

HOUSE BILL No. 2107

By Committee on Health and Human Services

1-19

1 AN ACT concerning public health; relating to the pharmacy act of the state
2 of Kansas; pertaining to biological products; amending K.S.A. 65-669,
3 65-1660 and 65-7007 and K.S.A. 2016 Supp. 65-1626, 65-1637, 65-
4 1637b, 65-1643, 65-2837a and 65-4202 and repealing the existing
5 sections.

6
7 *Be it enacted by the Legislature of the State of Kansas:*

8 Sec. 1. K.S.A. 65-669 is hereby amended to read as follows: 65-669.
9 A drug or device shall be deemed to be misbranded:

10 (a) If its labeling is false or misleading in any particular:

11 (b) If in package form unless it bears a label containing:

12 (1) The name and place of business of the manufacturer, the packer or
13 the distributor, except that in the case of a prescription drug it shall bear
14 the name and place of business of the person responsible for the
15 production of the finished dosage form of the drug, the packer and the
16 distributor; except that nothing in ~~either (1) or (2)~~ of this paragraph shall be
17 construed to apply to wholesalers and the requirement of ~~either (1) or (2)~~ *this*
18 *paragraph* shall be satisfied by stating such information on the label of the
19 drug and filing a statement with such information with the secretary which
20 shall be made available by the secretary on request to local, public and
21 private health agencies, poison control centers, licentiates of the healing
22 arts, the state board of pharmacy, consumers and others to promote the
23 purposes of this act; in no event, however, shall the label contain less
24 information than required under federal law; and

25 (2) an accurate statement of the quantity of the contents in terms of
26 weight, measure, or numerical count, except that under ~~either (2) or (3)~~ of this
27 paragraph reasonable variations shall be permitted and exemptions as to
28 small packages shall be allowed, in accordance with regulations prescribed
29 by the secretary, or issued under the federal act.

30 (c) If any word, statement, or other information required by or under
31 authority of this act to appear on the label or labeling is not prominently
32 placed thereon with such conspicuousness ~~as~~ as compared with other
33 words, statements, designs or devices, in the labeling, and in such terms
34 as to render it likely to be read and understood by the ordinary individual
35 under customary conditions of purchase and use.

36 (d) If it is for use by man and contains any quantity of narcotic or

Proposed Amendments for HB 2107
House Committee on Health and Human Services
January 30, 2017
Prepared by Eileen Ma
Office of Revisor of Statutes

1 hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal,
2 cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana,
3 morphine, opium, paraldehyde, peyote, or sulphomethane, or any
4 chemical derivative of such substance, which derivative has been by the
5 secretary after investigation, found to be, and by regulations under this act,
6 or by regulations issued pursuant to 21 U.S.C. § 352(d), designated as,
7 habit forming, unless its label bears the name and quantity or proportion of
8 such substance or derivative and in juxtaposition therewith the statement
9 "warning-may be habit forming."

10 (e) (1) If it is a drug, unless its label bears, to the exclusion of any
11 other nonproprietary name—~~except the applicable systematic chemical~~
12 ~~name or the chemical formula;~~ ~~(i);~~ (A) The established name—~~as defined~~
13 ~~in-subparagraph paragraph (2)) of this subsection of the drug, if such there~~
14 ~~be; and (ii) (B) in case it is fabricated from two or more ingredients, the~~
15 ~~established name of each active ingredient, including the kind and quantity~~
16 ~~of proportion of any alcohol, and also including, whether active or not, the~~
17 ~~established name and quantity or proportion of any bromides, ether,~~
18 ~~chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine,~~
19 ~~hyosine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury,~~
20 ~~ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation~~
21 ~~of any such substances, contained therein. The requirements for stating the~~
22 ~~quantity of the active ingredients, other than the quantity of those~~
23 ~~specifically named in this paragraph, shall apply only to prescription~~
24 ~~drugs. To the extent that compliance with the requirements of-~~elase-~~(ii) of~~
25 ~~this-subparagraph paragraph is impracticable, exemptions shall be allowed~~
26 ~~under regulations promulgated by the secretary, or under the federal act.~~

27 (2) As used in this-~~paragraph subsection (e)~~, the term "established
28 name," with respect to a drug or ingredient thereof, means:

29 (A) The applicable official name designated pursuant to 21 U.S.C. §
30 358-~~or~~;

31 (B) if there is no such name and such drug, or such ingredient, is an
32 article recognized in an official compendium, then the official title thereof
33 in such compendium; or

34 (C) if neither-~~elase subparagraph (A) nor-~~elase subparagraph (B)~~~~
35 ~~of this-subparagraph paragraph applies, then the common or usual name,~~
36 ~~if any, of such drug or of such ingredient. Where-~~elase subparagraph (B)~~~~
37 ~~of this-subparagraph paragraph applies to an article recognized in the~~
38 ~~United States-pharmacoepoeia pharmacopeia and in the homeopathic~~
39 ~~pharmacopoeia under different official titles, the official title used in the~~
40 ~~United States pharmacoepoeia pharmacopeia shall apply unless it is labeled~~
41 ~~and offered for sale as a homeopathic drug, in which case the official title~~
42 ~~used in the homeopathic pharmacopoeia shall apply.~~
43 (f) Unless its labeling bears:

1 (1) Adequate directions for use; and

2 (2) such adequate warning against use in those pathological
3 conditions or by children where its use may be dangerous to health, or
4 against unsafe dosage or methods or duration of administration or
5 application, in such manner and form, as are necessary for the protection
6 of users.

7 (3) ~~Where any requirement of *clause paragraph (1) or (2)* of this~~
8 ~~paragraph subsection~~, as applied to any drug or device, is not necessary for
9 the protection of the public health, the secretary shall promulgate
10 regulations exempting such drug or device from such requirements.
11 Articles exempted under regulations issued under 21 U.S.C. § 352(f) may
12 also be exempt.

13 (g) If it purports to be a drug the name of which is recognized in an
14 official compendium, unless it is packaged and labeled as prescribed
15 therein. The method of packing may be modified with the consent of the
16 secretary, or if consent is obtained under the federal act. Whenever a drug
17 is recognized in both the United States ~~pharmacopoeia~~ *pharmacopoeia* and
18 the homeopathic pharmacopoeia of the United States, it shall be subject to
19 the requirements of the United States ~~pharmacopoeia~~ *pharmacopoeia* with
20 respect to the packaging and labeling unless it is labeled and offered for
21 sale as a homeopathic drug, in which case it shall be subject to the
22 provisions of the homeopathic pharmacopoeia of the United States, and
23 not to those of the United States ~~pharmacopoeia~~ *pharmacopoeia*. In the
24 event of inconsistency between the requirements of this ~~paragraph~~
25 ~~subsection~~ and those of ~~paragraph subsection (e)~~ as to the name by which
26 the drug or its ingredients shall be designated, the requirements of
27 ~~paragraph subsection (e)~~ shall prevail.

