

Senate Substitute for HOUSE BILL No. 2055

By Committee on Public Health and Welfare

3-24

1 AN ACT concerning the state board of pharmacy; relating to powers,
2 duties and functions thereof; biological products; amending K.S.A. 65-
3 669, 65-1633, 65-1635, 65-1648, 65-1660 and 65-7007 and K.S.A.
4 2016 Supp. 65-1626, 65-1627, 65-1636, 65-1637, 65-1642, 65-1643,
5 65-1645, 65-1655, 65-1663, 65-1669, 65-1676, 65-2837a and 65-4202
6 and repealing the existing sections; also repealing K.S.A. 2016 Supp.
7 65-1637b and 65-1651a.

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

10 Section 1. K.S.A. 2016 Supp. 65-1626 is hereby amended to read as
11 follows: 65-1626. For the purposes of this act:

12 (a) "Administer" means the direct application of a drug, whether by
13 injection, inhalation, ingestion or any other means, to the body of a patient
14 or research subject by:

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

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

18 (3) a pharmacist as authorized in K.S.A. 65-1635a, and amendments
19 thereto.

20 (b) "Agent" means an authorized person who acts on behalf of or at
21 the direction of a manufacturer, *repackager*, *wholesale* distributor, *third-*
22 *party logistics provider* or dispenser but ~~shall~~ does not include a common
23 carrier, public warehouseman or employee of the carrier or warehouseman
24 when acting in the usual and lawful course of the carrier's or
25 warehouseman's business.

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

30 ~~(d) "Authorized distributor of record" means a wholesale distributor~~
31 ~~with whom a manufacturer has established an ongoing relationship to~~
32 ~~distribute the manufacturer's prescription drug. An ongoing relationship is~~
33 ~~deemed to exist between such wholesale distributor and a manufacturer~~
34 ~~when the wholesale distributor, including any affiliated group of the~~
35 ~~wholesale distributor, as defined in section 1504 of the internal revenue~~
36 ~~code, complies with any one of the following: (1) The wholesale~~

1 distributor has a written agreement currently in effect with the
2 manufacturer evidencing such ongoing relationship; and (2) the wholesale
3 distributor is listed on the manufacturer's current list of authorized
4 distributors of record, which is updated by the manufacturer on no less
5 than a monthly basis."Automated dispensing system" means a robotic or
6 mechanical system controlled by a computer that: (1) Performs operations
7 or activities, other than compounding or administration, relative to the
8 storage, packaging, labeling, dispensing or distribution of drugs; (2)
9 collects, controls and maintains all transaction information; and (3)
10 operates in accordance with the board's rules and regulations.

11 (e) "Biological product" means the same as defined in 42 U.S.C. §
12 262(i), as in effect on January 1, 2017.

13 (e)(f) "Board" means the state board of pharmacy created by K.S.A.
14 74-1603, and amendments thereto.

15 (f)(g) "Brand exchange," in the case of a drug prescribed, means the
16 dispensing of a different drug product of the same dosage form and
17 strength and of the same generic name as the brand name drug product
18 prescribed, and in the case of a biological product prescribed, means the
19 dispensing of an interchangeable biological product.

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

22 (h) "Chain pharmacy warehouse" means a permanent physical
23 location for drugs or devices, or both, that acts as a central warehouse and
24 performs intracompany sales or transfers of prescription drugs or devices
25 to chain pharmacies that have the same ownership or control. Chain
26 pharmacy warehouses must be registered as wholesale distributors.

27 (i) "Co-licensee/Co-licensed partner" means a person or
28 pharmaceutical manufacturer that has entered into an agreement with
29 another pharmaceutical manufacturer or an affiliate of the manufacturer to
30 engage in a business activity or occupation related to the manufacture or
31 distribution of a prescription drug and the national drug code on the drug
32 product label shall be used to determine the identity of the drug
33 manufacturer product.

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

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

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

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

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

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

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

12 ~~(k)~~(m) "Deliver" or "delivery" means the actual, constructive or
13 attempted transfer from one person to another of any drug whether or not
14 an agency relationship exists.

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

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

24 ~~(n)~~(p) "Dispenser" means:

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

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

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

40 ~~(p)~~(r) "Distributor" means a person ~~who~~ or entity that distributes a
41 drug.

42 ~~(q)~~(s) "Drop shipment" means the sale, by a manufacturer, ~~that~~
43 ~~manufacturer's co-licensee, that manufacturer's third party logistics~~

1 provider, *repackager* or that manufacturer's exclusive distributor, of the
2 manufacturer's prescription drug; to a wholesale distributor whereby the
3 wholesale distributor takes title but not possession of such prescription
4 drug and the wholesale distributor invoices the ~~pharmacy, the chain~~
5 ~~pharmacy warehouse, or other designated person authorized by law to~~
6 ~~dispense or administer such prescription drug, and the pharmacy, the chain~~
7 ~~pharmacy warehouse, or other designated person authorized by law to~~
8 ~~dispense or administer such prescription drug~~ *dispenser, and the dispenser*
9 receives delivery of the prescription drug directly from the manufacturer,
10 that manufacturer's co-licensee, that manufacturer's *repackager*, third-party
11 logistics provider; or that manufacturer's exclusive distributor, of such
12 prescription drug. Drop shipment shall be part of the "normal distribution
13 channel."

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

26 ~~(s)~~*(u)* "Durable medical equipment" means ~~technologically~~
27 ~~sophisticated medical devices that may be used in a residence, including~~
28 ~~the following equipment that:~~ (1) ~~Oxygen and oxygen delivery system~~
29 *Provides therapeutic benefits or enables an individual to perform certain*
30 *tasks that the individual is unable to otherwise undertake due to certain*
31 *medical conditions or illnesses;* (2) ~~ventilators is primarily and~~
32 *customarily used to serve a medical purpose;* (3) ~~respiratory disease~~
33 ~~management devices generally is not useful to a person in the absence of~~
34 *an illness or injury;* (4) ~~continuous positive airway pressure (CPAP)~~
35 ~~devices can withstand repeated use;~~ (5) ~~electronic and computerized~~
36 ~~wheelchairs and seating systems is appropriate for use in the home, long-~~
37 *term care facility or medical care facility, but may be transported to other*
38 *locations to allow the individual to complete instrumental activities of*
39 *daily living that are more complex tasks required for independent living;*
40 *and* (6) ~~apnea monitors;~~ (7) ~~transcutaneous electrical nerve stimulator~~
41 ~~(TENS) units;~~ (8) ~~low air loss cutaneous pressure management devices;~~ (9)
42 ~~sequential compression devices;~~ (10) ~~feeding pumps;~~ (11) ~~home~~
43 ~~phototherapy devices;~~ (12) ~~infusion delivery devices;~~ (13) ~~distribution of~~

1 ~~medical gases to end users for human consumption; (14) hospital beds;~~
2 ~~(15) nebulizers; or (16) may include devices and medical supplies or other~~
3 similar equipment determined by the board in rules and regulations
4 adopted by the board.

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

8 ~~(u)-(w)~~ "Electronic prescription application" means software that is
9 used to create electronic prescriptions and that is intended to be installed
10 on the prescriber's computers and servers where access and records are
11 controlled by the prescriber.

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

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

21 ~~(x)-(z)~~ "Electronically prepared prescription" means a prescription
22 that is generated using an electronic prescription application.

23 ~~(y)-(aa)~~ "Exclusive distributor" means ~~any entity that: (1) Contracts~~
24 ~~with a manufacturer to provide or coordinate warehousing, wholesale~~
25 ~~distribution or other services on behalf of a manufacturer and who takes~~
26 ~~title to that manufacturer's prescription drug, but who does not have~~
27 ~~general responsibility to direct the sale or disposition of the manufacturer's~~
28 ~~prescription drug; (2) is registered as a wholesale distributor under the~~
29 ~~pharmacy act of the state of Kansas; and (3) to be considered part of the~~
30 ~~normal distribution channel, must be an authorized distributor of record~~
31 ~~the wholesale distributor that directly purchased the product from the~~
32 ~~manufacturer and is the sole distributor of that manufacturer's product to~~
33 ~~a subsequent repackager, wholesale distributor or dispenser.~~

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

36 (cc) "Facsimile transmission" or "fax transmission" means the
37 transmission of a digital image of a prescription from the prescriber or the
38 prescriber's agent to the pharmacy. "Facsimile transmission" includes, but
39 is not limited to, transmission of a written prescription between the
40 prescriber's fax machine and the pharmacy's fax machine; transmission of
41 an electronically prepared prescription from the prescriber's electronic
42 prescription application to the pharmacy's fax machine, computer or
43 printer; or transmission of an electronically prepared prescription from the

1 prescriber's fax machine to the pharmacy's fax machine, computer or
2 printer.

3 ~~(aa)~~-(dd) "Generic name" means the established chemical name or
4 official name of a drug or drug product.

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

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

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

13 (B) residents of a juvenile detention facility, as defined by the revised
14 Kansas code for care of children and the revised Kansas juvenile justice
15 code;

16 (C) students of a public or private university or college, a community
17 college or any other institution of higher learning ~~which~~ that is located in
18 Kansas;

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

20 (E) persons receiving inpatient hospice services.

