

HOUSE BILL No. 2119

AN ACT concerning health and healthcare; providing for licensed pharmacists to administer certain drugs; authorizing certain business entities to hire physicians and chiropractors; requiring electronic prescriptions for certain controlled substances; amending K.S.A. 65-1626, 65-2803, 65-2836 and 65-2877a and repealing the existing sections.

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

New Section 1. (a) Every prescription order issued for a controlled substance in schedules II-V that contains an opiate, as described in the uniform controlled substances act, shall be transmitted electronically unless:

(1) Electronic prescription orders are not possible due to technological or electronic system failures;

(2) electronic prescribing is not available to the prescriber due to economic hardship or technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances exist, as demonstrated by the prescriber;

(3) the prescription order is for a compounded preparation containing two or more components or requires information that makes electronic submission impractical, such as complicated or lengthy instructions for use;

(4) the prescription order is issued by a licensed veterinarian;

(5) the prescriber reasonably determines that it would be impractical for the patient to obtain the substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition;

(6) the prescription order is issued pursuant to drug research or drug therapy protocols;

(7) the prescription order is by a prescriber who issues 50 or fewer prescription orders per year for controlled substances that contain opiates; or

(8) the United States food and drug administration requires the prescription order to contain elements that are not compatible or possible with electronic prescriptions.

(b) (1) A prescriber may request a waiver from the provisions of subsection (a) for a period not to exceed six months if such prescriber cannot comply with subsection (a) due to economic hardship, technological limitations that reasonably are not within the prescriber's control or other circumstance demonstrated by the prescriber. If a waiver is granted by the board, the prescriber may request that such waiver be renewed for a period not to exceed six months. Requests for a waiver or renewal shall be submitted to the board in such form and manner as prescribed by the board and shall include the reason for the request and any other information required by the board.

(2) If a prescriber prescribes a controlled substance by non-electronic prescription, such prescriber shall indicate the prescription is made pursuant to a waiver granted pursuant to this section. A pharmacist shall not be required to verify the validity of any waiver, either with the prescriber or the board, but may do so in accordance with K.S.A. 65-1637, and amendments thereto.

(c) The provisions of this section shall be a part of and supplemental to the pharmacy act of the state of Kansas.

(d) The provisions of this section shall take effect on and after July 1, 2021.

New Sec. 2. (a) Notwithstanding any other provision of law, a business entity issued a certificate of authorization by the board may employ or contract with one or more licensees of the board for the purpose of providing professional services for which such licensees hold a valid license issued by the board. Nothing in the Kansas healing arts act shall be construed to prohibit a licensee from being employed by or under contract to provide professional services for a business entity granted a certificate of authorization pursuant to this section. Medical care facilities, as defined by K.S.A. 65-425, and amendments thereto, that are in compliance with department of health and environment licensure requirements are exempt from the provisions of

this section. Nothing contained herein shall be construed to allow a corporation to practice optometry or dentistry, except as otherwise provided in K.S.A. 17-2706, and amendments thereto.

(b) (1) A business entity may apply to the state board of healing arts for a certificate of authorization, on a form and in a manner prescribed by the state board of healing arts, and shall include the following information:

(A) The name of the business entity;

(B) a list of the names of the owners and officers of the business entity;

(C) a description of the apportionment of liability of all partners or owners, if the business entity is organized as a limited partnership or a limited liability company;

(D) a list of each responsible official if the business entity is organized as a governmental unit; and

(E) a list of all licensed physicians and chiropractors to be hired by the business entity.

(2) As a condition of certification, a business entity shall be required to provide the state board of healing arts evidence of the following:

(A) The address of the business entity;

(B) a city or county occupational license; and

(C) licensure of all physicians and chiropractors to be employed by the business entity.

(3) A business entity applying for certification shall remit a fee set by the state board of healing arts through rules and regulations, not to exceed \$1,000.

(c) (1) If the state board of healing arts finds that such business entity is in compliance with all of the requirements of this section, the state board of healing arts shall issue a certificate of authorization to such business entity designating the business entity as authorized to employ individuals licensed to practice medicine and surgery or chiropractic, as applicable.