28 (h) If it has been found by the secretary or under the federal act to be
29 a drug liable to deterioration, unless it is packed in such form and manner,
30 and its label bears a statement of such precautions, as the regulations
31 adopted by the secretary require as necessary for the protection of public
32 health. No such regulations shall be established for any drug recognized in
33 an official compendium until the secretary shall have informed the
34 appropriate body charged with the revision of such compendium of the
35 need for such packaging or labeling requirements and such body shall have
36 failed within a reasonable time to prescribe such requirements.

37 (i) (1) If it is a drug and its container is so made, formed, or filled as
38 to be misleading; ~~or~~ (2) if it is an imitation of another drug; or (3) if it is
39 offered for sale under the name of another drug.

40 (j) If it is dangerous to health when used in the dosage, or with the
41 frequency of duration prescribed, recommended, or suggested in the
42 labeling thereof.

43 (k) If it is, or purports to be, or is represented as a drug composed

1 wholly or partly of insulin, unless: (1) It is from a batch with respect to
2 which a certificate or release has been issued pursuant to 21 U.S.C. § 356;
3 and (2) such certificate or release is in effect with respect to such drug.

4 (l) If it is, or purports to be, or is represented as a drug composed
5 wholly or partly of any kind of penicillin, streptomycin, chlortetracycline,
6 chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative
7 thereof, unless: (1) It is from a batch with respect to which a certificate or
8 release has been issued pursuant to 21 U.S.C. § 357; and (2) such
9 certificate or release is in effect with respect to such drug. This paragraph
10 *subsection* shall not apply to any drug or class of drugs exempted by
11 regulations promulgated under 21 U.S.C. § 357(c) or (d). For the purpose
12 of this subsection the term "antibiotic drug" means any drug intended for
13 use by man containing any quantity of any chemical substance which is
14 produced by a microorganism and which has the capacity to inhibit or
15 destroy microorganisms in dilute solution—(including the chemically
16 synthesized equivalent of any such substance).

17 (m) If it is a color additive, the intended use of which in or on drugs
18 is for the purpose of coloring only, unless its packaging and labeling are in
19 conformity with such packaging and labeling requirements applicable to
20 such color additive, prescribed under the provisions of K.S.A. 65-667, and
21 *amendments thereto*, or of the federal act.

22 (n) In the case of any prescription drug distributed or offered for sale
23 in this state, unless the manufacturer, packer, or distributor thereof
24 includes in all advertisements and other descriptive printed matter issued
25 or caused to be issued by the manufacturer, packer, or distributor with
26 respect to that drug a true statement of: (1) The established name, as
27 defined in subsection (e) (2) of this section; (2) the formula showing
28 quantitatively each ingredient of such drug to the extent required for labels
29 under 21 U.S.C. § 352(e); and (3) such other information in brief
30 summary relating to side effects, contraindications, and effectiveness as
31 shall be required in regulations issued under the federal act.

32 (o) If a trademark, trade name or other identifying mark, imprint or
33 device of another or any likeness of the foregoing has been placed thereon
34 or upon its container with intent to defraud.

35 (p) Drugs and devices which are, in accordance with the practice of
36 the trade, to be processed, labeled or repacked in substantial quantities at
37 establishments other than those where originally processed or packed shall
38 be exempt from any labeling or packaging requirements of this act if such
39 drugs and devices are being delivered, manufactured, processed, labeled,
40 repacked or otherwise held in compliance with regulations issued by the
41 secretary or under the federal act.

42 (q) A drug intended for use by ~~man~~ *humans* that:

43 ~~(A)~~ (1) Is a habit-forming drug to which K.S.A. 65-668, and

1 *amendments thereto, applies; or*
2 ~~(B)~~ (2) because of its toxicity or other potentiality for harmful effect,
3 or the method of its use, or the collateral measures necessary to its use, is
4 not safe for use except under the supervision of a practitioner licensed by
5 law to administer such drug; or

6 ~~(C)~~ (3) is limited by an approved application under 21 U.S.C. § 355
7 or K.S.A. 65-669a, and *amendments thereto*, to use under the professional
8 supervision of a practitioner licensed by law to administer such drug, shall
9 be dispensed only:

10 ~~(A)~~ (A) Upon a written prescription of a practitioner licensed by law to
11 administer such drug or upon the written prescription of a mid-level
12 practitioner as defined in ~~subsection (f)~~ of K.S.A. 65-1626, and
13 amendments thereto; or

14 ~~(B)~~ (B) upon an oral prescription of such practitioner or mid-level
15 practitioner which is reduced promptly to writing and filed by the
16 pharmacist; or

17 ~~(C)~~ (C) by refilling, any such written or oral prescription if such
18 refilling is authorized by the prescriber either in the original prescription or
19 by oral order which is reduced promptly to writing and filed by the
20 ~~pharmacist~~ pharmacist.

21 The act of dispensing a drug contrary to the provisions of this
22 ~~paragraph~~ *subsection* shall be deemed to be an act which results in a drug
23 being misbranded while held for sale.

24 (r) Any drug dispensed by filling or refilling a written or oral
25 prescription of a practitioner licensed by law to administer such drug or by
26 filling or refilling a written or oral prescription of a mid-level practitioner
27 as defined in ~~subsection (f)~~ of K.S.A. 65-1626, and amendments thereto,
28 shall be exempt from the requirements of this section, except subsections
29 (a), (i) (2) and (3), (k), and (l), and the packaging requirements of
30 subsections (g) and (h), if the drug bears a label containing the name and
31 address of the dispenser, the serial number and date of the prescription or
32 of its filling, the name of the prescriber and, if stated in the prescription,
33 the name of the patient, and the directions for use and cautionary
34 statements, if any, contained in such prescription. This exemption shall not
35 apply to any drug dispensed in the course of the conduct of a business of
36 dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in
37 violation of ~~paragraph~~ *subsection* (q) of this section.

38 (s) The secretary may, by regulation, remove drugs subject to
39 subsection (d) of this section and K.S.A. 65-669a, and *amendments*
40 *thereto*, from the requirements of ~~paragraph~~ *subsection* (g) of this section
41 when such requirements are not necessary for the protection of the public
42 health. Drugs removed from the prescription requirements of the federal
43 act by regulations issued thereunder may also, by *rules and regulations*

1 issued by the secretary, be removed from the requirements of ~~paragraph~~
2 ~~subsection (q)~~ of this section.

3 (t) A drug which is subject to ~~paragraph subsection (g)~~ of this section
4 shall be deemed to be misbranded if at any time prior to dispensing its
5 label fails to bear the statement "caution: federal law prohibits dispensing
6 without prescription," or "caution: state law prohibits dispensing without
7 prescription." A drug to which ~~paragraph subsection (q)~~ of this section
8 does not apply shall be deemed to be misbranded if at any time prior to
9 dispensing its label bears the caution statement quoted in the preceding
10 sentence.