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

22 (A) Any registered pharmacy;

23 (B) any office of a practitioner; or

24 (C) a location where no prescription-only drugs are dispensed and no
25 prescription-only drugs other than individual prescriptions are stored or
26 administered.

27 ~~(ee)~~-(gg) "*Interchangeable biological product*" means a biological
28 product that the FDA has:

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

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

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

38 ~~(dd)~~-(ii) "Intracompany transaction" means any transaction or transfer
39 between any division, subsidiary, parent or affiliated or related company
40 under common ownership or control of a corporate entity, or any
41 transaction or transfer between ~~co-licensees of a co-licensed product~~
42 *co-licensed partners.*

43 (jj) "*Label*" means a display of written, printed or graphic matter

1 upon the immediate container of any drug.

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

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

8 ~~(ee)~~-(mm) "Medical care facility" ~~shall have the meaning provided~~
9 means the same as defined in K.S.A. 65-425, and amendments thereto,
10 except that the term ~~shall also include~~ includes facilities licensed under the
11 provisions of K.S.A. ~~75-3307b~~ 2016 Supp. 39-2001 et seq., and
12 amendments thereto, except community mental health centers and
13 facilities for people with intellectual disability.

14 ~~(ff)~~-(nn) "Manufacture" means the production, preparation,
15 propagation, compounding, conversion or processing of a drug either
16 directly or indirectly by extraction from substances of natural origin,
17 independently by means of chemical or biological synthesis or by a
18 combination of extraction and chemical or biological synthesis ~~and~~
19 ~~includes any or the~~ packaging or repackaging of the drug or labeling or
20 relabeling of its container, except that this term ~~shall~~ does not include the
21 preparation or compounding of a drug by an individual for the individual's
22 own use or the preparation, compounding, packaging or labeling of a drug
23 by:

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

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

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

33 ~~(gg)~~-(oo) "Manufacturer" means a person licensed or approved by the
34 FDA to engage in the manufacture of drugs and devices:

35 (1) A person that holds an application approved under section 505 of
36 the federal food, drug and cosmetic act or a license issued under section
37 351 of the federal public health service act for such drug or, if such drug is
38 not the subject of an approved application or license, the person who
39 manufactured the drug;

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

43 (3) an affiliate of a person described in paragraph (1) or (2) that

1 *receives the product directly from a person described in paragraph (1) or*
2 *(2).*

3 ~~(hh)-(pp)~~ "Mid-level practitioner" means a certified nurse-midwife
4 engaging in the independent practice of midwifery under the independent
5 practice of midwifery act, an advanced practice registered nurse issued a
6 license pursuant to K.S.A. 65-1131, and amendments thereto, who has
7 authority to prescribe drugs pursuant to a written protocol with a
8 responsible physician under K.S.A. 65-1130, and amendments thereto, or a
9 physician assistant licensed pursuant to the physician assistant licensure
10 act who has authority to prescribe drugs pursuant to a written agreement
11 with a supervising physician under K.S.A. 65-28a08, and amendments
12 thereto.

13 ~~(ii)~~ "Normal distribution channel" means a chain of custody for a
14 prescription-only drug that goes from a manufacturer of the prescription-
15 only drug, from that manufacturer to that manufacturer's co-licensed
16 partner, from that manufacturer to that manufacturer's third-party logistics
17 provider or from that manufacturer to that manufacturer's exclusive
18 distributor, directly or by drop shipment, to:

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

21 ~~(2)~~ a wholesale distributor to a pharmacy to a patient or other
22 designated persons authorized by law to dispense or administer such drug
23 to a patient;

24 ~~(3)~~ a wholesale distributor to a chain pharmacy warehouse to that
25 chain pharmacy warehouse's intracompany pharmacy to a patient or other
26 designated persons authorized by law to dispense or administer such drug
27 to a patient; or

28 ~~(4)~~ a chain pharmacy warehouse to the chain pharmacy warehouse's
29 intracompany pharmacy to a patient or other designated persons authorized
30 by law to dispense or administer such drug to a patient.

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

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

37 ~~(jj)-(ss)~~ "Person" means individual, corporation, government,
38 governmental subdivision or agency, partnership, association or any other
39 legal entity.

40 ~~(kk)-(tt)~~ "Pharmacist" means any natural person licensed under this
41 act to practice pharmacy.

42 ~~(H)-(uu)~~ "Pharmacist-in-charge" means the pharmacist who is
43 responsible to the board for a registered establishment's compliance with

1 the laws and regulations of this state pertaining to the practice of
2 pharmacy, manufacturing of drugs and the distribution of drugs. The
3 pharmacist-in-charge shall supervise such establishment on a full-time or a
4 part-time basis and perform such other duties relating to supervision of a
5 registered establishment as may be prescribed by the board by rules and
6 regulations. Nothing in this definition shall relieve other pharmacists or
7 persons from their responsibility to comply with state and federal laws and
8 regulations.

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

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

28 ~~(oo)~~(xx) "Pharmacy prescription application" means software that is
29 used to process prescription information, is installed on a pharmacy's
30 computers or servers; and is controlled by the pharmacy.

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

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

42 ~~(rr)~~(aaa) "Preceptor" means a licensed pharmacist who possesses at
43 least two years' experience as a pharmacist and who supervises students

1 obtaining the pharmaceutical experience required by law as a condition to
2 taking the examination for licensure as a pharmacist.

3 ~~(ss)~~—(bbb) "Prescriber" means a practitioner or a mid-level
4 practitioner.

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

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

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

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

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

30 (hhh) "Professional incompetency" means:

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

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

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

39 ~~(yy)~~—(iii) "Readily retrievable" means that records kept by automatic
40 data processing applications or other electronic or mechanized record-
41 keeping systems can be separated out from all other records within a
42 reasonable time not to exceed 48 hours of a request from the board or
43 other authorized agent or that hard-copy records are kept on which certain

1 items are asterisked, redlined or in some other manner visually identifiable
2 apart from other items appearing on the records.

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

5 *(lll) "Repackager" means a person who owns or operates a facility*
6 *that repackages.*

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

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

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

24 ~~*(aaa)---*~~*(ppp) "Secretary" means the executive secretary of the board.*

25 ~~*(bbb)---*~~*(qqq) "Third-party logistics provider" means an entity that:--(1)*
26 *provides or coordinates warehousing, distribution or other logistic services*
27 *of a product in interstate commerce on behalf of a manufacturer,*
28 *wholesale distributor or dispenser; but does not take title to the*
29 ~~*prescription drug ownership of the product or have general*~~
30 ~~*responsibility to direct the prescription drug's sale or disposition of the product;--(2) is*~~
31 ~~*registered as a wholesale distributor under the pharmacy act of the state of*~~
32 ~~*Kansas; and (3) to be considered part of the normal distribution channel;*~~
33 ~~*must also be an authorized distributor of record.*~~

34 *(rrr) "Trading partner" means:*

35 *(1) A manufacturer, repackager, wholesale distributor or dispenser*
36 *from whom a manufacturer, repackager, wholesale distributor or dispenser*
37 *accepts direct ownership of a product or to whom a manufacturer,*
38 *repackager, wholesale distributor or dispenser transfers direct ownership*
39 *of a product; or*

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

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

3 ~~(eee)~~(ttt) "Unprofessional conduct" means:

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

5 (2) intentional adulteration or mislabeling of any drug, medicine,
6 chemical or poison;

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

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

10 (5) unlawful possession of drugs and unlawful diversion of drugs to
11 others;

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

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

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

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

19 (10) performing unnecessary tests, examinations or services ~~which~~
20 that have no legitimate pharmaceutical purpose.

21 ~~(ddd)~~(uuu) "Vaccination protocol" means a written protocol, agreed
22 to by a pharmacist and a person licensed to practice medicine and surgery
23 by the state board of healing arts, ~~which~~ that establishes procedures and
24 recordkeeping and reporting requirements for administering a vaccine by
25 the pharmacist for a period of time specified therein, not to exceed two
26 years.

27 ~~(eee)~~(vvv) "Valid prescription order" means a prescription that is
28 issued for a legitimate medical purpose by an individual prescriber
29 licensed by law to administer and prescribe drugs and acting in the usual
30 course of such prescriber's professional practice. A prescription issued
31 solely on the basis of an internet-based questionnaire or consultation
32 without an appropriate prescriber-patient relationship is not a valid
33 prescription order.

34 ~~(fff)~~(www) "Veterinary medical teaching hospital pharmacy" means
35 any location where prescription-only drugs are stored as part of an
36 accredited college of veterinary medicine and from which prescription-
37 only drugs are distributed for use in treatment of or administration to a
38 nonhuman.

