[As Amended by Senate Committee of the Whole]

Session of 2007

SENATE Substitute for HOUSE BILL No. 2531

By Committee on Ways and Means

3-28

AN ACT concerning the pharmacy act of the state of Kansas; amending K.S.A. 40-2123, 65-1627, 65-1645 and 65-1655 and K.S.A. 2006 Supp. 60-4403, 65-1626***[, 65-1635a]*** and 65-1643 and repealing the existing sections; also repealing K.S.A. 2006 Supp. 65-1626c.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 40-2123 is hereby amended to read as follows: 40-2123. (a) The plan shall offer coverage to every eligible person pursuant to which such person's covered expenses shall be indemnified or reimbursed subject to the provisions of K.S.A. 40-2124 and amendments thereto.

(b) Except for those expenses set forth in subsection (c) of this section, expenses covered under the plan shall include expenses for:

(1) Services of persons licensed to practice medicine and surgery which are medically necessary for the diagnosis or treatment of injuries, illnesses or conditions;

(2) services of advanced registered nurse practitioners who hold a certificate of qualification from the board of nursing to practice in an expanded role or physicians assistants acting under the direction of a responsible physician when such services are provided at the direction of a person licensed to practice medicine and surgery and meet the requirements of paragraph (b)(1) above;

(3) services of licensed dentists when such procedures would otherwise be performed by persons licensed to practice medicine and surgery;

(4) emergency care, surgery and treatment of acute episodes of illness or disease as defined in the plan and provided in a general hospital or ambulatory surgical center as such terms are defined in K.S.A. 65-425, and amendments thereto;

(5) medically necessary diagnostic laboratory and x-ray services;

(6) drugs and controlled substances prescribed by a practitioner, as defined in ~~subsection (x) of~~ K.S.A. 65-1626 and amendments thereto, or drugs and controlled substances prescribed by a mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626 and amendments thereto. Coverage for outpatient prescriptions shall be subject to a mandatory 50%

coinsurance provision, and coverage for prescriptions administered to inpatients shall be subject to a coinsurance provision as established in the plan; and

(7) subject to the approval of the commissioner, the board shall also review and recommend the inclusion of coverage for mental health services and such other primary and preventive health care services as the board determines would not materially impair affordability of the plan.

(c) Expenses not covered under the plan shall include expenses for:

(1) Illness or injury due to an act of war;

(2) services rendered prior to the effective date of coverage under this plan for the person on whose behalf the expense is incurred;

(3) services for which no charge would be made in the absence of insurance or for which the insured bears no legal obligation to pay;

(4) (A) services or charges incurred by the insured which are otherwise covered by:

(i) Medicare or state law or programs;

(ii) medical services provided for members of the United States armed forces and their dependents or for employees of such armed forces;

(iii) military service-connected disability benefits;

(iv) other benefit or entitlement programs provided for by the laws of the United States (except title XIX of the social security act of 1965);

(v) workers compensation or similar programs addressing injuries, diseases, or conditions incurred in the course of employment covered by such programs;

(vi) benefits payable without regard to fault pursuant to any motor vehicle or other liability insurance policy or equivalent self-insurance.

(B) This exclusion shall not apply to services or charges which exceed the benefits payable under the applicable programs listed above and which are otherwise eligible for payment under this section.

(5) Services the provision of which is not within the scope of the license or certificate of the institution or individual rendering such service;

(6) that part of any charge for services or articles rendered or prescribed which exceeds the rate established by K.S.A. 40-2131 and amendments thereto for such services;

(7) services or articles not medically necessary;

(8) care which is primarily custodial or domiciliary in nature;

(9) cosmetic surgery unless provided as the result of an injury or medically necessary surgical procedure;

(10) eye surgery if corrective lenses would alleviate the problem;

(11) experimental services or supplies not generally recognized as the normal mode of treatment for the illness or injury involved;

(12) service of a blood donor and any fee for failure of the insured to replace the first three pints of blood provided in each calendar year; and

(13) personal supplies or services provided by a health care facility or any other nonmedical or nonprescribed supply or service.

(d) Except as expressly provided for in this act, no law requiring the coverage or the offer of coverage of a health care service or benefit shall apply to the plan.

(e) A plan may incorporate provisions that will direct covered persons to the most appropriate lowest cost health care provider available.