11 (u) Nothing in this section shall be construed to relieve any person
12 from any requirement prescribed by or under authority of law with respect
13 to drugs now included or which may hereafter be included within the
14 classifications of narcotic drugs or marijuana as defined in the applicable
15 federal and state laws relating to narcotic drugs and marijuana.

16 Sec. 2. K.S.A. 2016 Supp. 65-1626 is hereby amended to read as
17 follows: 65-1626. For the purposes of this act:

18 (a) "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.

26 (b) "Agent" means an authorized person who acts on behalf of or at
27 the direction of a manufacturer, distributor or dispenser but shall not
28 include a common carrier, public warehouseman or employee of the carrier
29 or warehouseman when acting in the usual and lawful course of the
30 carrier's or warehouseman's business.

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

35 (d) "Authorized distributor of record" means a wholesale distributor
36 with whom a manufacturer has established an ongoing relationship to
37 distribute the manufacturer's prescription drug. An ongoing relationship is
38 deemed to exist between such wholesale distributor and a manufacturer
39 when the wholesale distributor, including any affiliated group of the
40 wholesale distributor, as defined in section 1504 of the internal revenue
41 code, complies with any one of the following: (1) The wholesale
42 distributor has a written agreement currently in effect with the
43 manufacturer evidencing such ongoing relationship; and (2) the wholesale

1 distributor is listed on the manufacturer's current list of authorized
2 distributors of record, which is updated by the manufacturer on no less
3 than a monthly basis.

4 (e) "Biological product" means the same as that term is defined in 42
5 U.S.C. § 262(i), as in effect on July 1, 2017.

6 (f) "Board" means the state board of pharmacy created by K.S.A. 74-
7 1603, and amendments thereto.

8 (g) "Brand exchange," in the case of a drug product prescribed,
9 means the dispensing of a different drug product of the same dosage form
10 and strength and of the same generic name as the brand name drug product
11 prescribed, and in the case of a biological product prescribed, means the
12 dispensing of a biological product determined by the federal food and
13 drug administration to be interchangeable with the biological product
14 prescribed.

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

17 (i) "Chain pharmacy warehouse" means a permanent physical
18 location for drugs or devices, or both, that acts as a central warehouse and
19 performs intracompany sales or transfers of prescription drugs or devices
20 to chain pharmacies that have the same ownership or control. Chain
21 pharmacy warehouses must be registered as wholesale distributors.

22 (j) "Co-licensee" means a pharmaceutical manufacturer that has
23 entered into an agreement with another pharmaceutical manufacturer to
24 engage in a business activity or occupation related to the manufacture or
25 distribution of a prescription drug and the national drug code on the drug
26 product label shall be used to determine the identity of the drug
27 manufacturer.

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

30 (l) "Deliver" or "delivery" means the actual, constructive or
31 attempted transfer from one person to another of any drug whether or not
32 an agency relationship exists.

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

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

41 (o) "Dispenser" means a practitioner or pharmacist who dispenses
42 prescription medication, or a physician assistant who has authority to
43 dispense prescription-only drugs in accordance with K.S.A. 65-28a08(b),

an interchangeable biological product

1 and amendments thereto.

2 (e) (p) "Distribute" means to deliver, other than by administering or
3 dispensing, any drug.

4 (f) (q) "Distributor" means a person who distributes a drug.

5 (f) (r) "Drop shipment" means the sale, by a manufacturer, that
6 manufacturer's co-licensee, that manufacturer's third party logistics
7 provider, or that manufacturer's exclusive distributor, of the manufacturer's
8 prescription drug, to a wholesale distributor whereby the wholesale
9 distributor takes title but not possession of such prescription drug and the
10 wholesale distributor invoices the pharmacy, the chain pharmacy
11 warehouse, or other designated person authorized by law to dispense or
12 administer such prescription drug, and the pharmacy, the chain pharmacy
13 warehouse, or other designated person authorized by law to dispense or
14 administer such prescription drug receives delivery of the prescription
15 drug directly from the manufacturer, that manufacturer's co-licensee, that
16 manufacturer's third party logistics provider, or that manufacturer's
17 exclusive distributor, of such prescription drug. Drop shipment shall be
18 part of the "normal distribution channel."

19 (f) (s) "Drug" means: (1) Articles recognized in the official United
20 States pharmacopeia *pharmacopeia*, or other such official compendiums
21 of the United States, or official national formulary, or any supplement of
22 any of them; (2) articles intended for use in the diagnosis, cure, mitigation,
23 treatment or prevention of disease in human or other animals; (3) articles,
24 other than food, intended to affect the structure or any function of the body
25 of human or other animals; and (4) articles intended for use as a
26 component of any articles specified in paragraph (1), (2) or (3); but does
27 not include devices or their components, parts or accessories, except that
28 the term "drug" shall not include amygdalin (laetrile) or any livestock
29 remedy, if such livestock remedy had been registered in accordance with
30 the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated,
31 prior to its repeal.

32 (f) (t) "Durable medical equipment" means technologically
33 sophisticated medical devices that may be used in a residence, including
34 the following: (1) Oxygen and oxygen delivery system; (2) ventilators; (3)
35 respiratory disease management devices; (4) continuous positive airway
36 pressure (CPAP) devices; (5) electronic and computerized wheelchairs and
37 seating systems; (6) apnea monitors; (7) transcutaneous electrical nerve
38 stimulator (TENS) units; (8) low air loss cutaneous pressure management
39 devices; (9) sequential compression devices; (10) feeding pumps; (11)
40 home phototherapy devices; (12) infusion delivery devices; (13)
41 distribution of medical gases to end users for human consumption; (14)
42 hospital beds; (15) nebulizers; or (16) other similar equipment determined
43 by the board in rules and regulations adopted by the board.

1 ~~(h)~~ *(u)* "Electronic prescription" means an electronically prepared
2 prescription that is authorized and transmitted from the prescriber to the
3 pharmacy by means of electronic transmission.

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

8 ~~(w)~~ *(w)* "Electronic signature" means a confidential personalized
9 digital key, code, number or other method for secure electronic data
10 transmissions which identifies a particular person as the source of the
11 message, authenticates the signatory of the message and indicates the
12 person's approval of the information contained in the transmission.

13 ~~(x)~~ *(x)* "Electronic transmission" means the transmission of an
14 electronic prescription, formatted as an electronic data file, from a
15 prescriber's electronic prescription application to a pharmacy's computer,
16 where the data file is imported into the pharmacy prescription application.

17 ~~(y)~~ *(y)* "Electronically prepared prescription" means a prescription
18 that is generated using an electronic prescription application.

19 ~~(z)~~ *(z)* "Exclusive distributor" means any entity that: (1) Contracts
20 with a manufacturer to provide or coordinate warehousing, wholesale
21 distribution or other services on behalf of a manufacturer and who takes
22 title to that manufacturer's prescription drug, but who does not have
23 general responsibility to direct the sale or disposition of the manufacturer's
24 prescription drug; (2) is registered as a wholesale distributor under the
25 pharmacy act of the state of Kansas; and (3) to be considered part of the
26 normal distribution channel, must be an authorized distributor of record.