(2) A certificate of authorization shall be renewed annually and accompanied by a fee to be fixed by the state board of healing arts. The renewal fee shall be accompanied by a form prescribed by the state board of healing arts.

(d) Except as provided in K.S.A. 40-3403, and amendments thereto, no business entity issued a certificate of authorization under this section shall be relieved of responsibility for the conduct or acts of its agents or employees by reason of its compliance with the provisions of this section, nor shall any individual licensed to practice the healing arts be relieved of responsibility and liability for services performed by reason of employment or relationship with such business entity. Nothing in this section shall exempt any business entity from the provisions of any other law applicable to the business entity.

(e) A business entity issued a certificate of authorization under this section shall not:

(1) In any manner, directly or indirectly, interfere with, diminish, restrict, substitute its judgment for or otherwise exercise control over the independent professional judgment and decisions of its employed licensees as it relates to the care of patients; or

(2) prohibit or restrict any employed licensee from discussing with or disclosing to any patient or other individual any medically appropriate healthcare information that such licensee deems appropriate regarding the nature of treatment options, the risks or alternatives thereto, the process used or the decision made by the business entity to approve or deny healthcare services, the availability of alternate therapies, consultations or tests, or from advocating on behalf of the patient.

(f) As used in this section:

(1) (A) "Business entity" means an employer located in Kansas that utilizes electronic medical records and offers medicine and surgery or chiropractic services solely for its employees and the dependents of

such employees at the employer's work site; an organization that is licensed to sell accident and sickness insurance in the state that is also a mutual or non-profit health carrier that utilizes electronic medical records, or a wholly owned subsidiary of such organization that provides medical services solely for the organization's enrollees and dependents of such enrollees; or an information technology company that designs, utilizes and provides electronic medical records for businesses and worksite medical clinics for employers located in Kansas and offers medicine and surgery or chiropractic services solely to its employees and the dependents of such employees at the employer's work sites in Kansas.

(B) "Business entity" does not include medical care facilities under K.S.A. 65-425, and amendments thereto, corporations licensed under K.S.A. 40-3214, and amendments thereto, and professional corporations organized pursuant to the professional corporation law of Kansas.

(2) "Physician" means a person licensed by the state board of healing arts to practice medicine and surgery.

(3) "Licensee" means a person licensed by the state board of healing arts to practice medicine and surgery or chiropractic and whose license is in a full active status and has not been revoked, suspended, limited or placed under probationary conditions.

(g) A business entity's certificate of authorization may be revoked, suspended or limited, may be publicly censured or placed under probationary conditions, or an application for a certificate or for reinstatement of a certificate may be denied upon a finding of the existence of any of the following grounds:

(1) The business entity has committed fraud or misrepresentation in applying for or securing an original, renewal or reinstated certificate.

(2) The business entity has willfully or repeatedly violated this act, the pharmacy act of the state of Kansas or the uniform controlled substances act or any rules and regulations adopted pursuant thereto, or any rules and regulations of the secretary of health and environment that are relevant to the practice of the healing arts.

(3) The business entity has had a certificate, or equivalent authorization, to employ licensees to practice the healing arts revoked, suspended or limited, has been censured or has had other disciplinary action taken or has had an application for a certificate or license denied, by the proper licensing authority of another state.

(4) The business entity has violated any lawful rule and regulation promulgated by the board.

(5) The business entity has failed to report or reveal the knowledge required to be reported or revealed under K.S.A. 65-28,122, and amendments thereto.

(6) The business entity has failed to report to the board any adverse action taken against the business entity by another state or licensing jurisdiction, a governmental agency, by a law enforcement agency or a court for acts or conduct similar to acts or conduct that would constitute grounds for disciplinary action under this section.

(7) The business entity has engaged in conduct likely to deceive, defraud or harm the public.

(8) The business entity has engaged in conduct that violates patient trust and exploits the licensee-patient relationship for corporate gain.

(9) The business entity has used any false, fraudulent or deceptive statement in any document connected with the practice of the healing arts, including the intentional falsifying or fraudulent altering of a patient healthcare record.