Sec. 2. K.S.A. 2006 Supp. 60-4403 is hereby amended to read as follows: 60-4403. (a) A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort does not violate K.S.A. 21-3406 and amendments thereto unless the medications or procedures are knowingly administered, prescribed or dispensed with the intent to cause death. A mid-level practitioner as defined in ~~subsection (ii) of~~ K.S.A. 65-1626 and amendments thereto who prescribes medications or procedures to relieve another person's pain or discomfort does not violate K.S.A. 21-3406 and amendments thereto unless the medications or procedures are knowingly prescribed with the intent to cause death.

(b) A licensed health care professional, family member or other legally authorized person who participates in the act of, or the decision making process which results in the withholding or withdrawal of a life-sustaining procedure does not violate K.S.A. 21-3406 and amendments thereto.

(c) Providing spiritual treatment through prayer alone, in lieu of medical treatment, does not violate K.S.A. 21-3406 and amendments thereto.

Sec. 3. K.S.A. 2006 Supp. 65-1626 is hereby amended to read as follows: 65-1626. 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) "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.

~~(c)~~ *(d)* "Board" means the state board of pharmacy created by K.S.A. 74-1603 and amendments thereto.

~~(d)~~ *(e)* "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name than the brand name drug product prescribed.

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

(g) "Chain pharmacy warehouse" means a permanent physical location for drugs or devices, or both, that act as a central warehouse and perform 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.

(h) "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.

~~(f)~~ *(i)* "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.

~~(g)~~ *(j)* "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.

~~(h)~~ *(k)* "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.

~~(i)~~ *(l)* "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

~~(j)~~ *(m)* "Distribute" means to deliver, other than by administering or dispensing, any drug.

~~(k)~~ *(n)* "Distributor" means a person who distributes a drug.

(o) "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".

~~(l)~~ *(p)* "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.

(q) "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.

(r) "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.

~~(m)~~ *(s)* "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

~~(n)~~ *(t)* "Generic name" means the established chemical name or official name of a drug or drug product.

~~(o)~~ *(u)* (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.

(v) "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.

~~(p)~~ *(w)* "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 the mentally retarded.

~~(q)~~ *(x)* "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.

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

(z) "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.

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

~~(s)~~ *(bb)* "Pharmacist" means any natural person licensed under this act to practice pharmacy.

~~(t)~~ *(cc)* "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.

~~(u)~~ *(dd)* "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.

~~(v)~~ *(ee)* "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.

~~(w)~~ *(ff)* "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.

~~(x)~~ *(gg)* "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, 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.

~~(y)~~ *(hh)* "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.

~~(z)~~ *(ii)* "Prescription" means, according to the context, either a prescription order or a prescription medication.

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

~~(bb)~~ *(kk)* "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 United States Code section 353, as amended) to be dispensed only pur-

suant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

~~(cc)~~ *(ll)* "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.

~~(dd)~~ *(mm)* "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.

~~(ee)~~ *(nn)* "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.

~~(ff)~~ *(oo)* "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.

~~(gg)~~ *(pp)* "Secretary" means the executive secretary of the board.

(qq) "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.

~~(hh)~~ *(rr)* "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.

~~(ii)~~ *(ss)* "Mid-level practitioner" means an advanced registered nurse practitioner issued a certificate of qualification 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)~~ *(tt)* "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 record-keeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

~~(kk)~~ *(uu)* "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 non-human.

(vv) "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.

(ww) "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.

Sec. 4. K.S.A. 65-1627 is hereby amended to read as follows: 65-1627. (a) The board may revoke, suspend, place in a probationary status or deny a renewal of any license of any pharmacist upon a finding that:

(1) The license was obtained by fraudulent means;

(2) the licensee has been convicted of a felony and the licensee fails to show that the licensee has been sufficiently rehabilitated to warrant the public trust;

(3) the licensee is found by the board to be guilty of unprofessional conduct or professional incompetency;

(4) the licensee is addicted to the liquor or drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(5) the licensee has violated a provision of the federal or state food, drug and cosmetic act, the uniform controlled substances act of the state of Kansas, or any rule and regulation adopted under any such act;

(6) the licensee is found by the board to have filled a prescription not in strict accordance with the directions of the practitioner or a mid-level practitioner;

