

Senate Substitute for HOUSE BILL No. 2279

By Committee on Public Health and Welfare

2-22

1 AN ACT concerning health professions and practices; relating to advanced
2 practice registered nurses; licensure thereof; authorizing the prescribing
3 of drugs without a supervising physician; requiring malpractice
4 insurance coverage; rules and regulations; amending K.S.A. 65-1130
5 and K.S.A. 2021 Supp. 65-1626 and 65-4101 and repealing the existing
6 sections.

7
8 *Be it enacted by the Legislature of the State of Kansas:*

9 Section 1. K.S.A. 65-1130 is hereby amended to read as follows: 65-
10 1130. (a) No professional nurse shall announce or represent to the public
11 that such person is an advanced practice registered nurse unless such
12 professional nurse has complied with requirements established by the
13 board and holds a valid license as an advanced practice registered nurse in
14 accordance with the provisions of this section.

15 (b) (1) The board shall establish standards and requirements for any
16 professional nurse who desires to obtain licensure as an advanced practice
17 registered nurse. Such standards and requirements shall include, but not be
18 limited to, standards and requirements relating to the education of
19 advanced practice registered nurses. The board may give such
20 examinations and secure such assistance as it deems necessary to
21 determine the qualifications of applicants.

22 (2) (A) *On and after July 1, 2023, an applicant for initial licensure as*
23 *an advanced practice registered nurse shall have a current advanced*
24 *practice registered nurse certification in such applicant's specific role and*
25 *population focus that has been granted by a national certifying*
26 *organization recognized by the board and whose certification standards*
27 *are approved by the board as equal to or greater than the corresponding*
28 *standards established by the board; and*

29 (B) *an advanced practice registered nurse whose initial licensure is*
30 *prior to July 1, 2023, may submit evidence of such certification to the*
31 *board upon renewal.*

32 (c) The board shall adopt rules and regulations *consistent with the*
33 *Kansas nurse practice act* applicable to advanced practice registered
34 nurses ~~which~~ *that*:

35 (1) Establish roles and identify titles and abbreviations of advanced
36 practice registered nurses ~~which~~ *that* are consistent with nursing practice

1 specialties recognized by the nursing profession.

2 (2) Establish education and qualifications necessary for licensure for
3 each role of advanced practice registered nurse established by the board at
4 a level adequate to assure the competent performance by advanced
5 practice registered nurses of functions and procedures which advanced
6 practice registered nurses are authorized to perform. Advanced practice
7 registered nursing is based on knowledge and skills acquired in basic
8 nursing education, licensure as a registered nurse and graduation from or
9 completion of a master's or higher degree in one of the advanced practice
10 registered nurse roles approved by the board of nursing.

11 (3) Define the role of advanced practice registered nurses and
12 establish limitations and restrictions on such role. The board shall adopt a
13 definition of the role under this paragraph ~~which~~ *that* is consistent with the
14 education and qualifications required to obtain a license as an advanced
15 practice registered nurse, ~~which~~ *that* protects the public from persons
16 performing functions and procedures as advanced practice registered
17 nurses for which they lack adequate education and qualifications and
18 ~~which~~ *that* authorizes advanced practice registered nurses to perform acts
19 generally recognized by the profession of nursing as capable of being
20 performed, in a manner consistent with the public health and safety, by
21 persons with postbasic education in nursing. In defining such role the
22 board shall consider:

23 (A) The education required for a licensure as an advanced practice
24 registered nurse;

25 (B) the type of nursing practice and preparation in specialized
26 advanced practice skills involved in each role of advanced practice
27 registered nurse established by the board;

28 (C) the scope and limitations of advanced practice nursing prescribed
29 by national advanced practice organizations *in accordance with the laws of*
30 *this state*; and

31 (D) acts recognized by the nursing profession as appropriate to be
32 performed by persons with postbasic education in nursing.

