21-12)

c. The technician has inadequate pharmacist supervision to perform; or (3-21-12)

d. Requires the use of a pharmacist's professional judgment. (3-21-12)

03. **Prohibited Tasks or Functions by a Technician**. A technician must not do any of the following which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a pharmacist's professional judgment: (3-21-12)

a. Receive a new verbal prescription drug order from a prescriber or other person authorized by law and, either manually or electronically, reduce the order to writing; (3-21-12)

b. Consult with the prescriber prior to filling if clarification of information is needed regarding a patient or the prescription drug order; (3-21-12)

c. Perform prospective drug review or interpret clinical data in a patient's medication record (e.g.,

contraindications, drug interactions, etc.); (3-21-12)

d. Perform professional consultation with a prescriber, nurse, or other healthcare professional; (3-21-12)

e. Supervise the packaging of drugs and check the completed procedure and product, unless checked in compliance with the verification technician procedures allowed in institutional facilities; (3-21-12)

f. Provide patient consultation on a new or refilled prescription or on over-the-counter drugs or supplements; and (3-21-12)

g. Supervise the pharmacy operations activities of student pharmacists and technicians. (3-21-12)

04. Technician Identification. (3-21-12)

a. Each technician must be identified by a clearly visible name badge designating the individual as a technician. The name badge must contain the individual's printed first name and the title of technician. (3-21-12)

b. Technicians must identify themselves as a technician on any phone calls initiated or received while on duty. (3-21-12)

401. -- 409. (RESERVED)

410. VERIFICATION TECHNICIAN PROGRAM.
Only **i**nstitutional pharmacies located within acute care hospitals may utilize a verification technician program. A verification technician program allows qualified technicians to verify the work of other technicians in the filling of floor and ward stock and unit dose distribution systems for patients whose orders have previously been reviewed and approved by a pharmacist. (3-21-12)

01. Written Program Filing. Prior to initiating a verification technician program, an institutional pharmacy must prepare a written program description that includes at least the following: (3-21-12)

a. The name of the pharmacist assigned as the coordinator of the verification technician program; (3-21-12)

b. A description of the duties of the coordinator sufficient to ensure and demonstrate compliance by the institutional pharmacy with these verification technician program rules; (3-21-12)

c. A description of the duties of technicians designated to perform the functions of verifying the work of other technicians; (3-21-12)

d. Identification of the types of drugs verification technicians are authorized to verify; (3-21-12)

e. A description of the specialized and advanced training that must be provided to each verification technician; and (3-21-12)

f. A description of the monitoring and evaluation processes used by the institutional pharmacy to ensure the ongoing competency of each verification technician. (3-21-12)

02. Program Requirements. Each institutional pharmacy utilizing a verification technician program must comply with the following requirements: (3-21-12)

a. A technician must neither be designated to perform, nor may the technician perform, verification functions without competently completing the required training. (3-21-12)

b. A verification technician may verify only manufacturer prepared or robotically prepared unit dose drugs identified in the written program description for floor or ward stock or unit dose distribution systems of

pharmacist reviewed and approved drug orders for hospital patients. If either the alteration of a unit dose or the combination of unit doses is required, a pharmacist must verify the resulting unit dose alteration or combination of unit doses. (3-21-12)

c. The institutional pharmacy must conduct ongoing monitoring and evaluation of each verification technician to ensure the ongoing competency of the technician. (3-21-12)

d. For each verification technician, an institutional pharmacy utilizing a verification technician program must maintain records containing: (3-21-12)

i. The date the technician was designated; (3-21-12)

ii. The date the technician completed the required training; (3-21-12)

iii. The dates and results of each competency evaluation; and (3-21-12)

iv. The dates of, and reasons for, any suspension or revocation of the technician's designation or other disciplinary action against the verification technician connected with the performance of the technician's duties in the verification technician program. (3-21-12)

e. While on duty, each verification technician must wear identification that includes the title, "Verification Technician." (3-21-12)

f. The duties of the verification technician program coordinator must include the supervision of verification technicians to ensure their duties are performed competently in a manner that protects patient safety. (3-21-12)

411. -- 499. (RESERVED)

500. UNPROFESSIONAL CONDUCT.
The following acts or practices by a pharmacist, student pharmacist, or technician are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (3-21-12)

01. Unethical Conduct. Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (3-21-12)

02. Lack of Fitness. A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (3-21-12)

03. On-Duty Intoxication or Impairment. Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (3-21-12)

04. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (3-21-12)

05. Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (3-21-12)

06. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. (4-4-13)

07. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (3-21-12)

08. Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (3-21-12)

09. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. The failure to retain appropriate documentation evidencing compliance with patient counseling requirements creates a rebuttable presumption of a violation of this rule. (3-21-12)

10. Substandard, Misbranded, or Adulterated Products. Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. (3-21-12)

11. Prescriber Incentives. Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (3-21-12)

12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (3-21-12)

13. Failure to Report. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (3-21-12)

14. Failure to Follow Board Order. Failure to follow an order of the Board. (3-21-12)

501. GROUNDS FOR DISCIPLINE.
The Board may refuse to issue or renew or may suspend, revoke, or restrict the registration of an individual on one (1) or more of the grounds provided in section 54-1726, Idaho Code. (3-21-12)

502. USE OF FALSE INFORMATION PROHIBITED.
Use of false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (3-21-12)

503. PRESCRIPTION DELIVERY RESTRICTIONS.
A pharmacist must not participate in any arrangement or agreement whereby filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not registered as a pharmacy except that a pharmacist or a pharmacy, by means of its agent, may deliver filled prescriptions to the patient, the patient's residence, the hospital or other institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed, or if a non-controlled substance, to the patient's licensed or registered healthcare provider. (4-4-13)

504. UNLAWFUL ADVERTISING.

01. Unlawful Advertising or Inducements. A licensee or registrant may not promote or induce, directly or indirectly, the provision of professional services or products through the dissemination of a public communication that contains a false, misleading, or deceptive statement or claim. (3-21-12)

02. Advertising Controlled Substances Prohibited. A person must not advertise to the public controlled substances, Schedules I through V, in any manner, and a pharmacy must not display these products to their patrons or members of the public. (3-21-12)

505. -- 599. (RESERVED)

Subchapter E -- Drug Outlet Practice Standards

(Rules 600 through 699 -- Drug Outlet Practice Standards)

600. PIC OR DIRECTOR.

01. Designated PIC or Director Required. A new pharmacy, outsourcing facility or central drug outlet must have a designated PIC or director by the date of opening and must not thereafter allow a vacancy or lapse in appointment of a designated PIC or director to continue for more than thirty (30) sequential days. (4-6-15)

02. Corresponding and Individual Responsibility. The pharmacy, outsourcing facility or central drug outlet and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI. (4-6-15)

601. PHARMACY SPACE AND FIXTURES.

01. Preparation Area Standards. A pharmacy must be well-lit, ventilated, temperature controlled, and have sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and sanitary condition appropriate for the safe preparation and compounding of prescriptions. (3-21-12)