(7) the licensee is found to be mentally or physically incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(8) the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act;

(9) the licensee has failed to comply with the requirements of the board relating to the continuing education of pharmacists;

(10) the licensee as a pharmacist in charge or consultant pharmacist under the provisions of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto has failed to comply with the requirements of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto;

(11) the licensee has knowingly submitted a misleading, deceptive, untrue or fraudulent misrepresentation on a claim form, bill or statement;

(12) the licensee has had a license to practice pharmacy revoked, suspended or limited, has been censured or has had other disciplinary action taken, or voluntarily surrendered the license after formal proceedings have been commenced, or has had an application for license denied, by the proper licensing authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof;

(13) the licensee has self-administered any controlled substance without a practitioner's prescription order or a mid-level practitioner's prescription order; or

(14) the licensee has assisted suicide in violation of K.S.A. 21-3406 and amendments thereto as established by any of the following:

(A) A copy of the record of criminal conviction or plea of guilty for a felony in violation of K.S.A. 21-3406 and amendments thereto.

(B) A copy of the record of a judgment of contempt of court for violating an injunction issued under K.S.A. 2002 Supp. 60-4404 and amendments thereto.

(C) A copy of the record of a judgment assessing damages under K.S.A. 2002 Supp. 60-4405 and amendments thereto; or

(15) the licensee has failed to furnish the board, its investigators or its representatives any information legally requested by the board.

(b) In determining whether or not the licensee has violated subsection (a)(3), (a)(4), (a)(7) or (a)(13), the board upon reasonable suspicion of such violation has authority to compel a licensee to submit to mental or physical examination or drug screen, or any combination thereof, by such persons as the board may designate. To determine whether reasonable suspicion of such violation exists, the investigative information shall be presented to the board as a whole. Information submitted to the board as a whole and all reports, findings and other records shall be confidential and not subject to discovery by or release to any person or entity. The licensee shall submit to the board a release of information authorizing the board to obtain a report of such examination or drug screen, or both. A person affected by this subsection shall be offered, at reasonable intervals, an opportunity to demonstrate that such person can resume the competent practice of pharmacy with reasonable skill and safety to patients. For the purpose of this subsection, every person licensed to practice pharmacy and who shall accept the privilege to practice pharmacy in this state by so practicing or by the making and filing of a renewal application to practice pharmacy in this state shall be deemed to have consented to submit to a mental or physical examination or a drug screen, or any combination thereof, when directed in writing by the board and further to have waived all objections to the admissibility of the testimony, drug screen or examination report of the person conducting such examination or drug screen, or both, at any proceeding or hearing before the board on the ground that such testimony or examination or drug screen report constitutes a privileged communication. In any proceeding by the board pursuant to the provisions of this subsection, the record of such board proceedings involving the mental and physical examination or drug screen, or any combination thereof, shall not be used in any other administrative or judicial proceeding.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist for disciplinary action under subsection (a) against the licensee and that the licensee's

continuation in practice would constitute an imminent danger to the public health and safety.

(d) The board may suspend, revoke, place in a probationary status or deny a renewal of any retail dealer's permit issued by the board when information in possession of the board discloses that such operations for which the permit was issued are not being conducted according to law or the rules and regulations of the board.

(e) The board may revoke, suspend, place in a probationary status or deny a renewal of the registration of a pharmacy upon a finding that: (1) Such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith; (2) the owner or any pharmacist employed at such pharmacy is convicted, subsequent to such owner's acquisition of or such employee's employment at such pharmacy, of a violation of the pharmacy act or uniform controlled substances act of the state of Kansas, or the federal or state food, drug and cosmetic act; (3) the owner or any pharmacist employed by such pharmacy has fraudulently claimed money for pharmaceutical services; or (4) the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof.