(10) The business entity has failed to furnish to the board, or its investigators or representatives, any information legally requested by the board.

(11) The business entity has had, or failed to report to the board, any adverse judgment, award or settlement against the business entity resulting from a medical liability claim related to acts or conduct

similar to acts or conduct that would constitute grounds for disciplinary action under this section.

(12) The business entity has been convicted of a felony or class A misdemeanor, or substantially similar offense in another jurisdiction, related to the practice of the healing arts.

(h) The state board of healing arts shall adopt all rules and regulations as necessary to implement and administer the provisions of this section.

(i) For the purposes of determining the impact on the healthcare stabilization fund of requiring business entities to comply with the provisions of the healthcare provider insurance availability act, the healthcare stabilization fund is hereby directed to conduct such actuarial and operational studies as are necessary to determine such impact, and to report the findings to the legislature on or before January 1, 2020.

(j) This section shall be a part of and supplemental to the Kansas healing arts act.

(k) The provisions of this section shall take effect on and after March 1, 2020.

Sec. 3. On and after March 1, 2020, K.S.A. 65-2803 is hereby amended to read as follows: 65-2803. (a) Unless otherwise specified by the board *or as provided in section 2, and amendments thereto*, it shall be unlawful for any person who does not have a license, registration, permit or certificate to engage in the practice of any profession regulated by the board or whose license, registration, permit or certificate to practice has been revoked or suspended to engage in the practice of any profession regulated by the board.

(b) This section shall not apply to any healthcare provider who in good faith renders emergency care or assistance at the scene of an emergency or accident as authorized by K.S.A. 65-2891, and amendments thereto.

(c) The commission of any act or practice declared to be a violation of this section may render the violator liable to the state or county for the payment of a civil penalty of up to \$1,000 per day for each day a person engages in the unlawful practice of a profession regulated by the board. In addition to such civil penalty, such violator may be assessed reasonable costs of investigation and prosecution.

(d) Violation of this section is a severity level 10, nonperson felony.

Sec. 4. On and after March 1, 2020, K.S.A. 65-2836 is hereby amended to read as follows: 65-2836. A licensee's license may be revoked, suspended or limited, or the licensee may be publicly censured or placed under probationary conditions, or an application for a license or for reinstatement of a license may be denied upon a finding of the existence of any of the following grounds:

(a) The licensee has committed fraud or misrepresentation in applying for or securing an original, renewal or reinstated license.

(b) The licensee has committed an act of unprofessional or dishonorable conduct or professional incompetency, except that the board may take appropriate disciplinary action or enter into a non-disciplinary resolution when a licensee has engaged in any conduct or professional practice on a single occasion that, if continued, would reasonably be expected to constitute an inability to practice the healing arts with reasonable skill and safety to patients or unprofessional conduct as defined in K.S.A. 65-2837, and amendments thereto.

(c) The licensee has been convicted of a felony or class A misdemeanor, or substantially similar offense in another jurisdiction, whether or not related to the practice of the healing arts, *or* the licensee has been convicted in a special or general court-martial, whether or not related to the practice of the healing arts. The board shall revoke a licensee's license following conviction of a felony or substantially similar offense in another jurisdiction, or following conviction in a general court-martial occurring after July 1, 2000, unless a $\frac{2}{3}$ majority of the board members present and voting determine by clear and

convincing evidence that such licensee will not pose a threat to the public in such person's capacity as a licensee and that such person has been sufficiently rehabilitated to warrant the public trust. In the case of a person who has been convicted of a felony or convicted in a general court-martial and who applies for an original license or to reinstate a canceled license, the application for a license shall be denied unless a $\frac{2}{3}$ majority of the board members present and voting on such application determine by clear and convincing evidence that such person will not pose a threat to the public in such person's capacity as a licensee and that such person has been sufficiently rehabilitated to warrant the public trust.

(d) The licensee has used fraudulent or false advertisements.

(e) The licensee is addicted to or has distributed intoxicating liquors or drugs for any other than lawful purposes.