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

37 ~~(bb)~~ *(bb)* "Generic name" means the established chemical name or
38 official name of a drug or drug product.

39 ~~(cc)~~ *(1)* "Institutional drug room" means any location where
40 prescription-only drugs are stored and from which prescription-only drugs
41 are administered or dispensed and which is maintained or operated for the
42 purpose of providing the drug needs of:

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

1 (B) residents of a juvenile detention facility, as defined by the revised
 2 Kansas code for care of children and the revised Kansas juvenile justice
 3 code;

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

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

8 (E) persons receiving inpatient hospice services.

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

10 (A) Any registered pharmacy;

11 (B) any office of a practitioner; or

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

15 ~~(ee)~~ *(dd)* "Interchangeable biological product" means a biological
 16 product that the federal food and drug administration has:

17 (1) Licensed and determined meets the standards for
 18 "interchangeability" as that term is defined in 42 U.S.C. § 262(k), as of
 19 July 1, 2017; or

20 (2) has determined to be therapeutically equivalent as set forth in the
 21 latest edition or supplement of the food and drug ~~administration~~ approved
 22 drug products with therapeutic equivalence evaluations.

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

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

30 ~~(ee)~~ *(gg)* "Medical care facility" shall have the meaning provided in
 31 K.S.A. 65-425, and amendments thereto, except that the term shall also
 32 include facilities licensed under the provisions of K.S.A. 75-3307b, and
 33 amendments thereto, except community mental health centers and
 34 facilities for people with intellectual disability.

35 ~~(ff)~~ *(hh)* "Manufacture" means the production, preparation,
 36 propagation, compounding, conversion or processing of a drug either
 37 directly or indirectly by extraction from substances of natural origin,
 38 independently by means of chemical synthesis or by a combination of
 39 extraction and chemical synthesis and includes any packaging or
 40 repackaging of the drug or labeling or relabeling of its container, except
 41 that this term shall not include the preparation or compounding of a drug
 42 by an individual for the individual's own use or the preparation,
 43 compounding, packaging or labeling of a drug by:

federal

administration's

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

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

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

10 ~~(g)~~ (i) "Manufacturer" means a person licensed or approved by the
11 FDA to engage in the manufacture of drugs and devices.

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

22 ~~(i)~~ (k) "Normal distribution channel" means a chain of custody for a
23 prescription-only drug that goes from a manufacturer of the prescription-
24 only drug, from that manufacturer to that manufacturer's co-licensed
25 partner, from that manufacturer to that manufacturer's third-party logistics
26 provider or from that manufacturer to that manufacturer's exclusive
27 distributor, directly or by drop shipment, to:

28 (1) A pharmacy to a patient or to other designated persons authorized
29 by law to dispense or administer such drug to a patient;

30 (2) a wholesale distributor to a pharmacy to a patient or other
31 designated persons authorized by law to dispense or administer such drug
32 to a patient;

33 (3) a wholesale distributor to a chain pharmacy warehouse to that
34 chain pharmacy warehouse's intracompany pharmacy to a patient or other
35 designated persons authorized by law to dispense or administer such drug
36 to a patient; or

37 (4) a chain pharmacy warehouse to the chain pharmacy warehouse's
38 intracompany pharmacy to a patient or other designated persons authorized
39 by law to dispense or administer such drug to a patient.

40 ~~(j)~~ (l) "Person" means individual, corporation, government, government,
41 governmental subdivision or agency, partnership, association or any other
42 legal entity.

43 ~~(k)~~ (m) "Pharmacist" means any natural person licensed under this

1 act to practice pharmacy.

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

12 ~~(mm)~~ (oo) "Pharmacist intern" means: (1) A student currently
13 enrolled in an accredited pharmacy program; (2) a graduate of an
14 accredited pharmacy program serving an internship; or (3) a graduate of a
15 pharmacy program located outside of the United States which is not
16 accredited and who has successfully passed equivalency examinations
17 approved by the board.

18 ~~(nn)~~ (pp) "Pharmacy," "drugstore" or "apothecary" means premises,
19 laboratory, area or other place: (1) Where drugs are offered for sale where
20 the profession of pharmacy is practiced and where prescriptions are
21 compounded and dispensed; or (2) which has displayed upon it or within it
22 the words "pharmacist," "pharmaceutical chemist," "pharmacy,"
23 "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of
24 these words or combinations of these words or words of similar import
25 either in English or any sign containing any of these words; or (3) where
26 the characteristic symbols of pharmacy or the characteristic prescription
27 sign "Rx" may be exhibited. As used in this subsection, premises refers
28 only to the portion of any building or structure leased, used or controlled
29 by the licensee in the conduct of the business registered by the board at the
30 address for which the registration was issued.

31 ~~(qq)~~ (qq) "Pharmacy prescription application" means software that is
32 used to process prescription information, is installed on a pharmacy's
33 computers or servers, and is controlled by the pharmacy.

34 ~~(rr)~~ (rr) "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 ~~(ss)~~ (ss) "Practitioner" means a person licensed to practice medicine
41 and 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 ~~(ff)~~ *(ff)* "Preceptor" means a licensed pharmacist who possesses at
3 least two years' experience as a pharmacist and who supervises students
4 obtaining the pharmaceutical experience required by law as a condition to
5 taking the examination for licensure as a pharmacist.

6 ~~(gg)~~ *(gg)* "Prescriber" means a practitioner or a mid-level practitioner.

7 ~~(hh)~~ *(hh)* "Prescription" or "prescription order" means: (1) An order to
8 be filled by a pharmacist for prescription medication issued and signed by
9 a prescriber in the authorized course of such prescriber's professional
10 practice; or (2) an order transmitted to a pharmacist through word of
11 mouth, note, telephone or other means of communication directed by such
12 prescriber, regardless of whether the communication is oral, electronic,
13 facsimile or in printed form.

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

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

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

29 ~~(mmm)~~ *(zz)* "Professional Incompetency" means:

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

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

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

38 ~~(nnn)~~ *(aaa)* "Readily retrievable" means that records kept by automatic
39 data processing applications or other electronic or mechanized record-
40 keeping systems can be separated out from all other records within a
41 reasonable time not to exceed 48 hours of a request from the board or
42 other authorized agent or that hard-copy records are kept on which certain
43 items are asterisked, redlined or in some other manner visually identifiable

1 apart from other items appearing on the records.

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

9 ~~(aaa)~~ *(ccc)* "Secretary" means the executive secretary of the board.

