

**65-1626. Definitions.** For the purposes of this act:

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

- (1) A practitioner or pursuant to the lawful direction of a practitioner;
- (2) the patient or research subject at the direction and in the presence of the practitioner; or
- (3) a pharmacist as authorized in K.S.A. 65-1635a, and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(c) "Application service provider" means an entity that sells electronic prescription or pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its server.

(d) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following: (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(e) "Biological Product" has the meaning as defined in 42 U.S.C. Sec. 262(i);

(f) "Board" means the state board of pharmacy created by K.S.A. 74-1603, and amendments thereto.

(g) "Brand exchange" in the case of a drug product prescribed means the dispensing of a different drug product of the same dosage form and strength and of the same generic name as the brand name drug product prescribed, and in the case of a biological product prescribed, means the dispensing of a biological product determined by the federal FDA to be interchangeable with the biological product prescribed.

(h) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

(i) "Chain pharmacy warehouse" means a permanent physical location for drugs or devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs or devices to chain pharmacies that have the same ownership or control. Chain pharmacy warehouses must be registered as wholesale distributors.

(j) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug product label shall be used to determine the identity of the drug manufacturer.

(k) "DEA" means the U.S. department of justice, drug enforcement administration.

(l) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

(m) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to patients, and complete the final check before dispensing.

(n) "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner.

(o) "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

(p) "Distribute" means to deliver, other than by administering or dispensing, any drug.

(q) "Distributor" means a person who distributes a drug.

(r) "Drop shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug, and the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug receives delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipment shall be part of the "normal distribution channel."

(s) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (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 articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated prior to its repeal.

(t) "Durable medical equipment" means technologically sophisticated medical devices that may be used in a residence, including the following: (1) Oxygen and oxygen delivery system; (2) ventilators; (3) respiratory disease management devices; (4) continuous positive airway pressure (CPAP) devices; (5) electronic and computerized wheelchairs and seating systems; (6) apnea monitors; (7) transcutaneous electrical nerve stimulator (TENS) units; (8) low air loss cutaneous pressure management devices; (9) sequential compression devices; (10) feeding pumps; (11) home phototherapy devices; (12) infusion delivery devices; (13) distribution of medical gases to end users for human consumption; (14) hospital beds; (15) nebulizers; (16) other similar equipment determined by the board in rules and regulations adopted by the board.

u) "Electronic prescription" means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

(v) "Electronic prescription application" means software that is used to create electronic prescriptions and that is intended to be installed on the prescriber's computers and servers where access and records are controlled by the prescriber.

(w) "Electronic signature" means a confidential personalized digital key, code, number or other method for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message and indicates the person's approval of the information contained in the transmission.

(x) "Electronic transmission" means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

(y) "Electronically prepared prescription" means a prescription that is generated using an electronic prescription application.

(z) "Exclusive distributor" means any entity that: (1) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; (2) is registered as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the normal distribution channel, must be an authorized distributor of record.

(aa) "Facsimile transmission" or "fax transmission" means the transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes but is not limited to transmission of a written prescription between the prescriber's fax machine and the pharmacy's fax machine; transmission of an electronically prepared prescription from the prescriber's electronic prescription application to the pharmacy's fax machine, computer or printer; or transmission of an electronically prepared prescription from the prescriber's fax machine to the pharmacy's fax machine, computer or printer.

(bb) "Generic name" means the established chemical name or official name of a drug or drug product.

(cc) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

- (A) Inmates of a jail or correctional institution or facility;
- (B) residents of a juvenile detention facility, as defined by the revised Kansas code for care of children and the revised Kansas juvenile justice code;
- (C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas;
- (D) employees of a business or other employer; or
- (E) persons receiving inpatient hospice services.

(2) "Institutional drug room" does not include:

- (A) Any registered pharmacy;
- (B) any office of a practitioner; or
- (C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

(dd) "Interchangeable," in reference to a biological product, means (1) A product that the federal Food and Drug Administration has determined to meet the standards of "interchangeable" or "interchangeability" pursuant to 42 U.S.C. sec. 262(k)(4), and is identified as interchangeable in the federal Food and Drug Administration List of Licensed Products with Reference Product Exclusivity and Biosimilar or Interchangeable Evaluations, also referred to as the "Purple Book"; or (2) A product that the federal Food and Drug Administration has determined to be therapeutically equivalent to another biologic product, and has been granted an "A" rating as set forth in the latest edition or supplement of the federal Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book."