33 (d) (1) An advanced practice registered nurse may prescribe ~~drugs~~
34 ~~pursuant to a written protocol as authorized by a responsible physician.~~
35 ~~Each written protocol shall contain a precise and detailed medical plan of~~
36 ~~care for each classification of disease or injury for which the advanced~~
37 ~~practice registered nurse is authorized to prescribe and shall specify all~~
38 ~~drugs which may be prescribed by the advanced practice registered nurse.~~
39 ~~Any written durable medical equipment and prescribe, procure and~~
40 ~~administer any drug consistent with such licensee's specific role and~~
41 ~~population focus, except an advanced practice registered nurse shall not~~
42 ~~prescribe any drug that is intended to cause an abortion. Any drug that is~~
43 ~~a controlled substance shall be prescribed, procured or administered in~~

1 *accordance with the uniform controlled substances act.*

2 (2) *A prescription order shall include the name, address and telephone*
3 *number of the ~~responsible physician~~ advanced practice registered nurse.*
4 *The ~~An~~ advanced practice registered nurse may not dispense drugs; but*
5 *may request, receive and sign for professional samples and may distribute*
6 *professional samples to patients ~~pursuant to a written protocol as~~*
7 *authorized by a responsible physician.*

8 (3) *In order to prescribe controlled substances, the advanced practice*
9 *registered nurse shall:*

10 ~~(1)~~ (A) *Register with the federal drug enforcement administration;*
11 *and*

12 ~~(2)~~ *notify the board of the name and address of the responsible*
13 *physician or physicians. In no case shall the scope of authority of the*
14 *advanced practice registered nurse exceed the normal and customary*
15 *practice of the responsible physician*

16 *(B) comply with federal drug enforcement administration*
17 *requirements related to controlled substances.*

18 (4) *An advanced practice registered nurse certified in the role of*
19 *registered nurse anesthetist while functioning as a registered nurse*
20 *anesthetist under K.S.A. 65-1151 through 65-1164, and amendments*
21 *thereto, shall be subject to the provisions of K.S.A. 65-1151 through 65-*
22 *1164, and amendments thereto, with respect to drugs and anesthetic agents*
23 *and shall not be subject to the provisions of this subsection. ~~For the~~*
24 *purposes of this subsection, "responsible physician" means a person*
25 *licensed to practice medicine and surgery in Kansas who has accepted*
26 *responsibility for the protocol and the actions of the advanced practice*
27 *registered nurse when prescribing drugs.*

28 (5) *An advanced practice registered nurse shall maintain malpractice*
29 *insurance coverage as a condition of rendering professional clinical*
30 *services as an advanced practice registered nurse in this state and shall*
31 *provide proof of insurance at the time of licensure and renewal of license.*
32 *The requirements of this subsection shall not apply to an advanced*
33 *practice registered nurse who:*

34 (i) *Practices solely in employment for which the advanced practice*
35 *registered nurse is covered under the federal tort claims act or the Kansas*
36 *tort claims act;*

37 (ii) *practices solely as a charitable healthcare provider under K.S.A.*
38 *75-6102, and amendments thereto; or*

39 (iii) *is serving on active duty in the armed forces of the United States.*

40 (e) *As used in this section, "drug" means those articles and substances*
41 *defined as drugs in K.S.A. 65-1626 and 65-4101, and amendments thereto.*

42 (f) *A person registered to practice as an advanced registered nurse*
43 *practitioner in the state of Kansas immediately prior to the effective date of*

1 this act shall be deemed to be licensed to practice as an advanced practice
2 registered nurse under this act and such person shall not be required to file
3 an original application for licensure under this act. Any application for
4 registration filed which has not been granted prior to the effective date of
5 this act shall be processed as an application for licensure under this act.

6 (g) An advanced practice registered nurse certified in the role of
7 certified nurse-midwife and engaging in the independent practice of
8 midwifery under the independent practice of midwifery act with respect to
9 prescribing drugs shall be subject to the provisions of the independent
10 practice of midwifery act and shall not be subject to the provisions of this
11 section.

12 (h) *This section shall not supersede the requirements outlined in*
13 *K.S.A. 65-4a08(b), and amendments thereto.*

14 Sec. 2. K.S.A. 2021 Supp. 65-1626 is hereby amended to read as
15 follows: 65-1626. As used in the pharmacy act of the state of Kansas:

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

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

21 (1) A practitioner or pursuant to the lawful direction of a practitioner;

22 (2) the patient or research subject at the direction and in the presence
23 of the practitioner; or

24 (3) a pharmacist as authorized in K.S.A. 65-1635a, *and amendments*
25 *thereto*, or K.S.A. 2021 Supp. 65-16,129, and amendments thereto.