10 ~~(bbb)~~ *(ddd)* "Third party logistics provider" means an entity that: (1)
11 Provides or coordinates warehousing, distribution or other services on
12 behalf of a manufacturer, but does not take title to the prescription drug or
13 have general responsibility to direct the prescription drug's sale or
14 disposition; (2) is registered as a wholesale distributor under the pharmacy
15 act of the state of Kansas; and (3) to be considered part of the normal
16 distribution channel, must also be an authorized distributor of record.

17 ~~(eee)~~ *(eee)* "Unprofessional conduct" means:

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

19 (2) intentional adulteration or mislabeling of any drug, medicine,
20 chemical or poison;

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

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

24 (5) unlawful possession of drugs and unlawful diversion of drugs to
25 others;

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

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

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

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

33 (10) performing unnecessary tests, examinations or services which
34 have no legitimate pharmaceutical purpose.

35 ~~(ddd)~~ *(fff)* "Vaccination protocol" means a written protocol, agreed to
36 by a pharmacist and a person licensed to practice medicine and surgery by
37 the state board of healing arts, which establishes procedures and
38 recordkeeping and reporting requirements for administering a vaccine by
39 the pharmacist for a period of time specified therein, not to exceed two
40 years.

41 ~~(eee)~~ *(ggg)* "Valid prescription order" means a prescription that is
42 issued for a legitimate medical purpose by an individual prescriber
43 licensed by law to administer and prescribe drugs and acting in the usual

1 course of such prescriber's professional practice. A prescription issued
2 solely on the basis of an internet-based questionnaire or consultation
3 without an appropriate prescriber-patient relationship is not a valid
4 prescription order.

5 ~~(fff)~~ *(hhh)* "Veterinary medical teaching hospital pharmacy" means
6 any location where prescription-only drugs are stored as part of an
7 accredited college of veterinary medicine and from which prescription-
8 only drugs are distributed for use in treatment of or administration to a
9 nonhuman.

10 ~~(ggg)~~ *(iii)* "Wholesale distributor" means any person engaged in
11 wholesale distribution of prescription drugs or devices in or into the state,
12 including, but not limited to, manufacturers, repackagers, own-label
13 distributors, private-label distributors, jobbers, brokers, warehouses,
14 including manufacturers' and distributors' warehouses, co-licensees,
15 exclusive distributors, third party logistics providers, chain pharmacy
16 warehouses that conduct wholesale distributions, and wholesale drug
17 warehouses, independent wholesale drug traders and retail pharmacies that
18 conduct wholesale distributions. Wholesale distributor shall not include
19 persons engaged in the sale of durable medical equipment to consumers or
20 patients.

21 ~~(hhh)~~ *(iii)* "Wholesale distribution" means the distribution of
22 prescription drugs or devices by wholesale distributors to persons other
23 than consumers or patients, and includes the transfer of prescription drugs
24 by a pharmacy to another pharmacy if the total number of units of
25 transferred drugs during a twelve-month period does not exceed 5% of the
26 total number of all units dispensed by the pharmacy during the
27 immediately preceding twelve-month period. Wholesale distribution does
28 not include:

29 (1) The sale, purchase or trade of a prescription drug or device, an
30 offer to sell, purchase or trade a prescription drug or device or the
31 dispensing of a prescription drug or device pursuant to a prescription;

32 (2) the sale, purchase or trade of a prescription drug or device or an
33 offer to sell, purchase or trade a prescription drug or device for emergency
34 medical reasons;

35 (3) intracompany transactions, as defined in this section, unless in
36 violation of own use provisions;

37 (4) the sale, purchase or trade of a prescription drug or device or an
38 offer to sell, purchase or trade a prescription drug or device among
39 hospitals, chain pharmacy warehouses, pharmacies or other health care
40 entities that are under common control;

41 (5) the sale, purchase or trade of a prescription drug or device or the
42 offer to sell, purchase or trade a prescription drug or device by a charitable
43 organization described in 503(c)(3) of the internal revenue code of 1954 to

1 a nonprofit affiliate of the organization to the extent otherwise permitted
2 by law;

3 (6) the purchase or other acquisition by a hospital or other similar
4 health care entity that is a member of a group purchasing organization of a
5 prescription drug or device for its own use from the group purchasing
6 organization or from other hospitals or similar health care entities that are
7 members of these organizations;

8 (7) the transfer of prescription drugs or devices between pharmacies
9 pursuant to a centralized prescription processing agreement;

10 (8) the sale, purchase or trade of blood and blood components
11 intended for transfusion;

12 (9) the return of recalled, expired, damaged or otherwise non-salable
13 prescription drugs, when conducted by a hospital, health care entity,
14 pharmacy, chain pharmacy warehouse or charitable institution in
15 accordance with the board's rules and regulations;

16 (10) the sale, transfer, merger or consolidation of all or part of the
17 business of a retail pharmacy or pharmacies from or with another retail
18 pharmacy or pharmacies, whether accomplished as a purchase and sale of
19 stock or business assets, in accordance with the board's rules and
20 regulations;

21 (11) the distribution of drug samples by manufacturers' and
22 authorized distributors' representatives;

23 (12) the sale of minimal quantities of drugs by retail pharmacies to
24 licensed practitioners for office use; or

25 (13) the sale or transfer from a retail pharmacy or chain pharmacy
26 warehouse of expired, damaged, returned or recalled prescription drugs to
27 the original manufacturer, originating wholesale distributor or to a third
28 party returns processor in accordance with the board's rules and
29 regulations.

30 Sec. 3. K.S.A. 2016 Supp. 65-1637 is hereby amended to read as
31 follows: 65-1637. In every store, shop or other place defined in this act as
32 a "pharmacy" there shall be a pharmacist in charge and, except as
33 otherwise provided by law, the compounding and dispensing of
34 prescriptions shall be limited to pharmacists only. Except as otherwise
35 provided by the pharmacy act of this state, when a pharmacist is not in
36 attendance at a pharmacy, the premises shall be enclosed and secured.
37 Prescription orders may be written, oral, telephonic or by electronic
38 transmission unless prohibited by law. Blank forms for written prescription
39 orders may have two signature lines. If there are two lines, one signature
40 line shall state: "dispense as written" and the other signature line shall
41 state: "brand exchange permissible." Prescriptions shall only be filled or
42 refilled in accordance with the following requirements:

43 (a) All prescriptions shall be filled in strict conformity with any

1 directions of the prescriber, except that:

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

7 (2) ~~that~~ a pharmacist who receives a prescription order for a brand
8 name drug product may exercise brand exchange with a view toward
9 achieving a lesser cost to the purchaser unless:

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

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

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

19 (D) the federal food and drug administration has determined that a
20 drug product of the same generic name is not bioequivalent to the
21 prescribed brand name prescription medication; and

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

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

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

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

34 (D) ~~the federal food and drug administration has not determined the~~
35 ~~biological product to be interchangeable with the prescribed biological~~
36 ~~product.~~

37 (b) A pharmacist who selects an interchangeable biological product
38 shall ~~prior to dispensing an interchangeable biological product~~ inform
39 the patient or the patient's representative that an interchangeable
40 biological product will ~~be~~ substituted for the biological product
41 prescribed.