(f) The licensee has willfully or repeatedly violated this act, the pharmacy act of the state of Kansas or the uniform controlled substances act, or any rules and regulations adopted pursuant thereto, or any rules and regulations of the secretary of health and environment ~~which~~ *that* are relevant to the practice of the healing arts.

(g) The licensee has unlawfully invaded the field of practice of any branch of the healing arts in which the licensee is not licensed to practice.

(h) The licensee has engaged in the practice of the healing arts under a false or assumed name, or the impersonation of another practitioner. The provisions of this subsection relating to an assumed name shall not apply to licensees practicing under a professional corporation, *under a business entity that holds a certificate of authorization pursuant to section 2, and amendments thereto*, or under any other legal entity duly authorized to provide such professional services in the state of Kansas.

(i) The licensee's ability to practice the healing arts with reasonable skill and safety to patients is impaired by reason of physical or mental illness, or condition or use of alcohol, drugs or controlled substances. All information, reports, findings and other records relating to impairment shall be confidential and not subject to discovery by or release to any person or entity outside of a board proceeding.

(j) The licensee has had a license to practice the healing arts revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for a license denied, by the proper licensing authority of another state, territory, District of Columbia, or other country.

(k) The licensee has violated any lawful rule and regulation promulgated by the board or violated any lawful order or directive of the board previously entered by the board.

(l) The licensee has failed to report or reveal the knowledge required to be reported or revealed under K.S.A. 65-28,122, and amendments thereto.

(m) The licensee, if licensed to practice medicine and surgery, has failed to inform in writing a patient suffering from any form of abnormality of the breast tissue for which surgery is a recommended form of treatment, of alternative methods of treatment recognized by licensees of the same profession in the same or similar communities as being acceptable under like conditions and circumstances.

(n) The licensee has cheated on or attempted to subvert the validity of the examination for a license.

(o) The licensee has been found to be mentally ill, disabled, not guilty by reason of insanity, not guilty because the licensee suffers from a mental disease or defect or incompetent to stand trial by a court of competent jurisdiction.

(p) The licensee has prescribed, sold, administered, distributed or given a controlled substance to any person for other than medically accepted or lawful purposes.

(q) The licensee has violated a federal law or regulation relating to controlled substances.

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

(s) Sanctions or disciplinary actions have been taken against the licensee by a peer review committee, healthcare facility, a governmental agency or department or a professional association or society for acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(t) The licensee has failed to report to the board any adverse action taken against the licensee by another state or licensing jurisdiction, a peer review body, a healthcare facility, a professional association or society, a governmental agency, by a law enforcement agency or a court for acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(u) The licensee has surrendered a license or authorization to practice the healing arts in another state or jurisdiction, has surrendered the authority to utilize controlled substances issued by any state or federal agency, has agreed to a limitation to or restriction of privileges at any medical care facility or has surrendered the licensee's membership on any professional staff or in any professional association or society while under investigation for acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(v) The licensee has failed to report to the board surrender of the licensee's license or authorization to practice the healing arts in another state or jurisdiction or surrender of the licensee's membership on any professional staff or in any professional association or society while under investigation for acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(w) The licensee has an adverse judgment, award or settlement against the licensee resulting from a medical liability claim related to acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(x) The licensee has failed to report to the board any adverse judgment, settlement or award against the licensee resulting from a medical malpractice liability claim related to acts or conduct similar to acts or conduct ~~which~~ *that* would constitute grounds for disciplinary action under this section.

(y) The licensee has failed to maintain a policy of professional liability insurance as required by K.S.A. 40-3402 or 40-3403a, and amendments thereto.

(z) The licensee has failed to pay the premium surcharges as required by K.S.A. 40-3404, and amendments thereto.

(aa) The licensee has knowingly submitted any misleading, deceptive, untrue or fraudulent representation on a claim form, bill or statement.

(bb) The licensee as the supervising physician for a physician assistant has failed to adequately direct and supervise the physician assistant in accordance with the physician assistant licensure act or rules and regulations adopted under such act.

