Session of 2021

HOUSE BILL No. 2342

By Representative Vaughn

2-10

1	AN ACT concerning health and healthcare; relating to the practice of
2	pharmacy; allowing a pharmacist to prescribe and dispense self-
3	administered contraceptives; amending K.S.A. 65-1626a and K.S.A.
4	2020 Supp. 65-1626 and repealing the existing sections.
5	
6	Be it enacted by the Legislature of the State of Kansas:
7	New Section 1. (a) A licensed pharmacist may prescribe and dispense
8	self-administered oral hormonal contraceptives to a person who is:
9	(1) 18 years of age or older, regardless of whether such person has
10	evidence of a previous prescription from a physician for a self-
11	administered oral hormonal contraceptive; or
12	(2) under 18 years of age, if such person has evidence of a previous
13	prescription from a physician for a self-administered oral hormonal
14	contraceptive.
15	(b) A pharmacist who prescribes a self-administered oral hormonal
16	contraceptive under this section shall:
17	(1) Attend training approved by the board related to prescribing self-
18	administered oral hormonal contraceptives;
19	(2) provide a self-screening risk assessment tool for the person
20	seeking a self-administered oral hormonal contraceptive prescription to be
21	used prior to dispensing any such prescription;
22	(3) refer the person seeking a self-administered oral hormonal
23	contraceptive prescription to such person's primary care provider or
24	women's healthcare practitioner upon prescribing and dispensing the self-
25	administered oral hormonal contraceptive prescription; and
26	(4) dispense the self-administered oral hormonal contraceptive as
27	soon as practicable after the pharmacist issues the prescription.
28	(c) For purposes of this section, "self-administered oral hormonal
29	contraceptive" means a drug composed of a combination of hormones that
30	is approved by the United States food and drug administration to prevent
31	pregnancy and may only be taken orally by the patient to whom the drug is
32	(d) The board of pharmacy shall adopt rules and regulations to
33 34	(d) The board of pharmacy shall adopt rules and regulations to implement and administer the provisions of this section, including:
34 35	(1) Standard procedures for the prescribing of self-administered oral
35 36	hormonal contraceptives by pharmacists; and
50	normonal contraceptives by pharmacists, and

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1 (2) a prohibition on pharmacists requiring an appointment be 2 scheduled in order to prescribe or dispense a self-administered oral 3 hormonal contraceptive prescription.

4 (e) This section shall be a part of and supplemental to the pharmacy 5 act of the state of Kansas.

6 Sec. 2. K.S.A. 2020 Supp. 65-1626 is hereby amended to read as 7 follows: 65-1626. For the purposes of this act:

8 (a) "Administer" means the direct application of a drug, whether by 9 injection, inhalation, ingestion or any other means, to the body of a patient 10 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 presenceof 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.

16 (b) "Agent" means an authorized person who acts on behalf of or at 17 the direction of a manufacturer, repackager, wholesale distributor, third-18 party logistics provider or dispenser but does not include a common 19 carrier, public warehouseman or employee of the carrier or warehouseman 20 when acting in the usual and lawful course of the carrier's or 21 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. 741603, 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.

41 (h) "Brand name" means the registered trademark name given to a 42 drug product by its manufacturer, labeler or distributor.

43 (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.

5 (j) "Common carrier" means any person who undertakes, whether 6 directly or by any other arrangement, to transport property, including 7 drugs, for compensation.

8 (k) "Compounding" means the combining of components into a 9 compounded preparation under either of the following conditions:

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

15 (2) for the purpose of, or incidental to, research, teaching or chemical 16 analysis, and not for sale or dispensing.

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

20 Compounding does not include reconstituting any oral or topical drug 21 according to the FDA-approved labeling for the drug or preparing any 22 sterile or nonsterile preparation that is essentially a copy of a commercially 23 available product.

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

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

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

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

38 (p) "Dispenser" means:

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

43 (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.

5 (q) "Distribute" or "distribution" means to deliver, offer to deliver, 6 sell, offer to sell, purchase, trade, transfer, broker, give away, handle, store 7 or receive, other than by administering or dispensing, any product, but 8 does not include dispensing a product pursuant to a prescription executed 9 in accordance with 21 U.S.C. § 353 or the dispensing of a product 10 approved under 21 U.S.C. § 360b.

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

(s) "Drop shipment" means the sale, by a manufacturer, repackager or exclusive distributor, of the manufacturer's prescription drug to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the dispenser, and the dispenser receives delivery of the prescription drug directly from the manufacturer, repackager, third-party logistics provider or exclusive distributor, of such prescription drug.