26 (c) "Agent" means an authorized person who acts on behalf of or at
27 the direction of a manufacturer, repackager, wholesale distributor, third-
28 party logistics provider or dispenser but does not include a common
29 carrier, public warehouseman or employee of the carrier or warehouseman
30 when acting in the usual and lawful course of the carrier's or
31 warehouseman's business.

32 (d) "Automated dispensing system" means a robotic or mechanical
33 system controlled by a computer that:

34 (1) Performs operations or activities, other than compounding or
35 administration, relative to the storage, packaging, labeling, dispensing or
36 distribution of drugs;

37 (2) collects, controls and maintains all transaction information; and

38 (3) operates in accordance with the board's rules and regulations.

39 (e) "Biological product" means the same as defined in 42 U.S.C. §
40 262(i), as in effect on January 1, 2017.

41 (f) "Board" means the state board of pharmacy created by K.S.A. 74-
42 1603, and amendments thereto.

43 (g) "Brand exchange," in the case of a drug prescribed, means the

1 dispensing of a different drug product of the same dosage form and
2 strength and of the same generic name as the brand name drug product
3 prescribed, and in the case of a biological product prescribed, means the
4 dispensing of an interchangeable biological product.

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

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

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

15 (k) (1) "Compounding" means the combining of components into a
16 compounded preparation under either of the following conditions:

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

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

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

27 (3) Compounding does not include reconstituting any mixed drug
28 according to the FDA-approved labeling for the drug.

29 (l) "Current good manufacturing practices" or "CGMP" means the
30 requirements for ensuring that drugs and drug products are consistently
31 manufactured, repackaged, produced, stored and dispensed in accordance
32 with 21 C.F.R. §§ 207, 210 and 211.

33 (m) "DEA" means the United States department of justice, drug
34 enforcement administration.

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

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

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

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

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

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

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

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

9 (p) "Direct supervision" means the process by which the responsible
10 pharmacist shall observe and direct the activities of a pharmacist intern or
11 pharmacy technician, be readily and immediately available at all time
12 activities are performed, provide personal assistance, direction and
13 approval throughout the time the activities are performed and complete the
14 final check before dispensing.

15 (q) "Dispense" or "dispensing" means to deliver prescription
16 medication to the ultimate user or research subject by or pursuant to the
17 lawful order of a practitioner or pursuant to the prescription of a mid-level
18 practitioner, including, but not limited to, delivering prescription
19 medication to a patient by mail, common carrier, personal delivery or
20 third-party delivery to any location requested by the patient.

21 (r) "Dispenser" means:

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

26 (2) a retail pharmacy, hospital pharmacy or group of pharmacies
27 under common ownership and control that do not act as a wholesale
28 distributor.

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

35 (t) "Distributor" means a person or entity that distributes a drug or
36 device.

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

39 (v) "Drop shipment" means the sale, by a manufacturer, repackager or
40 exclusive distributor, of the manufacturer's prescription drug to a
41 wholesale distributor whereby the wholesale distributor takes title but not
42 possession of such prescription drug and the wholesale distributor invoices
43 the dispenser, and the dispenser receives delivery of the prescription drug

1 directly from the manufacturer, repackager, third-party logistics provider
2 or exclusive distributor, of such prescription drug.

3 (w) "Drug" means *articles*:

4 (1) ~~Articles~~—Recognized in the official United States pharmacopeia, or
5 other such official compendiums of the United States, or official national
6 formulary, or any supplement to any of them;

7 (2) ~~articles~~—intended for use in the diagnosis, cure, mitigation,
8 treatment or prevention of disease in human or other animals;

9 (3) ~~articles~~—other than food, intended to affect the structure or any
10 function of the body of human or other animals; and

11 (4) ~~articles~~—intended for use as a component of any articles specified
12 in paragraph (1), (2) or (3); but does not include devices or their
13 components, parts or accessories, except that the term "drug" ~~shall~~ *does*
14 not include amygdalin (laetrile) or any livestock remedy, if such livestock
15 remedy had been registered in accordance with the provisions of article 5
16 of chapter 47 of the Kansas Statutes Annotated, prior to its repeal.