(cc) The licensee has assisted suicide in violation of K.S.A. 21-3406, prior to its repeal, or K.S.A. 2018 Supp. 21-5407, and amendments thereto, as established by any of the following:

(1) A copy of the record of criminal conviction or plea of guilty for a felony in violation of K.S.A. 21-3406, prior to its repeal, or K.S.A. 2018 Supp. 21-5407, and amendments thereto.

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

(3) A copy of the record of a judgment assessing damages under K.S.A. 60-4405, and amendments thereto.

(dd) The licensee has given a worthless check or stopped payment on a debit or credit card for fees or moneys legally due to the board.

(ee) The licensee has knowingly or negligently abandoned medical records.

Sec. 5. On and after March 1, 2020, K.S.A. 65-2877a is hereby amended to read as follows: 65-2877a. ~~The healing arts act and any other~~ No provision of law prohibiting practice of the healing arts by a general corporation shall ~~not~~ apply to a healing arts school approved by the board if the healing arts school is a non-profit entity under section 501(c)(3) of the internal revenue code of 1986, is approved by the state board of regents, and as part of its academic requirements provides clinical training to its students under the supervision of persons who are licensed to practice a branch of the healing arts in this state.

New Sec. 6. (a) (1) A licensed pharmacist may administer a drug by injection that, in the judgment of the prescriber, may be safely self-administered by a patient, to a patient pursuant to a prescription order, unless the prescription order includes the words "not to be administered by a pharmacist," or words of like effect.

(2) Nothing in this section shall replace, repeal or supersede the requirements prescribed in K.S.A. 65-4a10, and amendments thereto.

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

Sec. 7. K.S.A. 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 *or section 6*, and amendments thereto.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, repackager, wholesale distributor, third-party logistics provider or dispenser but does 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) "Automated dispensing system" means a robotic or mechanical system controlled by a computer that: (1) Performs operations or activities, other than compounding or administration, relative to the storage, packaging, labeling, dispensing or distribution of drugs; (2) collects, controls and maintains all transaction information; and (3) operates in accordance with the board's rules and regulations.

(e) "Biological product" means the same as defined in 42 U.S.C. § 262(i), as in effect on January 1, 2017.

(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 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 an interchangeable biological product.

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

(i) "Co-licensed partner" means a person or pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer or an affiliate of the manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a product.

(j) "Common carrier" means any person who undertakes, whether directly or by any other arrangement, to transport property, including drugs, for compensation.

(k) "Compounding" means the combining of components into a compounded preparation under either of the following conditions:

(1) As the result of a practitioner's prescription drug order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice to meet the specialized medical need of an individual patient of the practitioner that cannot be filled by an FDA-approved drug; or

(2) for the purpose of, or incidental to, research, teaching or chemical analysis, and not for sale or dispensing.

Compounding includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

Compounding does not include reconstituting any oral or topical drug according to the FDA-approved labeling for the drug or preparing any sterile or nonsterile preparation that is essentially a copy of a commercially available product.

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

(m) "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.

(n) "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.

(o) "Dispense" or "dispensing" 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.

(p) "Dispenser" means:

(1) A practitioner or pharmacist who dispenses prescription medication, or a physician assistant who has authority to dispense prescription-only drugs in accordance with K.S.A. 65-28a08(b), and amendments thereto; or

(2) a retail pharmacy, hospital pharmacy or group of pharmacies under common ownership and control that do not act as a wholesale distributor, or affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

(q) "Distribute" or "distribution" means to deliver, offer to deliver, sell, offer to sell, purchase, trade, transfer, broker, give away, handle, store or receive, other than by administering or dispensing, any product, but does not include dispensing a product pursuant to a prescription executed in accordance with 21 U.S.C. § 353 or the dispensing of a product approved under 21 U.S.C. § 360b.

(r) "Distributor" means a person or entity that distributes a drug.

(s) "Drop shipment" means the sale, by a manufacturer, repackager or 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 dispenser, and the dispenser receives delivery of the prescription drug directly from the manufacturer, repackager, third-party logistics provider or exclusive distributor, of such prescription drug.