(ee) "Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

(ff) "Intracompany transaction" means any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership or control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product.

(gg) "Medical care facility" shall have the meaning provided in K.S.A. 65-425, and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b, and amendments thereto, except community mental health centers and facilities for people with intellectual disability.

(hh) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by:

(1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice;

(2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or

(3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(ii) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs and devices.

(hh) "Mid-level practitioner" means an advanced practice registered nurse issued a license pursuant to K.S.A. 65-1131, and amendments thereto, who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130, and amendments thereto, or a physician assistant licensed pursuant to the physician assistant licensure act who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-28a08, and amendments thereto.

(jj) "Normal distribution channel" means a chain of custody for a prescription-only drug that goes from a manufacturer of the prescription-only drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, directly or by drop shipment, to:

(1) A pharmacy to a patient or to other designated persons authorized by law to dispense or administer such drug to a patient;

(2) a wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

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

(ll) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(mm) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(nn) "Pharmacist intern" means: (1) A student currently enrolled in an accredited pharmacy program; (2) a graduate of an accredited pharmacy program serving an internship; or (3) a graduate of a pharmacy program located outside of the United States which is not accredited and who has successfully passed equivalency examinations approved by the board.

(oo) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

(pp) "Pharmacy prescription application" means software that is used to process prescription information, is installed on a pharmacy's computers or servers, and is controlled by the pharmacy.

(qq) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

(rr) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

(ss) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

(tt) "Prescriber" means a practitioner or a mid-level practitioner.

(uu) "Prescription" or "prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a prescriber in the authorized course of such prescriber's professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such prescriber, regardless of whether the communication is oral, electronic, facsimile or in printed form.

(vv) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

(ww) "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 U.S.C. § 353, as amended), to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

(xx) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

(yy) "Professional incompetency" means:

- (1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;
- (2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(zz) "Readily retrievable" means that records kept by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records within a reasonable time not to exceed 48 hours of a request from the board or other authorized agent or that hard-copy records are kept on which certain items are asterisked, redlined or in some other manner visually identifiable apart from other items appearing on the records.

(aaa) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

(bbb) "Secretary" means the executive secretary of the board.

(ccc) "Third party logistics provider" means an entity that: (1) Provides or coordinates warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; (2) is registered as a wholesale distributor under the pharmacy act of the state of Kansas; and (3) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(ddd) "Unprofessional conduct" means:

- (1) Fraud in securing a registration or permit;
- (2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;
- (3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;
- (4) intentionally falsifying or altering records or prescriptions;
- (5) unlawful possession of drugs and unlawful diversion of drugs to others;
- (6) willful betrayal of confidential information under K.S.A. 65-1654, and amendments thereto;
- (7) conduct likely to deceive, defraud or harm the public;
- (8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;
- (9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or
- (10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

(eee) "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

(fff) "Valid prescription order" means a prescription that is issued for a legitimate medical purpose by an individual prescriber licensed by law to administer and prescribe drugs and acting in the usual course of such prescriber's professional practice. A prescription issued solely on the basis of an internet-based questionnaire or consultation without an appropriate prescriber-patient relationship is not a valid prescription order.

(ggg) "Veterinary medical teaching hospital pharmacy" means any location where prescription-only drugs are stored as part of an accredited college of veterinary medicine and from which prescription-only drugs are distributed for use in treatment of or administration to a nonhuman.

(hhh) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including, but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain

pharmacy warehouses that conduct wholesale distributions, and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions. Wholesale distributor shall not include persons engaged in the sale of durable medical equipment to consumers or patients.

(iii) "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the total number of units of transferred drugs during a twelve-month period does not exceed 5% of the total number of all units dispensed by the pharmacy during the immediately preceding twelve-month period. Wholesale distribution does not include: (1) The sale, purchase or trade of a prescription drug or device, an offer to sell, purchase or trade a prescription drug or device or the dispensing of a prescription drug or device pursuant to a prescription; (2) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device for emergency medical reasons; (3) intracompany transactions, as defined in this section, unless in violation of own use provisions; (4) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control; (5) the sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law; (6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; (7) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement; (8) the sale, purchase or trade of blood and blood components intended for transfusion; (9) the return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with the board's rules and regulations; (10) the sale, transfer, merger or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's rules and regulations; (11) the distribution of drug samples by manufacturers' and authorized distributors' representatives; (12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use; or (13) the sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer, originating wholesale distributor or to a third party returns processor in accordance with the board's rules and regulations.