39 ~~(ggg)~~(xxx) "Wholesale distributor" means any person engaged in
40 wholesale distribution of prescription drugs ~~or devices in or into the state,~~
41 ~~including, but not limited to, manufacturers, repackagers, own-label~~
42 ~~distributors, private-label distributors, jobbers, brokers, warehouses,~~
43 ~~including manufacturers' and distributors' warehouses, co-licensees,~~

1 ~~exclusive distributors, third party logistics providers, chain pharmacy~~
2 ~~warehouses that conduct wholesale distributions, and wholesale drug~~
3 ~~warehouses, independent wholesale drug traders and retail pharmacies that~~
4 ~~conduct wholesale distributions. Wholesale distributor shall not include~~
5 ~~persons engaged in the sale of durable medical equipment to consumers or~~
6 ~~patients, other than a manufacturer, co-licensed partner, third-party~~
7 ~~logistics provider or repackager.~~

8 ~~(hhh)-(yyy) "Wholesale distribution" means the distribution or receipt~~
9 ~~of prescription drugs or devices by wholesale distributors to or by persons~~
10 ~~other than consumers or patients, and includes the transfer of prescription~~
11 ~~drugs by a pharmacy to another pharmacy if the total number of units of~~
12 ~~transferred drugs during a twelve-month period does not exceed 5% of the~~
13 ~~total number of all units dispensed by the pharmacy during the~~
14 ~~immediately preceding twelve-month period in which a change of~~
15 ~~ownership occurs. Wholesale distribution does not include:~~

16 ~~(1) The sale, purchase or trade of a prescription drug or device, an~~
17 ~~offer to sell, purchase or trade a prescription drug or device or the~~
18 ~~dispensing of a prescription drug or device pursuant to a prescription;~~

19 ~~(2) the sale, purchase or trade distribution of a prescription drug or~~
20 ~~device or an offer to sell, purchase or trade distribute a prescription drug or~~
21 ~~device for emergency medical reasons, including a public health~~
22 ~~emergency declaration pursuant to section 319 of the public health service~~
23 ~~act, except that, for purposes of this paragraph, a drug shortage not~~
24 ~~caused by a public health emergency shall not constitute an emergency~~
25 ~~medical reason;~~

26 ~~(3) intracompany transactions, as defined in this section, unless in~~
27 ~~violation of own use provisions distribution of any drug between members~~
28 ~~of an affiliate or within a manufacturer;~~

29 ~~(4) the sale, purchase or trade distribution of a prescription drug or~~
30 ~~device or an offer to sell, purchase or trade distribute a prescription drug or~~
31 ~~device among hospitals, chain pharmacy warehouses, pharmacies or other~~
32 ~~health care entities that are under common control;~~

33 ~~(5) the sale, purchase or trade distribution of a prescription drug or~~
34 ~~device or the offer to sell, purchase or trade distribute a prescription drug~~
35 ~~or device by a charitable organization described in 503(c)(3) of the internal~~
36 ~~revenue code of 1954 to a nonprofit affiliate of the organization to the~~
37 ~~extent otherwise permitted by law;~~

38 ~~(6) the purchase or other acquisition by a dispenser; hospital or other~~
39 ~~similar health care entity that is a member of a group purchasing~~
40 ~~organization of a prescription drug or device for its own use from the~~
41 ~~group purchasing organization or from other hospitals or similar health~~
42 ~~care entities that are members of these organizations for use by such~~
43 ~~dispenser; hospital or other health care entity;~~

1 ~~(7) the transfer of prescription drugs or devices between pharmacies~~
2 ~~pursuant to a centralized prescription processing agreement~~ *the*
3 *distribution of a drug by the manufacturer of such drug;*

4 ~~(8) the sale, purchase or trade of blood and blood components~~
5 ~~intended for transfusion~~ *the receipt or transfer of a drug by an authorized*
6 *third-party logistics provider; provided that such third-party logistics*
7 *provider does not take ownership of the drug;*

8 ~~(9) the return of recalled, expired, damaged or otherwise non-salable~~
9 ~~prescription drugs, when conducted by a hospital, health care entity,~~
10 ~~pharmacy, chain pharmacy warehouse or charitable institution in~~
11 ~~accordance with the board's rules and regulations~~ *the transport of a drug*
12 *by a common carrier; provided that the common carrier does not take*
13 *ownership of the drug;*

14 ~~(10) the sale, transfer, merger or consolidation of all or part of the~~
15 ~~business of a retail pharmacy or pharmacies from or with another retail~~
16 ~~pharmacy or pharmacies, whether accomplished as a purchase and sale of~~
17 ~~stock or business assets, in accordance with the board's rules and~~
18 ~~regulations~~ *the distribution of a drug or an offer to distribute a drug by an*
19 *authorized repackager that has taken ownership or possession of the drug*
20 *and repacks it in accordance with section 582(e) of the federal food, drug*
21 *and cosmetic act;*

22 ~~(11) the distribution of drug samples by manufacturers' and~~
23 ~~authorized distributors' representatives~~ *saleable drug returns when*
24 *conducted by a dispenser;*

25 ~~(12) the sale~~ *distribution* of minimal quantities of drugs by *licensed*
26 *retail pharmacies to licensed practitioners for office use;*

27 ~~(13) the distribution of a collection of finished medical devices,~~
28 ~~including a product or biological product in accordance with 21 U.S.C. §~~
29 ~~353(e)(4)(M);~~

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

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

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

38 ~~(17) the distribution of medical gas;~~

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

41 ~~(19) the transfer of a product by a hospital or other health care~~
42 ~~entity, or by a wholesale distributor or manufacturer operating under the~~
43 ~~direction of a hospital or other health care entity, to a repackager~~

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

6 ~~(13)(20) the sale or transfer from a retail pharmacy or chain~~
7 ~~pharmacy warehouse of expired, damaged, returned or recalled~~
8 ~~prescription drugs to the original manufacturer, originating wholesale~~
9 ~~distributor or to a third-party returns processor in accordance with the~~
10 ~~board's rules and regulations.~~

11 Sec. 2. K.S.A. 2016 Supp. 65-1627 is hereby amended to read as
12 follows: 65-1627. (a) The board may revoke, suspend, place in a
13 probationary status or deny ~~a~~ *an application or* renewal of any license of
14 any pharmacist upon a finding that:

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

18 (2) the licensee has been convicted of a *misdemeanor involving*
19 *moral turpitude or gross immorality or any felony* and the licensee fails to
20 show that the licensee has been sufficiently rehabilitated to warrant the
21 public trust;

22 (3) the licensee is found by the board to be guilty of unprofessional
23 conduct or professional incompetency;

24 (4) the licensee is addicted to the liquor or drug habit to such a degree
25 as to render the licensee unfit to practice the profession of pharmacy;

26 (5) the licensee has violated a provision of the federal or state food,
27 drug and cosmetic act, the uniform controlled substances act of the state of
28 Kansas, or any rule and regulation adopted under any such act;

29 (6) the licensee is found by the board to have filled a prescription not
30 in strict accordance with the directions of the practitioner or a mid-level
31 practitioner;

32 (7) the licensee is found to be mentally or physically incapacitated to
33 such a degree as to render the licensee unfit to practice the profession of
34 pharmacy;

35 (8) the licensee has violated any of the provisions of the pharmacy act
36 of the state of Kansas or any rule and regulation adopted by the board
37 pursuant to the provisions of such pharmacy act;

38 (9) the licensee has failed to comply with the *continuing education*
39 ~~requirements of the board relating to the continuing education of~~
40 ~~pharmacists for license renewal;~~

41 (10) the licensee as a pharmacist in charge or consultant pharmacist
42 under the provisions of ~~subsection (e) or (d) of~~ K.S.A. 65-1648(c) or (d),
43 and amendments thereto, has failed to comply with the requirements of

- 1 ~~subsection (c) or (d) of K.S.A. 65-1648(c) or (d), and amendments thereto;~~
2 (11) the licensee has knowingly submitted a misleading, deceptive,
3 untrue or fraudulent misrepresentation on a claim form, bill or statement;
4 (12) the licensee has had a license to practice pharmacy revoked,
5 suspended or limited, has been censured or has had other disciplinary
6 action taken, or voluntarily surrendered the license after formal
7 proceedings have been commenced, or has had an application for license
8 denied, by the proper licensing authority of another state, territory, District
9 of Columbia or other country, a certified copy of the record of the action of
10 the other jurisdiction being conclusive evidence thereof;
11 (13) the licensee has self-administered any controlled substance
12 without a practitioner's prescription order or a mid-level practitioner's
13 prescription order; or
14 (14) the licensee has assisted suicide in violation of K.S.A. 21-3406,
15 prior to its repeal, or K.S.A. 2016 Supp. 21-5407, and amendments
16 thereto, as established by any of the following:
17 (A) A copy of the record of criminal conviction or plea of guilty for a
18 felony in violation of K.S.A. 21-3406, prior to its repeal, or K.S.A. 2016
19 Supp. 21-5407, and amendments thereto.
20 (B) A copy of the record of a judgment of contempt of court for
21 violating an injunction issued under K.S.A. 60-4404, and amendments
22 thereto.
23 (C) A copy of the record of a judgment assessing damages under
24 K.S.A. 60-4405, and amendments thereto;~~or~~
25 (15) the licensee has failed to furnish the board, its investigators or its
26 representatives any information legally requested by the board;
27 (16) *the licensee has violated or failed to comply with any lawful*
28 *order or directive of the board; or*
29 (17) *the licensee has violated any of the provisions of the prescription*
30 *monitoring program act of the state of Kansas or any rule and regulation*
31 *of the board pursuant to the provisions of the prescription monitoring*
32 *program act.*
33 (b) In determining whether or not the licensee has violated subsection
34 (a)(3), (a)(4), (a)(7) or (a)(13), the board upon reasonable suspicion of
35 such violation has authority to compel a licensee to submit to mental or
36 physical examination or drug screen, or any combination thereof, by such
37 persons as the board may designate. To determine whether reasonable
38 suspicion of such violation exists, the investigative information shall be
39 presented to the board as a whole. Information submitted to the board as a
40 whole and all reports, findings and other records shall be confidential and
41 not subject to discovery by or release to any person or entity. The licensee
42 shall submit to the board a release of information authorizing the board to
43 obtain a report of such examination or drug screen, or both. A person