(f) A registration to manufacture ~~or~~ *drugs,* to distribute at wholesale a drug*, to sell durable medical equipment* or a registration for the place of business where any such operation is conducted may be suspended, revoked, placed in a probationary status or the renewal of such registration may be denied by the board upon a finding that the registrant or the registrant's agent: (1) Has materially falsified any application filed pursuant to or required by the pharmacy act of the state of Kansas; (2) has been convicted of a felony under any federal or state law relating to the manufacture or distribution of drugs; (3) has had any federal registration for the manufacture or distribution of drugs suspended or revoked; (4) has refused to permit the board or its duly authorized agents to inspect the registrant's establishment in accordance with the provisions of K.S.A. 65-1629 and amendments thereto; (5) has failed to keep, or has failed to file with the board or has falsified records required to be kept or filed by the provisions of the pharmacy act of the state of Kansas or by the board's rules and regulations; or (6) has violated the pharmacy act of the state of Kansas or rules and regulations adopted by the state board of pharmacy under the pharmacy act of the state of Kansas or has violated the uniform controlled substances act or rules and regulations adopted by the state

board of pharmacy under the uniform controlled substances act.

(g) Orders under this section, and proceedings thereon, shall be subject to the provisions of the Kansas administrative procedure act.

[Sec. 5. K.S.A. 2006 Supp. 65-1635a is hereby amended to read as follows: 65-1635a. (a) A pharmacist *or a pharmacy student or intern who is working under the direct supervision and control of a pharmacist* ***may administer vaccine to a person 18 years of age or older pursuant to a vaccination protocol if the pharmacist****, pharmacy student or intern* ***has successfully completed a course of study and training, approved by the accreditation council for pharmacy or the board, in vaccination storage, protocols, injection technique, emergency procedures and recordkeeping*** *and has taken a course in cardiopulmonary resuscitation (CPR) and has a current CPR certificate when administering vaccine****. A pharmacist*** *or pharmacy student or intern* ***who successfully completes such a course of study and training shall maintain proof of completion and, upon request, provide a copy of such proof to the board.***

[(b) All vaccinees will be given a written immunization record for their personal files. The administering pharmacist *or pharmacist supervising an administering pharmacy student or intern* ***shall promptly report a record of the immunization to the vaccinee's primary-care provider by electronic facsimile or mail. If the vaccinee does not have a primary care provider, then the administering pharmacist*** *or pharmacist supervising an administering pharmacy student or intern* ***shall promptly report a record of the immunization to the person licensed to practice medicine and surgery by the state board of healing arts who has entered into the vaccination protocol with the pharmacist. The immunization will also be reported to appropriate county or state immunization registries.***

[(c) A pharmacist*, pharmacy student or intern* ***may not delegate to any person the authority granted under this act to administer a vaccine.***

[(d) This section shall be a part of and supplemental to the pharmacy act of the state of Kansas.]

Sec. ~~5.~~ ***[6.]*** K.S.A. 2006 Supp. 65-1643 is hereby amended to read as follows: 65-1643. It shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the identity and exact location of the pharmacy. The issuance of a regis-

tration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

(b) For any person to manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety.

(c) For any person to distribute at wholesale any drugs without first obtaining a registration so to do from the board.

(d) For any person to sell or offer for sale at public auction or private sale in a place where public auctions are conducted, any drugs without first having obtained a registration from the board so to do, and it shall be necessary to obtain the permission of the board in every instance where any of the products covered by this section are to be sold or offered for sale.

(e) For any person to in any manner distribute or dispense samples of any drugs without first having obtained a permit from the board so to do, and it shall be necessary to obtain permission from the board in every instance where the samples are to be distributed or dispensed. Nothing in this subsection shall be held to regulate or in any manner interfere with the furnishing of samples of drugs to duly licensed practitioners, to mid-level practitioners, to pharmacists or to medical care facilities.

(f) Except as otherwise provided in this subsection (f), for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee

under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute 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 product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection (u) of K.S.A. 65-1626 and amendments thereto, for the designation of a pharmacy or drugstore.

(g) For any person to sell any drugs manufactured and sold only in the state of Kansas, unless the label and directions on such drugs shall first have been approved by the board.

(h) For any person to operate an institutional drug room without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1637a and amendments thereto and any rules and regulations adopted pursuant thereto.

(i) For any person to be a pharmacy student without first obtaining a registration to do so from the board, in accordance with rules and regulations adopted by the board, and paying a pharmacy student registration fee of $25 to the board.

(j) For any person to operate a veterinary medical teaching hospital pharmacy without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1662 and amendments thereto and any rules and regulations adopted pursuant thereto.