02. Equipment and Fixture Standards. A pharmacy must be equipped with a sink with hot and cold water, appropriate fixtures for waste disposal, and refrigerated storage equipment of reasonable capacity. (3-21-12)

03. Additional Retail Pharmacy Requirements. A retail pharmacy that is new or remodeled after the effective date of this rule must: (3-21-12)

a. Provide and maintain a patient consultation area that affords the patient auditory and visual privacy, is accessible through an entrance and exit that does not require the patient to enter or traverse any part of the secured area of the pharmacy, and is compliant with the Americans with Disabilities Act; and (4-4-13)

b. Include a lavatory facility in the pharmacy restricted to pharmacy staff. (3-21-12)

602. PHARMACY TECHNICAL EQUIPMENT.

01. Technical Equipment. A pharmacy must have appropriate technical equipment to maintain the electronic recordkeeping requirements of these rules and any additional equipment and supplies required by its scope of practice to ensure public safety. (3-21-12)

02. PHI Transmission Equipment Location. A non-institutional pharmacy that uses a fax machine or other equipment to electronically send or receive PHI must locate and maintain the equipment within the secured pharmacy. (3-21-12)

03. Separate Telephone. Pharmacies remodeled or constructed after the effective date of this rule must have a separate and distinct telephone line from that of the business that must not be answerable by non-pharmacy personnel. If a pharmacy uses an automatic answering system, messages must not be retrieved or pharmacy services performed by non-pharmacy personnel. (4-4-13)

603. PHARMACY REFERENCES.
Required pharmacy references include the latest hard copy or electronic editions and supplements of the following: (3-21-12)

01. Pharmacy Laws and Rules. Idaho Pharmacy Laws and Rules. (3-21-12)

02. Current Pharmacy Reference. One (1) of the following current pharmacy references: (3-21-12)

a. Facts and Comparisons; (3-21-12)

b. Clinical Pharmacology; (3-21-12)

c. Micromedex; or (3-21-12)

d. Lexicomp. (3-21-12)

03. Additional Current Pharmacy Reference. One (1) additional current pharmacy reference relevant to the practice setting. (3-21-12)

604. PHARMACY PRODUCT STORAGE AND REMOVAL.
Prescription drugs, devices, and other products restricted to sale or dispensing by, or under the supervision of, a pharmacist must be stored in the pharmacy and must not be sold, delivered, or otherwise removed from a pharmacy unless a pharmacist is present, except: (3-20-14)

01. Emergency Drug Access and Pharmacist Absence. As allowed by these rules for emergency access to an institutional pharmacy; (3-20-14)

02. Institutional Facility Alternative Storage. In an institutional facility these restricted products may also be stored in an alternative designated area that is appropriately equipped to ensure compliance with drug product storage requirements, to provide adequate security and protection from diversion, and that otherwise complies with applicable requirements of these rules; (3-20-14)

03. Storage for Delivery. Filled prescriptions may be picked up for delivery from a pharmacy when the pharmacy is closed for business if: (3-20-14)

a. The prescriptions are placed in a secured delivery area equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion; (3-20-14)

b. The secured delivery area has walls that extend to the roof and solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner so that the hinge hardware is tamper-proof when closed; (4-11-15)

c. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements; (3-20-14)

d. The secured delivery area is attached or located adjacent to the pharmacy that filled the prescriptions; (3-20-14)

e. The PIC, or a pharmacist designated by the PIC, and the approved transport agent solely have access to the secure delivery area. Two (2) factor credentialing is required for entry, which must include two (2) of the following: (3-20-14)

i. Something known (a knowledge factor); (4-11-15)

ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)

iii. Something biometric (fingerprint, retinal scan, etc.); (4-11-15)

f. The pharmacy has a means of recording the time of entry and the identity of all persons who access the secured delivery area; (3-20-14)

g. The pharmacy maintains immediately retrievable records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery; (3-20-14)

h. The pharmacy maintains written policies and procedures for secured delivery area storage and removal of prescriptions; and (3-20-14)

i. The PIC of a pharmacy that ships drugs by common carrier must require the common carrier to conduct criminal background checks on its employees who have access to the secured delivery area. (3-20-14)

04. Qualified Returns to the Secured Delivery Area. A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area: (3-20-14)

a. Emergency kits; (3-20-14)

b. Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and (3-20-14)

c. Those deemed qualified for return pursuant to the Restricted Return of Drugs or Devices rule. (3-20-14)

605. PHARMACY SECURITY.
A pharmacy 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. New construction or a remodeled pharmacy must meet the following minimum security requirements: (4-11-15)

01. Alarm. At least while closed an alarm or other comparable monitoring system is required. (4-11-15)

02. Walls. Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

03. Doors. Solid core or metal doors are required. (4-11-15)

04. Hinges and Locks. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

05. Differential Hours. When closed for business, a pharmacy must be: (4-11-15)

a. Completely enclosed in a manner sufficient to provide adequate security; or (4-11-15)

b. Located within a larger business establishment that is also closed. In such cases, the establishment must meet these minimum security requirements, and no person is allowed entry to the establishment unless a pharmacist is present. (4-11-15)

06. Drop Box. If used, a “drop box” or “mail slot” allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment. (4-11-15)

606. PHARMACY NOTIFICATION AND ADVERTISING OF HOURS OPEN FOR BUSINESS.

01. Notification of Business Hours. A pharmacy must notify the Board and prominently display the hours open to the public for business, if applicable, on or adjacent to its entrance and the entrance of the business establishment in which it is located if the open hours are different. (3-21-12)

02. Notification of Change of Business Hours. The Board and the public must be notified of changes to the hours that a pharmacy is open to the public for business, including changes resulting in differential hours, at least seven (7) days prior to the change except changes of hours in recognition of state holidays set forth in Section 73-108, Idaho Code. A change of hours for a holiday must be prominently posted for public notice at least seven (7) days in advance. (4-4-13)

607. PHARMACY STAFFING AND RATIO.

01. Staffing. A pharmacy must be staffed sufficiently to allow for appropriate supervision, to otherwise operate in compliance with the law, and if applicable, to remain open during the hours posted as open to the public for business. (3-21-12)

02. Ratio. The ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) student pharmacists and technicians in total in any practice setting. A pharmacist must not operate a pharmacy, allow the operation of a pharmacy, or be required to operate a pharmacy with a ratio that results in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, or welfare. (3-21-12)

608. PHARMACY STRUCTURAL REMODEL APPROVAL.
Prior to the commencement of structural remodeling that impacts the periphery or security of an existing pharmacy, a floor plan must be submitted to, and approved by, the Board. The prescription preparation area (including the patient consultation, merchandising, and waiting areas, if applicable), storeroom, restroom, partitions (including, but not limited to, walls, doors, and windows), trade fixtures, and appropriate elevations must be indicated on the submitted floor plan. (3-21-12)