1 affected by this subsection shall be offered, at reasonable intervals, an
2 opportunity to demonstrate that such person can resume the competent
3 practice of pharmacy with reasonable skill and safety to patients. For the
4 purpose of this subsection, every person licensed to practice pharmacy and
5 who shall accept the privilege to practice pharmacy in this state by so
6 practicing or by the making and filing of a renewal application to practice
7 pharmacy in this state shall be deemed to have consented to submit to a
8 mental or physical examination or a drug screen, or any combination
9 thereof, when directed in writing by the board and further to have waived
10 all objections to the admissibility of the testimony, drug screen or
11 examination report of the person conducting such examination or drug
12 screen, or both, at any proceeding or hearing before the board on the
13 ground that such testimony or examination or drug screen report
14 constitutes a privileged communication. In any proceeding by the board
15 pursuant to the provisions of this subsection, the record of such board
16 proceedings involving the mental and physical examination or drug screen,
17 or any combination thereof, shall not be used in any other administrative
18 or judicial proceeding.

19 (c) The board may temporarily suspend or temporarily limit the
20 license of any licensee in accordance with the emergency adjudicative
21 proceedings under the Kansas administrative procedure act if the board
22 determines that there is cause to believe that grounds exist for disciplinary
23 action under subsection (a) against the licensee and that the licensee's
24 continuation in practice would constitute an imminent danger to the public
25 health and safety.

26 (d) The board may suspend, revoke, place in a probationary status or
27 deny a renewal of any retail dealer's permit issued by the board when
28 information in possession of the board discloses that such operations for
29 which the permit was issued are not being conducted according to law or
30 the rules and regulations of the board. When the board determines that
31 action under this subsection requires the immediate protection of the
32 public interest, the board shall conduct an emergency proceeding in
33 accordance with K.S.A. 77-536, and amendments thereto, under the
34 Kansas administrative procedure act.

35 (e) The board may revoke, suspend, place in a probationary status or
36 deny a renewal of the registration of a pharmacy upon a finding that:

37 (1) Such pharmacy has been operated in such manner that violations
38 of the provisions of the pharmacy act of the state of Kansas or of the rules
39 and regulations of the board have occurred in connection therewith;

40 (2) the owner or any pharmacist employed at such pharmacy is
41 convicted, subsequent to such owner's acquisition of or such employee's
42 employment at such pharmacy, of a violation of the pharmacy act or
43 uniform controlled substances act of the state of Kansas, or the federal or

1 state food, drug and cosmetic act;

2 (3) the owner or any pharmacist employed by such pharmacy has
3 fraudulently claimed money for pharmaceutical services; or

4 (4) the registrant has had a registration revoked, suspended or limited,
5 has been censured or has had other disciplinary action taken, or an
6 application for registration denied, by the proper registering authority of
7 another state, territory, District of Columbia or other country, a certified
8 copy of the record of the action of the other jurisdiction being conclusive
9 evidence thereof. When the board determines that action under this
10 subsection requires the immediate protection of the public interest, the
11 board shall conduct an emergency proceeding in accordance with K.S.A.
12 77-536, and amendments thereto, under the Kansas administrative
13 procedure act.

14 (f) A registration to manufacture *or repackage* drugs, to ~~distribute at~~
15 ~~operate as a wholesale-a drug distributor,~~ to sell durable medical
16 equipment *or to operate as a third-party logistics provider*; or a
17 registration for the place of business where any such operation is
18 conducted, may be suspended, revoked, placed in a probationary status or
19 the renewal of such registration may be denied by the board upon a finding
20 that the registrant or the registrant's agent:

21 (1) Has materially falsified any application filed pursuant to or
22 required by the pharmacy act of the state of Kansas;

23 (2) has been convicted of a felony under any federal or state law
24 relating to the manufacture or distribution of drugs;

25 (3) has had any federal registration for the manufacture or distribution
26 of drugs suspended or revoked;

27 (4) has refused to permit the board or its duly authorized agents to
28 inspect the registrant's establishment in accordance with the provisions of
29 K.S.A. 65-1629, and amendments thereto;

30 (5) has failed to keep, ~~or~~ has failed to file with the board or has
31 falsified records required to be kept or filed by the provisions of the
32 pharmacy act of the state of Kansas or by the board's rules and regulations;
33 or

34 (6) has violated the pharmacy act of the state of Kansas or rules and
35 regulations adopted by the state board of pharmacy under the pharmacy act
36 of the state of Kansas ~~or~~, has violated the uniform controlled substances
37 act or rules and regulations adopted by the state board of pharmacy under
38 the uniform controlled substances act *or has violated a provision of the*
39 *federal drug supply chain security act or any rule or regulation adopted*
40 *under such act*. When the board determines that action under this
41 subsection requires the immediate protection of the public interest, the
42 board shall conduct an emergency proceeding in accordance with K.S.A.
43 77-536, and amendments thereto, under the Kansas administrative

1 procedure act.

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

4 Sec. 3. K.S.A. 65-1633 is hereby amended to read as follows: 65-
5 1633. Every pharmacist who changes residential address *or email address*
6 shall within 30 days thereof ~~by letter~~ notify the ~~executive~~ secretary ~~of the~~
7 ~~board~~ of such change *on a form prescribed and furnished by the board*,
8 and upon receipt of the notice the ~~executive~~ secretary shall make the
9 proper alterations in the record kept for that purpose.

10 Sec. 4. K.S.A. 65-1635 is hereby amended to read as follows: 65-
11 1635. (a) Nothing contained in the pharmacy act of the state of Kansas
12 shall prohibit any duly licensed practitioner from purchasing and keeping
13 drugs, from compounding prescriptions or from administering, supplying
14 or dispensing to such practitioner's patients such drugs as may be fit,
15 proper and necessary. Except as provided in subsection (b) or (c), such
16 drugs shall be dispensed by such practitioner and shall comply with the
17 Kansas food, drug and cosmetic act and be subject to inspection as
18 provided by law.

19 (b) Nothing contained in the pharmacy act of the state of Kansas shall
20 be construed to prohibit any nurse or other person, acting under the
21 direction of a duly licensed practitioner, from administering drugs to a
22 patient.

23 (c) Nothing contained in the pharmacy act of the state of Kansas shall
24 be construed to prohibit any registered nurse, acting under the supervision
25 of a person who is licensed to practice medicine and surgery as of July 1,
26 1982, from dispensing drugs to patients of such person so long as the
27 principal office of such person is, and as of July 1, 1982, was, located in a
28 city not having a registered pharmacy within its boundaries. For the
29 purposes of this subsection (c), "supervision" means guidance and
30 direction of the dispensing of drugs by the person licensed to practice
31 medicine and surgery who shall be physically present in the general
32 location at which the drugs are being dispensed.

33 (d) Nothing contained in the pharmacy act of the state of Kansas shall
34 be construed to prohibit a duly registered ~~wholesaler~~ *wholesale distributor*
35 from distributing a prescription-only drug pursuant to a veterinarian
36 practitioner's written prescription or order; where a valid veterinarian-
37 client-patient relationship, VCPR, as defined in K.S.A. 47-816, and
38 amendments thereto, exists, to the layman responsible for the control of
39 the animal.

40 (e) *Nothing contained in the pharmacy act of the state of Kansas*
41 *shall require an in-person examination or encounter between a person*
42 *licensed to practice medicine and surgery and the patient prior to a*
43 *pharmacist filling or refilling any prescription.*

1 Sec. 5. K.S.A. 2016 Supp. 65-1636 is hereby amended to read as
2 follows: 65-1636. (a) Except as otherwise provided in this act, the sale and
3 ~~distribution~~ *dispensing* of drugs shall be limited to pharmacies operating
4 under registrations as required by this act, and the actual sale or
5 ~~distribution~~ *dispensing* of drugs shall be made by a pharmacist or other
6 persons acting under the immediate personal direction and supervision of
7 the pharmacist.

8 (b) The donation, acceptance, transfer, distribution or dispensing of
9 any drug in compliance with the provisions of the utilization of unused
10 medications act and any rules and regulations promulgated thereunder
11 shall not constitute a violation of this section.