(k) For any person to sell or distribute in a pharmacy a controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, unless:

(1) (A) Such controlled substance is sold or distributed by a licensed pharmacist, a registered pharmacy technician or a pharmacy intern or clerk supervised by a licensed pharmacist; and

(B) any person purchasing, receiving or otherwise acquiring any such controlled substance produces a photo identification showing the date of birth of the person and signs a log. The log or database required by the board shall be available for inspection during regular business hours to the board of pharmacy and any law enforcement officer; or

(2) there is a lawful prescription.

(l) For any person to sell or distribute in a pharmacy four or more packages or containers of any controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, to a specific

customer within any seven-day period.

(m) For any person to sell or lease or offer for sale or lease durable medical equipment without first obtaining a registration from the board, in accordance with rules and regulations adopted by the board, except that this subsection shall not apply to:

(1) Sales not made in the regular course of the person's business; or

(2) sales by charitable organizations exempt from federal income taxation pursuant to the internal revenue code of 1986, as amended.

Sec. ~~6.~~ ***[7.]*** K.S.A. 65-1645 is hereby amended to read as follows: 65-1645. (a) Application for registrations or permits under K.S.A. 65-1643 and amendments thereto shall be made on a form prescribed and furnished by the board. Applications for registration to distribute at wholesale any drugs shall contain such information as may be required by the board in accordance with the provisions of K.S.A. 65-1655 and amendments thereto. The application shall be accompanied by the fee prescribed by the board under the provisions of this section. When such application and fees are received by the executive secretary of the board on or before the due date, such application shall have the effect of temporarily renewing the applicant's registration or permit until actual issuance or denial of the renewal. However, if at the time of filing a proceeding is pending before the board which may result in the suspension, probation, revocation or denial of the applicant's registration or permit, the board may declare, by emergency order, that such application for renewal shall not have the effect of temporarily renewing such applicant's registration or permit. Separate applications shall be made and separate registrations or permits issued for each separate place at which is carried on any of the operations for which a registration or permit is required by K.S.A. 65-1643 and amendments thereto except that the board may provide for a single registration for a business entity registered to manufacture any drugs or registered to distribute at wholesale any drugs and operating more than one facility within the state, or for a parent entity with divisions, subsidiaries or affiliate companies, or any combination thereof, within the state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(b) The nonrefundable fees required for the issuing of the licenses, registrations or permits under the pharmacy act of the state of Kansas shall be fixed by the board as herein provided, subject to the following:

(1) Pharmacy, new registration not more than $150, renewal not more than $125;

(2) pharmacist, new license by examination not more than $350;

(3) pharmacist, reinstatement application fee not more than $250;

(4) pharmacist, biennial renewal fee not more than $200;

(5) pharmacist, evaluation fee not more than $250;
(6) pharmacist, reciprocal licensure fee not more than $250;
(7) pharmacist, penalty fee, not more than $500;
(8) manufacturer, new registration not more than $500, renewal not more than $400;
(9) wholesaler, new registration not more than $500, renewal not more than $400, except that a wholesaler dealing exclusively in nonprescription drugs, the manufacturing, distributing or dispensing of which does not require registration under the uniform controlled substances act, shall be assessed a fee for registration and reregistration not to exceed $50;
(10) special auction not more than $50;
(11) samples distribution not more than $50;
(12) institutional drug room, new registration not more than $40, renewal not more than $35;
(13) retail dealer selling more than 12 different nonprescription drug products, new permit not more than $12, renewal not more than $12;
(14) certification of grades for each applicant for examination and registration not more than $25; ~~or~~
(15) veterinary medical teaching hospital pharmacy, new registration not more than $40, renewal not more than $35*; or*
(16) durable medical equipment registration fee, not more than $300.

(c) For the purpose of fixing fees, the board may establish classes of retail dealers' permits for retail dealers selling more than 12 different nonprescription drug products, and the board may fix a different fee for each such class of permit.

(d) The board shall determine annually the amount necessary to carry out and enforce the provisions of this act for the next ensuing fiscal year and shall fix by rules and regulations the fees authorized for such year at the sum deemed necessary for such purposes. The fees fixed by the board under this section immediately prior to the effective date of this act shall continue in effect until different fees are fixed by the board by rules and regulations as provided under this section.