609. PHARMACY CHANGE OF OWNERSHIP OR PERMANENT CLOSING.

01. Board Notification. The registrant must notify the Board of a pharmacy's change of ownership or permanent closure at least ten (10) days prior to the event. The notice must include: (3-21-12)

a. The name and address of the pharmacy to be sold or closed; (3-21-12)

b. The date of sale or closure; (3-21-12)

c. The name and address of the business acquiring the prescription inventory; and (3-21-12)

d. The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. (3-21-12)

02. Public Notice. A registrant must notify the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the date of closure and the new location of the prescription files. Notice must be provided by prominent posting in a public area of the pharmacy. (3-21-12)

03. Pharmacy Signs. Unless sold and transferred to another pharmacy operator, a registrant must remove or completely cover each sign and other exterior indication that the premises was a pharmacy within thirty (30) days after the date a pharmacy permanently ceases operations. (3-21-12)

04. Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must: (4-4-13)

a. Adequately secure and protect the prescription files from unlawful use or disclosure; (4-4-13)

b. Secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition; and (4-4-13)

c. Retain a closing inventory of controlled substances. (4-4-13)

05. Pharmacy Change of Ownership. A change of ownership of a currently registered pharmacy will require the submission and approval of a new pharmacy registration application but will not require an onsite inspection prior to issuance of a pharmacy registration unless structural remodeling occurs. (3-21-12)

610. CENTRALIZED PHARMACY SERVICES.
A pharmacy may centralize pharmacy services if: (7-1-13)

01. Written Contract. The originating pharmacy has a written contract with the central drug outlet or central pharmacist outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or the two (2) are jointly owned; (7-1-13)

02. Training. The central drug outlet or central pharmacist provides a training and orientation program that ensures the pharmacists who are providing centralized pharmacy services are competent to perform such services; (7-1-13)

03. Communication. Appropriate communications exist to allow the central drug outlet or central pharmacist to readily communicate with prescribers, the institutional facility, or the originating pharmacy; (7-1-13)

04. Secure Common 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 central pharmacist to information required to perform centralized pharmacy services; (7-1-13)

05. Continuous Quality Improvement Program. The parties implement and maintain a quality improvement program designated to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; (7-1-13)

06. Audit Trail Documentation. The central drug outlet or central pharmacist maintains an electronic recordkeeping system that must have audit trail functionality that documents for each prescription drug order the identity and location of each individual involved in each step of the centralized pharmacy services; (7-1-13)

07. Privacy. The parties demonstrate adequate security to protect the privacy of PHI and the centralized pharmacy services are performed from a secure area that is restricted to authorized personnel; (7-1-13)

08. Policies and Procedures. The parties adopt policies and procedures that are sufficiently detailed to ensure compliance with pertinent federal and Idaho law and protect public health, safety and welfare. (7-1-13)

09. Location. Centralized pharmacy services must be performed from a pharmacy, central drug outlet, or remote office location. (7-1-13)

10. Exemption. A single prescription drug order may be shared by an originating pharmacy and a central drug outlet or central pharmacist. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription or as a wholesale distribution. (7-1-13)

611. PHARMACY AUTHORIZED ENTRY.

01. Open Pharmacy. A person other than a pharmacist, student pharmacist, or technician must not enter or work in the secured pharmacy, except that a pharmacist may authorize other persons to be present temporarily in the pharmacy for legitimate business purposes if under the direct supervision of a pharmacist at all times. (4-11-15)

02. Closed Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist. (4-11-15)

03. Non-Institutional Temporary Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except: (4-11-15)

a. If a technician or student pharmacist is on duty to allow brief pharmacist absences within the business establishment; or (4-11-15)

b. When a pharmacist performs professional services in the peripheral areas immediately outside of the pharmacy. (4-11-15)

04. Institutional Pharmacy Temporary Pharmacist Absence. To accommodate periods of temporary absence of a pharmacist from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions: (4-11-15)

a. No other person may be allowed access or entrance to the pharmacy; (4-11-15)

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and (4-11-15)

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. (4-11-15)

612. -- 614. (RESERVED)

615. DRUG DISTRIBUTION.

01. Authorized Distributors. The following drug outlets may distribute legend drugs in or into Idaho, in compliance with these rules, pursuant to the following restrictions: (4-11-15)

a. A licensed or registered wholesale distributor and a registered manufacturer in compliance with the Idaho Wholesale Distribution Act and the Idaho Pharmacy Act; (4-11-15)

b. An FDA and Idaho registered outsourcing facility in compliance with 21 U.S.C. Section 353b of the Food, Drug and Cosmetic Act; (4-11-15)

c. A dispenser without being licensed or registered as a wholesale distributor according to the following restrictions: (4-11-15)

i. A dispenser may distribute to authorized recipients for an emergency medical purpose in which an alternative source for a drug is not reasonably available in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining a drug. The amount of the drug distributed in an emergency must not reasonably exceed the amount required for immediate use; (4-11-15)

ii. A dispenser may distribute intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity; (4-11-15)

iii. A pharmacy may distribute to another pharmacy pursuant to a sale, transfer, merger or consolidation of all or a part of a pharmacy, whether accomplished as a sale of stock or business assets; (4-11-15)

iv. A pharmacy may distribute compound positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; and (4-11-15)

v. A pharmacy may distribute minimal quantities of prescription drugs to a prescriber for in-office administration, including the distribution of compounded drug product in the absence of a patient specific prescription drug order if: (4-11-15)

(1) The compounded drug product is not sterile and not intended to be sterile; (4-11-15)

(2) The compounded drug product is not further dispensed or distributed by the practitioner; and (4-11-15)

(3) The quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the pharmacy, which may include a drug compounded for the purpose of, or incident to, research, teaching or chemical analysis. (4-11-15)

02. Distribution. An authorized distributor must furnish: (4-11-15)

a. Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs; (4-11-15)

b. Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law; (4-11-15)

c. Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and (4-11-15)

d. Drug product only to the premises listed on the authorized receiving person's license or registration. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery. (4-11-15)

03. Controlled Substance Distribution Invoice. Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: (4-11-15)

a. The date of the transaction; (4-11-15)

b. The name, address, and DEA registration number of the distributing dispenser; (4-11-15)

c. The name, address, and DEA registration number or the receiving dispenser; (4-11-15)

d. The drug name, strength, and quantity for each product distributed; and (4-11-15)

e. The signature of the person receiving the drugs. (4-11-15)

04. Monitoring Purchase Activity. An authorized distributor must have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, and orders of unusual frequency. (4-11-15)

05. Reporting. An authorized distributor must report specified data on controlled substances distributed at least monthly to the Board in a form and manner prescribed by the Board, except when distributing intracompany. (4-11-15)

06. Prohibited Acts. The following acts are prohibited: (4-11-15)

a. Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit; and (4-11-15)

b. Failing to obtain a license or registration when one is required to distribute in or into Idaho. (4-11-15)

616. – 619. (RESERVED)

620. INSTITUTIONAL FACILITY: PRACTICE OF PHARMACY AND ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
These institutional facility rules are applicable to the practice of pharmacy and the administration and control of drugs and devices by institutional facilities or by persons employed by them. (3-25-16)

