As Amended by House Committee

Session of 2021

HOUSE BILL No. 2280

By Committee on Health and Human Services

2-9

AN ACT concerning the state board of pharmacy; relating to powers, duties and functions thereof; pertaining to confidentiality of investigations, inspections and audits; licensing; registration and permitting requirements; exhibition of titles; fees; prescription orders; defining telepharmacy and requiring rules and regulations be adopted for oversight and administration thereof; amending K.S.A. 65-636, 65-1627, 65-1631, 65-1637, 65-1643, 65-1645, 65-1656, 65-1657, 65-1658, 65-1663 and 65-1676 and K.S.A. 2020 Supp. 65-1626 and repealing the existing sections.

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

New Section 1. (a) Any complaint, investigation, report, record or other information relating to a complaint or investigation that is received, obtained or maintained by the board shall be confidential and shall not be disclosed by the board or its employees in a manner that identifies or enables identification of the person who is the subject or source of the information, except the information may be disclosed:

(1) In any proceeding conducted by the board under the law or in an appeal of an order of the board entered in a proceeding, or to any party to a proceeding or appeal or the party's attorney;

(2) to the person who is the subject of the information or to any person or entity when requested by the person who is the subject of the information, but the board may require disclosure in such a manner that will prevent identification of any other person who is the subject or source of the information; or

(3) to a state or federal licensing, regulatory or enforcement agency with jurisdiction over the subject of the information or to an agency with jurisdiction over acts or conduct similar to acts or conduct that would constitute grounds for action under this act. Any confidential complaint or report, record or other information disclosed by the board as authorized by this section shall not be disclosed by the receiving agency except as otherwise authorized by law.

(b) Except as provided in subsection (a), no applicant, registrant or individual shall have access to any complaint, investigation, report, record or information concerning a complaint or investigation in progress until the investigation and any enforcement action is completed. This section

shall not be construed to authorize the release of records, reports or other information that are subject to other specific state or federal laws concerning their disclosure.

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

New Sec. 2. (a) (1) As a condition of probation or other disciplinary action under K.S.A. 65-1627 or 65-1657, and amendments thereto, the board may require that a licensee or registrant be subject to additional compliance inspections or audits and pay the actual costs of such inspections and audits.

(2) If a licensee or registrant fails to comply with a board order regarding the costs of additional inspections and audits, the board may impose additional disciplinary action against the licensee or registrant for failure to comply with a lawful order of the board under K.S.A. 65-1627, and amendments thereto.

(b) Upon the request of a facility that is registered or applying for registration or renewal with the board, the board may conduct an inspection of the place of business where any such operation is conducted, regardless of whether the facility is located in Kansas. The costs of such inspection shall be paid by the registrant or applicant. The registrant or applicant shall deposit a reasonable sum, as determined by the board, necessary to cover the board's estimated cost of performing the inspection prior to scheduling the inspection. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the registrant or applicant a written invoice for the remaining amount. If the amount deposited exceeds the actual costs incurred, the board shall remit the difference to the registrant or applicant.

(c) Actual costs under this section include, but are not limited to:

(1) Salaries and wages;

(2) travel, mileage and lodging;

(3) subsistence allowances;

(4) document storage, shipping and handling; or

(5) other expenses deemed reasonable and necessary by the board.

(d) All moneys assessed and collected under this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto, and deposited in the state treasury to the credit of the state board of pharmacy fee fund.

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

New Sec. 3. (a) As used in this section:

(1) "Telepharmacy" means the practice of pharmacy by a pharmacist located in Kansas using telecommunications or other automations and technologies to deliver personalized, electronically documented, real-time

pharmaceutical care to patients or their agents, who are located at sites other than where the pharmacist is located, including prescription dispensing and counseling and to oversee and supervise telepharmacy outlet operations.

(2) "Telepharmacy outlet" means a pharmacy site located in Kansas that:

(A) Is registered as a pharmacy under the act;

(B) is owned by the managing pharmacy;

(C) is connected via computer link, video link and audio link or other functionally equivalent telecommunications equipment with a supervising pharmacy located in Kansas; and

(D) has a pharmacy technician on site who performs activities under the electronic supervision of a pharmacist located in Kansas.

(b) A pharmacist shall be in attendance at the telepharmacy outlet by connecting to the telepharmacy outlet via computer link, video link and audio link or other functionally equivalent telecommunications equipment and shall be available to consult with and assist the pharmacy technician in performing activities.

(c) Not later than January 1, 2023, the board shall adopt rules and regulations necessary to specify additional criteria for a managing pharmacy and telepharmacy outlet under this section, including, but not limited to:

(1) Application requirements;

(2) structural, security, technology and equipment requirements;

(3) staffing, training and electronic supervision requirements;

(4) inventory record keeping and storage requirements;

(5) labeling requirements;

(6) establishment of policies and procedures;

(7) ~~the minimum and maximum distances from the nearest pharmacy where a telepharmacy outlet may be established, if necessary and applicable, and facilities that may be exempt from this requirement;~~

~~(8)~~ the number of telepharmacy outlets that may be operated by a supervising pharmacy;

~~(9) the maximum number of prescriptions that may be dispensed by a telepharmacy outlet;~~

~~(10)~~**(8)** use of automated dispensing machines; and

~~(11)~~**(9)** criteria for requesting exemptions or waivers from the requirements set forth in rules and regulations adopted under this subsection.

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

New Sec. 4. (a) The board shall require an applicant for registration as a manufacturer or virtual manufacturer 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) all addresses, telephone numbers and the names of contact individuals for all facilities used by the applicant for the storage, handling and distribution of prescription drugs or devices;

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

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

(A) If an individual, the name of the individual;

(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 of the corporation and the name of the state of incorporation; or

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

(6) any other information as the board deems appropriate.

Changes in any information in this subsection shall be submitted to the board in a form and manner prescribed by the board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration as a manufacturer or virtual manufacturer, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, manufacture of drugs or devices, 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) discipline, censure, warning, 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 the federal, state or local law enforcement officials those records required by the federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

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

(c) After consideration of the qualifications for applicants for registration as a manufacturer or virtual manufacturer, 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 as a manufacturer or virtual manufacturer shall be in addition to the authority of the board under K.S.A. 65-1627(f) and 65-1645(e), and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered as a manufacturer or virtual manufacturer have appropriate education or experience 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 drug supply chain security act, 21 U.S.C. § 351 et seq., in effect on July 1, 2021.

(f) Each facility that manufactures drugs or devices shall undergo an inspection by the board or a third party recognized by the board 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 adopt rules and regulations not later than July 1, 2022, to establish standards and requirements for the issuance and maintenance of a manufacturer and virtual manufacturer registration, including inspections.