(t) "Drug" means: (1) Articles recognized in the official United States pharmacopeia, or other such official compendiums of the United States, or official national formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of human or other animals; and (4) articles intended for use as a component of any articles specified in paragraph (1), (2) or (3); 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.

(u) "Durable medical equipment" means equipment that: (1) Provides therapeutic benefits or enables an individual to perform certain tasks that the individual is unable to otherwise undertake due to certain medical conditions or illnesses; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to a person in the absence of an illness or injury; (4) can withstand repeated use; (5) is appropriate for use in the home, long-term care facility or medical care facility, but may be transported to other locations to allow the individual to complete instrumental activities of daily living that are more complex tasks required for independent living; and (6) may include devices and medical supplies or other similar equipment determined by the board in rules and regulations adopted by the board.

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

(w) "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.

(x) "Electronic signature" means a confidential personalized digital key, code, number or other method for secure electronic data transmissions that 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.

(y) "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.

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

(aa) "Exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor or dispenser.

(bb) "FDA" means the U.S. department of health and human services, food and drug administration.

(cc) "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.

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

(ee) "Health care entity" means any person that provides diagnostic, medical, surgical or dental treatment or rehabilitative care but does not include any retail pharmacy or wholesale distributor.

(ff) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and that 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 that 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.

(gg) "Interchangeable biological product" means a biological product that the FDA has:

(1) Licensed and determined meets the standards for "interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on January 1, 2017; or

(2) determined to be therapeutically equivalent as set forth in the latest edition or supplement to the FDA's approved drug products with therapeutic equivalence evaluations.

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

(ii) "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-licensed partners.

(jj) "Label" means a display of written, printed or graphic matter upon the immediate container of any drug.

(kk) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug.

(ll) "Long-term care facility" means "nursing facility," as defined in K.S.A. 39-923, and amendments thereto.

(mm) "Medical care facility" means the same as defined in K.S.A. 65-425, and amendments thereto, except that the term also includes facilities licensed under the provisions of K.S.A. 2018 Supp. 39-2001 et seq., and amendments thereto, except community mental health centers and facilities for people with intellectual disability.

(nn) "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 or biological synthesis or by a combination of extraction and chemical or biological synthesis or the packaging or repackaging of the drug or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for 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.

(oo) "Manufacturer" means:

(1) A person that holds an application approved under section 505 of the federal food, drug and cosmetic act or a license issued under section 351 of the federal public health service act for such drug or, if such drug is not the subject of an approved application or license, the person who manufactured the drug;

(2) a co-licensed partner of the person described in paragraph (1) that obtains the drug directly from a person described in paragraph (1) or (3); or

(3) an affiliate of a person described in paragraph (1) or (2) that receives the product directly from a person described in paragraph (1) or (2).

(pp) "*Medication order*" means an order by a prescriber for a registered patient of a Kansas licensed medical care facility.

(qq) "Mid-level practitioner" means a certified nurse-midwife engaging in the independent practice of midwifery under the independent practice of midwifery act, 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 agreement with a supervising physician under K.S.A. 65-28a08, and amendments thereto.

~~(qq)~~(rr) "Nonresident pharmacy" means a pharmacy located outside of Kansas.

~~(rr)~~(ss) "Outsourcing facility" or "virtual outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs and has registered with the FDA as an outsourcing facility pursuant to 21 U.S.C. § 353b.

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

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

(~~uu~~)(vv) "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.

~~(vv)~~(ww) "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 that is not accredited and who has successfully passed equivalency examinations approved by the board.

~~(ww)~~(xx) "Pharmacy," "drugstore" 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; (2) that 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.

~~(xx)~~(yy) "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.

~~(yy)~~(zz) "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.

~~(zz)~~(aaa) "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.

~~(aaa)~~(bbb) "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.

~~(bbb)~~(ccc) "Prescriber" means a practitioner or a mid-level practitioner.

~~(ccc)~~(ddd) "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.

~~(ddd)~~(eee) "Prescription medication" means any drug, including label and container according to context, that is dispensed pursuant to a prescription order.

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

~~(fff)~~(ggg) "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.