19 (t) "Drug" means: (1) Articles recognized in the official United States 20 pharmacopeia, or other such official compendiums of the United States, or 21 official national formulary, or any supplement to any of them; (2) articles 22 intended for use in the diagnosis, cure, mitigation, treatment or prevention 23 of disease in human or other animals; (3) articles, other than food, 24 intended to affect the structure or any function of the body of human or 25 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 26 27 or their components, parts or accessories, except that the term "drug" shall 28 not include amygdalin (laetrile) or any livestock remedy, if such livestock remedy had been registered in accordance with the provisions of article 5 29 30 of chapter 47 of the Kansas Statutes Annotated, prior to its repeal.

31 (u) "Durable medical equipment" means equipment that: (1) Provides 32 therapeutic benefits or enables an individual to perform certain tasks that 33 the individual is unable to otherwise undertake due to certain medical 34 conditions or illnesses; (2) is primarily and customarily used to serve a 35 medical purpose; (3) generally is not useful to a person in the absence of 36 an illness or injury; (4) can withstand repeated use; (5) is appropriate for 37 use in the home, long-term care facility or medical care facility, but may 38 be transported to other locations to allow the individual to complete 39 instrumental activities of daily living that are more complex tasks required 40 for independent living; and (6) may include devices and medical supplies 41 or other similar equipment determined by the board in rules and 42 regulations adopted by the board.

43 (v) "Electronic prescription" means an electronically prepared

prescription that is authorized and transmitted from the prescriber to the
 pharmacy by means of electronic transmission.

3 (w) "Electronic prescription application" means software that is used 4 to create electronic prescriptions and that is intended to be installed on the 5 prescriber's computers and servers where access and records are controlled 6 by the prescriber.

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

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

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

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

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

24 (cc)"Facsimile transmission" or "fax transmission" means the 25 transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes, but 26 is not limited to, transmission of a written prescription between the 27 28 prescriber's fax machine and the pharmacy's fax machine; transmission of 29 an electronically prepared prescription from the prescriber's electronic 30 prescription application to the pharmacy's fax machine, computer or 31 printer; or transmission of an electronically prepared prescription from the 32 prescriber's fax machine to the pharmacy's fax machine, computer or 33 printer.

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

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

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

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

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(B) residents of a *juvenile correctional facility or* juvenile detention 1 facility, as defined by the revised Kansas code for care of children and the 2 revised Kansas juvenile justice code in K.S.A. 2020 Supp 38-2302, and 3 4 amendments thereto;

5 (C) students of a public or private university or college, a community 6 college or any other institution of higher learning that is located in Kansas; 7

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

persons receiving inpatient hospice services. (E)

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

(A) Any registered pharmacy; 10 11

any office of a practitioner; or (B)

a location where no prescription-only drugs are dispensed and no 12 (C) prescription-only drugs other than individual prescriptions are stored or 13 administered 14

"Interchangeable biological product" means a biological product 15 (gg) that the FDA has: 16

17 (1) Licensed and determined meets the standards for "interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on 18 19 January 1, 2017; or

20 (2) determined to be therapeutically equivalent as set forth in the 21 latest edition or supplement to the FDA's approved drug products with 22 therapeutic equivalence evaluations.

23 (hh) "Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the 24 25 pharmacy.

(ii) "Intracompany transaction" means any transaction or transfer 26 between any division, subsidiary, parent or affiliated or related company 27 under common ownership or control of a corporate entity, or any 28 29 transaction or transfer between co-licensed partners.

(jj) "Label" means a display of written, printed or graphic matter 30 31 upon the immediate container of any drug.

(kk) "Labeling" means the process of preparing and affixing a label to 32 any drug container, exclusive of the labeling by a manufacturer, packer or 33 distributor of a non-prescription drug or commercially packaged legend 34 35 drug.

36 (ll) "Long-term care facility" means "nursing facility," as defined in 37 K.S.A. 39-923, and amendments thereto.

38 (mm) "Medical care facility" means the same as defined in K.S.A. 39 65-425, and amendments thereto, except that the term also includes facilities licensed under the provisions of K.S.A. 2020 Supp. 39-2001 et 40 41 seq., and amendments thereto, except community mental health centers and facilities for people with intellectual disability. 42

(nn) "Manufacture" means the production, preparation, propagation, 43

compounding, conversion or processing of a drug either directly or 1 2 indirectly by extraction from substances of natural origin, independently by means of chemical or biological synthesis or by a combination of 3 extraction and chemical or biological synthesis or the packaging or 4 repackaging of the drug or labeling or relabeling of its container, except 5 6 that this term does not include the preparation or compounding of a drug 7 by an individual for the individual's own use or the preparation, 8 compounding, packaging or labeling of a drug by:

9 (1) A practitioner or a practitioner's authorized agent incident to such 10 practitioner's administering or dispensing of a drug in the course of the 11 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.