(g) The board may register a manufacturer or virtual manufacturer that is licensed or registered under the laws of another state if:

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

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

(h) The board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a manufacturer and virtual manufacturer 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 trading partners;

(11) creation and maintenance of records, including transaction records;

(12) procedures for operation; and

(13) procedures for compliance with the requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

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

Sec. 5. K.S.A. 65-636 is hereby amended to read as follows: 65-636. It shall be unlawful for any ~~person,~~ *individual* who is not legally licensed as a pharmacist by the state board of pharmacy~~,~~ or any ~~person~~ *individual*, firm or corporation who does not have in continuous employ, at each place of business, a pharmacist licensed by the state board of pharmacy, to take, use or exhibit the title "drugstore," "pharmacy" or "apothecary" or any combination of such titles, or any title or description of like import, or any other term designed to take the place of such title*, if such title is being used in the context of health, medical or pharmaceutical care and the individual, firm or corporation has not provided a disclaimer sufficient to notify consumers that a pharmacist is not employed*.

Sec. 6. K.S.A. 2020 Supp. 65-1626 is hereby amended to read as follows: 65-1626. ~~For the purposes of this act~~*As used in the pharmacy act of the state of Kansas*:

(a) *"Address" means, with respect to prescriptions, the physical address where a patient resides, including street address, city and state.*

(b) "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 K.S.A.2020 Supp. 65-16,129, and amendments thereto.

~~(b)~~*(c)* "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) *(1)* "Compounding" means the combining of components into a compounded preparation under either of the following conditions:

~~(1)~~*(A)* 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)~~*(B)* for the purpose of, or incidental to, research, teaching or chemical analysis, and not for sale or dispensing.

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

(3) Compounding does not include reconstituting any ~~oral or topical~~ *mixed* 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) *"Current good manufacturing practices" or "CGMP" means the*

requirements for ensuring that drugs and drug products are consistently manufactured, repackaged, produced, stored and dispensed in accordance with 21 C.F.R.§§ 207, 210 and 211.

(m) "DEA" means the ~~U.S.~~ *United States* department of justice, drug enforcement administration.

~~(m)~~*(n)* "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.

(o) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part or accessory that:

(1) (A) Is recognized in the official national formulary, or the United States pharmacopoeia, or any supplement thereof;

(B) is intended for use in the diagnosis of disease or other conditions;

(C) is used for the cure, mitigation, treatment or prevention of disease in human or other animals; or

(D) is intended to affect the structure or any function of the body of human or other animals; and

(2) (A) does not achieve its primary intended purposes through chemical action within or on the body of human or other animals; and

(B) is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

~~(n)~~*(p)* "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a ~~pharmacy student~~ *pharmacist intern* or pharmacy technician ~~to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to patients~~, *be readily and immediately available at all time activities are performed, provide personal assistance, direction and approval throughout the time the activities are performed* and complete the final check before dispensing. *Except as otherwise provided by the pharmacy act of the state of Kansas or by rules and regulations of the board, "direct supervision" shall be in person.*

~~(o)~~*(q)* "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**, including, but not limited to, delivering prescription medication to a patient by mail, common carrier, personal delivery or third-party delivery to any location requested by the patient**.

~~(p)~~*(r)* "Dispenser" means:

(1) A practitioner or pharmacist who dispenses prescription ~~medication,~~ *drugs or devices* 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)~~*(s)* "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)~~*(t)* "Distributor" means a person or entity that distributes a drug *or device*.

(u) "Diversion" means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

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

~~(w)~~*(z)* "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)~~*(aa)* "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)~~*(bb)* "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)~~*(cc)* "Electronically prepared prescription" means a prescription that is generated using an electronic prescription application.

~~(aa)~~*(dd)* "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)~~*(ee)* "FDA" means the ~~U.S.~~ *United States* department of health and human services, food and drug administration.

~~(cc)~~*(ff)* "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)~~*(gg)* "Generic name" means the established chemical name or official name of a drug or drug product.

~~(ee)~~*(hh)* "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)~~*(ii)* (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 correctional facility or* juvenile detention facility, as defined ~~by the revised Kansas code for care of children and the revised Kansas juvenile justice code~~ *in K.S.A. 2020 Supp. 38-2302, and amendments thereto*;

(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)~~*(jj)* "Interchangeable biological product" means a biological product that the FDA has~~:~~

~~(1) Licensed and determined meets~~ *identified in the "purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations" as meeting* 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)~~*(kk)* "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)~~*(ll)* "Label" means a display of written, printed or graphic matter upon the immediate container of any drug.

~~(kk)~~*(mm)* "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)~~*(nn)* "Long-term care facility" means "nursing facility," as defined in K.S.A. 39-923, and amendments thereto.

~~(mm)~~*(oo)* "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. 2019 Supp. 39-2001 et seq., and amendments thereto, except community mental health centers and facilities for people with intellectual disability~~ *psychiatric hospitals and psychiatric residential treatment facilities as defined by K.S.A. 2020 Supp. 39-3002, and amendments thereto*.

~~(nn)~~*(pp)* "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)~~*(qq)* "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)~~*(rr)* "Medication order" means ~~an order by a prescriber for a registered patient of a Kansas licensed medical care facility~~ *a written or oral order by a prescriber or the prescriber's authorized agent for administration of a drug or device to a patient in a Kansas licensed medical care facility or in a Kansas licensed nursing facility or nursing facility for mental health, as defined by K.S.A. 39-923, and amendments*

thereto.

~~(qq)~~*(ss)* "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.

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

~~(ss)~~*(uu)* "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.

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

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

~~(vv)~~*(xx)* "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.

~~(ww)~~*(yy)* "Pharmacist intern" *or "intern"* means: (1) A student currently enrolled in *and in good standing with* 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.

~~(xx)~~*(zz)* "Pharmacy," "drugstore" or "apothecary" means premises, laboratory, area or other place*, including any electronic medium*: (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~~ *in any language or on* any sign containing any of these words *as used in the context of health, medical or pharmaceutical care or services*; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited *in the context of health, medical or pharmaceutical care or services*. 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.

~~(yy)~~*(aaa)* "Pharmacy prescription application" means software that is used to process prescription information~~, is~~ *and is either* installed on a pharmacy's computers or servers and is controlled by the pharmacy *or is maintained on the servers of an entity that sells electronic pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its server*.

~~(zz)~~*(bbb)* "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.

~~(aaa)~~*(ccc)* "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.

~~(bbb)~~*(ddd)* "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~~ *and is responsible for the actions of pharmacist interns obtaining pharmaceutical experience*.

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

~~(ddd)~~*(fff)* "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~~ *the front and back of a lawful written,*

electronic or facsimile order from a prescriber or an oral order from a prescriber or the prescriber's authorized agent that communicates the prescriber's instructions for a prescription drug or device to be dispensed.

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

~~(fff)~~*(hhh)* "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.

~~(ggg)~~*(iii)* "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.

~~(hhh)~~*(jjj)* "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.

~~(iii)~~*(lll)* "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.