42 (c) Prescription orders shall be recorded in writing by the pharmacist
43 and the record so made by the pharmacist shall constitute the original

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1 prescription to be dispensed by the pharmacist. This record, if telephoned
2 by other than the physician shall bear the name of the person so
3 telephoning. Nothing in this paragraph shall be construed as altering or
4 affecting in any way laws of this state or any federal act requiring a written
5 prescription order.

6 ~~(e)~~ (d) (1) Except as provided in paragraph (2), no prescription shall
7 be refilled unless authorized by the prescriber either in the original
8 prescription or by oral order which is reduced promptly to writing and
9 filled by the pharmacist.

10 (2) A pharmacist may refill a prescription order issued on or after the
11 effective date of this act for any prescription drug or *biological product*
12 except a drug listed on schedule II of the uniform controlled substances act
13 or a narcotic drug listed on any schedule of the uniform controlled
14 substances act without the prescriber's authorization when all reasonable
15 efforts to contact the prescriber have failed and when, in the pharmacist's
16 professional judgment, continuation of the medication is necessary for the
17 patient's health, safety and welfare. Such prescription refill shall only be in
18 an amount judged by the pharmacist to be sufficient to maintain the patient
19 until the prescriber can be contacted, but in no event shall a refill under
20 this paragraph be more than a seven day supply or one package of the
21 drug. However, if the prescriber states on a prescription that there shall be
22 no emergency refilling of that prescription, then the pharmacist shall not
23 dispense any emergency medication pursuant to that prescription. A
24 pharmacist who refills a prescription order under this ~~subsection (e)~~ (2)
25 *paragraph* shall contact the prescriber of the prescription order on the next
26 business day subsequent to the refill or as soon thereafter as possible. No
27 pharmacist shall be required to refill any prescription order under this
28 ~~subsection (e)~~ (2) *paragraph*. A prescriber shall not be subject to liability
29 for any damages resulting from the refilling of a prescription order by a
30 pharmacist under this ~~subsection (e)~~ (2) *paragraph* unless such damages
31 are occasioned by the gross negligence or willful or wanton acts or
32 omissions by the prescriber.

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

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

43 ~~(f)~~ (g) Any pharmacist who exercises brand exchange and dispenses a

1 less expensive drug or interchangeable biological product shall not charge
2 the purchaser more than the regular and customary retail price for the
3 dispensed drug or biological product.

4 Nothing contained in this section shall be construed as preventing a
5 pharmacist from refusing to fill or refill any prescription if in the
6 pharmacist's professional judgment and discretion such pharmacist is of
7 the opinion that it should not be filled or refilled.

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

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

15 (2) an electronic prescribing technology;

16 (3) a pharmacy benefits management system; or

17 (4) a pharmacy record.

18 (f) Entry into an electronic records system as described in subsection
19 (b) shall be presumed to provide notice to the prescriber. Otherwise, the
20 pharmacist shall communicate the biological product dispensed to the
21 prescriber using facsimile, telephone, electronic transmission or other
22 prevailing means, provided that communication shall not be required
23 where:

24 (1) There is no federal food and drug administration approved
25 interchangeable biological product for the product prescribed; or

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

28 (g) The pharmacist shall maintain a record of the biological product
29 dispensed for at least five years.

30 (h) The board shall maintain a link on its website to the current list of
31 all biological products that the federal food and drug administration has
32 determined to be interchangeable biological products.

33 Sec. 4. K.S.A. 2016 Supp. 65-1637b is hereby amended to read as
34 follows: 65-1637b. (a) The pharmacist shall exercise professional
35 judgment regarding the accuracy, validity and authenticity of any
36 prescription order consistent with federal and state laws and rules and
37 regulations. A pharmacist shall not dispense a prescription drug if the
38 pharmacist, in the exercise of professional judgment, determines that the
39 prescription is not a valid prescription order.

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

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

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

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

15 (4) In consultation with industry, the state board of pharmacy shall
16 conduct a study on the issues of electronic transmission of prior
17 authorizations and step therapy protocols. ~~The report on the results of such~~
18 ~~study shall be completed and submitted to the legislature no later than~~
19 ~~January 15, 2013.~~

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

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

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

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

36 (e) Regardless of the means of transmission to a pharmacy, only a
37 pharmacist or a pharmacist intern shall be authorized to receive a new
38 prescription order from a prescriber or transmitting agent. A pharmacist, a
39 pharmacist intern or a registered pharmacy technician may receive a refill
40 or renewal order from a prescriber or transmitting agent if such registered
41 pharmacy technician's supervising pharmacist has authorized that function.

42 (f) A refill is one or more dispensings of a prescription drug or device
43 that results in the patient's receipt of the quantity authorized by the

1 prescriber for a single fill as indicated on the prescription order. A
2 prescription for a schedule III, IV or V controlled substance may authorize
3 no more than five refills within six months following the date on which the
4 prescription is issued.

5 (g) Prescriptions shall only be filled or refilled in accordance with the
6 following requirements:

7 (1) All prescriptions shall be filled in strict conformity with any
8 directions of the prescriber, except that a pharmacist who receives a
9 prescription order for a brand name drug product may exercise brand
10 exchange with a view toward achieving a lesser cost to the purchaser
11 unless:

12 (A) The prescriber, in the case of a prescription electronically signed
13 by the prescriber, includes the statement "dispense as written" on the
14 prescription;

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

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

21 (D) the federal food and drug administration has determined that a
22 drug product of the same generic name is not bioequivalent to the
23 prescribed brand name prescription medication.

24 (2) All prescriptions shall be filled in strict conformity with any
25 directions of the prescriber, except that a pharmacist who receives a
26 prescription order for a biological product may exercise brand exchange
27 with a view toward achieving a lesser cost to the purchaser unless:

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

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

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

37 (D) ~~the federal food and drug administration has not determined~~ the
38 biological product ~~to be interchangeable with~~ the prescribed biological
39 product.

40 (h) If a prescription order contains a statement that during any
41 particular time the prescription may be refilled at will, there shall be no
42 limitation as to the number of times that such prescription may be refilled
43 except that it may not be refilled after the expiration of the time specified

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1 or one year after the prescription was originally issued, whichever occurs
2 first.