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(oo) "Manufacturer" means:

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

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

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

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

(qq) "Mid-level practitioner" means a certified nurse-midwife 32 33 engaging in the independent practice of midwifery under the independent 34 practice of midwifery act, an advanced practice registered nurse issued a license pursuant to K.S.A. 65-1131, and amendments thereto, who has 35 36 authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130, and amendments thereto, or a 37 38 physician assistant licensed pursuant to the physician assistant licensure 39 act who has authority to prescribe drugs pursuant to a written agreement 40 with a supervising physician under K.S.A. 65-28a08, and amendments 41 thereto

42 (rr) "Nonresident pharmacy" means a pharmacy located outside of 43 Kansas.

(ss) "Outsourcing facility" or "virtual outsourcing facility" means a 1 2 facility at one geographic location or address that is engaged in the compounding of sterile drugs and has registered with the FDA as an 3 4 outsourcing facility pursuant to 21 U.S.C. § 353b.

5 (tt) "Person" means individual, corporation, government, 6 governmental subdivision or agency, partnership, association or any other 7 legal entity.

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

10 (vv) "Pharmacist-in-charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and 11 regulations of this state pertaining to the practice of pharmacy, 12 manufacturing of drugs and the distribution of drugs. The pharmacist-in-13 14 charge shall supervise such establishment on a full-time or a part-time 15 basis and perform such other duties relating to supervision of a registered 16 establishment as may be prescribed by the board by rules and regulations. 17 Nothing in this definition shall relieve other pharmacists or persons from 18 their responsibility to comply with state and federal laws and regulations.

19 (ww) "Pharmacist intern" means: (1) A student currently enrolled in 20 an accredited pharmacy program; (2) a graduate of an accredited pharmacy 21 program serving an internship; or (3) a graduate of a pharmacy program 22 located outside of the United States that is not accredited and who has 23 successfully passed equivalency examinations approved by the board.

24 (xx) "Pharmacy," "drugstore" or "apothecary" means premises, 25 laboratory, area or other place:

26 (1) Where drugs are offered for sale where the profession of 27 pharmacy is practiced and where prescriptions are compounded and 28 dispensed;

(2) that has displayed upon it or within it the words "pharmacist," 29 "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," 30 "druggist," "drugs," "drug sundries" or any of these words or combinations 31 32 of these words or words of similar import either in English or any sign 33 containing any of these words; or

34 (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, 35 36 premises refers only to the portion of any building or structure leased, used 37 or controlled by the licensee in the conduct of the business registered by 38 the board at the address for which the registration was issued.

39 (yy) "Pharmacy prescription application" means software that is used 40 to process prescription information, is installed on a pharmacy's computers 41 or servers and is controlled by the pharmacy.

42 (zz) "Pharmacy technician" means an individual who, under the direct 43 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) "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) "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.

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

(ddd) "Prescription" or "prescription order" means: (1) An order to be 15 16 filled by a pharmacist for prescription medication issued and signed by a prescriber in the authorized course of such prescriber's professional 17 18 practice; or (2) an order transmitted to a pharmacist through word of 19 mouth, note, telephone or other means of communication directed by such 20 prescriber, regardless of whether the communication is oral, electronic, 21 facsimile or in printed form; or (3) an order to be filled by a pharmacist 22 for prescription medicine issued and signed by a pharmacist for a self-23 administered oral hormonal contraceptive pursuant to section 1, and 24 amendments thereto.

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

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

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

40 (hhh) "Product" means the same as defined by part H of the federal
41 drug supply chain security act, 21 U.S.C. § 351 et seq. and 21 U.S.C. §
42 360eee.

43 (iii) "Professional incompetency" means:

1 (1) One or more instances involving failure to adhere to the 2 applicable standard of pharmaceutical care to a degree that constitutes 3 gross negligence, as determined by the board;

4 (2) repeated instances involving failure to adhere to the applicable 5 standard of pharmaceutical care to a degree that constitutes ordinary 6 negligence, as determined by the board; or

7 (3) a pattern of pharmacy practice or other behavior that demonstrates 8 a manifest incapacity or incompetence to practice pharmacy.

9 (jjj) "Readily retrievable" means that records kept by automatic data 10 processing applications or other electronic or mechanized record-keeping 11 systems can be separated out from all other records within a reasonable 12 time not to exceed 48 hours of a request from the board or other authorized 13 agent or that hard-copy records are kept on which certain items are 14 asterisked, redlined or in some other manner visually identifiable apart 15 from other items appearing on the records.