~~(jjj)~~*(mmm)* "Readily retrievable" *or "readily available"* means that records kept *in hard copy or* by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records *quickly and easily during an inspection or investigation, or* within a reasonable time not to exceed 48 hours of a *written* 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~~.

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

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

~~(nnn)~~*(ppp)* "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.

~~(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.~~

~~(ppp)~~*(qqq)* "~~Returns processor" or "reverse logistics provider~~*Reverse distributor*" 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.

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

~~(rrr)~~*(sss)* "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.

~~(sss)~~*(ttt)* "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.

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

~~(uuu)~~*(vvv)* "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.

~~(vvv)~~*(www)* "Vaccination protocol" means a written protocol, agreed to *and signed* 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.

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

~~(xxx)~~*(yyy)* "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.

(zzz) "Virtual manufacturer" means an entity that engages in the manufacture of a drug or device for which it:

(1) Owns the new drug application or abbreviated new drug application number, if a prescription drug;

(2) owns the unique device identification number, as available, for a prescription device;

(3) contracts with a contract manufacturing organization for the physical manufacture of the drug or device;

(4) is not involved in the physical manufacture of the drug or device; and

(5) does not store or take physical possession of the drug or device.

(aaaa) "Virtual wholesale distributor" means a wholesale distributor that sells, brokers or transfers a drug or device but never physically possesses the product.

~~(yyy)~~*(bbbb)* "Wholesale distributor" means any person engaged in

wholesale distribution *or reverse distribution* of ~~prescription~~ drugs *or devices*, other than a manufacturer, co-licensed partner~~,~~ *or* third-party logistics provider ~~or repackager~~.

~~(zzz)~~*(cccc)* "Wholesale distribution" means the distribution or receipt of ~~prescription~~ drugs *or devices* 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 *or device* pursuant to a prescription;

(2) the distribution of a ~~prescription~~ drug *or device* or an offer to distribute a ~~prescription~~ drug *or device* 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 *or device* 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 device,* or an offer to distribute a ~~prescription~~ drug *or device,* among hospitals or other health care entities under common control;

(5) the distribution of a ~~prescription~~ drug *or device,* or the offer to distribute a ~~prescription~~ drug *or device,* by a charitable organization described in ~~503~~ *section 501*(c)(3) of the internal revenue code of ~~1954~~ *1986* 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; *or*

~~(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)~~*(7)* 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~~ *reverse distributor registered* in accordance with the board's rules and regulations.

Sec. 7. K.S.A. 65-1627 is hereby amended to read as follows: 65-1627. (a) The board may *deny an application or renewal, limit, condition,* revoke, suspend, place in a probationary status or ~~deny an application or renewal of any~~ *publicly or privately censure the* license of any pharmacist upon a finding that:

(1) The licensee has obtained, renewed or reinstated, or attempted to obtain, renew or reinstate, a license by false or fraudulent means, including misrepresentation of a material fact;

(2) the licensee has been convicted of a misdemeanor involving moral turpitude or gross immorality or any 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 *federal or state* 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 continuing education requirements of the board for license renewal;

(10) the licensee as a ~~pharmacist in charge~~ *"pharmacist-in-charge"* or consultant pharmacist under the provisions of K.S.A. 65-1648(c) or (d), and amendments thereto, has failed to comply with the requirements of K.S.A. 65-1648(c) or (d), 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, prior to its repeal, or K.S.A. 2019 Supp. 21-5407, 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, prior to its repeal, or K.S.A. 2019 Supp. 21-5407, 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. 60-4404, and amendments thereto ~~.~~*; or*

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

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

(16) the licensee has violated or failed to comply with any lawful order or directive of the board; ~~or~~

(17) the licensee has violated any of the provisions of the prescription monitoring program act of the state of Kansas or any rule and regulation of the board pursuant to the provisions of the prescription monitoring program act*; or*

(18) the licensee has failed to keep, 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, the federal or state uniform controlled substances act or rules and regulations adopted 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~~ *an application or* 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 *or may be* issued are not being conducted according to law or the rules and regulations of the board. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act.

(e) The board may *deny an application or renewal, limit, condition,* revoke, suspend, place in a probationary status or ~~deny a renewal of~~ *publicly or privately censure* the registration of ~~a~~ *any* 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*, pharmacy* 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, *the federal or state uniform controlled substances act* or the federal or state food, drug and cosmetic act;

(3) the owner*, pharmacy* 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. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act*;*

(5) the registrant has obtained, renewed or attempted to obtain or renew a registration by false or fraudulent means, including misrepresentation of a material fact or falsification of any application;

(6) the registrant has refused to permit the board or its duly authorized agents to inspect the registrant's establishment in accordance with the provisions of the pharmacy act of the state of Kansas, federal or

state uniform controlled substances act or the federal or state food, drug and cosmetic act;

(7) the registrant has failed to keep, 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, the federal or state uniform controlled substances act or rules and regulations adopted by the board;

(8) such pharmacy has been operated in such manner that violations of the provisions of the federal or state food, drug and cosmetic act, the federal or state uniform controlled substances act, or any rule and regulation adopted under any such act have occurred in connection therewith;

(9) such pharmacy has been operated in such manner that the violations of the provisions of the prescription monitoring program act of the state of Kansas or any rule and regulation of the board have occurred in connection therewith;

(10) the registrant has failed to furnish the board, its investigators or its representatives any information legally requested by the board; or

(11) the registrant has violated or failed to comply with any lawful order or directive of the board.

(f) A registration to manufacture or repackage drugs *or devices*, to operate as a wholesale distributor, ~~to sell durable medical equipment or to operate as a~~ third-party logistics provider, *outsourcing facility, institutional drug room or automated dispensing system, or to sell durable medical equipment,* or a registration for the place of business where any such operation is conducted, may be *limited, conditioned,* suspended, revoked, placed in a probationary status*, publicly or privately censured* or the *application for or* 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~~ *obtained, renewed or attempted to obtain or renew a registration by false or fraudulent means, including misrepresentation of a material fact or falsification of any application*;

(2) has been convicted of a felony under any federal or state law relating to the manufacture*, compounding, dispensing* or distribution of drugs *or devices*;

(3) has had any federal registration for the manufacture*, compounding, dispensing* or distribution of drugs *or devices* suspended*, limited, denied, disciplined, censured* 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~~ *the pharmacy act of the state of Kansas, the federal or state uniform controlled substances act or the*

federal or state food, drug and cosmetic act;

(5) has failed to keep, 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~~, *the federal or state uniform controlled substances act or rules and regulations adopted by the board;*

(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, has violated the uniform controlled substances act or rules and regulations adopted by the state board of pharmacy under the uniform controlled substances act*, has violated the federal uniform controlled substances act, has violated the federal or state food, drug and cosmetic act or any rules and regulations adopted under any such act,* or has violated a provision of the federal drug supply chain security act or any rule or regulation adopted under such act. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act*;*

(7) 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. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act;

(8) has failed to furnish the board, its investigators or its representatives any information legally requested by the board; or

(9) the registrant has violated or failed to comply with any lawful order or directive of the board.