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

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

14 (2) A pharmacist may refill a prescription order issued on or after the
15 effective date of this act for any prescription drug except a drug listed on
16 schedule II of the uniform controlled substances act or a narcotic drug
17 listed on any schedule of the uniform controlled substances act without the
18 prescriber's authorization when all reasonable efforts to contact the
19 prescriber have failed and when, in the pharmacist's professional
20 judgment, continuation of the medication is necessary for the patient's
21 health, safety and welfare. Such prescription refill shall only be in an
22 amount judged by the pharmacist to be sufficient to maintain the patient
23 until the prescriber can be contacted, but in no event shall a refill under
24 this paragraph be more than a seven day supply or one package of the
25 drug. However, if the prescriber states on a prescription that there shall be
26 no emergency refilling of that prescription, then the pharmacist shall not
27 dispense any emergency medication pursuant to that prescription. A
28 pharmacist who refills a prescription order under this ~~subsection (j)(2)~~
29 *paragraph* shall contact the prescriber of the prescription order on the next
30 business day subsequent to the refill or as soon thereafter as possible. No
31 pharmacist shall be required to refill any prescription order under this
32 ~~subsection (j)(2) paragraph~~. A prescriber shall not be subject to liability
33 for any damages resulting from the refilling of a prescription order by a
34 pharmacist under this ~~subsection (j)(2) paragraph~~ unless such damages are
35 occasioned by the gross negligence or willful or wanton acts or omissions
36 by the prescriber.

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

41 (l) Any pharmacist who exercises brand exchange and dispenses a
42 less expensive drug *or biological* product shall not charge the purchaser
43 more than the regular and customary retail price for the dispensed drug *or*

1 *biological product.*

2 (m) Nothing contained in this section shall be construed as preventing
3 a pharmacist from refusing to fill or refill any prescription if in the
4 pharmacist's professional judgment and discretion such pharmacist is of
5 the opinion that it should not be filled or refilled.

6 Sec. 5. K.S.A. 2016 Supp. 65-1643 is hereby amended to read as
7 follows: 65-1643. It shall be unlawful:

8 (a) For any person to operate, maintain, open or establish any
9 pharmacy within this state without first having obtained a registration from
10 the board. Each application for registration of a pharmacy shall indicate
11 the person or persons desiring the registration, including the pharmacist in
12 charge, as well as the location, including the street name and number, and
13 such other information as may be required by the board to establish the
14 identity and exact location of the pharmacy. The issuance of a registration
15 for any pharmacy shall also have the effect of permitting such pharmacy to
16 operate as a retail dealer without requiring such pharmacy to obtain a retail
17 dealer's permit. On evidence satisfactory to the board: (1) That the
18 pharmacy for which the registration is sought will be conducted in full
19 compliance with the law and the rules and regulations of the board; (2) that
20 the location and appointments of the pharmacy are such that it can be
21 operated and maintained without endangering the public health or safety;
22 and (3) that the pharmacy will be under the supervision of a pharmacist, a
23 registration shall be issued to such persons as the board shall deem
24 qualified to conduct such a pharmacy.

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

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

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

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

8 (f) Except as otherwise provided in this subsection~~(f)~~, for any person
9 operating a store or place of business to sell, offer for sale or distribute any
10 drugs to the public without first having obtained a registration or permit
11 from the board authorizing such person so to do. No retail dealer who sells
12 12 or fewer different nonprescription drug products shall be required to
13 obtain a retail dealer's permit under the pharmacy act of the state of Kansas
14 or to pay a retail dealer new permit or permit renewal fee under such act. It
15 shall be lawful for a retail dealer who is the holder of a valid retail dealer's
16 permit issued by the board or for a retail dealer who sells 12 or fewer
17 different nonprescription drug products to sell and distribute
18 nonprescription drugs which are prepackaged, fully prepared by the
19 manufacturer or distributor for use by the consumer and labeled in
20 accordance with the requirements of the state and federal food, drug and
21 cosmetic acts. Such nonprescription drugs shall not include: (1) A
22 controlled substance; (2) a prescription-only drug; or (3) a drug product
23 intended for human use by hypodermic injection; but such a retail dealer
24 shall not be authorized to display any of the words listed in subsection~~(dd)~~
25 ~~(ff)~~ of K.S.A. 65-1626, and amendments thereto, for the designation of a
26 pharmacy or drugstore.

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

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

34 (i) For any person to operate a veterinary medical teaching hospital
35 pharmacy without first having obtained a registration to do so from the
36 board. Such registration shall be subject to the provisions of K.S.A. 65-
37 1662, and amendments thereto and any rules and regulations adopted
38 pursuant thereto.

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

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

1 supervised by a licensed pharmacist;

2 (B) any person purchasing, receiving or otherwise acquiring any such
3 controlled substance produces a photo identification showing the date of
4 birth of the person and signs a log and enters in the log, or allows the seller
5 to enter in the log, such person's address and the date and time of sale or
6 allows the seller to enter such information into an electronic logging
7 system pursuant to K.S.A. 2016 Supp. 65-16,102, and amendments
8 thereto. The log or database required by the board shall be available for
9 inspection during regular business hours to the board of pharmacy and any
10 law enforcement officer;

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

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

16 (2) there is a lawful prescription.

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

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

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

30 (1) Sales not made in the regular course of the person's business; or
31 (2) sales by charitable organizations exempt from federal income
32 taxation pursuant to the internal revenue code of 1986, as amended.

33 Sec. 6. K.S.A. 65-1660 is hereby amended to read as follows: 65-
34 1660. (a) Except as otherwise provided in this section, the provisions of
35 the pharmacy act of the state of Kansas shall not apply to dialysates,
36 devices or drugs which are designated by the board for the purposes of this
37 section relating to treatment of a person with chronic kidney failure
38 receiving dialysis and which are prescribed or ordered by a physician or a
39 mid-level practitioner for administration or delivery to a person with
40 chronic kidney failure if:

41 (1) The wholesale distributor is registered with the board and
42 lawfully holds the drug or device; and

43 (2) the wholesale distributor: (A) Delivers the drug or device to: (i) A

1 person with chronic kidney failure for self-administration at the person's
2 home or specified address; (ii) a physician for administration or delivery to
3 a person with chronic kidney failure; or (iii) a medicare approved renal
4 dialysis facility for administering or delivering to a person with chronic
5 kidney failure; and (B) has sufficient and qualified supervision to
6 adequately protect the public health.

7 (b) The wholesale distributor pursuant to subsection (a) shall be
8 supervised by a pharmacist consultant pursuant to rules and regulations
9 adopted by the board.

10 (c) The board shall adopt such rules or regulations as are necessary to
11 effectuate the provisions of this section.

12 (d) As used in this section, "physician" means a person licensed to
13 practice medicine and surgery; "mid-level practitioner" means mid-level
14 practitioner as such term is defined in ~~subsection (f)~~ of K.S.A. 65-1626,
15 and amendments thereto.

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

18 Sec. 7. K.S.A. 2016 Supp. 65-2837a is hereby amended to read as
19 follows: 65-2837a. (a) It shall be unlawful for any person licensed to
20 practice medicine and surgery to prescribe, order, dispense, administer,
21 sell, supply or give or for a mid-level practitioner as defined in K.S.A. 65-
22 1626(f), and amendments thereto, to prescribe, administer, supply or give
23 any amphetamine or sympathomimetic amine designated in schedule II, III
24 or IV under the uniform controlled substances act, except as provided in
25 this section. Failure to comply with this section by a licensee shall
26 constitute unprofessional conduct under K.S.A. 65-2837, and amendments
27 thereto.