**History:** L. 1953, ch. 290, § 3; L. 1975, ch. 319, § 2; L. 1977, ch. 217, § 1; L. 1978, ch. 242, § 1; L. 1978, ch. 243, § 1; L. 1979, ch. 193, § 1; L. 1982, ch. 182, § 138; L. 1986, ch. 235, § 1; L. 1986, ch. 231, § 9; L. 1986, ch. 236, § 1; L. 1987, ch. 235, § 5; L. 1987, ch. 236, § 1; L. 1988, ch. 297, § 2; L. 1989, ch. 193, § 1; L. 1989, ch. 192, § 2; L. 1989, ch. 192, § 3; L. 1991, ch. 272, § 10; L. 1996, ch. 229, § 118; L. 1997, ch. 112, § 1; L. 1999, ch. 38, § 1; L. 1999, ch. 149, § 6; L. 2000, ch. 89, § 1; L. 2000, ch. 159, § 10; L. 2001, ch. 31, § 1; L. 2002, ch. 25, § 2; L. 2003, ch. 124, § 8; L. 2006, ch. 169, § 117; L. 2007, ch. 177, § 30; L. 2011, ch. 114, § 55; L. 2012, ch. 107, § 1, May 17; L. 2012, ch. 166, § 11; July 1.

**65-1636. Sale of drugs limited to pharmacies.** (a) Except as otherwise provided in this act, the sale and distribution of drugs shall be limited to pharmacies operating under registrations as required by this act, and the actual sale or distribution of drugs shall be made by a pharmacist or other persons acting under the immediate personal direction and supervision of the pharmacist.

(b) The donation, acceptance, transfer, distribution or dispensing of any drug in compliance with the provisions of the cancer drug repository program established by K.S.A 2008 Supp. 65-1664 through 65-1667, and amendments thereto, and any rules and regulations promulgated thereunder shall not constitute a violation of this section.

(c) The donation, acceptance, transfer, distribution or dispensing of any drug in compliance with the provisions of the utilization of unused medications act and any rules and regulations promulgated thereunder shall not constitute a violation of this section.

**History:** L. 1953, ch. 290, § 22; L. 1975, ch. 319, § 22; L. 1986, ch. 231, § 24; L. 2009, ch. 48, § 1; July 1.

**65-1637. Pharmacist required to be in charge of pharmacy; compounding, filling and refilling of prescriptions; refusal to fill; brand exchange (Exact caption not yet provided).** In every store, shop or other place defined in this act as a "pharmacy" there shall be a pharmacist in charge and, except as otherwise provided by law, the compounding and dispensing of prescriptions shall be limited to pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral, telephonic or by electronic transmission unless prohibited by law. Blank forms for written prescription orders may have two signature lines. If there are two lines, one signature line shall state: "Dispense as written" and the other signature line shall state: "Brand exchange permissible." Prescriptions shall only be filled or refilled in accordance with the following requirements:

(a) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except:

(1) That a pharmacist may provide up to three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply; **and**

(2) that a pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written," or

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription, or

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated, or

(D) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication.

(3) that a pharmacist who received a prescription order for a biological product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written," or

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription, or

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated, or

(D) after the pharmacist advises the person who requests the prescription that the pharmacist intends to dispense an interchangeable biological product in substitution, such person requests that the product prescribed be dispensed, or

(E) the federal Food and Drug Administration has not determined the biological product to be interchangeable with the prescribed biological product.

(b) A pharmacist who selects an interchangeable biological product shall, prior to dispensing an interchangeable biological product, inform the patient, or the patient's representative, that an interchangeable biological product will be substituted for the biological product prescribed and that the patient, or the patient's representative, has the right to refuse such substitution and to request that the prescribed biological product be dispensed.