(g) *Any licensee, permit holder or registrant who is disciplined under this section, K.S.A. 65-1657, 65-1663 or 65-1676, and amendments thereto, for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's or registrant's permanent record. The board shall adopt rules and regulations to establish violations that are minor violations under this section. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; assist in the practice of pharmacy; provide home medical equipment and services; adversely affect the public health, safety or welfare; result in economic or physical harm to*

an individual; or create a significant threat of such harm.

(1) The request for expungement may be filed no sooner than five years after the date on which the licensee, permit holder or registrant has completed disciplinary sanctions imposed and if the licensee, permit holder or registrant has not been disciplined for any subsequent violation within this period of time.

(2) No individual may have such individual's record expunged under this section more than once.

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

Sec. 8. K.S.A. 65-1631 is hereby amended to read as follows: 65-1631. (a) It shall be unlawful for any ~~person~~ *individual* to practice as a pharmacist in this state unless such ~~person~~ *individual* is licensed by the board as a pharmacist. Except as otherwise provided in subsection (d), every applicant for licensure as a pharmacist shall be at least 18 years of age, shall be a graduate of a school or college of pharmacy or department of a university recognized and approved by the board, shall file proof satisfactory to the board, substantiated by proper affidavits, of a minimum of one year of pharmaceutical experience, acceptable to the board, under the supervision of a preceptor and shall pass an examination approved by the board. Pharmaceutical experience as required in this section shall be under the supervision of a preceptor and shall be predominantly related to the dispensing of prescription medication, compounding prescriptions, preparing pharmaceutical preparations and keeping records and making reports required under state and federal statutes. A school or college of pharmacy or department of a university recognized and approved by the board under this subsection ~~(a)~~ shall have a standard of education not below that of the university of Kansas school of pharmacy. The board shall adopt rules and regulations establishing the criteria ~~which~~ *that* a school or college of pharmacy or department of a university shall satisfy in meeting the standard of education established under this subsection ~~(a)~~. *The board is authorized to adopt rules and regulations necessary to establish the criteria for a pharmacist to be designated by the board and act as a preceptor.*

(b) All applications for licensure by examination shall be made on a form to be prescribed and furnished by the board. Each application for a new license by examination shall be accompanied by a license fee fixed by the board as provided in K.S.A. 65-1645, and amendments thereto.

(c) The board is authorized to adopt rules and regulations relating to the ~~grades which~~ *score that* an applicant must receive in order to pass the ~~examination~~ *examinations required for licensure ~~and the maximum number of times an applicant may take each examination~~*. **The board shall only accept a passing score on an examination required for licensure**

from an applicant's first five attempts taking such examination.

(d) Notwithstanding the preceding provisions of this section, the board may in its discretion license as a pharmacist, without examination, any ~~person~~ *individual* who is duly registered or licensed by examination in some other state, except that the board may require that such ~~person~~ *individual* take the ~~law examination~~ *multi-state jurisprudence examination* approved by the board. *The board is authorized to adopt rules and regulations relating to the score that such individual shall be required to receive in order to pass the multi-state jurisprudence examination and the maximum number of times such individual may take the examination as well as the maximum number of times that such individual may have attempted the North American pharmacist licensure examination, regardless of the score achieved.* Such ~~person~~ *individual* shall file proof satisfactory to the board of having the education and training required of applicants for licensure under the provisions of the pharmacy act of this state. ~~Persons~~ *Individuals* who are registered or licensed as pharmacists by examination in other states shall be required to satisfy only the requirements ~~which~~ *that* existed in this state at the time they become registered or licensed in such other states. The provisions of this subsection shall apply only if the state in which the ~~person~~ *individual* is registered or licensed grants, under like conditions, reciprocal registrations or licenses as pharmacists, without examination, to pharmacists duly licensed by examination in this state. Reciprocal licensure shall not be denied to any applicant otherwise qualified for reciprocal licensure under this section who has met the internship requirements of the state from which the applicant is reciprocating or who has at least one year of practice as a licensed pharmacist. A reciprocal licensure may be denied for *failure to satisfy the rules and regulations adopted by the board or for* any of the reasons set forth in ~~subsections (a)(1) through (a)(13) of~~ K.S.A. 65-1627*(a)(1) through (a)(13),* and amendments thereto.

(e) In the event that an applicant for reciprocal licensure has not been subject to laws requiring continuing education as a condition for renewal of a registration or license, such applicant shall be required to satisfy the board through a competency examination that the applicant has the knowledge and ability to meet Kansas standards for licensure as a pharmacist.

(f) ~~No applicant who has taken the examination for licensure approved by the board and has failed to complete it successfully shall be considered for licensure by reciprocity within one year from the date such applicant sat for the examination.~~

~~(g)~~ All applicants for reciprocal licensure shall file their applications on a form to be prescribed and furnished by the board and such application shall be accompanied by a reciprocal licensure fee fixed by the board as

provided in K.S.A. 65-1645, and amendments thereto. The reciprocal licensure fee established by this section immediately prior to the effective date of this act shall continue in effect until a different reciprocal licensure fee is fixed by the board by rules and regulations as provided in K.S.A. 65-1645, and amendments thereto.

~~(h)~~*(g)* The board shall take into consideration any felony conviction of such ~~person~~ *individual*, but such conviction shall not automatically operate as a bar to licensure.

~~(i)~~*(h)* All applicants for licensure who graduate from a school or college of pharmacy outside the United States or who graduate from a school or college of pharmacy not approved by the board shall submit information to the board, as specified by rules and regulations, and this information shall be accompanied by an evaluation fee fixed by the board as provided in K.S.A. 65-1645, and amendments thereto, ~~which evaluation fee~~ *that* shall be in addition to any other fee paid by the applicant under the pharmacy act of the state of Kansas. The evaluation fee fixed by the board under this section immediately prior to the effective date of this act shall continue in effect until a different evaluation fee is fixed by the board by rules and regulations as provided in K.S.A. 65-1645, and amendments thereto. The board may contract with investigative agencies, commissions or consultants to assist the board in obtaining information about such schools or colleges of pharmacy. In entering such contracts the authority to approve schools or colleges of pharmacy shall remain solely with the board.

~~(j)~~*(i)* All applicants for licensure who graduate from a school or college of pharmacy outside the United States or who are not citizens of the United States shall provide proof to the board that the applicant has a reasonable ability to communicate with the general public in English. The board may require such applicant to take the test of English as a foreign language and to attain the grade for passing such test as established by the board by rules and regulations.

~~(k)~~*(j)* Every registered pharmacist holding a valid registration as a pharmacist in effect on the day preceding the effective date of this act shall be deemed to be a licensed pharmacist under this act, and such ~~person~~ *individual* shall not be required to file an original application hereunder for a license.