(III) "Repackage" means changing the container, wrapper, quantity orlabel of a drug to further the distribution of the drug.

18 (mmm) "Repackager" means a person who owns or operates a facility19 that repackages.

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

(000) "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.

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

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

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

43 (sss) "Trading partner" means:

(1) A manufacturer, repackager, wholesale distributor or dispenser 1 from whom a manufacturer, repackager, wholesale distributor or dispenser 2 accepts direct ownership of a product or to whom a manufacturer, 3 repackager, wholesale distributor or dispenser transfers direct ownership of 4 5 a product; or

6 (2) a third-party logistics provider from whom a manufacturer, 7 repackager, wholesale distributor or dispenser accepts direct possession of 8 a product or to whom a manufacturer, repackager, wholesale distributor or dispenser transfers direct possession of a product. 9

(ttt) "Transaction" means the transfer of product between persons in 10 which a change of ownership occurs. 11

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"Unprofessional conduct" means: (uuu) (1) Fraud in securing a registration or permit;

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(2) intentional adulteration or mislabeling of any drug, medicine, 14 15 chemical or poison;

16 (3) causing any drug, medicine, chemical or poison to be adulterated 17 or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

19 (5) unlawful possession of drugs and unlawful diversion of drugs to 20 others:

21 (6) willful betrayal of confidential information under K.S.A. 65-1654, 22 and amendments thereto;

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

(8) making a false or misleading statement regarding the licensee's 24 25 professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or 26 27 exploitation related to the licensee's professional practice; or

28 (10) performing unnecessary tests, examinations or services that have 29 no legitimate pharmaceutical purpose.

(vvv) "Vaccination protocol" means a written protocol, agreed to by a 30 pharmacist and a person licensed to practice medicine and surgery by the 31 32 state board of healing arts, that establishes procedures and recordkeeping 33 and reporting requirements for administering a vaccine by the pharmacist 34 for a period of time specified therein, not to exceed two years.

(www) "Valid prescription order" means a prescription that is issued 35 for a legitimate medical purpose by an individual prescriber licensed by 36 37 law to administer and prescribe drugs and acting in the usual course of 38 such prescriber's professional practice. A prescription issued solely on the 39 basis of an internet-based questionnaire or consultation without an appropriate prescriber-patient relationship is not a valid prescription order. 40

(xxx) "Veterinary medical teaching hospital pharmacy" means any 41 location where prescription-only drugs are stored as part of an accredited 42 43 college of veterinary medicine and from which prescription-only drugs are

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distributed for use in treatment of or administration to a nonhuman. 1

2 "Wholesale distributor" means any person engaged in (yyy) 3 wholesale distribution of prescription drugs, other than a manufacturer, co-4 licensed partner, third-party logistics provider or repackager.

"Wholesale distribution" means the distribution or receipt of 5 (zzz) 6 prescription drugs to or by persons other than consumers or patients, in 7 which a change of ownership occurs. Wholesale distribution does not 8 include. 9

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

(2) the distribution of a prescription drug or an offer to distribute a 10 prescription drug for emergency medical reasons, including a public health 11 emergency declaration pursuant to section 319 of the public health service 12 act, except that, for purposes of this paragraph, a drug shortage not caused 13 14 by a public health emergency shall not constitute an emergency medical 15 reason:

16 (3) intracompany distribution of any drug between members of an affiliate or within a manufacturer: 17

18 (4) the distribution of a prescription drug or an offer to distribute a 19 prescription drug among hospitals or other health care entities under 20 common control:

21 (5) the distribution of a prescription drug or the offer to distribute a 22 prescription drug by a charitable organization described in $\frac{503(c)(3)}{50}$ 23 501(c)(3) of the internal revenue code of $\frac{1954}{1986}$ to a nonprofit affiliate 24 of the organization to the extent otherwise permitted by law;

25 (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 26 27 entity;

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

29 (8) the receipt or transfer of a drug by an authorized third-party logistics provider, provided that such third-party logistics provider does 30 31 not take ownership of the drug;

32 (9) the transport of a drug by a common carrier, provided that the 33 common carrier does not take ownership of the drug;

34 (10) the distribution of a drug or an offer to distribute a drug by an 35 authorized repackager that has taken ownership or possession of the drug 36 and repacks it in accordance with section 582(e) of the federal food, drug 37 and cosmetic act;

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

39 the distribution of minimal quantities of drugs by licensed retail (12)40 pharmacies to licensed practitioners for office use;

41 (13) the distribution of a collection of finished medical devices, 42 including a product or biological product in accordance with 21 U.S.C. § 43 353(e)(4)(M);