621. INSTITUTIONAL FACILITY: WITH ONSITE PHARMACY -- MINIMUM RESPONSIBILITIES.

01. Institutional Pharmacy Staffing. The director must be assisted by a sufficient number of additional pharmacists, student pharmacists, and technicians as may be required to operate the pharmacy

competently, safely, and adequately to meet the needs of the patients of the facility. (3-21-12)

02. Inventory Management. The professional staff of the institutional facility must cooperate with the director to manage the responsibilities of ordering, administering, and accounting for drugs, devices, and other pharmaceutical materials. (3-21-12)

03. Prescribers Authorized by Institutional Facility. The institutional facility must designate and notify the pharmacy of the prescribers authorized to issue drug orders for facility patients. (3-21-12)

04. Approved Use of Abbreviations and Chemical Symbols. A listing of acceptable, or alternatively unacceptable, abbreviations and chemical symbols used by prescribers on drug orders must be developed and distributed by the appropriate committee of the institutional facility. (3-21-12)

05. Director Participation in Patient Care Evaluation Program. The director must participate in the aspects of the institutional facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness. (3-21-12)

622. INSTITUTIONAL PHARMACY: DIRECTOR: MINIMUM RESPONSIBILITIES.
Each institutional pharmacy must be supervised and directed by an Idaho-licensed pharmacist (referred to herein as "the director") who is knowledgeable in, and thoroughly familiar with, the specialized functions of institutional pharmacies. The director is responsible for ensuring compliance with applicable law and for each activity of the institutional pharmacy, including at least the following: (3-21-12)

01. Policies and Procedures. In coordination with the appropriate institutional facility personnel, the adoption of policies and procedures with sufficient specificity regarding the handling, storage, and dispensing of drugs within the institution to protect public health and safety and ensure compliance with these rules and other applicable law. (3-21-12)

02. Formulary or Drug List Development. The participation in any development of a formulary or drug list for the facility. (3-21-12)

03. Product Procurement. The procurement of drugs, chemicals, biologicals, devices, or other products used by the institutional facility for patient pharmaceutical care services or for which a drug order is required. (3-21-12)

04. Drug Use, Storage, and Accountability. The safe and efficient dispensing, distribution, control, and secured storage of, and accountability for, drugs within the facility, including at least the following: (3-21-12)

a. Ensuring that drugs stored within the institutional pharmacy or in alternative secured storage areas have proper sanitation, temperature, light, ventilation, moisture control, segregation and security; (3-21-12)

b. Ensuring that outdated or other unusable drugs are identified and stored in a manner that prevents their distribution or administration prior to disposition; (3-21-12)

c. Ensuring that emergency drugs are in adequate and proper supply at designated locations; (3-21-12)

d. Ensuring that requirements applicable to the purchasing, storing, distribution, dispensing, recordkeeping, and disposal of controlled substances are met throughout the institution, including but not limited to, ensuring that controlled substances stored in surgery or emergency departments, nursing stations, ambulatory clinics, diagnostic laboratories or other locations outside of the pharmacy are inaccessible to unauthorized personnel; (3-21-12)

e. Ensuring accurate filling and labeling of containers from which drugs are to be administered or dispensed; (3-21-12)

f. Ensuring appropriate admixture of parenteral products, including serving in an advisory capacity

for nursing personnel concerning incompatibility and the provision of proper incompatibility information; and (3-21-12)

g. Ensuring appropriate provision and maintenance, in both the pharmacy and patient care areas, of a sufficient inventory of antidotes and other emergency drugs, current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and other materials and information determined necessary by the appropriate institutional facility personnel. (3-21-12)

05. Emergency Drug Access Protocol. In coordination with the appropriate institutional facility personnel, the development of an emergency drug access protocol and related training of R.N.s to ensure appropriate knowledge of the proper methods of access, removal of drugs, documentation, and other required procedures prior to the R.N.'s designation for access to emergency drug supplies. (3-21-12)

06. Suspected Adverse Drug Reaction Reporting. The reporting in a timely manner of a suspected adverse drug reaction to the ordering physician and to the appropriate institutional facility personnel. The director may use discretion and, if deemed necessary or advisable for public health or safety, report a suspected reaction to others such as MedWatch, the manufacturer, and the USP. (3-21-12)

07. Records Maintenance. The maintenance of records of institutional pharmacy transactions required by law. (3-21-12)

08. Teaching, Research, and Patient Care Evaluation Programs. The cooperation with any teaching and research programs and the participation in any patient care evaluation programs relating to pharmaceutical utilization and effectiveness within the institutional facility. (3-21-12)

09. Continuous Quality Improvement Program. The development and implementation of a continuous quality improvement program to review and evaluate pharmaceutical services and recommend improvements. (3-21-12)

10. Director Change. Both an outgoing and incoming director must report to the Board a change in the institutional pharmacy director within ten (10) days of the change. (4-4-13)

623. -- 629. (RESERVED)

630. INSTITUTIONAL FACILITY: GENERAL STANDARDS FOR ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
Within an institutional facility, drugs and devices may be dispensed for administration to, or for self-administration or use by, a patient only as permitted by applicable law and these rules consistent with usual and customary standards of good medical practice: (3-25-16)

01, Drugs and Devices Dispensed for Administration Within an Institutional Facility. Drugs and devices must only be dispensed to inpatients of an institutional facility: (3-25-16)

a. Upon the drug orders of licensed facility prescribers; (3-21-12)

b. Pursuant to an emergency protocol for the administration of drugs without an order in life or death situations; or (3-25-16)

c. For self-administration or use if specifically authorized by the treating or ordering prescriber, the patient has been appropriately educated and trained to perform self-administration, and there is no risk of harm. (3-25-16)

02. Drugs and Devices Dispensed for Administration or Use Outside an Institutional Facility. A drug or device prepared for self-administration or use by a patient while outside the confines of the institutional facility must comply with the standard prescription drug labeling requirements, subject to the following: (3-25-16)

a. Permissible dispensing; (3-25-16)

i. In limited quantities and reasonable time duration as a continuation of or supplemental to treatment that was administered at the hospital to the following: (3-25-16)

(1) To emergency room patients pursuant to these rules; and (3-25-16)

(2) To other outpatients who receive treatment or consultation on the premises; (3-25-16)

ii. To hospital employees, medical staff, and students at the hospital and their dependents, for their own personal use only and not for resale. (3-25-16)

b. Impermissible dispensing; (3-25-16)

i. To former patients, employees, medical staff, students, and their dependents; and (3-25-16)

ii. To walk up customers who have no connection to the hospital. (3-25-16)

03. Controlled Substances Reporting and Documentation. Distribution, dispensing, delivery, or administration of controlled substances within an institutional facility or by facility personnel must be properly and adequately documented and reported in the time and manner required by the appropriate committee of the institutional facility and the director. (3-21-12)