Sec. 9. K.S.A. 65-1637 is hereby amended to read as follows: 65-1637. (a) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of any prescription order consistent with federal and state laws and rules and regulations. Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law, a pharmacist shall not dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determines that the

prescription is not a valid prescription order.

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

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

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

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

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

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

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

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

(e) Regardless of the means of transmission to a pharmacy, ~~only~~ a pharmacist or a pharmacist intern shall be authorized to receive a new prescription order *or a refill or renewal order* from a prescriber or transmitting agent. A ~~pharmacist, a pharmacist intern or a~~ registered pharmacy technician may receive a refill ~~or~~, renewal *or* order *for continuation of therapy that contains no changes from the original prescription* from a prescriber or transmitting agent if such registered pharmacy technician's supervising pharmacist has authorized that function.

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

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

(g) All prescriptions shall be filled or refilled in strict conformity with any directions of the prescriber, except that:

(1) A pharmacist who receives a prescription order for a brand name drug product~~, excluding a biological product~~, may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:

(A) The prescriber~~, in the case of a prescription electronically signed by the prescriber, includes the statement~~ *indicates* "dispense as written" on the prescription **or when communicating a prescription by oral order**;

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

~~(C) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated~~*the FDA has determined that a biological product is not an interchangeable biological product for the prescribed biological product*; or

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

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

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

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

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

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

~~(D) the biological product is not an interchangeable biological product for the prescribed biological~~ product*except for a prescription for a controlled substance, a pharmacist may use professional judgment to make the following adaptations to a prescription order if a patient consents, the prescriber has not indicated "dispense as written" on the prescription, the pharmacist documents the adaptation on the patient's prescription record and the pharmacist notifies the prescriber:*

(A) Change the prescribed quantity if:

(i) The prescribed quantity or package size is not commercially available;

(ii) the change in quantity is related to a change in dosage form; or

(iii) the change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program;

(B) change the prescribed dosage form, strength or directions for use if it is in the best interest of the patient and the change achieves the intent of the prescriber; or

(C) complete missing information on the prescription order if there is evidence to support the change.

(h) A pharmacist who selects an interchangeable biological product shall inform the patient or the patient's representative that an interchangeable biological product has been substituted for the prescribed biological product.

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

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

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

(2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug, except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug

listed on any schedule of the uniform controlled substances act, without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a ~~seven-day~~ *30-day* supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this paragraph shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this paragraph. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this paragraph unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.

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

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

(n) Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law, nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if, in the pharmacist's professional judgment and discretion, such pharmacist is of the opinion that it should not be filled or refilled.

(o) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) An inter-operable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefits management system; or

(4) a pharmacy record.

(p) Entry into an electronic records system as described in subsection

(o) shall be presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that communication shall not be required where:

(1) There is no FDA-approved interchangeable biological product for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(q) A pharmacist shall maintain a record of any biological product dispensed for at least five years.

(r) The board shall maintain a link on its website to the current lists of all biological products that the FDA has determined to be interchangeable biological products.

Sec. 10. K.S.A. 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~~ *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 registration 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; and (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 violate the federal drug supply chain security act, 21 U.S.C. § 351 et seq.

(c) For any person to distribute at wholesale any drugs *or devices* without first obtaining a registration as a wholesale distributor from the board.

(d) For any person to operate as a third-party logistics provider within this state without having first obtained a registration from the board.

(e) For any person to in any manner distribute or dispense samples of any drugs *or devices* 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, 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~~ *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 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 K.S.A. 65-1626~~(hh)~~*(zz)*, 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~~ *manufacture within this state any drugs or devices except under the personal and immediate supervision of a pharmacist or such other individual as may be approved by the board after an investigation and a determination by the board that such individual 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 individual shall manufacture any drugs or devices without first obtaining a registration to do so from 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 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.

(j) For any person to sell or distribute in a pharmacy a controlled substance designated in K.S.A. 65-4113~~(c)~~*(d)* or ~~(f)~~ *(e)*, and amendments thereto, unless:

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

(B) any ~~person~~ *individual* purchasing, receiving or otherwise acquiring any such controlled substance produces a *valid* photo identification showing the date of birth of the ~~person~~ *individual* and signs a log and enters in the log, or allows the seller to enter in the log, such ~~person's~~ *individual's* address and the date and time of sale or allows the seller to enter such information into an electronic logging system pursuant to K.S.A. 65-16,102, and amendments thereto. 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;

(C) the seller determines that the name entered in the log corresponds to the name provided on such identification and that the date and time entered are correct; and

(D) the seller enters in the log the name of the controlled substance and the quantity sold; or

(2) there is a lawful prescription.

(k) For any pharmacy to allow customers to have direct access to any controlled substance designated in K.S.A. 65-4113~~(c)~~*(d)* or ~~(f)~~ *(e)*, and amendments thereto. Such controlled substance shall be placed behind the counter or stored in a locked cabinet that is located in an area of the pharmacy to which customers do not have direct access.

(l) A seller who in good faith releases information in a log pursuant to subsection (j) to any law enforcement officer is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton or willful misconduct.

(m) For any person to sell or lease or offer for sale or lease durable medical equipment *or to supply medical grade oxygen to an end user* 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~~.

(n) For any person to operate as an outsourcing facility within this state, or operate as an outsourcing facility outside of Kansas and ship, mail or deliver drugs into this state, without having first obtained a registration from the board.

(o) For any person to operate an automated dispensing system within

this state without having first obtained a registration from the board.

(p) For any person to distribute drugs or devices into Kansas as an out-of-state manufacturer of such drugs or devices without first obtaining a registration as a manufacturer from the board.

Sec. 11. 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 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, and K.S.A.~~ 65-1655a and 65-1655b, 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 secretary 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 that 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.

(b) *An application for a registration or permit under K.S.A. 65-1643, and amendments thereto, submitted for a facility physically located outside of the state of Kansas shall be accompanied by an additional non-resident fee prescribed by the board by rules and regulations pursuant to this section. Such fee shall not exceed $350 for a new registration and $250 for a renewal.*

(c) 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~~ *$250*, renewal not more than ~~$125~~ *$250*;

(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~~ *$350*;

(7) pharmacist, penalty fee, not more than $500;

(8) manufacturer *or virtual manufacturer*, new registration not more than $500, renewal not more than ~~$400~~ *$500*;

(9) wholesale distributor, new registration not more than $500, renewal not more than ~~$400~~ *$500*, except that a wholesale distributor 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 ~~re-registration~~ *renewal* not to exceed ~~$50~~ *$100*;

(10) special auction not more than $50;

(11) samples distribution not more than ~~$50~~ *$100*, renewal not more than ~~$50~~ *$100*;

(12) institutional drug room, new registration not more than ~~$40~~ *$100*, renewal not more than ~~$35~~ *$100*;

(13) retail dealer selling more than 12 different nonprescription drug products, new permit not more than ~~$12~~ *$50*, renewal not more than ~~$12~~ *$50*;

(14) certification of grades for each applicant for examination and registration not more than $25;

(15) veterinary medical teaching hospital pharmacy, new registration not more than $40, renewal not more than $35;

(16) durable medical equipment registration fee, not more than ~~$300~~ *$400*, renewal not more than ~~$300~~ *$400*;

(17) third-party logistics provider, new registration not more than $500, renewal not more than ~~$400~~ *$500*, except that a third-party logistics provider exclusively providing 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 ~~re-registration~~ *renewal* not to exceed ~~$50~~ *$100*;

(18) outsourcing facility, new registration not more than $500, renewal not more than ~~$400~~ *$500*;

(19) repackager, new registration not more than $500, renewal not more than ~~$400~~ *$500*; or

(20) automated dispensing system registration fee, not more than $40, renewal not more than $35.