1 (14) the distribution of an intravenous drug that, by its formulation, is 2 intended for the replenishment of fluids and electrolytes, including 3 sodium, chloride and potassium, or calories, including dextrose and amino 4 acids;

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

7 (16) the distribution of a drug that is intended for irrigation, or sterile 8 water, whether intended for such purposes or for injection;

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(17) the distribution of medical gas;

10 (18) facilitating the distribution of a product by providing solely 11 administrative services, including processing of orders and payments;

(19) the transfer of a product by a hospital or other health care entity, 12 or by a wholesale distributor or manufacturer operating under the direction 13 of a hospital or other health care entity, to a repackager described in 14 section 581(16)(B) and registered under section 510 of the food, drug and 15 16 cosmetic act for the purpose of repackaging the drug for use by that 17 hospital or other health care entity, or other health care entities under common control, if ownership of the drug remains with the hospital or 18 19 other health care entity at all times; or

(20) the sale or transfer from a retail pharmacy of expired, damaged,
returned or recalled prescription drugs to the original manufacturer,
originating wholesale distributor or to a third-party returns processor in
accordance with the board's rules and regulations.

Sec. 3. K.S.A. 65-1626a is hereby amended to read as follows: 65-1626a. (a) For the purpose of the pharmacy act of the state of Kansas, the following persons shall be deemed to be engaged in the practice of pharmacy:

(1) Persons who publicly profess to be a pharmacist, or publicly
 profess to assume the duties incident to being a pharmacist and their
 knowledge of drugs or drug actions, or both; and

(2) persons who attach to their name any words or abbreviation
 indicating that they are a pharmacist licensed to practice pharmacy in
 Kansas.

34 (b) (1) "Practice of pharmacy" means the interpretation and evaluation of prescription orders; the compounding, dispensing and 35 labeling of drugs and devices pursuant to prescription orders; the 36 37 administering of vaccine pursuant to a vaccination protocol; the 38 participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of prescription drugs 39 and prescription devices and the maintenance of proper records thereof in 40 41 accordance with law; consultation with patients and other health care 42 practitioners about the safe and effective use of prescription drugs and 43 prescription devices; performance of collaborative drug therapy

1 management pursuant to a written collaborative practice agreement with 2 one or more physicians who have an established physician-patient relationship; the prescribing and dispensing of self-administered oral 3 hormonal contraceptives pursuant to section 1, and amendments thereto, 4 5 and participation in the offering or performing of those acts, services, 6 operations or transactions necessary in the conduct, operation, 7 management and control of a pharmacy. Nothing in this section shall be 8 construed to add any additional requirements for registration or for a permit under the pharmacy act of the state of Kansas or for approval under 9 subsection (g) of K.S.A. 65-1643, and amendments thereto, or to prevent 10 persons other than pharmacists from engaging in drug utilization review, 11 12 or to require persons lawfully in possession of prescription drugs or prescription devices to meet any storage or record keeping requirements 13 14 except such storage and record keeping requirements as may be otherwise 15 provided by law or to affect any person consulting with a health care 16 practitioner about the safe and effective use of prescription drugs or 17 prescription devices.

18 (2) "Collaborative drug therapy management" means a practice of 19 pharmacy where a pharmacist performs certain pharmaceutical-related 20 patient care functions for a specific patient which have been delegated to 21 the pharmacist by a physician through a collaborative practice agreement. 22 A physician who enters into a collaborative practice agreement is 23 responsible for the care of the patient following initial diagnosis and 24 assessment and for the direction and supervision of the pharmacist 25 throughout the collaborative drug therapy management process. Nothing in this subsection shall be construed to permit a pharmacist to alter a 26 27 physician's orders or directions, diagnose or treat any disease, 28 independently prescribe drugs or independently practice medicine and 29 surgery.

30 (3) "Collaborative practice agreement" means a written agreement or 31 protocol between one or more pharmacists and one or more physicians that 32 provides for collaborative drug therapy management. Such collaborative 33 practice agreement shall contain certain specified conditions or limitations 34 pursuant to the collaborating physician's order, standing order, delegation 35 or protocol. A collaborative practice agreement shall be: (A) Consistent 36 with the normal and customary specialty, competence and lawful practice 37 of the physician; and (B) appropriate to the pharmacist's training and 38 experience.

39 (4) "Physician" means a person licensed to practice medicine and40 surgery in this state.

41 Sec. 4. K.S.A. 65-1626a and K.S.A. 2020 Supp. 65-1626 are hereby 42 repealed.

43 Sec. 5. This act shall take effect and be in force from and after its

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1 publication in the statute book.