04. Patient's Personal Drug Supplies. If an admitted patient brings a drug into the institutional facility, the drug must not be administered or used except pursuant to a drug order and only if it can be precisely identified and the quantity and quality of the drug visually evaluated by a pharmacist. (3-21-12)

a. If a patient's drug will not be administered or used, the pharmacy must package, seal, and return the drug to an adult member of the patient's immediate family or store and return it to the patient upon discharge. (3-21-12)

b. Drugs not returned to the patient or the patient's family may be disposed of after a reasonable number of days following discharge or death. (3-21-12)

05. Suspected Adverse Drug Reaction Reporting. Suspected adverse drug reactions must be communicated in a timely manner to the pharmacy. (3-21-12)

06. Required Pharmacy Returns. Discontinued, expired, and damaged drugs and containers with worn, illegible, or missing labels must be returned to the pharmacy for proper handling. (3-21-12)

631. INSTITUTIONAL FACILITY: EMERGENCY DRUG ACCESS.
The director must make advance arrangements necessary to facilitate continuity of patient care and for the provision of drugs to the medical staff and other authorized personnel of the institutional facility in emergencies and during the absences of a pharmacist in compliance with this rule. (4-11-15)

01. Emergency Pharmacy Access. If a drug is unavailable from any other authorized emergency source in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug and in the absence of a pharmacist from the premises of the institutional facility, it may be retrieved from an institutional pharmacy by an R.N. as follows: (3-21-12)

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; (3-21-12)

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access; and (3-21-12)

c. Only a non-controlled substance may be removed and only in an amount necessary to treat a patient's immediate need until the pharmacy is again attended by a pharmacist. (3-21-12)

02. Emergency Cabinets. A cabinet or similar enclosure located outside an institutional pharmacy may be used for emergency access of drugs by an R.N. as follows: (3-21-12)

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; and (3-21-12)

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. (3-21-12)

03. Emergency Drug Access. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows: (4-11-15)

a. Removal of a drug must be pursuant to a valid drug order; (3-21-12)

b. Removal of a drug must be documented in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The initials or other unique identifier of the designated nurse. (4-4-13)

c. The removal record and a copy of the drug order must be left conspicuously in the pharmacy, emergency cabinet, or alternative location to facilitate prompt accuracy verification and initialing by a pharmacist. (3-21-12)

632. INSTITUTIONAL FACILITY: EMERGENCY DRUG SUPPLY PREPARATION AND MONITORING.
The director or PIC and the appropriate institutional facility personnel must jointly approve and develop a listing of drugs, by identity and quantity, for inclusion in an emergency cabinet, emergency kit, crash cart, or other similar resource that is specifically approved for use by that type of institutional facility and for delivery to patients receiving emergency treatment. In addition to other applicable provisions of these rules, approved drugs are subject to the following limitations, restrictions, and requirements: (3-21-12)

01. Prepackaged Amounts. The drugs must be prepackaged in amounts sufficient to satisfy immediate therapeutic requirements only, except when delivered in a hospital emergency room consistent with these rules; (4-4-13)

02. Content Labeling. The drugs must be labeled as required by these rules for prepackaged products and with any additional information as may be required to prevent misunderstanding or risk of harm to patients; (3-21-12)

03. Access Documentation. Access to the emergency drugs must be documented by drug orders and, if applicable, proofs of use; (3-21-12)

04. Drug Expiration Monitoring. Drug expiration dates must be monitored and the drugs replaced as needed to ensure the emergency drug supply contains no outdated products; and (3-21-12)

05. Regular Inventory and Inspection. Emergency drug supplies must be regularly inventoried and inspected to ensure that they are properly stored and secured against pilferage or tampering. (3-21-12)

633. INSTITUTIONAL FACILITY: EMERGENCY KITS AND CRASH CARTS -- GENERAL RULES.
Emergency drugs prepared and packaged as required by these rules may be approved for inclusion in emergency kits

or crash carts for use by personnel with authority granted by state or federal law to administer prescription drugs. (3-21-12)

01. Storage and Security. Emergency kits or crash carts must be sealed in a tamper-evident manner and stored in limited access areas to prevent unauthorized access and to ensure a proper environment for preservation of the drugs within them. (3-21-12)

02. Exterior Kit Labeling. The exterior of emergency kits must be clearly labeled as an emergency drug kit to be used only in emergencies. Additionally, an immediately retrievable list of the drugs contained therein must include: (3-21-12)

a. The name, strength, and quantity of each drug; (3-21-12)

b. The expiration date of the first expiring drug; and (3-21-12)

c. The name, address, and telephone number of the supplying pharmacist, if applicable. (3-21-12)

03. Drug Removal. Drugs must only be removed from emergency kits or crash carts by persons with authority granted by state or federal law to administer prescription drugs, pursuant to a valid drug order, or by a pharmacist. (3-21-12)

04. Notification of Authorized Use. Whenever an emergency kit or crash cart is opened, the pharmacy must be notified and the kit or cart must restocked and resealed within a reasonable time. (3-21-12)

05. Notification of Unauthorized Use. If an emergency kit or crash cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the institutional facility must be promptly notified. (3-21-12)

634. INSTITUTIONAL FACILITY: NURSING HOME EMERGENCY KITS.
In nursing homes without an institutional pharmacy, drugs may be provided by a licensed pharmacy, retained by the facility, in emergency kits located at the facility**.** (3-21-12)

01. Provider Pharmacy Documentation. The nursing home must document the pharmacy retained in writing. (3-21-12)

02. Provider Pharmacy Ownership of Prescription Drug. Prescription drugs included in a nursing home emergency kit must remain the property of, and under the responsibility of, the supplying pharmacy. (3-21-12)

635. HOME HEALTH OR HOSPICE EMERGENCY KITS.
A pharmacy may supply emergency kits for state licensed or Medicare certified home health or hospice agencies, or both, as follows: (3-21-12)

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

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

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

636. INSTITUTIONAL FACILITY: HOSPITAL FLOOR STOCK.
Hospitals may use floor stock drugs if limited to a formulary of drugs and routinely used items developed and

approved by the director in coordination with the appropriate institutional facility personnel. (3-21-12)

01. Pharmacist Routine Monitoring. Floor stock drugs must be routinely monitored by a pharmacist to ensure appropriate use and storage. (3-21-12)

02. Prescription Drugs. Prescription drugs included in floor stock must be in unit dose or unit-of-use packaging. (3-21-12)

03. Controlled Substances. For controlled substances included in the floor stock formulary, the director must ensure that: (3-21-12)

a. The floor stock contains appropriate controlled substances that are prepackaged in amounts sufficient for only immediate therapeutic requirements; (3-21-12)

b. Controlled substances maintained as floor stock are accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; (3-21-12)

c. Controlled substances removed from floor stock are documented by appropriate written drug orders and proofs of use, if applicable, and in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The signature or electronic personal verification of the person delivering the drug; and (3-21-12)

d. Controlled substances are inventoried at least weekly. (3-21-12)

637. INSTITUTIONAL FACILITY: EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.
Drugs may be delivered by an RN to outpatients being treated in a hospital emergency room as follows: (4-4-13)