~~(c)~~*(d)* 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)~~*(e)* 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)~~*(f)* The board may deny renewal of any registration or permit required by K.S.A. 65-1643, and amendments thereto, on any ground that 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 shall expire every year. The expiration date shall be established by rules and regulations adopted by the board. All registrations and permits shall be renewed annually. Notice of renewal of registrations and permits shall be sent 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 prior to 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 notice of renewal shall not relieve the registrant or permittee from the penalty hereby imposed if the renewal is not made as prescribed.

~~(f)~~*(g)* 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 this section.

~~(g)~~*(h)* 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~~ *individual* taking the examination.

Sec. 12. K.S.A. 65-1656 is hereby amended to read as follows: 65-1656. (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit a pharmacist licensed in this state from filling or refilling a valid prescription for prescription drugs not listed in schedule II of the uniform controlled substances act, ~~which~~ *that* is on file in a pharmacy licensed *or registered* in any state and has been transferred from one pharmacy to another ~~by any means, including by way of electronic data processing equipment,~~ upon the following conditions and exceptions:

(1) Prior to dispensing pursuant to any such prescription, the dispensing pharmacist shall:

(A) ~~Advise the patient that the prescription file at such other pharmacy must be canceled before the dispensing pharmacist will be able to fill the prescription;~~

~~(B) determine that the prescription is valid and on file at such other pharmacy and that such prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on such prescription;~~

~~(C) notify the pharmacy where the prescription is on file that the prescription must be canceled;~~

~~(D) record the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the name of the drug and the original amount dispensed, the date of original dispensing and the number of remaining authorized refills~~ *Ensure records and notifications are in compliance with rules and regulations adopted by the board*; and

~~(E)~~*(B)* obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the professional judgment of the dispensing pharmacist, so requires. Any interference with the professional judgment of the dispensing pharmacist by any other licensed pharmacist, agents of the licensed pharmacist or employees shall be grounds for revocation or suspension of the registration issued to the pharmacy.

(2) Upon receipt of a request for *the transfer of a* prescription ~~information set forth in subsection (a)(1)(D)~~ *record*, if the requested pharmacist is satisfied in the professional judgment of the pharmacist that such request is valid and legal, the requested ~~pharmacist~~ *pharmacy* shall:

(A) Provide such information accurately and completely;

(B) ~~record on the prescription the name of the requesting pharmacy and pharmacist and the date of request~~*ensure records and notifications are made in compliance with rules and regulations adopted by the board*; and

(C) ~~cancel the prescription on file. No further prescription transfer shall be given or medication dispensed pursuant to such original prescription~~*provide information in a timely manner to avoid interruption in the medication therapy of the patient*.

(3) ~~In the event that, after the information set forth in subsection (a)(1)(D) has been provided, a prescription is not dispensed by the requesting pharmacist, then such pharmacist shall provide notice of this fact to the pharmacy from which such information was obtained, such notice shall then cancel the prescription in the same manner as set forth in subsection (a)(2)(C).~~

~~(4)~~ When filling or refilling a valid prescription on file in another state, the dispensing pharmacist shall be required to follow all the requirements of Kansas law ~~which~~ *that* apply to the dispensing of prescription drugs. If anything in Kansas law prevents the filling or refilling of the original prescription it shall be unlawful to dispense pursuant to this section.

~~(5)~~*(4)* In addition to any other requirement of this section, the transfer of original prescription information for a controlled substance listed in schedules III, IV and V for the purposes of refill dispensing shall be made in accordance with the requirements of ~~section 1306.25 of chapter 21 of the code of federal regulations~~ *21 C.F.R. § 1306.25*.

(b) Two or more pharmacies may establish and use a common

electronic file to maintain required dispensing information. Pharmacies using such a common electronic file are not required to physically transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file, except that any such common file must contain complete and adequate records of such prescription and refill dispensed as required by the pharmacy act of the state of Kansas.

(c) The board may ~~formulate~~ *adopt* such rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes of and to enforce the provisions of this section except that the board shall not impose greater requirements on either common electronic files or a hard copy record system.

(d) ~~Drugs shall in no event be dispensed more frequently or in larger amounts than the prescriber ordered without direct prescriber authorization by way of a new prescription order~~*Nothing in this section shall prevent a pharmacy from forwarding to another pharmacy an original, unfilled prescription for a noncontrolled substance or electronically forwarding an original, unfilled, electronic prescription for a controlled substance, at the request of the patient, in compliance with the provisions of the federal or state uniform controlled substances act*.

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

Sec. 13. K.S.A. 65-1657 is hereby amended to read as follows: 65-1657. (a) No nonresident pharmacy shall ship, mail or deliver, in any manner, prescription drugs *or devices* to a patient*, patient's agent or prescriber's office* in this state unless registered under this section as a nonresident pharmacy. Applications for a nonresident pharmacy registration under this section shall be made on a form furnished by the board. A nonresident pharmacy registration shall be granted for a period of one year upon compliance by the nonresident pharmacy with the provisions of this section and rules and regulations adopted pursuant to this section and upon payment of the registration fee established under K.S.A. 65-1645, and amendments thereto, for a pharmacy registration. A nonresident pharmacy registration shall be renewed annually on forms provided by the board, upon compliance by the nonresident pharmacy with the provisions of this section and rules and regulations adopted pursuant to this section and upon payment of the renewal fee established under K.S.A. 65-1645, and amendments thereto, for the renewal of a pharmacy registration.