17 (x) "Durable medical equipment" means equipment that:

18 (1) Provides therapeutic benefits or enables an individual to perform
19 certain tasks that the individual is unable to otherwise undertake due to
20 certain medical conditions or illnesses;

21 (2) is primarily and customarily used to serve a medical purpose;

22 (3) generally is not useful to a person in the absence of an illness or
23 injury;

24 (4) can withstand repeated use;

25 (5) is appropriate for use in the home, long-term care facility or
26 medical care facility, but may be transported to other locations to allow the
27 individual to complete instrumental activities of daily living that are more
28 complex tasks required for independent living; and

29 (6) may include devices and medical supplies or other similar
30 equipment determined by the board in rules and regulations adopted by the
31 board.

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

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

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

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

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

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

11 (ee) "FDA" means the United States department of health and human
12 services, food and drug administration.

13 (ff) "Facsimile transmission" or "fax transmission" means the
14 transmission of a digital image of a prescription from the prescriber or the
15 prescriber's agent to the pharmacy. "Facsimile transmission" includes, but
16 is not limited to, transmission of a written prescription between the
17 prescriber's fax machine and the pharmacy's fax machine; transmission of
18 an electronically prepared prescription from the prescriber's electronic
19 prescription application to the pharmacy's fax machine, computer or
20 printer; or transmission of an electronically prepared prescription from the
21 prescriber's fax machine to the pharmacy's fax machine, computer or
22 printer.

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

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

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

32 (A) Inmates of a jail or correctional institution or facility;

33 (B) residents of a juvenile correctional facility or juvenile detention
34 facility, as defined in K.S.A. 38-2302, and amendments thereto;

35 (C) students of a public or private university or college, a community
36 college or any other institution of higher learning that is located in Kansas;

37 (D) employees of a business or other employer; or

38 (E) persons receiving inpatient hospice services.

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

40 (A) Any registered pharmacy;

41 (B) any office of a practitioner; or

42 (C) a location where no prescription-only drugs are dispensed and no
43 prescription-only drugs other than individual prescriptions are stored or

1 administered.

2 (jj) "Interchangeable biological product" means a biological product
3 that the FDA has identified in the "purple book: lists of licensed biological
4 products with reference product exclusivity and biosimilarity or
5 interchangeability evaluations" as meeting the standards for
6 "interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on
7 January 1, 2017.

8 (kk) "Intracompany transaction" means any transaction or transfer
9 between any division, subsidiary, parent or affiliated or related company
10 under common ownership or control of a corporate entity, or any
11 transaction or transfer between co-licensed partners.

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

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

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

20 (oo) "Medical care facility" means the same as defined in K.S.A. 65-
21 425, and amendments thereto, ~~except that the term~~ and also includes
22 psychiatric hospitals and psychiatric residential treatment facilities as
23 defined by K.S.A. 39-2002, and amendments thereto.

24 (pp) "Manufacture" means the production, preparation, propagation,
25 compounding, conversion or processing of a drug either directly or
26 indirectly by extraction from substances of natural origin, independently
27 by means of chemical or biological synthesis or by a combination of
28 extraction and chemical or biological synthesis or the packaging or
29 repackaging of the drug or labeling or relabeling of its container, except
30 that this term does not include the preparation or compounding of a drug
31 by an individual for the individual's own use or the preparation,
32 compounding, packaging or labeling of a drug by:

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

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

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

42 (qq) "Manufacturer" means:

43 (1) A person that holds an application approved under section 505 of

1 the federal food, drug and cosmetic act or a license issued under section
2 351 of the federal public health service act for such drug or, if such drug is
3 not the subject of an approved application or license, the person who
4 manufactured the drug;

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

8 (3) an affiliate of a person described in paragraph (1) or (2) that
9 receives the product directly from a person described in paragraph (1) or
10 (2).

11 (rr) "Medication order" means a written or oral order by a prescriber
12 or the prescriber's authorized agent for administration of a drug or device
13 to a patient in a Kansas licensed medical care facility or in a Kansas
14 licensed nursing facility or nursing facility for mental health, as such terms
15 are defined by K.S.A. 39-923, and amendments thereto.