01. Prerequisites: (4-4-13)

a. In the presence of a prescriber, acting as an agent of that prescriber, or outside the presence of a prescriber, when there is no prescriber present in the hospital in accordance with applicable state and federal law; (4-4-13)

b. Pursuant to a valid drug order issued by a prescriber; (4-4-13)

c. When no pharmacist is on duty in the community; and (4-4-13)

d. When drugs are stored and accessed in accordance with applicable laws and rules. (4-4-13)

02. Limitations. No more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (3-21-12)

03. Documentation. Delivery must be documented as required by these rules for institutional facility emergency drug access. (4-4-13)

04. Labeling. The institutional pharmacy must prepackage and affix a label to the container with the information required by the standard prescription drug labeling rules, except that blank spaces may be left for the

names of the patient and prescriber and directions for use. (4-4-13)

638. -- 639. (RESERVED)

640. INSTITUTIONAL FACILITY: OFFSITE PHARMACY PRACTICE STANDARDS.

01. Offsite Pharmacy Services. If an institutional facility without an institutional pharmacy obtains drugs, devices, or other pharmacy services from outside the institutional facility, arrangements must be made to ensure that the offsite pharmacy provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and properly serve the needs of the facility. (3-21-12)

02. Written Agreement. The arrangements must be made in writing and must, at a minimum, specify that: (3-21-12)

a. An offsite pharmacist will act in the capacity of a part-time director; (3-21-12)

b. For nursing homes, on-call services by a pharmacist will be available at all times; (3-21-12)

c. The pharmacy will provide adequate storage facilities for drugs; and (3-21-12)

d. Drugs housed in an LTCF must be labeled as required by the standard prescription drug labeling rule and, unless maintained in an electronic record, must include a lot number for administration of recalls. (4-4-13)

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY.
A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13)

01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13)

02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13)

03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13)

04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. (7-1-13)

642. -- 649. (RESERVED)

650. INSTITUTIONAL FACILITY: CENTRALIZED PHARMACY SERVICES.
In addition to the rules for centralized pharmacy services, an institutional facility that centralizes pharmacy services must be in compliance with the following rules: (7-1-13)

01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13)

02. Policies and Procedures. An institutional pharmacy and its contracted central drug outlet or central pharmacist that provides centralized pharmacy services must adopt policies and procedures and retain documentation that evidences at least the following: (7-1-13)

a. A copy of the contract if required by these rules; (7-1-13)

b. Identification of the directors or PICs; (7-1-13)

c. The protocol for ensuring that the central drug outlet maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; (7-1-13)

d. The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central drug outlet or central pharmacist and for maintaining the security of the drugs; (7-1-13)

e. Essential information utilized by the institutional facility, such as its formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to the information; and (7-1-13)

f. The protocol for the central drug outlet or central pharmacist to perform a review of the patient's profile, including but not limited to performing a prospective drug review. (7-1-13)

651. -- 669. (RESERVED)

670. VDO: OWNER AND MANAGER RESPONSIBILITIES.
Owners and managers of VDOs each have corresponding and individual responsibility for unauthorized drug distribution from, or other unlawful conduct in, the registered outlet and must have sufficient understanding of the regulated activities to detect improper conduct. (3-21-12)

671. VDO: POLICIES AND PROCEDURES.
Owners or managers must adopt policies and procedures for the handling of veterinary drug orders, managing product inventory, and other topics as needed to ensure compliance with applicable law and Board rules. (3-21-12)

672. VDO: REQUIRED REFERENCES.
The current Board rules applicable to the practice setting must also be made readily available to VDTs and other employees of the VDO for reference purposes. (3-21-12)

673. VDO: STAFFING.

01. Sufficient Staffing. VDOs must employ sufficient VDTs to ensure that one (1) VDT is on duty at all times the establishment is open to the public for business. (3-21-12)

02. Notification of Personnel Changes. Notification of VDT personnel changes must be provided to the Board within ten (10) days of the change and must include the names and addresses of both the resigning and the newly hired VDTs. (3-21-12)

674. VDO: DRUG PRODUCT INVENTORY AND MANAGEMENT.

01. Authorized Prescription Drugs. VDOs are authorized to stock, and VDTs are authorized to prepare and deliver, prescription veterinary drugs except the following: (3-21-12)

a. Controlled substances listed in Schedules I through V of either the state or federal Controlled Substances Acts; (3-21-12)

b. Euthanasia drugs or products; (3-21-12)

c. Tranquilizer drugs or products; (3-21-12)

d. Curare, succinylcholine, or other neuromuscular paralyzing drugs; and (3-21-12)

e. General anesthesia drugs or products. (3-21-12)

02. Prescription Drug Storage and Security. Prescription drugs must be separated from other drugs and stored in an area equipped with adequate security to prevent diversion, and only VDTs and authorized government inspectors or agents may have access to prescription drug areas. (3-21-12)

03. Returned Prescription Drugs. Prescription drugs returned to a VDO from a client must be treated as damaged or outdated drugs. Returned drugs may not be returned to stock or dispensed, distributed, or resold. (3-21-12)

04. Product Maintenance. The complete product inventory must be reviewed on at least a semi-annual basis to identify and remove from stock outdated, deteriorated, or damaged products for proper reclamation, destruction, or return. (3-21-12)

675. -- 699. (RESERVED)

Subchapter F -- Limited Service Outlet Practice Standards
(Rules 700 through 799 -- Limited Service Outlet Practice Standards)

700. LIMITED SERVICE PHARMACY.
A limited service outlet with a pharmacy must adopt policies and procedures that are sufficiently detailed to ensure the protection of public health, safety, and welfare and that include at least the following: (3-21-12)

01. Description of Services. A description of the type and method of specialized services to be provided; (3-21-12)

02. Times of Operation. The days and hours of operation; (3-21-12)

03. Drug Information. The types and schedules of drugs to be stored, distributed, or dispensed; and (3-21-12)

04. Equipment and Supplies. The equipment and supplies to be used. (3-21-12)

701. -- 709. (RESERVED)

710. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES.
Pharmacies and pharmacists commencing retail telepharmacy operations with a remote dispensing site after August 23, 2011, must comply with the following requirements: (3-21-12)

01. Telepharmacy Practice Sites and Settings. Prior to engaging in the practice of telepharmacy with a remote dispensing site, the supervising pharmacy must demonstrate that there is limited access to pharmacy services in the community in which the remote site is located. (3-21-12)

a. Information justifying the need for the remote dispensing site must be submitted with the initial registration application. (3-21-12)

b. The Board will consider the availability of pharmacists in the community, the population of the community to be served by the remote dispensing site, and the need for the service. (3-21-12)

c. The remote dispensing site must be located in a medical care facility operating in areas otherwise unable to obtain pharmaceutical care services on a timely basis. (3-21-12)

d. The Board will not approve a remote dispensing site if a retail pharmacy that dispenses prescriptions to outpatients is located within the same community as the proposed remote dispensing site. (3-21-12)