(b) As conditions for the granting of a registration and for the renewal of a registration for a nonresident pharmacy, the nonresident pharmacy shall comply with the following:

(1) Provide information to the board to indicate the person or persons

applying for the registration, the location of the pharmacy from which the prescription drugs will be dispensed, the names and titles of all principal owners and corporate officers, if any, and the names of all pharmacists dispensing prescription drugs to residents of Kansas;

(2) be registered and in good standing in the state in which such pharmacy is located;

(3) maintain, in readily retrievable form, records of prescription drugs dispensed to Kansas patients;

(4) supply upon request, all information needed by the board to carry out the board's responsibilities under this section and rules and regulations adopted pursuant to this section;

(5) maintain pharmacy hours that permit the timely dispensing of drugs to Kansas patients and provide reasonable access for the patients to consult with a licensed pharmacist about such patients' medications;

(6) provide toll-free telephone communication consultation between a Kansas patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that the telephone ~~number(s)~~ *number* will be placed upon the label affixed to each prescription drug container dispensed in Kansas; and

(7) provide to the board such other information as the board may reasonably request to administer the provisions of this section.

(c) ~~When any nonresident pharmacy fails to supply requested information to the board or fails to respond to proper inquiry of the board, after receiving notice by certified mail, the board may assess a civil fine in accordance with the provisions in K.S.A. 65-1658, and amendments thereto.~~

~~(d)~~ Each nonresident pharmacy shall comply with the following unless compliance would be in conflict with specific laws or rules and regulations of the state in which the pharmacy is located:

(1) All statutory and regulatory requirements of Kansas for controlled substances, including those that are different from federal law;

(2) labeling of all prescriptions dispensed, to include, but not be limited to, identification of the product and quantity dispensed;

(3) all the statutory and regulatory requirements of Kansas for dispensing prescriptions in accordance with the quantities indicated by the prescriber; and

(4) the Kansas law regarding the maintenance and use of the patient medication profile record system.

~~(e)~~*(d)* In addition to ~~subsection (d)~~ *the* requirements *of subsection (c)*, each nonresident pharmacy shall comply with all the statutory and regulatory requirements of Kansas regarding drug product selection laws whether or not such compliance would be in conflict with specific laws or rules and regulations of the state in which the pharmacy is located, except

that compliance ~~which~~ *that* constitutes only a minor conflict with specific laws or rules and regulations of the state in which the pharmacy is located would not be required under this subsection.

~~(f)~~*(e)* Each nonresident pharmacy shall develop and provide the board with a policy and procedure manual that sets forth:

(1) Normal delivery protocols and times;

(2) the procedure to be followed if the patient's medication is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;

(3) the procedure to be followed upon receipt of a prescription for an acute illness, ~~which policy~~ *that* shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy at the earliest possible time, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and

(4) the procedure to be followed when the nonresident pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

~~(g) Except in emergencies that constitute an immediate threat to the public health and require prompt action by the board, the board may file a complaint against any nonresident pharmacy that violates any provision of this section. This complaint shall be filed with the regulatory or licensing agency of the state in which the nonresident pharmacy is located. If the regulatory or licensing agency of the state in which the nonresident pharmacy is located fails to resolve the violation complained of within a reasonable time, not less than 180 days from the date that the complaint is filed, disciplinary proceedings may be initiated by the board. The board also may initiate disciplinary actions against a nonresident pharmacy if the regulatory or licensing agency of the state in which the nonresident pharmacy is located lacks or fails to exercise jurisdiction.~~

(f) The board may limit, condition, revoke, suspend, place in a probationary status or publicly or privately censure a registration or deny an application for issuance or renewal of any registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

~~(h)~~*(g)* The board shall adopt rules and regulations that make exceptions to the requirement of registration by a nonresident pharmacy when the out-of-state pharmacy supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located, or when the prescriptions being mailed into the state of Kansas by a nonresident pharmacy occurs only in isolated transactions. In determining whether the prescriptions being mailed into the state of Kansas by a nonresident

pharmacy are isolated transactions, the board shall consider whether the pharmacy has promoted its services in this state and whether the pharmacy has a contract with any employer or organization to provide pharmacy services to employees or other beneficiaries in this state.

~~(i)~~*(h)* It is unlawful for any nonresident pharmacy ~~which~~ *that* is not registered under this act to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy ~~which~~ *that* has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

~~(j)~~*(i)* Upon request of the board, the attorney general may bring an action in a court of competent jurisdiction for injunctive relief to restrain a violation of the provisions of this section or any rules and regulations adopted by the board under authority of this section. The remedy provided under this subsection shall be in addition to any other remedy provided under this section or under the pharmacy act of the state of Kansas.

~~(k)~~*(j)* The board may adopt rules and regulations as necessary and as are consistent with this section to carry out the provisions of this section.

~~(l) The executive secretary of the board shall remit all moneys received from fees under this section to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the manner specified under K.S.A. 74-1609, and amendments thereto.~~

~~(m)~~*(k)* A violation of this section is a severity level 10, nonperson felony.

~~(n)~~*(l)* This section shall be *a* part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 14. K.S.A. 65-1658 is hereby amended to read as follows: 65-1658. The state board of pharmacy, in addition to any other penalty prescribed under the pharmacy act of the state of Kansas, may assess a civil fine, after notice and an opportunity to be heard in accordance with the Kansas administrative procedure act, against any licensee or registrant under ~~subsections (a), (c), (d) and (e) of~~ K.S.A. 65-1627*(a), (c), (d), (e) and (f), 65-1643, 65-1657, 65-1663 and 65-1676*, and amendments thereto, for violation of the pharmacy act of the state of Kansas ~~or~~, rules and regulations of the state board of pharmacy adopted under the pharmacy act of the state of Kansas or for violation of the *federal or state* uniform controlled substances act or rules and regulations of the state board of pharmacy adopted under the *federal or state* uniform controlled substances act~~,~~ *or for violation of the federal or state food, drug and cosmetic act or any rules and regulations adopted under any such act* in an amount not to exceed $5,000 for each violation. All fines assessed and collected under

this section shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. ~~Of the amount so remitted, an amount equal to the board's actual costs related to the case in which the fine was assessed, as certified by the president of the board to the state treasurer, shall be,~~ credited to the state board of pharmacy fee fund~~, and the balance shall be credited to the state general fund~~.

Sec. 15. K.S.A. 65-1663 is hereby amended to read as follows: 65-1663. (a) It shall be unlawful for any ~~person~~ *individual* to function as a pharmacy technician in this state unless such ~~person~~ *individual* is registered with the board as a pharmacy technician. Every ~~person~~ *individual* registered as a pharmacy technician shall have graduated from an accredited high school or its equivalent, obtained a graduate equivalent diploma ~~(~~*,* GED~~)~~*,* or be enrolled and in good standing in a high school education program. Every ~~person~~ *individual* registered as a pharmacy technician shall pass one or more examinations identified and approved by the board within the period or periods of time specified by the board after becoming registered. The board shall adopt rules and regulations identifying the required examinations, when they must be passed and establishing the criteria for the required examinations and passing scores. The board may include as a required examination any national pharmacy technician certification examination. The board shall adopt rules and regulations restricting the tasks a pharmacy technician may perform prior to passing any required examinations.