16 (ss) "Mid-level practitioner" means a certified nurse-midwife
17 engaging in the independent practice of midwifery under the independent
18 practice of midwifery act, an advanced practice registered nurse issued a
19 license pursuant to K.S.A. 65-1131, and amendments thereto, who has
20 authority to prescribe drugs ~~pursuant to a written protocol with a~~
21 ~~responsible physician~~ under K.S.A. 65-1130, and amendments thereto, or a
22 physician assistant licensed pursuant to the physician assistant licensure
23 act who has authority to prescribe drugs pursuant to a written agreement
24 with a supervising physician under K.S.A. 65-28a08, and amendments
25 thereto.

26 (tt) "Nonresident pharmacy" means a pharmacy located outside of
27 Kansas.

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

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

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

37 (xx) "Pharmacist-in-charge" means the pharmacist who is responsible
38 to the board for a registered establishment's compliance with the laws and
39 regulations of this state pertaining to the practice of pharmacy,
40 manufacturing of drugs and the distribution of drugs. The pharmacist-in-
41 charge shall supervise such establishment on a full-time or a part-time
42 basis and perform such other duties relating to supervision of a registered
43 establishment as may be prescribed by the board by rules and regulations.

1 Nothing in this definition shall relieve other pharmacists or persons from
2 their responsibility to comply with state and federal laws and regulations.

3 (yy) "Pharmacist intern" or "intern" means:

4 (1) A student currently enrolled in and in good standing with an
5 accredited pharmacy program;

6 (2) a graduate of an accredited pharmacy program serving an
7 internship; or

8 (3) a graduate of a pharmacy program located outside of the United
9 States that is not accredited and who has successfully passed equivalency
10 examinations approved by the board.

11 (zz) "Pharmacy," "drugstore" or "apothecary" means premises,
12 laboratory, area or other place, including any electronic medium:

13 (1) Where drugs are offered for sale where the profession of
14 pharmacy is practiced and where prescriptions are compounded and
15 dispensed;

16 (2) that has displayed upon it or within it the words "pharmacist,"
17 "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore,"
18 "druggist," "drugs," "drug sundries" or any of these words or combinations
19 of these words or words of similar import in any language or on any sign
20 containing any of these words as used in the context of health, medical or
21 pharmaceutical care or services; or

22 (3) where the characteristic symbols of pharmacy or the characteristic
23 prescription sign "Rx" may be exhibited in the context of health, medical
24 or pharmaceutical care or services. As used in this subsection, premises
25 refers only to the portion of any building or structure leased, used or
26 controlled by the licensee in the conduct of the business registered by the
27 board at the address for which the registration was issued.

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

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

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

1 to a prescription-only drug.

2 (ddd) "Preceptor" means a licensed pharmacist who possesses at least
3 two years' experience as a pharmacist and who supervises and is
4 responsible for the actions of pharmacist interns obtaining pharmaceutical
5 experience.

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

7 (fff) "Prescription" or "prescription order" means the front and back
8 of a lawful written, electronic or facsimile order from a prescriber or an
9 oral order from a prescriber or the prescriber's authorized agent that
10 communicates the prescriber's instructions for a prescription drug or
11 device to be dispensed.

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

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

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

27 (jjj) "Product" means the same as defined by part H of the federal
28 drug supply chain security act, 21 U.S.C. § 351 et seq. and 21 U.S.C. §
29 360eee.

30 (lll) "Professional incompetency" means:

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

34 (2) repeated instances involving failure to adhere to the applicable
35 standard of pharmaceutical care to a degree that constitutes ordinary
36 negligence, as determined by the board; or

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

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

1 written request from the board or other authorized agent.

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

4 (ooo) "Repackager" means a person who owns or operates a facility
5 that repackages.

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

13 (qqq) "Reverse distributor" means a person who owns or operates an
14 establishment that disposes of or otherwise processes saleable or
15 nonsaleable products received from an authorized trading partner such that
16 the product may be processed for credit to the purchaser, manufacturer or
17 seller or disposed of for no further distribution.

18 (rrr) "Secretary" means the executive secretary of the board.

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

24 (ttt) "Trading partner" means:

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

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

34 (uuu) "Transaction" means the transfer of product between persons in
35 which a change of ownership occurs.