(c) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the physician shall bear the name of the person so telephoning. Nothing in this paragraph shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(d) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug **or biological product** except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act without the prescriber's authorization when all reasonable efforts to contact the

prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this subsection (c)(2) shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this subsection (c)(2). A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this subsection (c)(2) unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

(d) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the physician shall bear the name of the person so telephoning. Nothing in this paragraph shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(e) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug or **biological product** except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this subsection (c)(2) shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this subsection (c)(2). A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this subsection (c)(2) unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

(f) If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.

(g) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.

(h) Any pharmacist who exercises brand exchange and dispenses a less expensive drug **or interchangeable biological** product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug **or biological product**. Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.

(i) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through one of the following means: (i) an interoperable electronic medical records system; (ii) an electronic prescribing technology; (iii) a pharmacy benefit management system; or (iv) a pharmacy record. Entry into an electronic records system as described in this paragraph is presumed to provide 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 communication shall not be required where:

(1) there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed; or (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(j) The pharmacist shall maintain a record of the biological product dispensed for at least two years.

(k) The board shall maintain a link on its website to the current list of all biological products that the federal Food and Drug Administration has determined to be interchangeable biological products.

**65-1637b. Transmission of prescription drug orders; filling and refilling of prescriptions; refusal to fill; brand exchange (Exact caption not yet provided).** (a) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of any prescription order consistent with federal and state laws and rules and regulations. A pharmacist shall not dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determines that the prescription is not a valid prescription order.

(b) The prescriber may authorize an agent to transmit to the pharmacy a prescription order orally, by facsimile transmission or by electronic transmission provided that the first and last names of the transmitting agent are included in the order.

(c) (1) A new written or electronically prepared and transmitted prescription order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the first and last names of the transmitting agent shall be included in the order.

(2) If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy.

(3) An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to electronic transmission. An electronically prepared and transmitted prescription which is printed following electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

(4) In consultation with industry, the state board of pharmacy shall conduct a study on the issues of electronic transmission of prior authorizations and step therapy protocols. The report on the results of such study shall be completed and submitted to the legislature no later than January 15, 2013.

(5) The board is hereby authorized to conduct pilot projects related to any new technology implementation when deemed necessary and practicable, except that no state moneys shall be expended for such purpose.

(d) An authorization to refill a prescription order or to renew or continue an existing drug therapy may be transmitted to a pharmacist through oral communication, in writing, by facsimile transmission or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent, and the first and last names of the transmitting agent are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the refill order or renewal order differs in any manner from the original order, such as a change of the drug strength, dosage form or directions for use, the prescriber shall sign the order as provided by paragraph (1).

(e) Regardless of the means of transmission to a pharmacy, only a pharmacist or a pharmacist intern shall be authorized to receive a new prescription order from a prescriber or transmitting agent. A pharmacist, a pharmacist intern or a registered pharmacy technician may receive a refill or renewal order from a prescriber or transmitting agent if such registered pharmacy technician's supervising pharmacist has authorized that function.

(f) A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription order.

(1) A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.

(2) A prescription for a schedule III, IV or V controlled substance may authorize no more than five refills within six months following the date on which the prescription is issued.

(g) Prescriptions shall only be filled or refilled in accordance with the following requirements:

(1) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except that a pharmacist who receives a prescription order for a brand name drug may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription manually or electronically signed by the prescriber and prepared on a form containing two signature lines, signs the signature line following the statement "dispense as written";

(B) the prescriber, in the case of a written prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription;

(C) The person, or representative of the person, for whom the medication is prescribed, requests the product prescribed be dispensed.

(D) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated; or

(E) the federal food and drug administration has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication.

(2) All prescriptions shall be filled in strict conformity with any directions of the prescriber, except that a pharmacist who receives a prescription order for a biological product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber, in the case of a prescription signed by the prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written," or

(B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription, or

(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated, or

(D) the person, or representative of the person, for whom the medication is prescribed requests the product prescribed be dispensed, or

(E) the federal Food and Drug Administration has not determined the biological product to be interchangeable with the prescribed biological product.

(h) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.

(i) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the prescriber, shall bear the name of the person so telephoning. Nothing in this section shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.

(j) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a seven day supply or one package of the drug.

However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this subsection (j)(2) shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this subsection (j)(2). A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this subsection (j)(2) unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

(k) If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.

(l) Any pharmacist who exercises brand exchange and dispenses a less expensive drug **or biological** product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug **or biological product**.

(m) Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.

**History:** L. 2012, ch. 107, § 3, May 17.