(b) All applications for registration shall be made on a form to be prescribed and furnished by the board. Each application for registration shall be accompanied by a registration fee fixed by the board by rule and regulation not to exceed $50.

(c) The board shall take into consideration any felony conviction of an applicant, but such conviction shall not automatically operate as a bar to registration.

(d) Except as otherwise provided in this subsection, each pharmacy technician registration issued by the board shall expire every two years. The expiration date shall be established by rules and regulations adopted by the board. To provide for a system of biennial renewal of pharmacy technician registrations, the board may provide by rules and regulations that registrations issued or renewed may expire less than two years from the date of issuance or renewal. Each applicant for renewal of a pharmacy technician registration shall be made on a form prescribed and furnished by the board and shall be accompanied by a renewal fee fixed by the board by ~~rule and regulation~~ *rules and regulations* not to exceed ~~$25~~ *$50*. Pharmacy technician registration renewal fees may be prorated for registration periods ~~which~~ *that* are less than biennial in accordance with rules and regulations of the board. Except as otherwise provided in this

subsection, the application for registration renewal, when accompanied by the renewal fee and evidence satisfactory to the board that the ~~person~~ *individual* has successfully complied with the rules and regulations of the board establishing the requirements for a program of continuing pharmacy technician education and received by the secretary on or before the date of expiration of the registration, shall have the effect of temporarily renewing the applicant's registration until actual issuance or denial of the renewal registration. 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, the board may by emergency order declare that the application for renewal shall not have the effect of temporarily renewing such applicant's registration. If the renewal fee is not paid prior to the expiration date of the renewal year, the registration is void.

(e) Continuing pharmacy technician education requirements shall be fixed by the board at not more than 20 clock hours biennially of a program of continuing education approved by the board. Continuing education hours may be prorated for licensure periods that are less than biennial in accordance with rules and regulations of the board.

(f) (1) The board may limit, *condition, revoke,* suspend ~~or revoke~~*, place in a probationary status or publicly or privately censure* a registration or deny an application for issuance or renewal of any registration as a pharmacy technician on any ground, which would authorize the board to take action against the license of a pharmacist under K.S.A. 65-1627, and amendments thereto.

(2) The board may require a physical or mental examination, or both, of ~~a person~~ *an individual* applying for or registered as a pharmacy technician.

(3) The board may temporarily suspend or temporarily limit the registration of any pharmacy technician 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 this section against the registrant and that the registrant's continuation of pharmacy technician functions would constitute an imminent danger to the public health and safety.

(4) Proceedings under this section shall be subject to the Kansas administrative procedure act.

(g) Every registered pharmacy technician, within 30 days of obtaining new employment or ceasing employment as a pharmacy technician, shall notify the secretary of the name and address of the new employer or cessation of employment.

(h) Every pharmacy technician who changes their residential address, email address or legal name shall, within 30 days thereof, notify the secretary of such change on a form prescribed and furnished by the board.

(i) Each pharmacy shall at all times maintain a list of the names of pharmacy technicians employed by the pharmacy. A pharmacy technician shall work under the direct supervision and control of a pharmacist, and while on duty, shall wear a name badge or similar identification with the pharmacy technician's name and designation as a pharmacy technician. It shall be the responsibility of the supervising pharmacist to determine that the pharmacy technician is in compliance with the applicable rules and regulations of the board, and the supervising pharmacist shall be responsible for the acts and omissions of the pharmacy technician in the performance of the pharmacy technician's duties. The ratio of pharmacy technicians to pharmacists in the prescription area of a pharmacy shall be prescribed by the board by rule and regulation. Any change in the ratio of pharmacy technicians to pharmacists in the prescription area of the pharmacy must be adopted by a vote of no less than six members of the board.

(j) Every registered pharmacy technician shall display the current registration in that part of the place of business in which such ~~person~~ *individual* is engaged in pharmacy technician activities.

(k) Every pharmacy technician registered after July 1, 2017, shall be required to pass a certified pharmacy technician examination approved by the board.

(l) The board shall adopt such rules and regulations as are necessary to ensure that pharmacy technicians are adequately trained as to the nature and scope of their lawful duties.

(m) The board may adopt rules and regulations as may be necessary to carry out the purposes and enforce the provisions of this act.

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

Sec. 16. K.S.A. 65-1676 is hereby amended to read as follows: 65-1676. (a) It shall be unlawful for any ~~person~~ *individual* to function as a pharmacist intern in this state unless such ~~person~~ *individual* is registered with the board as a pharmacist intern.

(b) All applications for registration shall be made on a form to be prescribed and furnished by the board. Each application for registration shall be accompanied by a registration fee fixed by the board by ~~rule and regulation~~ *rules and regulations* not to exceed ~~$25~~ *$50*.

(c) Each pharmacist intern registration issued by the board shall expire six years from the date of issuance.

(d) (1) The board may limit, *condition, revoke,* suspend ~~or revoke~~*, place in a probationary status or publicly or privately censure* a registration or deny an application for issuance or renewal of any registration as a pharmacist intern on any ground that would authorize the board to take action against the license of a pharmacist under K.S.A. 65-

1627, and amendments thereto.

(2) The board may temporarily suspend or temporarily limit the registration of any pharmacist intern 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 this section against the registrant and that the registrant's continuation of pharmacist intern functions would constitute an imminent danger to the public health and safety.

(3) Proceedings under this section shall be subject to the Kansas administrative procedure act.

(e) Every registered pharmacist intern, within 30 days of obtaining new employment, shall furnish the secretary notice of the name and address of the new employer.

(f) Every pharmacist intern who changes their residential address, email address or legal name shall, within 30 days thereof, notify the secretary of such change on a form prescribed and furnished by the board.

(g) Each pharmacy shall at all times maintain a list of the names of pharmacist interns employed by the pharmacy. A pharmacist intern shall work under the direct supervision and control of a pharmacist. It shall be the responsibility of the supervising pharmacist to determine that the pharmacist intern is in compliance with the applicable rules and regulations of the board, and the supervising pharmacist shall be responsible for the acts and omissions of the pharmacist intern in the performance of the pharmacist intern's duties.

(h) ~~A person~~*An individual* holding a pharmacist intern registration shall display such registration in that part of the place of business in which such ~~person~~ *individual* is engaged in pharmacist intern activities.

(i) The board shall adopt such rules and regulations as are necessary to ensure that pharmacist interns are adequately trained as to the nature and scope of their lawful duties. The board may adopt rules and regulations as may be necessary to carry out the purposes of and enforce the provisions of this section.

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

Sec. 17. K.S.A. 65-636, 65-1627, 65-1631, 65-1637, 65-1643, 65-1645, 65-1656, 65-1657, 65-1658, 65-1663 and 65-1676 and K.S.A. 2020 Supp. 65-1626 are hereby repealed.

Sec. 18. This act shall take effect and be in force from and after its publication in the statute book.