12 Sec. 6. K.S.A. 2016 Supp. 65-1637 is hereby amended to read as
13 follows: 65-1637. ~~In every store, shop or other place defined in this act as~~
14 ~~a "pharmacy" there shall be a pharmacist in charge and, except as~~
15 ~~otherwise provided by law, the compounding and dispensing of~~
16 ~~prescriptions shall be limited to pharmacists only. Except as otherwise~~
17 ~~provided by the pharmacy act of this state, when a pharmacist is not in~~
18 ~~attendance at a pharmacy, the premises shall be enclosed and secured.~~
19 ~~Prescription orders may be written, oral, telephonic or by electronic~~
20 ~~transmission unless prohibited by law. Blank forms for written prescription~~
21 ~~orders may have two signature lines. If there are two lines, one signature~~
22 ~~line shall state: "Dispense as written" and the other signature line shall~~
23 ~~state: "Brand-exchange permissible." Prescriptions shall only be filled or~~
24 ~~refilled in accordance with the following requirements:~~

25 ~~(a) All prescriptions shall be filled in strict conformity with any~~
26 ~~directions of the prescriber, except:~~

27 ~~(1) That a pharmacist may provide up to three-month supply of a~~
28 ~~prescription drug that is not a controlled substance or psychotherapeutic~~
29 ~~drug when a practitioner has written a drug order to be filled with a~~
30 ~~smaller supply but included sufficient numbers of refills for a three-month~~
31 ~~supply; and~~

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

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

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

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

1 ~~(D) the federal food and drug administration has determined that a~~
2 ~~drug product of the same generic name is not bioequivalent to the~~
3 ~~prescribed brand name prescription medication.~~

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

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

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

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

42 ~~(e) If a prescription order contains a statement that during any~~
43 ~~particular time the prescription may be refilled at will, there shall be no~~

1 limitation as to the number of times that such prescription may be refilled
2 except that it may not be refilled after the expiration of the time specified
3 or one year after the prescription was originally issued, whichever occurs
4 first.

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

8 Nothing contained in this section shall be construed as preventing a
9 pharmacist from refusing to fill or refill any prescription if in the
10 pharmacist's professional judgment and discretion such pharmacist is of
11 the opinion that it should not be filled or refilled. *(a) The pharmacist shall*
12 *exercise professional judgment regarding the accuracy, validity and*
13 *authenticity of any prescription order consistent with federal and state*
14 *laws and rules and regulations. A pharmacist shall not dispense a*
15 *prescription drug if the pharmacist, in the exercise of professional*
16 *judgment, determines that the prescription is not a valid prescription*
17 *order.*

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

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

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

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

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

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

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

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

9 (e) *Regardless of the means of transmission to a pharmacy, only a*
10 *pharmacist or a pharmacist intern shall be authorized to receive a new*
11 *prescription order from a prescriber or transmitting agent. A pharmacist,*
12 *a pharmacist intern or a registered pharmacy technician may receive a*
13 *refill or renewal order from a prescriber or transmitting agent if such*
14 *registered pharmacy technician's supervising pharmacist has authorized*
15 *that function.*

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

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

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

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

28 (A) *The prescriber, in the case of a prescription electronically signed*
29 *by the prescriber, includes the statement "dispense as written" on the*
30 *prescription;*

31 (B) *the prescriber, in the case of a written 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 determined that a*
38 *drug product of the same generic name is not bioequivalent to the*
39 *prescribed brand name prescription medication;*

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

1 *supply; or*

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

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

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

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

14 *(D) the biological product is not an interchangeable biological*
15 *product for the prescribed biological product.*

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

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

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

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

37 *(2) A pharmacist may refill a prescription order issued on or after the*
38 *effective date of this act for any prescription drug, except a drug listed on*
39 *schedule II of the uniform controlled substances act or a narcotic drug*
40 *listed on any schedule of the uniform controlled substances act, without*
41 *the prescriber's authorization when all reasonable efforts to contact the*
42 *prescriber have failed and when, in the pharmacist's professional*
43 *judgment, continuation of the medication is necessary for the patient's*

1 health, safety and welfare. Such prescription refill shall only be in an
2 amount judged by the pharmacist to be sufficient to maintain the patient
3 until the prescriber can be contacted, but in no event shall a refill under
4 this paragraph be more than a seven-day supply or one package of the
5 drug. However, if the prescriber states on a prescription that there shall be
6 no emergency refilling of that prescription, then the pharmacist shall not
7 dispense any emergency medication pursuant to that prescription. A
8 pharmacist who refills a prescription order under this paragraph shall
9 contact the prescriber of the prescription order on the next business day
10 subsequent to the refill or as soon thereafter as possible. No pharmacist
11 shall be required to refill any prescription order under this paragraph. A
12 prescriber shall not be subject to liability for any damages resulting from
13 the refilling of a prescription order by a pharmacist under this paragraph
14 unless such damages are occasioned by the gross negligence or willful or
15 wanton acts or omissions by the prescriber.

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

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

23 (n) Nothing contained in this section shall be construed as preventing
24 a pharmacist from refusing to fill or refill any prescription if, in the
25 pharmacist's professional judgment and discretion, such pharmacist is of
26 the opinion that it should not be filled or refilled.

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

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

34 (2) an electronic prescribing technology;

35 (3) a pharmacy benefits management system; or

36 (4) a pharmacy record.

37 (p) Entry into an electronic records system as described in subsection
38 (o) shall be presumed to provide notice to the prescriber. Otherwise, the
39 pharmacist shall communicate the biological product dispensed to the
40 prescriber using facsimile, telephone, electronic transmission or other
41 prevailing means, provided that communication shall not be required
42 where:

43 (1) There is no FDA-approved interchangeable biological product for

1 *the product prescribed; or*

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

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

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

9 New Sec. 7. (a) An automated dispensing system shall be under the
10 supervision of a pharmacist licensed in Kansas, who may be retained on a
11 part-time basis and who shall be responsible for recordkeeping and storage
12 of all drugs and verifying and documenting each prescription drug
13 prepared or dispensed by such system.

14 (b) The board shall adopt such rules and regulations relating to
15 automated dispensing systems as necessary for proper control and
16 operation.

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

19 Sec. 8. K.S.A. 2016 Supp. 65-1642 is hereby amended to read as
20 follows: 65-1642. (a) Each pharmacy shall be equipped with proper
21 pharmaceutical utensils, in order that prescriptions can be properly filled
22 and United States ~~pharmacopoeia~~ *pharmacopeia* and national formulary
23 preparations properly compounded, and with proper sanitary appliances
24 ~~which~~ *that* shall be kept in a clean and orderly manner. The board shall
25 prescribe the minimum of such professional and technical equipment
26 which a pharmacy shall at all times possess.

27 (b) Each pharmacy shall keep a suitable book or file ~~which that~~
28 records every prescription order filled at the pharmacy and a medication
29 profile record system as provided under subsection (d). The book or file of
30 prescription orders shall be kept for a period of not less than five years.
31 The book or file of prescription orders shall at all times be open to
32 inspection by members of the board, the secretary of health and
33 environment, the duly authorized agents or employees of such board or
34 secretary and other proper authorities.

35 (c) (1) A medication profile record system shall be maintained in all
36 pharmacies for persons for whom prescriptions are dispensed. The
37 following information shall be recorded: (A) The name and address of the
38 patient for whom the medication is intended; (B) the prescriber's name, the
39 original date the prescription is dispensed and the number or designation
40 identifying the prescription; (C) the name, strength and quantity of the
41 drug dispensed and the name of the dispensing pharmacist; and (D) drug
42 allergies and sensitivities.

43 (2) Upon receipt of a prescription order, the pharmacist shall examine

1 the patient's medication profile record before dispensing the medication to
2 determine the possibility of a harmful drug interaction or reaction to
3 medication. Upon recognizing a potential harmful drug interaction or
4 reaction to the medication, the pharmacist shall take appropriate action to
5 avoid or minimize the problem—~~which~~ *that* shall, if necessary, include
6 consultation with the prescriber with documentation of actions taken on
7 the prescription record.

8 (3) A medication profile record shall be maintained for a period of not
9 less than five years from the date of the last entry in the record.

10 (4) All prescription drug orders communicated by way of electronic
11 transmission shall conform to federal and state laws and the provisions of
12 the board's rules and regulations.

13 (d) No registration shall be issued or continued for the conduct of a
14 pharmacy until or unless the provisions of this section have been complied
15 with.

16 (e) *Each pharmacy shall comply with the requirements of the federal*
17 *drug supply chain security act, 21 U.S.C. § 351 et seq.*

18 Sec. 9. K.S.A. 2016 Supp. 65-1643 is hereby amended to read as
19 follows: 65-1643. It shall be unlawful:

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

37 (b) For any person to ~~manufacture within this state any drugs except~~
38 ~~under the personal and immediate supervision of a pharmacist or such~~
39 ~~other person or persons as may be approved by the board after an~~
40 ~~investigation and a determination by the board that such person or persons~~
41 ~~is qualified by scientific or technical training or experience to perform~~
42 ~~such duties of supervision as may be necessary to protect the public health~~
43 ~~and safety; and no person shall manufacture any such drugs without first~~

1 ~~obtaining a registration so to do from the board. Such registration shall be~~
2 ~~subject to such rules and regulations with respect to requirements,~~
3 ~~sanitation and equipment, as the board may from time to time adopt for the~~
4 ~~protection of public health and safety violate the federal drug supply chain~~
5 ~~security act, 21 U.S.C. § 351 et seq.~~

6 (c) For any person to distribute at wholesale any drugs without first
7 obtaining a registration ~~so to do~~ as a wholesale distributor from the board.