02. Independent Entity Contract. Unless jointly owned, a supervising pharmacy and a remote dispensing site must enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract. (3-21-12)

a. A copy of the contract must be submitted to the Board with the initial registration application and at any time there is a substantial change in a contract term. (3-21-12)

b. The contract must be retained by the supervising pharmacy. (3-21-12)

03. PIC Responsibility. Unless an alternative PIC from the supervising pharmacy is specifically designated in writing, the PIC of the supervising pharmacy is also considered the responsible PIC for the remote dispensing site. (3-21-12)

04. Remote Dispensing Site Limitations. The Board may limit the number of remote dispensing sites under the supervision and management of a single pharmacy. (3-21-12)

05. Technician Staffing. Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified technician with at least two thousand (2,000) hours pharmacy technician experience in Idaho and under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is open. Supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist must supervise telepharmacy operations electronically from the supervising pharmacy. (3-24-16)

06. Common Electronic Recordkeeping System. The remote dispensing site and the supervising pharmacy must utilize a common electronic recordkeeping system that must be capable of the following: (3-21-12)

a. Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site; and (3-21-12)

b. Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy. (3-21-12)

07. Records Maintenance. Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, federal law. (3-21-12)

08. Video and Audio Communication Systems. A supervising pharmacy of an ADS system used in a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of such video and audio surveillance for a minimum of ninety (90) days. (4-11-15)

a. Adequate supervision by the pharmacist in this setting is maintaining constant visual supervision and auditory communication with the site and full supervisory control of the automated system that must not be delegated to another person or entity. (3-21-12)

b. Video monitors used for the proper identification and communication with persons receiving prescription drugs must be a minimum of twelve inches (12”) wide and provided at both the pharmacy and the remote location for direct visual contact between the pharmacist and the patient or the patient’s agent. (3-21-12)

c. Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed if any component of the communication system is malfunctioning until system corrections or repairs are completed. (3-21-12)

09. Access and Operating Limitations. Unless a pharmacist is present, a remote dispensing site must not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing site, and the PIC must periodically review the record of entries. (3-21-12)

10. Delivery and Storage of Drugs. If controlled substances are maintained or dispensed from the

remote dispensing site, transfers of controlled substances from the supervising pharmacy to the remote dispensing site must comply with applicable state and federal requirements. (3-21-12)

a. Drugs must only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, drug strength, and quantities included in the container. Drugs must not be delivered to the remote dispensing site unless a technician or pharmacist is present to accept delivery and verify that the drugs sent were actually received. The technician or pharmacist who receives and checks the order must verify receipt by signing and dating the list of drugs delivered. (3-21-12)

b. If performed by a technician, a pharmacist at the supervising pharmacy must ensure, through use of the electronic audio and video communications systems or bar code technology, that a technician has accurately and correctly restocked drugs into the ADS system or cabinet. (3-21-12)

c. Drugs at the remote dispensing site must be stored in a manner to protect their identity, safety, security, and integrity and comply with the drug product storage requirements of these rules. (3-21-12)

d. Drugs, including previously filled prescriptions, not contained within an ADS system must be stored in a locked cabinet within a secured area of a remote dispensing site and access must be limited to pharmacists from the supervising pharmacy and the technicians authorized in writing by the PIC. (3-21-12)

11. Wasting or Discarding of Drugs Prohibited. Wasting or discarding of drugs resulting from the use of an ADS system in a remote dispensing site is prohibited. (3-21-12)

12. Returns Prohibited. The technician at a remote dispensing site must not accept drugs returned by a patient or patient's agent. (3-21-12)

13. Security. A remote dispensing site must be equipped with adequate security. (4-11-15)

a. At least while closed, a remote dispensing site must utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. The site must have a means of recording the time of entry and the identity of all persons who access the site, which must be retained for ninety (90) days. Two (2) factoring credentialing is required for entry, which must include two (2) of the following: (4-11-15)

i. Something known (a knowledge factor); (4-11-15)

ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)

iii. Something biometric (finger print, retinal scan, etc.); (4-11-15)

b. A remote dispensing site must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All remote dispensing sites must meet the following security requirements: (4-11-15)

i. Walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

ii. Solid core or metal doors are required. (4-11-15)

iii. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

c. Access to the area of the remote dispensing site where prescription drugs are prepared, distributed, dispensed or stored must be limited to technicians and pharmacists. Any other persons requiring access to the remote dispensing site for legitimate business reasons may only be present in the secured area with the permission and under the supervision of a pharmacist, which may be satisfied via audio/video communication. (4-11-15)

d. A remote dispensing site must be closed for business and secured during all times a pharmacist or technician is not present. (4-11-15)

14. Patient Counseling. A remote dispensing site must include an appropriate area for patient counseling. (3-21-12)

a. The area must be readily accessible to patients and must be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. (3-21-12)

b. Unless onsite, a pharmacist must use the video and audio communication system to counsel each patient or the patient's caregiver on new medications. (3-21-12)

15. Remote Dispensing Site Sign. A remote dispensing site must display a sign, easily visible to the public, that informs patients that: (3-21-12)

a. The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy; (3-21-12)

b. Identifies the city or township where the supervising pharmacy is located; and (3-21-12)

c. Informs patients that a pharmacist is required to speak with the patient using audio and video communication systems each time a new medication is delivered or if counseling is accepted at a remote dispensing site. (3-21-12)

16. Pharmacist Inspection of Remote Dispensing Site. A pharmacist must complete and document a monthly in-person inspection of a remote dispensing site and inspection reports must be retained. (3-21-12)

17. Continuous Quality Improvement Program. The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. (4-11-15)

711. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: PRESCRIPTION DRUG ORDERS.
Prescription drug orders dispensed from a remote dispensing site must be previously filled by the supervising pharmacy or, unless a pharmacist is present, must only be filled on the premises of a remote dispensing site through the use of an ADS system and as follows: (3-21-12)

01. Pharmacist Verification of New Prescription Drug Order Information. If a technician at the remote dispensing site enters original or new prescription drug order information into the automated pharmacy system, the pharmacist at the supervising pharmacy must, prior to approving, verify the information entered against a faxed, electronic, or video image of the original prescription. (3-21-12)

a. The technician may transmit the prescription drug order to the pharmacist by scanning it into the electronic recordkeeping system if the means of scanning, transmitting, or storing the image does not obscure the prescription information or render the prescription information illegible. (3-21-12)

b. Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription via video communication systems between the remote dispensing site and the supervising pharmacy. Using the video communication, the pharmacist must verify the accuracy of the drug dispensed and must check the prescription label for accuracy. (3-21-12)

c. Except when prohibited by law for controlled substances, the technician may also transmit the prescription drug order to the supervising pharmacist by fax. (3-21-12)

d. A technician at a remote dispensing site must not receive oral prescription drug orders from a

prescriber or a prescriber's agent. Oral prescription drug orders must be communicated directly to a pharmacist. (3-21-12)

02. Pharmacist and Technician Identification. The initials or other unique identifiers of the pharmacist and technician involved in the dispensing must appear in the prescription record. (3-21-12)

03. Pharmacist Verification of Drug Product and Label. A pharmacist must compare, via video communication, the drug stock, the drug dispensed, and the label including the beyond use date. (3-21-12)

04. Electronic Verification System. The remote dispensing site must use an electronic verification system that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. The technician must electronically verify each prescription prepared for dispensing. (3-21-12)

712. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: POLICIES AND PROCEDURES.