36 (vvv) "Unprofessional conduct" means:

37 (1) Fraud in securing a registration or permit;

38 (2) intentional adulteration or mislabeling of any drug, medicine,
39 chemical or poison;

40 (3) causing any drug, medicine, chemical or poison to be adulterated
41 or mislabeled, knowing the same to be adulterated or mislabeled;

42 (4) intentionally falsifying or altering records or prescriptions;

43 (5) unlawful possession of drugs and unlawful diversion of drugs to

1 others;

2 (6) willful betrayal of confidential information under K.S.A. 65-1654,
3 and amendments thereto;

4 (7) conduct likely to deceive, defraud or harm the public;

5 (8) making a false or misleading statement regarding the licensee's
6 professional practice or the efficacy or value of a drug;

7 (9) commission of any act of sexual abuse, misconduct or
8 exploitation related to the licensee's professional practice; or

9 (10) performing unnecessary tests, examinations or services that have
10 no legitimate pharmaceutical purpose.

11 (www) "Vaccination protocol" means a written protocol, agreed to
12 and signed by a pharmacist and a person licensed to practice medicine and
13 surgery by the state board of healing arts, that establishes procedures and
14 recordkeeping and reporting requirements for administering a vaccine by
15 the pharmacist for a period of time specified therein, not to exceed two
16 years.

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

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

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

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

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

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

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

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

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

41 (bbbb) "Wholesale distributor" means any person engaged in
42 wholesale distribution or reverse distribution of drugs or devices, other
43 than a manufacturer, co-licensed partner or third-party logistics provider.

1 (cccc) "Wholesale distribution" means the distribution or receipt of
2 drugs or devices to or by persons other than consumers or patients, in
3 which a change of ownership occurs. "Wholesale distribution" does not
4 include:

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

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

12 (3) intracompany distribution;

13 (4) the distribution of a drug or device, or an offer to distribute a drug
14 or device, among hospitals or other ~~health care~~ *healthcare* entities under
15 common control;

16 (5) the distribution of a drug or device, or the offer to distribute a
17 drug or device, by a charitable organization described in section 501(c)(3)
18 of the internal revenue code of 1986 to a nonprofit affiliate of the
19 organization to the extent otherwise permitted by law;

20 (6) the distribution of an intravenous drug used to maintain the
21 equilibrium of water and minerals in the body, such as dialysis solutions;
22 or

23 (7) the sale or transfer from a retail pharmacy of expired, damaged,
24 returned or recalled prescription drugs to the original manufacturer,
25 originating wholesale distributor or to a reverse distributor registered in
26 accordance with the board's rules and regulations.

27 Sec. 3. K.S.A. 2021 Supp. 65-4101 is hereby amended to read as
28 follows: 65-4101. As used in this act:

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

32 (1) A practitioner or pursuant to the lawful direction of a practitioner;
33 or

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

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

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

1 (d) "Board" means the state board of pharmacy.

2 (e) "Bureau" means the bureau of narcotics and dangerous drugs,
3 United States department of justice, or its successor agency.

4 (f) "Controlled substance" means any drug, substance or immediate
5 precursor included in any of the schedules designated in K.S.A. 65-4105,
6 65-4107, 65-4109, 65-4111 and 65-4113, and amendments thereto.

7 (g) (1) "Controlled substance analog" means a substance that is
8 intended for human consumption, and at least one of the following:

9 (A) The chemical structure of the substance is substantially similar to
10 the chemical structure of a controlled substance listed in or added to the
11 schedules designated in K.S.A. 65-4105 or 65-4107, and amendments
12 thereto;

13 (B) the substance has a stimulant, depressant or hallucinogenic effect
14 on the central nervous system substantially similar to the stimulant,
15 depressant or hallucinogenic effect on the central nervous system of a
16 controlled substance included in the schedules designated in K.S.A. 65-
17 4105 or 65-4107, and amendments thereto; or

18 (C) with respect to a particular individual, such individual represents
19 or intends the substance to have a stimulant, depressant or hallucinogenic
20 effect on the central nervous system substantially similar to the stimulant,
21 depressant or hallucinogenic effect on the central nervous system of a
22 controlled substance included in the schedules designated in K.S.A. 65-
23 4105 or 65-4107, and amendments thereto.

24 (2) "Controlled substance analog" does not include:

25 (A) A controlled substance;

26 (B) a substance for which there is an approved new drug application;
27 or

28 (C) a substance with respect to which an exemption is in effect for
29 investigational use by a particular person under section 505 of the federal
30 food, drug and cosmetic act, 21 U.S.C. § 355, to the extent conduct with
31 respect to the substance is permitted by the exemption.