8 (d) For any person to ~~sell or offer for sale at public auction or private~~
9 ~~sale in a place where public auctions are conducted, any drugs without first~~
10 ~~having obtained a registration from the board so to do, and it shall be~~
11 ~~necessary to obtain the permission of the board in every instance where~~
12 ~~any of the products covered by this section are to be sold or offered for~~
13 ~~sale operate as a third-party logistics provider within this state without~~
14 ~~having first obtained a registration from the board.~~

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

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

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

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

5 (i) For any person to operate a veterinary medical teaching hospital
6 pharmacy without first having obtained a registration to do so from the
7 board. Such registration shall be subject to the provisions of K.S.A. 65-
8 1662, and amendments thereto, and any rules and regulations adopted
9 pursuant thereto.

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

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

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

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

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

30 (2) there is a lawful prescription.

31 (k) For any pharmacy to allow customers to have direct access to any
32 controlled substance designated in ~~subsection (e) or (f)~~ of K.S.A. 65-
33 4113(e) or (f), and amendments thereto. Such controlled substance shall be
34 placed behind the counter or stored in a locked cabinet that is located in an
35 area of the pharmacy to which customers do not have direct access.

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

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

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

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

8 (o) *For any person to operate an automated dispensing system within*
9 *this state without having first obtained a registration from the board.*

10 Sec. 10. K.S.A. 2016 Supp. 65-1645 is hereby amended to read as
11 follows: 65-1645. (a) Application for registrations or permits under K.S.A.
12 65-1643, and amendments thereto, shall be made on a form prescribed and
13 furnished by the board. Applications for registration ~~to distribute at~~
14 ~~wholesale any drugs~~ shall contain such information as may be required by
15 the board in accordance with the provisions of K.S.A. 65-1655, and
16 amendments thereto, *and sections 13 and 14, and amendments thereto.*
17 The application shall be accompanied by the fee prescribed by the board
18 under the provisions of this section. When such application and fees are
19 received by the ~~executive secretary of the board~~ on or before the due date,
20 such application shall have the effect of temporarily renewing the
21 applicant's registration or permit until actual issuance or denial of the
22 renewal. However, if at the time of filing a proceeding is pending before
23 the board ~~which~~ *that* may result in the suspension, probation, revocation or
24 denial of the applicant's registration or permit, the board may declare, by
25 emergency order, that such application for renewal shall not have the effect
26 of temporarily renewing such applicant's registration or permit. Separate
27 applications shall be made and separate registrations or permits issued for
28 each separate place at which is carried on any of the operations for which a
29 registration or permit is required by K.S.A. 65-1643, and amendments
30 thereto.

31 (b) The nonrefundable fees required for the issuing of the licenses,
32 registrations or permits under the pharmacy act of the state of Kansas shall
33 be fixed by the board as herein provided, subject to the following:

34 (1) Pharmacy, new registration not more than \$150, renewal not more
35 than \$125;

36 (2) pharmacist, new license by examination not more than \$350;

37 (3) pharmacist, reinstatement application fee not more than \$250;

38 (4) pharmacist, biennial renewal fee not more than \$200;

39 (5) pharmacist, evaluation fee not more than \$250;

40 (6) pharmacist, reciprocal licensure fee not more than \$250;

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

42 (8) manufacturer, new registration not more than \$500, renewal not
43 more than \$400;

1 (9) ~~wholesaler~~*wholesale distributor*, new registration not more than
2 \$500, renewal not more than \$400, except that a ~~wholesaler~~ *wholesale*
3 *distributor* dealing exclusively in nonprescription drugs, the
4 manufacturing, distributing or dispensing of which does not require
5 registration under the uniform controlled substances act, shall be assessed
6 a fee for registration and re-registration not to exceed \$50;

7 (10) special auction not more than \$50;

8 (11) samples distribution not more than \$50, renewal not more than
9 \$50;

10 (12) institutional drug room, new registration not more than \$40,
11 renewal not more than \$35;

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

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

16 (15) veterinary medical teaching hospital pharmacy, new registration
17 not more than \$40, renewal not more than \$35;~~or~~

18 (16) durable medical equipment registration fee, not more than \$300,
19 renewal not more than \$300;

20 (17) *third-party logistics provider*, new registration not more than
21 \$500, renewal not more than \$400, except that a *third-party logistics*
22 *provider exclusively providing nonprescription drugs, the manufacturing,*
23 *distributing or dispensing of which does not require registration under the*
24 *uniform controlled substances act, shall be assessed a fee for registration*
25 *and re-registration not to exceed \$50;*

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

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

30 (20) *automated dispensing system registration fee*, not more than
31 \$40, renewal not more than \$35.

32 (c) For the purpose of fixing fees, the board may establish classes of
33 retail dealers' permits for retail dealers selling more than 12 different
34 nonprescription drug products, and the board may fix a different fee for
35 each such class of permit.

36 (d) The board shall determine annually the amount necessary to carry
37 out and enforce the provisions of this act for the next ensuing fiscal year
38 and shall fix by rules and regulations the fees authorized for such year at
39 the sum deemed necessary for such purposes. The fees fixed by the board
40 under this section immediately prior to the effective date of this act shall
41 continue in effect until different fees are fixed by the board by rules and
42 regulations as provided under this section.

43 (e) The board may deny renewal of any registration or permit

1 required by K.S.A. 65-1643, and amendments thereto, on any ground
2 ~~which that~~ would authorize the board to suspend, revoke or place on
3 probation a registration or permit previously granted pursuant to the
4 provisions of K.S.A. 65-1643, and amendments thereto. Registrations and
5 permits issued under the provisions of K.S.A. 65-1643 and 65-1644, and
6 amendments thereto, shall be conspicuously displayed in the place for
7 which the registration or permit was granted. Such registrations or permits
8 shall not be transferable. All such registrations and permits shall expire
9 every year. The expiration date shall be established by rules and
10 regulations adopted by the board. All registrations and permits shall be
11 renewed annually. Notice of renewal of registrations and permits shall be
12 ~~mailed~~ sent by the board to each registrant or permittee at least 30 days
13 prior to expiration of the registration or permit. If application for renewal
14 is not made prior to expiration, the existing registration or permit shall
15 lapse and become null and void on the date of its expiration, and no new
16 registration or permit shall be granted except upon payment of the required
17 renewal fee plus a penalty equal to the renewal fee. Failure of any
18 registrant or permittee to receive such notice of renewal shall not relieve
19 the registrant or permittee from the penalty hereby imposed if the renewal
20 is not made as prescribed.

21 (f) In each case in which a license of a pharmacist is issued or
22 renewed for a period of time less than two years, the board shall prorate to
23 the nearest whole month the license or renewal fee established pursuant to
24 this section.

25 (g) The board may require that fees paid for any examination under
26 the pharmacy act of the state of Kansas be paid directly to the examination
27 service by the person taking the examination.

28 Sec. 11. K.S.A. 65-1648 is hereby amended to read as follows: 65-
29 1648. (a) Any medical care facility pharmacy registered by the board may
30 keep drugs in such facility and may supply drugs to its inpatients and
31 outpatients. Distribution and control of prescription medications in a
32 medical care facility pharmacy shall be under the supervision of a
33 pharmacist in charge. A designated registered nurse or nurses or a licensed
34 physician assistant approved by the pharmacist in charge and under the
35 supervision of the pharmacist in charge shall be in charge of the
36 distribution and control of drugs of a medical care facility pharmacy when
37 a pharmacist is not on the premises. Drugs supplied to outpatients when a
38 pharmacist is not on the premises shall be limited to the quantity necessary
39 until a prescription can be filled.

40 (b) Nothing contained in this act shall be construed as prohibiting an
41 adult care home ~~which that~~ utilizes the services of a pharmacist, from
42 maintaining an emergency medication kit approved by the adult care
43 home's medical staff composed of a duly licensed practitioner and a

1 pharmacist. The emergency medication kit shall be used only in
2 emergency cases under the supervision and direction of a duly licensed
3 practitioner, and a pharmacist shall have supervisory responsibility of
4 maintaining said emergency medication kit.

5 (c) Every adult care home—~~which~~ *that* maintains an emergency
6 medication kit under subsection (b) shall comply with the following
7 requirements:

8 (1) Drugs in an emergency medication kit shall be maintained under
9 the control of the pharmacist in charge of the pharmacy from which the kit
10 came until administered to the patient upon the proper order of a
11 practitioner.

12 (2) Drugs contained within the emergency medication kit may
13 include controlled substances, but in such case a pharmaceutical services
14 committee shall be responsible for specifically limiting the type and
15 quantity of controlled substance to be placed in each emergency kit.

16 (3) Administration of controlled substances contained within the
17 emergency medication kit shall be in compliance with the provisions of the
18 uniform controlled substances act.