A supervising pharmacy commencing telepharmacy operations with a remote dispensing site must adopt policies and procedures that address each of the following areas prior to engaging in the practice of telepharmacy. (3-21-12)

01. Minimum Standards. The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality, including at least: (3-21-12)

a. Identification of personnel authorized to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site; (3-21-12)

b. Procedures for the procurement of drugs and devices to the remote site and into any ADS systems used; and (3-21-12)

c. The criteria for monthly in-person pharmacist inspections of the remote dispensing site and appropriate documentation. (3-21-12)

02. Training Standards. The adoption of standards and training required for remote dispensing site technicians and pharmacists to ensure the competence and ability of each person that operates the ADS system, electronic recordkeeping, and communication systems and a requirement for retention of training documentation. (3-21-12)

03. Written Recovery Plan. A written plan for recovery from an event that interrupts or prevents pharmacist supervision of, or otherwise compromises, the dispensing of drugs from the remote dispensing site that includes at least the following: (3-21-12)

a. Procedures for response while the communication or electronic recordkeeping systems are experiencing downtime or for an ADS system malfunction; and (3-21-12)

b. Procedures for the maintenance and testing of the written plan for recovery. (3-21-12)

713. -- 729. (RESERVED)

730. OUT-OF-STATE MAIL SERVICE PHARMACY.

An out-of-state mail service pharmacy, during its regular hours of operation, but no less than forty (40) hours in six (6) days per week, provide a toll-free telephone service to facilitate communication between Idaho patients and a pharmacist with access to the patient records. This toll-free number must be disclosed on the prescription label for drugs dispensed to Idaho patients. (4-4-13)

731. -- 739. (RESERVED)

740. OUTSOURCING FACILITY.

01. Federal Act Compliance. An outsourcing facility must ensure compliance with 21 U.S.C. Section

353b of the Federal Food, Drug and Cosmetic Act. (4-6-15)

02. Adverse Event Reports. Outsourcing facilities must submit a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with the content and format requirement established in Section 310.305 of Title 21 of the Code of Federal Regulations to the Board. (4-6-15)

03. Policies and Procedures. An outsourcing facility must adopt policies and procedures for maintaining records pertaining to compounding, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (4-6-15)

741. -- 749. (RESERVED)

750. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: (3-21-12)

a. Operational procedures for the appropriate provision and delivery of equipment; (3-21-12)

b. Operational procedures for maintenance and repair of equipment; and (3-21-12)

c. Recordkeeping requirements for documenting the acquisition and provision of products. (3-21-12)

02. Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: (4-4-13)

a. Pure oxygen for human application; (3-21-12)

b. Nitrous oxide; (3-21-12)

c. Sterile sodium chloride; and (3-21-12)

d. Sterile water for injection. (3-21-12)

03. Prescriber's Order Required. Prescription drugs and devices may only be sold or delivered by a DME outlet upon the lawful order of a prescriber. DME outlets may hold drugs that are not prescription drugs for sale. (3-21-12)

751. -- 799. (RESERVED)

Subchapter G -- Wholesaler and Manufacturer Practice Standards
(Rules 800 through 999 -- Wholesaler and Manufacturer Practice Standards)

800. WHOLESALER: STANDARDS.
These wholesaler rules establish the minimum standards for the storage and handling of drugs by wholesalers and their officers, designated representative, agents, and employees and for the establishment and maintenance of records required for persons engaged in wholesale drug distribution. (3-21-12)

801. WHOLESALER: FACILITY REQUIREMENTS.
Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must: (3-21-12)

01. Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations; (3-21-12)

02. Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; (3-21-12)

03. Quarantine Area Required. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened; (3-21-12)

04. Maintenance Requirements. Be maintained in a clean and orderly condition; and (3-21-12)

05. Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind. (3-21-12)

802. WHOLESALER: FACILITY SECURITY.
Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (3-21-12)

01. Access from Outside. Access from outside the premises must be kept to a minimum and well controlled; (3-21-12)

02. Perimeter Lighting. The outside perimeter of the premises must be well lighted; (3-21-12)

03. Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel; (3-21-12)

04. Alarm Systems. Facilities must be equipped with an alarm systems to detect entry after hours; and (3-21-12)

05. Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering. (3-21-12)

803. WHOLESALER: DRUG STORAGE REQUIREMENTS.
Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs. (3-21-12)

804. WHOLESALER DRUG SHIPMENT INSPECTION REQUIREMENTS.

01. Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. (3-21-12)

02. Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents. (3-21-12)

805. WHOLESALER: QUARANTINE.
Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (3-21-12)

01. Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (3-21-12)

02. Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards. (3-21-12)

806. WHOLESALER: RECORDKEEPING REQUIREMENTS.
Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. (3-21-12)

01. Record Contents. The records must include at least: (3-21-12)

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; (3-21-12)

b. The identity and quantity of the drugs received and distributed or disposed of; and (3-21-12)

c. The dates of receipt and distribution or other disposition of the drugs. (3-21-12)

02. Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location. (3-21-12)

807. WHOLESALER: PERSONNEL.

01. Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (3-21-12)

02. Adequate Personnel. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities. (3-21-12)

03. Designated Representative Continuing Education. A wholesaler's designated representative must complete training and continuing education on state and federal laws pertaining to wholesale distribution of prescription drugs provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. (3-21-12)

808. WHOLESALER: POLICIES AND PROCEDURES.
Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following: (3-21-12)

01. Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation. (3-21-12)

02. Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (3-21-12)

a. A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (3-21-12)

b. A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (3-21-12)

c. An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design. (3-21-12)

03. Crisis Preparation. **W**holesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency. (3-21-12)

809. -- 849. (RESERVED)

850. DRUG MANUFACTURER OR WHOLESALER TRANSACTION RESTRICTION.
A manufacturer or wholesaler may furnish non-prescription drugs only to a person or drug outlet licensed or registered by the Board. Before furnishing non-prescription drugs to a person or drug outlet, the manufacturer or wholesaler must affirmatively verify that the recipient is legally authorized to receive the non-prescription drugs. (3-21-12)

851. -- 899. (RESERVED)

900. DRUG MANUFACTURERS.
These rules are applicable to drug manufacturers located within the state of Idaho. Non-resident manufacturers engaged in wholesale drug distribution in or into Idaho must comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. (3-21-12)

901. DRUG MANUFACTURER: STANDARDS.
A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements. (3-21-12)

902. DRUG MANUFACTURER: RECORDS.
A manufacturer must adopt policies and procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (3-21-12)

903. -- 999. (RESERVED)

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