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

37 (i) "Cultivate" means the planting or promotion of growth of five or
38 more plants that contain or can produce controlled substances.

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

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

- 1 (l) "Dispense" means to deliver a controlled substance to an ultimate
2 user or research subject by or pursuant to the lawful order of a practitioner,
3 including the packaging, labeling or compounding necessary to prepare the
4 substance for that delivery, or pursuant to the prescription of a mid-level
5 practitioner.
- 6 (m) "Dispenser" means a practitioner or pharmacist who dispenses, or
7 a physician assistant who has authority to dispense prescription-only drugs
8 in accordance with K.S.A. 65-28a08(b), and amendments thereto.
- 9 (n) "Distribute" means to deliver other than by administering or
10 dispensing a controlled substance.
- 11 (o) "Distributor" means a person who distributes.
- 12 (p) "Drug" means *substances*:
- 13 (1) ~~Substances~~—Recognized as drugs in the official United States
14 pharmacopeia, official homeopathic pharmacopoeia of the United States or
15 official national formulary or any supplement to any of them;
- 16 (2) ~~substances~~—intended for use in the diagnosis, cure, mitigation,
17 treatment or prevention of disease in human or animals;
- 18 (3) ~~substances~~—(other than food), intended to affect the structure or
19 any function of the body of human or animals; and
- 20 (4) ~~substances~~—intended for use as a component of any article
21 specified in paragraph (1), (2) or (3). ~~†~~"Drug" does not include devices or
22 their components, parts or accessories.
- 23 (q) "Immediate precursor" means a substance that the board has
24 found to be and by rule and regulation designates as being the principal
25 compound commonly used or produced primarily for use and that is an
26 immediate chemical intermediary used or likely to be used in the
27 manufacture of a controlled substance, the control of which is necessary to
28 prevent, curtail or limit manufacture.
- 29 (r) "Electronic prescription" means an electronically prepared
30 prescription that is authorized and transmitted from the prescriber to the
31 pharmacy by means of electronic transmission.
- 32 (s) "Electronic prescription application" means software that is used
33 to create electronic prescriptions and that is intended to be installed on the
34 prescriber's computers and servers where access and records are controlled
35 by the prescriber.
- 36 (t) "Electronic signature" means a confidential personalized digital
37 key, code, number or other method for secure electronic data transmissions
38 that identifies a particular person as the source of the message,
39 authenticates the signatory of the message and indicates the person's
40 approval of the information contained in the transmission.
- 41 (u) "Electronic transmission" means the transmission of an electronic
42 prescription, formatted as an electronic data file, from a prescriber's
43 electronic prescription application to a pharmacy's computer, where the

1 data file is imported into the pharmacy prescription application.

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

4 (w) "Facsimile transmission" or "fax transmission" means the
5 transmission of a digital image of a prescription from the prescriber or the
6 prescriber's agent to the pharmacy. "Facsimile transmission" includes, but
7 is not limited to, transmission of a written prescription between the
8 prescriber's fax machine and the pharmacy's fax machine; transmission of
9 an electronically prepared prescription from the prescriber's electronic
10 prescription application to the pharmacy's fax machine, computer or
11 printer; or transmission of an electronically prepared prescription from the
12 prescriber's fax machine to the pharmacy's fax machine, computer or
13 printer.

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

17 (y) "Isomer" means all enantiomers and diastereomers.

18 (z) "Manufacture" means the production, preparation, propagation,
19 compounding, conversion or processing of a controlled substance either
20 directly or indirectly or by extraction from substances of natural origin or
21 independently by means of chemical synthesis or by a combination of
22 extraction and chemical synthesis and includes any packaging or
23 repackaging of the substance or labeling or relabeling of its container,
24 except that this term does not include the preparation or compounding of a
25 controlled substance by an individual for the individual's own lawful use
26 or the preparation, compounding, packaging or labeling of a controlled
27 substance:

28 (1) By a practitioner or the practitioner's agent pursuant to a lawful
29 order of a practitioner as an incident to the practitioner's administering or
30 dispensing of a controlled substance in the course of the practitioner's
31 professional practice; or

32 (2) by a practitioner or by the practitioner's authorized agent under
33 such practitioner's supervision for the purpose of or as an incident to
34 research, teaching or chemical analysis or by a pharmacist or medical care
35 facility as an incident to dispensing of a controlled substance.