(e) The board may deny renewal of any registration or permit required by K.S.A. 65-1643 and amendments thereto on any ground which would authorize the board to suspend, revoke or place on probation a registration or permit previously granted pursuant to the provisions of K.S.A. 65-1643 and amendments thereto. Registrations and permits issued under the provisions of K.S.A. 65-1643 and 65-1644 and amendments thereto shall be conspicuously displayed in the place for which the registration or permit was granted. Such registrations or permits shall not be transferable. All such registrations and permits except retail dealer permits shall expire on June 30 following date of issuance. Retail dealers'

permits shall expire on the last day of February. All registrations and permits shall be renewed annually. Application blanks for renewal of registrations and permits shall be mailed by the board to each registrant or permittee at least 30 days prior to expiration of the registration or permit. If application for renewal is not made before 30 days after such expiration, the existing registration or permit shall lapse and become null and void on the date of its expiration, and no new registration or permit shall be granted except upon payment of the required renewal fee plus a penalty equal to the renewal fee. Failure of any registrant or permittee to receive such application blank shall not relieve the registrant or permittee from the penalty hereby imposed if the renewal is not made as prescribed.

(f) In each case in which a license of a pharmacist is issued or renewed for a period of time less than two years, the board shall prorate to the nearest whole month the license or renewal fee established pursuant to ~~K.S.A. 65-1645 and amendments thereto~~ *this section*.

(g) The board may require that fees paid for any examination under the pharmacy act of the state of Kansas be paid directly to the examination service by the person taking the examination.

Sec. ~~7.~~ ***[8.]*** K.S.A. 65-1655 is hereby amended to read as follows: 65-1655. (a) The board shall require an applicant for registration to distribute at wholesale any drugs under K.S.A. 65-1643 and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant;

(3) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) such other information as the board deems appropriate. Changes in any information in this subsection (a) shall be submitted to the board as required by such board.

(b) In reviewing the qualifications for applicants for initial registration

or renewal of registration to distribute at wholesale any drugs, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(2) any felony convictions of the applicant under federal or state laws;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with registration requirements under previously granted registrations, if any;

(7) compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

(8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration to distribute at wholesale any drugs, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to distribute at wholesale any drugs shall be in addition to the authority of the board under subsection (e) of K.S.A. 65-1627 and amendments thereto or subsection (e) of K.S.A. 65-1645 and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered to distribute at wholesale any drugs have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

(e) The board by rules and regulations may implement this section to conform to any requirements of the federal prescription drug marketing act of 1987 (21 U.S.C. 321 et seq.) in effect on the effective date of this act.

(f) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board to inspect and accredit wholesale distributors for the purpose of inspecting

the wholesale distribution operations prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. The board shall have the authority to waive registration requirements for wholesale distributors that are accredited by an accrediting agency approved by the board. The board shall adopt rules and regulations to establish standards and requirements for the issuance and maintenance of a wholesale distributor registration, including inspections of wholesale distributor facilities domiciled in the state.

(1) Individual or third party inspectors must demonstrate to the board that they have received training or demonstrate familiarity with the inspection standards. Evidence such as a letter of certification from a training program, notice from the inspector's employing third party organization or other means recognized by the board shall be accepted as meeting the requirement.

(2) The board may register a wholesale distributor that is licensed or registered under the laws of another state if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) the applicant is inspected and accredited by a third party recognized and approved by the board.

(g) A person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in federal food and drug administration regulations 21 C.F.R. Part 205 to provide wholesale distribution services.

(h) The board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a wholesale distributor registration, including, but not limited to, requirements regarding the following: (1) An application and renewal fee; (2) a surety bond; (3) registration and periodic inspections; (4) certification of a designated representative; (5) designation of a registered agent; (6) storage of drugs and devices; (7) handling, transportation and shipment of drugs and devices; (8) security; (9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board; (10) due diligence regarding other wholesale distributors; (11) creation and maintenance of records, including transaction records; and (12) procedures for operation.

~~(f)~~ *(i)* This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

Sec. ~~8.~~ ***[9.]*** K.S.A. 40-2123, 65-1627, 65-1645 and 65-1655 and K.S.A. 2006 Supp. 60-4403, 65-1626, 65-1626c***[, 65-1635a]*** and 65-1643 are hereby repealed.

Sec. ~~9.~~ ***[10.]*** This act shall take effect and be in force from and after its publication in the statute book.