28 (b) When any licensee prescribes, orders, dispenses, administers,
29 sells, supplies or gives or when any mid-level practitioner as defined in
30 K.S.A. 65-1626(f), and amendments thereto, prescribes, administers, sells,
31 supplies or gives any amphetamine or sympathomimetic amine designated
32 in schedule II, III or IV under the uniform controlled substances act, the
33 patient's medical record shall adequately document the purpose for which
34 the drug is being given. Such purpose shall be restricted to one or more of
35 the following:

- 36 (1) The treatment of narcolepsy.
- 37 (2) The treatment of drug-induced brain dysfunction.
- 38 (3) The treatment of attention-deficit/hyperactivity disorder.
- 39 (4) The differential diagnostic psychiatric evaluation of depression.
- 40 (5) The treatment of depression shown by adequate medical records
41 and documentation to be unresponsive to other forms of treatment.
- 42 (6) The clinical investigation of the effects of such drugs or
43 compounds, in which case, before the investigation is begun, the licensee

1 shall, in addition to other requirements of applicable laws, apply for and
2 obtain approval of the investigation from the board of healing arts.

3 (7) The treatment of obesity with controlled substances, as may be
4 defined by rules and regulations adopted by the board of healing arts.

5 (8) The treatment of binge eating disorder.

6 (9) The treatment of any other disorder or disease for which such
7 drugs or compounds have been found to be safe and effective by
8 competent scientific research which findings have been generally accepted
9 by the scientific community, in which case, the licensee before prescribing,
10 ordering, dispensing, administering, selling, supplying or giving the drug
11 or compound for a particular condition, or the licensee before authorizing
12 a mid-level practitioner to prescribe the drug or compound for a particular
13 condition, shall obtain a determination from the board of healing arts that
14 the drug or compound can be used for that particular condition.

15 Sec. 8. K.S.A. 2016 Supp. 65-4202 is hereby amended to read as
16 follows: 65-4202. As used in this act: (a) "Board" means the state board of
17 nursing.

18 (b) The "practice of mental health technology" means the
19 performance, under the direction of a physician licensed to practice
20 medicine and surgery or registered professional nurse, of services in caring
21 for and treatment of the mentally ill, emotionally disturbed, or people with
22 intellectual disability for compensation or personal profit, which services:

23 (1) Involve responsible nursing and therapeutic procedures for
24 patients with mental illness or intellectual disability requiring interpersonal
25 and technical skills in the observations and recognition of symptoms and
26 reactions of such patients, the accurate recording of such symptoms and
27 reactions and the carrying out of treatments and medications as prescribed
28 by a licensed physician or a mid-level practitioner as defined in ~~subsection~~
29 ~~(f)~~ of K.S.A. 65-1626, and amendments thereto; ~~and~~

30 (2) require an application of techniques and procedures that involve
31 understanding of cause and effect and the safeguarding of life and health
32 of the patient and others; and

33 (3) require the performance of duties that are necessary to facilitate
34 rehabilitation of the patient or are necessary in the physical, therapeutic
35 and psychiatric care of the patient and require close work with persons
36 licensed to practice medicine and surgery, psychiatrists, psychologists,
37 rehabilitation therapists, social workers, registered nurses, and other
38 professional personnel.

39 (c) A "licensed mental health technician" means a person who
40 lawfully practices mental health technology as defined in this act.

41 (d) An "approved course in mental health technology" means a
42 program of training and study including a basic curriculum which shall be
43 prescribed and approved by the board in accordance with the standards

1 prescribed herein, the successful completion of which shall be required
2 before licensure as a mental health technician, except as hereinafter
3 provided.

4 Sec. 9. K.S.A. 65-7007 is hereby amended to read as follows: 65-
5 7007. (a) Each regulated chemical distributor and retailer shall submit to
6 the bureau:

7 (1) Any regulated transaction involving an extraordinary quantity of a
8 regulated chemical, an uncommon method of payment or delivery, or any
9 other circumstance that may indicate that the regulated chemical will be
10 used in violation of this act.

11 (2) Any proposed regulated transaction with a person whose
12 description or other identifying characteristic the bureau has previously
13 furnished to the regulated chemical distributor or retailer.

14 (3) Any unusual or excessive loss or disappearance of a regulated
15 chemical under the control of the regulated chemical distributor or retailer.
16 The regulated person responsible for reporting a loss in-transit is the
17 distributor.

18 (b) Each report submitted pursuant to subsection (a), whenever
19 possible shall be made orally to the bureau at the earliest practicable
20 opportunity after the regulated chemical distributor or retailer becomes
21 aware of the circumstances involved and as much in advance of the
22 conclusion of the transaction as possible. Written reports of these
23 transactions shall subsequently be filed within 15 days after the regulated
24 chemical distributor or retailer becomes aware of the circumstances of the
25 event. A transaction may not be completed with a person whose
26 description or identifying characteristics have previously been furnished to
27 the regulated distributor by the bureau unless the transaction is approved
28 by the bureau.

29 (c) This section shall not apply to any of the following:

30 (1) Any pharmacist, pharmacy or other authorized person who sells
31 or furnishes a substance listed in ~~subsection (1)~~ of K.S.A. 65-7003, and
32 amendments thereto, upon the prescription or order of a practitioner as
33 defined under ~~subsection (x)~~ of K.S.A. 65-1626, and amendments thereto;

34 (2) any practitioner as defined under ~~subsection (x)~~ of K.S.A. 65-
35 1626, and amendments thereto, who administers, dispenses or furnishes a
36 substance listed in ~~subsection (1)~~ of K.S.A. 65-7003, and amendments
37 thereto, to such patients within the scope of a practitioner's professional
38 practice. Such administration or dispensing shall be in the patient record;

39 (3) ~~any~~ sale, transfer, furnishing or receipt of any drug which
40 contains any substance listed in ~~subsection (1)~~ of K.S.A. 65-7003, and
41 amendments thereto, and which is lawfully sold, transferred or furnished
42 over-the-counter without a prescription pursuant to the federal food, drug
43 and cosmetic act or regulations adopted thereunder; and

1 (4) a regulated chemical retailer who only sells or distributes
2 regulated chemicals that are nonprescription, over-the-counter medicines
3 with less than three grams of base ingredient in the package in the
4 following manner:

5 (A) Blister packs of not more than two dosage units per blister;

6 (B) liquid cold or cough medicines;

7 (C) liquid cold or cough gel capsules; and

8 (D) nasal drops or sprays.

9 Sec. 10. K.S.A. 65-669, 65-1660 and 65-7007 and K.S.A. 2016 Supp.
10 65-1626, 65-1637, 65-1637b, 65-1643, 65-2837a and 65-4202 are hereby
11 repealed.

12 Sec. 11. This act shall take effect and be in force from and after its
13 publication in the statute book.