19 (4) The consultant pharmacist of the adult care home shall be
20 responsible for developing procedures, proper control and accountability
21 for the emergency medication kit and shall maintain complete and accurate
22 records of the controlled substances, if any, placed in the emergency kit.
23 Periodic physical inventory of the kit shall be required.

24 (d) (1) The ~~state~~ department of health and environment, any county,
25 city-county or multicounty health department, indigent health care clinic,
26 federally qualified health center and any private not-for-profit family
27 planning clinic, when registered by the board, may keep drugs for the
28 purpose of distributing drugs to patients being treated by that health
29 department, indigent health care clinic, federally qualified health center or
30 family planning clinic. Distribution and control of prescription
31 medications in a health department, indigent health care clinic, federally
32 qualified health center or family planning clinic shall be under the
33 supervision of a pharmacist in charge. A designated registered nurse or
34 nurses or a licensed physician assistant approved by the pharmacist in
35 charge shall be in charge of distribution and control of drugs in the health
36 department, indigent health care clinic, federally qualified health center or
37 family planning clinic under the supervision of the pharmacist in charge
38 when a pharmacist is not on the premises. Drugs supplied to patients when
39 a pharmacist is not on the premises shall be limited to the quantity
40 necessary to complete a course of treatment as ordered by the practitioner
41 supervising such treatment.

42 (2) The board shall adopt rules and regulations relating to specific
43 drugs to be used, to recordkeeping and to storage of drugs by a health

1 department, indigent health care clinic, federally qualified health center or
2 family planning clinic as are necessary for proper control of drugs.

3 (3) *Any medical care facility pharmacy registered by the board shall*
4 *comply with the applicable requirements of the federal drug supply chain*
5 *security act, 21 U.S.C. § 351 et seq.*

6 Sec. 12. K.S.A. 2016 Supp. 65-1655 is hereby amended to read as
7 follows: 65-1655. (a) The board shall require an applicant for registration
8 ~~to distribute at as a wholesale any drugs distributor~~ under K.S.A. 65-1643,
9 and amendments thereto, or an applicant for renewal of such a registration,
10 to provide the following information:

11 (1) The name, full business address and telephone number of the
12 applicant;

13 (2) all trade or business names used by the applicant;

14 (3) addresses, telephone numbers, and the names of contact persons
15 for all facilities used by the applicant for the storage, handling and
16 distribution of prescription drugs;

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

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

20 (A) If a person, the name of the person;

21 (B) if a partnership, the name of each partner; and the name of the
22 partnership;

23 (C) if a corporation, the name and title of each corporate officer and
24 director, the corporate names and the name of the state of incorporation;

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

27 (6) such other information as the board deems appropriate.

28 Changes in any information in this subsection ~~(a)~~ shall be submitted to
29 the board as required by ~~such~~ the board.

30 (b) In reviewing the qualifications for applicants for initial
31 registration or renewal of registration ~~to distribute at as a wholesale any~~
32 ~~drugs distributor~~, the board shall consider the following factors:

33 (1) Any convictions of the applicant under any federal, state or local
34 laws relating to drug samples, wholesale or retail drug distribution or
35 distribution of controlled substances;

36 (2) any felony convictions of the applicant under federal or state
37 laws;

38 (3) the applicant's past experience in the manufacture or distribution
39 of prescription drugs, including controlled substances;

40 (4) the furnishing by the applicant of false or fraudulent material in
41 any application made in connection with drug manufacturing or
42 distribution;

43 (5) suspension or revocation by federal, state or local government of

1 any license or registration currently or previously held by the applicant for
2 the manufacture or distribution of any drugs, including controlled
3 substances;

4 (6) compliance with registration requirements under previously
5 granted registrations, if any;

6 (7) compliance with requirements to maintain or make available to
7 the board or to federal state or local law enforcement officials those
8 records required by federal food, drug and cosmetic act; and rules and
9 regulations adopted pursuant thereto; and

10 (8) any other factors or qualifications the board considers relevant to
11 and consistent with the public health and safety.

12 (c) After consideration of the qualifications for applicants for
13 registration ~~to distribute at as a wholesale any drugs distributor~~, the board
14 may deny an initial application for registration or application for renewal
15 of a registration if the board determines that the granting of such
16 registration would not be in the public interest. The authority of the board
17 under this subsection to deny a registration ~~to distribute at as a wholesale~~
18 ~~any drugs distributor~~ shall be in addition to the authority of the board
19 under ~~subsection (e) of K.S.A. 65-1627(e)~~, and amendments thereto, or
20 ~~subsection (e) of K.S.A. 65-1645(e)~~, and amendments thereto.

21 (d) The board by rules and regulations shall require that personnel
22 employed by persons registered ~~to distribute at as a wholesale any drugs~~
23 ~~distributor~~ have appropriate education or experience, or both, to assume
24 responsibility for positions related to compliance with state registration
25 requirements.

26 (e) The board by rules and regulations may implement this section to
27 conform to any requirements of the federal ~~prescription drug marketing act~~
28 ~~of 1987 drug supply chain security act~~ (, 21 U.S.C. § ~~321 351~~ et seq.), in
29 effect on the effective date of this act.

30 (f) Each facility that engages in wholesale distribution must undergo
31 an inspection by the board or a third party recognized by the board to
32 inspect ~~and accredit~~ wholesale distributors for the purpose of inspecting
33 the wholesale distribution operations prior to initial registration and
34 periodically thereafter in accordance with a schedule to be determined by
35 the board but not less than once every three years. ~~The board shall have the~~
36 ~~authority to waive registration requirements for wholesale distributors that~~
37 ~~are accredited by an accrediting agency approved by the board.~~ The board
38 shall adopt rules and regulations to establish standards and requirements
39 for the issuance and maintenance of a wholesale distributor registration,
40 including inspections of wholesale distributor facilities domiciled in the
41 state.

42 (1) Individual or third party inspectors must demonstrate to the board
43 that they have received training or demonstrate familiarity with the

1 inspection standards. Evidence such as a letter of certification from a
2 training program, notice from the inspector's employing third party
3 organization or other means recognized by the board shall be accepted as
4 meeting the requirement.

5 (2) The board may register a wholesale distributor that is licensed or
6 registered under the laws of another state if:

7 (A) The requirements of that state are deemed by the board to be
8 substantially equivalent; or

9 (B) the applicant is inspected ~~and accredited~~ by a third party
10 recognized and approved by the board.

11 (g) A person licensed or approved by the ~~federal food and drug~~
12 ~~administration FDA~~ to engage in ~~the manufacture of drugs or devices~~
13 ~~engaged in~~ wholesale distribution need only satisfy the minimum federal
14 requirements for licensure provided in ~~federal food and drug~~
15 ~~administration FDA~~ regulations 21 C.F.R. Part 205 to provide wholesale
16 distribution services.

17 (h) The board by rule and regulation shall establish standards and
18 requirements for the issuance and maintenance of a wholesale distributor
19 registration, including, but not limited to, requirements regarding the
20 following:

21 (1) An application and renewal fee;

22 (2) a surety bond;

23 (3) registration and periodic inspections;

24 (4) certification of a designated representative;

25 (5) designation of a registered agent;

26 (6) storage of drugs and devices;

27 (7) handling, transportation and shipment of drugs and devices;

28 (8) security;

29 (9) examination of drugs and devices and treatment of those found to
30 be unacceptable as defined by the board;

31 (10) due diligence regarding other ~~wholesale distributors trading~~
32 ~~partners~~;

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

35 (12) procedures for operation; *and*

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

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

40 New Sec. 13. (a) The board shall require an applicant for registration
41 to operate as a third-party logistics provider under K.S.A. 65-1643, and
42 amendments thereto, or an applicant for renewal of such a registration, to
43 provide the following information:

- 1 (1) The name, full business address and telephone number of the
2 applicant;
- 3 (2) all trade or business names used by the applicant;
- 4 (3) addresses, telephone numbers, and the names of contact persons
5 for all facilities used by the applicant for the storage, handling and
6 distribution of prescription drugs;
- 7 (4) the type of ownership or operation of the applicant;
- 8 (5) the name of the owner or operator, or both, of the applicant,
9 including:
 - 10 (A) If a person, the name of the person;
 - 11 (B) if a partnership, the name of each partner, and the name of the
12 partnership;
 - 13 (C) if a corporation, the name and title of each corporate officer and
14 director, the corporate names and the name of the state of incorporation;
 - 15 (D) if a sole proprietorship, the full name of the sole proprietor and
16 the name of the business entity; and
 - 17 (6) such other information as the board deems appropriate.
- 18 Changes in any information in this subsection shall be submitted to the
19 board as required by the board.
- 20 (b) In reviewing the qualifications for applicants for initial
21 registration or renewal of registration to operate as a third-party logistics
22 provider, the board shall consider the following factors:
 - 23 (1) Any convictions of the applicant under any federal, state or local
24 laws relating to drug samples, wholesale or retail drug distribution or
25 distribution of controlled substances;
 - 26 (2) any felony convictions of the applicant under federal or state
27 laws;
 - 28 (3) the applicant's past experience in the manufacture or distribution
29 of prescription drugs, including controlled substances;
 - 30 (4) the furnishing by the applicant of false or fraudulent material in
31 any application made in connection with drug manufacturing or
32 distribution;
 - 33 (5) suspension or revocation by any federal, state or local government
34 of any license or registration currently or previously held by the applicant
35 for the manufacture or distribution of any drugs, including controlled
36 substances;
 - 37 (6) compliance with registration requirements under previously
38 granted registrations, if any;
 - 39 (7) compliance with requirements to maintain or make available to
40 the board or to federal state or local law enforcement officials those
41 records required by the federal food, drug and cosmetic act, and rules and
42 regulations adopted pursuant thereto; and
 - 43 (8) any other factors or qualifications the board considers relevant to

1 and consistent with the public health and safety.