~~(ggg)~~(hhh) "Product" means the same as defined by part H of the federal drug supply chain security act, 21 U.S.C. § 351 et seq. and 21 U.S.C. § 360eee.

~~(hhh)~~(iii) "Professional incompetency" means:

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

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

~~(iii)~~(jjj) "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.

~~(jjj)~~(lll) "Repackage" means changing the container, wrapper, quantity or label of a drug to further the distribution of the drug.

~~(lll)~~(mmm) "Repackager" means a person who owns or operates a facility that repackages.

~~(mmm)~~(nnn) "Retail dealer" means a person selling at retail

nonprescription drugs that 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.

~~(nnn)~~(ooo) "Return" means providing product to the authorized immediate trading partner from whom such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

~~(ooo)~~(ppp) "Returns processor" or "reverse logistics provider" means a person who owns or operates an establishment that disposes of or otherwise processes saleable or nonsaleable products received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer or seller or disposed of for no further distribution.

~~(ppp)~~(qqq) "Secretary" means the executive secretary of the board.

~~(qqq)~~(rrr) "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistic services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser, but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

~~(rrr)~~(sss) "Trading partner" means:

(1) A manufacturer, repackager, wholesale distributor or dispenser from whom a manufacturer, repackager, wholesale distributor or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct ownership of a product; or

(2) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct possession of a product.

~~(sss)~~(ttt) "Transaction" means the transfer of product between persons in which a change of ownership occurs.

~~(ttt)~~(uuu) "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 that have no legitimate pharmaceutical purpose.

~~(uuu)~~(vvv) "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, that 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.

~~(vvv)~~(www) "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.

~~(www)~~(xxx) "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.

~~(xxx)~~(yyy) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs, other than a manufacturer, co-licensed partner, third-party logistics provider or repackager.

~~(yyy)~~(zzz) "Wholesale distribution" means the distribution or receipt of prescription drugs to or by persons other than consumers or patients, in which a change of ownership occurs. Wholesale distribution does not include:

(1) The dispensing of a prescription drug pursuant to a prescription;

(2) the distribution of a prescription drug or an offer to distribute a prescription drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the public health service act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(3) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(4) the distribution of a prescription drug or an offer to distribute a prescription drug among hospitals or other health care entities under common control;

(5) the distribution of a prescription drug or the offer to distribute a prescription drug 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 dispenser, hospital or other health care entity for use by such dispenser, hospital or other health care entity;

(7) the distribution of a drug by the manufacturer of such drug;

(8) the receipt or transfer of a drug by an authorized third-party logistics provider, provided that such third-party logistics provider does not take ownership of the drug;

(9) the transport of a drug by a common carrier, provided that the common carrier does not take ownership of the drug;

(10) the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the federal food, drug and cosmetic act;

(11) saleable drug returns when conducted by a dispenser;

(12) the distribution of minimal quantities of drugs by licensed retail pharmacies to licensed practitioners for office use;

(13) the distribution of a collection of finished medical devices, including a product or biological product in accordance with 21 U.S.C. § 353(e)(4)(M);

(14) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, including sodium, chloride and potassium, or calories, including dextrose and amino acids;

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments;

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating under

the direction of a hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 of the food, drug and cosmetic act for the purpose of repackaging the drug for use by that hospital or other health care entity, or other health care entities under common control, if ownership of the drug remains with the hospital or other health care entity at all times; or

(20) the sale or transfer from a retail pharmacy 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. 8. K.S.A. 65-1626 is hereby repealed.

Sec. 9. On and after March 1, 2020, K.S.A. 65-2803, 65-2836 and 65-2877a are hereby repealed.

Sec. 10. This act shall take effect and be in force from and after its publication in the statute book.

I hereby certify that the above BILL originated in the HOUSE, and was adopted by that body

HOUSE adopted
Conference Committee Report _____

Speaker of the House.

Chief Clerk of the House.

Passed the SENATE
as amended _____

SENATE adopted
Conference Committee Report _____

President of the Senate.

Secretary of the Senate.

APPROVED _____

Governor.