36 (aa) "Marijuana" means all parts of all varieties of the plant Cannabis
37 whether growing or not, the seeds thereof, the resin extracted from any
38 part of the plant and every compound, manufacture, salt, derivative,
39 mixture or preparation of the plant, its seeds or resin. It does not include:

40 (1) The mature stalks of the plant, fiber produced from the stalks, oil
41 or cake made from the seeds of the plant, any other compound,
42 manufacture, salt, derivative, mixture or preparation of the mature stalks,
43 except the resin extracted therefrom, fiber, oil or cake or the sterilized seed

1 of the plant that is incapable of germination;

2 (2) any substance listed in schedules II through V of the uniform
3 controlled substances act;

4 (3) cannabidiol (other trade name: 2-[(3-methyl-6-(1-methylethenyl)-
5 2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol); or

6 (4) industrial hemp as defined in K.S.A. 2021 Supp. 2-3901, and
7 amendments thereto, when cultivated, produced, possessed or used for
8 activities authorized by the commercial industrial hemp act.

9 (bb) "Medical care facility" shall have the meaning ascribed to that
10 term in K.S.A. 65-425, and amendments thereto.

11 (cc) "Mid-level practitioner" means a certified nurse-midwife
12 engaging in the independent practice of midwifery under the independent
13 practice of midwifery act, an advanced practice registered nurse issued a
14 license pursuant to K.S.A. 65-1131, and amendments thereto, who has
15 authority to prescribe drugs pursuant to a written protocol with a
16 responsible physician under K.S.A. 65-1130, and amendments thereto, or a
17 physician assistant licensed under the physician assistant licensure act who
18 has authority to prescribe drugs pursuant to a written agreement with a
19 supervising physician under K.S.A. 65-28a08, and amendments thereto.

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

24 (1) Opium and opiate and any salt, compound, derivative or
25 preparation of opium or opiate;

26 (2) any salt, compound, isomer, derivative or preparation thereof that
27 is chemically equivalent or identical with any of the substances referred to
28 in paragraph (1) but not including the isoquinoline alkaloids of opium;

29 (3) opium poppy and poppy straw;

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

35 (ee) "Opiate" means any substance having an addiction-forming or
36 addiction-sustaining liability similar to morphine or being capable of
37 conversion into a drug having addiction-forming or addiction-sustaining
38 liability. It does not include, unless specifically designated as controlled
39 under K.S.A. 65-4102, and amendments thereto, the dextrorotatory isomer
40 of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does
41 include its racemic and levorotatory forms.

42 (ff) "Opium poppy" means the plant of the species *Papaver*
43 *somniferum* L. except its seeds.

1 (gg) "Person" means an individual, corporation, government, or
2 governmental subdivision or agency, business trust, estate, trust,
3 partnership or association or any other legal entity.

4 (hh) "Pharmacist" means any natural person licensed under K.S.A.
5 65-1625 et seq., and amendments thereto, to practice pharmacy.

6 (ii) "Pharmacist intern" means:

7 (1) A student currently enrolled in an accredited pharmacy program;

8 (2) a graduate of an accredited pharmacy program serving such
9 person's internship; or

10 (3) a graduate of a pharmacy program located outside of the United
11 States that is not accredited and who had successfully passed equivalency
12 examinations approved by the board.

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

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

18 (ll) "Practitioner" means a person licensed to practice medicine and
19 surgery, dentist, podiatrist, veterinarian, optometrist, or scientific
20 investigator or other person authorized by law to use a controlled
21 substance in teaching or chemical analysis or to conduct research with
22 respect to a controlled substance.

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

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

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

33 (pp) "Ultimate user" means a person who lawfully possesses a
34 controlled substance for such person's own use or for the use of a member
35 of such person's household or for administering to an animal owned by
36 such person or by a member of such person's household.

37 Sec. 4. K.S.A. 65-1130 and K.S.A. 2021 Supp. 65-1626 and 65-4101
38 are hereby repealed.

39 Sec. 5. This act shall take effect and be in force from and after its
40 publication in the statute book.