2 (c) After consideration of the qualifications for applicants for
3 registration to operate as a third-party logistics provider, the board may
4 deny an initial application for registration or application for renewal of a
5 registration if the board determines that the granting of such registration
6 would not be in the public interest. The authority of the board under this
7 subsection to deny a registration to operate a third-party logistics provider
8 shall be in addition to the authority of the board under K.S.A. 65-1627(e)
9 or 65-1645(e), and amendments thereto.

10 (d) The board by rules and regulations shall require that personnel
11 employed by persons registered to operate as a third-party logistics
12 provider have appropriate education or experience, or both, to assume
13 responsibility for positions related to compliance with state registration
14 requirements.

15 (e) The board by rules and regulations may implement this section to
16 conform to any requirements of the federal drug supply chain security act,
17 21 U.S.C. § 351 et seq., in effect on the effective date of this act.

18 (f) Each facility that operates as a third-party logistics provider must
19 undergo an inspection by the board or a third party recognized by the
20 board to inspect third-party logistics provider operations prior to initial
21 registration and periodically thereafter in accordance with a schedule to be
22 determined by the board, but not less than once every three years. The
23 board shall adopt rules and regulations to establish standards and
24 requirements for the issuance and maintenance of a third-party logistics
25 provider registration, including inspections of third-party logistics provider
26 facilities domiciled in the state.

27 (1) Individual or third-party inspectors must demonstrate to the board
28 that they have received training or demonstrate familiarity with the
29 inspection standards. Evidence, such as a letter of certification from a
30 training program, notice from the inspector's employing third-party
31 organization or other means recognized by the board shall be accepted as
32 meeting the requirement.

33 (2) The board may register a third-party logistics provider that is
34 licensed or registered under the laws of another state if:

35 (A) The requirements of that state are deemed by the board to be
36 substantially equivalent; or

37 (B) the applicant is inspected by a third party recognized and
38 approved by the board.

39 (g) A person licensed or approved by the FDA to engage in third-
40 party logistics need only satisfy the minimum federal requirements for
41 licensure provided in FDA regulations 21 C.F.R. part 205 to provide third-
42 party logistics services.

43 (h) The board by rules and regulations shall establish standards and

1 requirements for the issuance and maintenance of a third-party logistics
2 provider registration, including, but not limited to, requirements regarding
3 the following:

- 4 (1) An application and renewal fee;
- 5 (2) a surety bond;
- 6 (3) registration and periodic inspections;
- 7 (4) certification of a designated representative;
- 8 (5) designation of a registered agent;
- 9 (6) storage of drugs and devices;
- 10 (7) handling, transportation and shipment of drugs and devices;
- 11 (8) security;
- 12 (9) examination of drugs and devices and treatment of those found to
13 be unacceptable as defined by the board;
- 14 (10) due diligence regarding other trading partners;
- 15 (11) creation and maintenance of records, including transaction
16 records;
- 17 (12) procedures for operation; and
- 18 (13) procedures for compliance with the requirements of the federal
19 drug supply chain security act, 21 U.S.C. § 351 et seq.

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

22 New Sec. 14. (a) The board shall require an applicant for registration
23 as an outsourcing facility under K.S.A. 65-1643, and amendments thereto,
24 or an applicant for renewal of such a registration, to provide the following
25 information:

- 26 (1) The name, full business address and telephone number of the
27 applicant;
- 28 (2) all trade or business names used by the applicant;
- 29 (3) the type of ownership or operation of the applicant;
- 30 (4) the name of the owner or operator, or both, of the applicant,
31 including:
 - 32 (A) If a person, the name of the person;
 - 33 (B) if a partnership, the name of each partner, and the name of the
34 partnership;
 - 35 (C) if a corporation, the name and title of each corporate officer and
36 director, the corporate names and the name of the state of incorporation;
 - 37 (D) if a sole proprietorship, the full name of the sole proprietor and
38 the name of the business entity;
- 39 (5) a copy of the valid FDA registration as an outsourcing facility as
40 required by 21 U.S.C. § 353b;
- 41 (6) the name and license number of the pharmacist who is designated
42 as the pharmacist-in-charge of the outsourcing facility;
- 43 (7) a copy of a current inspection report resulting from an FDA

1 inspection that indicates compliance with the requirements of the federal
2 food, drug and cosmetic act, including guidance documents and current
3 good manufacturing practices established by the FDA, or if no FDA
4 inspection has been conducted within the prior two-year period, the
5 outsourcing facility must undergo an inspection pursuant to subsection (e);
6 and

7 (8) such other information as the board deems appropriate.

8 Changes in any information in this subsection shall be submitted to the
9 board as required by the board.

10 (b) In reviewing the qualifications for applicants for initial
11 registration or renewal of registration as an outsourcing facility, the board
12 shall consider the following factors:

13 (1) Any convictions of the applicant under any federal, state or local
14 laws relating to drug samples, wholesale or retail drug distribution or
15 distribution of controlled substances;

16 (2) any felony convictions of the applicant under federal or state
17 laws;

18 (3) the applicant's past experience in the manufacture or distribution
19 of prescription drugs, including controlled substances;

20 (4) the furnishing by the applicant of false or fraudulent material in
21 any application made in connection with drug manufacturing or
22 distribution;

23 (5) suspension or revocation by any federal, state or local government
24 of any license or registration currently or previously held by the applicant
25 for the manufacture or distribution of any drugs, including controlled
26 substances;

27 (6) compliance with registration requirements under previously
28 granted registrations, if any;

29 (7) compliance with requirements to maintain or make available to
30 the board or to federal state or local law enforcement officials those
31 records required by the federal food, drug and cosmetic act, and rules and
32 regulations adopted pursuant thereto; and

33 (8) any other factors or qualifications the board considers relevant to
34 and consistent with the public health and safety.

35 (c) After consideration of the qualifications for applicants for
36 registration as an outsourcing facility, the board may deny an initial
37 application for registration or application for renewal of a registration if
38 the board determines that the granting of such registration would not be in
39 the public interest. The authority of the board under this subsection to deny
40 a registration to operate as an outsourcing facility shall be in addition to
41 the authority of the board under K.S.A. 65-1627(e) or 65-1645(e), and
42 amendments thereto.

43 (d) The board by rules and regulations shall require that personnel

1 employed by persons registered as an outsourcing facility have appropriate
2 education or experience, or both, to assume responsibility for positions
3 related to compliance with state registration requirements.

4 (e) Each outsourcing facility must undergo an inspection by the board
5 or a third party recognized by the board for the purpose of inspecting
6 operations prior to initial registration and periodically thereafter in
7 accordance with a schedule to be determined by the board, but not less
8 than once every three years. The board shall adopt rules and regulations to
9 establish standards and requirements for the issuance and maintenance of
10 an outsourcing facility registration, including inspections of facilities
11 domiciled in the state.

12 (f) The board by rules and regulations shall establish standards and
13 requirements for the issuance and maintenance of an outsourcing facility
14 registration, including, but not limited to, requirements regarding the
15 following:

- 16 (1) An application and renewal fee;
- 17 (2) a surety bond;
- 18 (3) registration and periodic inspections;
- 19 (4) certification of a designated representative;
- 20 (5) designation of a registered agent;
- 21 (6) storage of drugs and devices;
- 22 (7) handling, transportation and shipment of drugs and devices;
- 23 (8) security;
- 24 (9) examination of drugs and devices and treatment of those found to
25 be unacceptable as defined by the board;
- 26 (10) due diligence regarding other trading partners;
- 27 (11) creation and maintenance of records, including transaction
28 records; and
- 29 (12) procedures for operation.

30 (g) Notwithstanding any other provision, no outsourcing facility may
31 distribute or dispense any drug to any person pursuant to a prescription
32 unless it is also registered as a pharmacy in this state and meets all other
33 applicable requirements of federal and state law.

34 (h) This section shall be part of and supplemental to the pharmacy act
35 of the state of Kansas.

36 Sec. 15. K.S.A. 2016 Supp. 65-1663 is hereby amended to read as
37 follows: 65-1663. (a) It shall be unlawful for any person to function as a
38 pharmacy technician in this state unless such person is registered with the
39 board as a pharmacy technician. *Every person registered as a pharmacy*
40 *technician shall have graduated from an accredited high school or its*
41 *equivalent, obtained a graduate equivalent diploma (GED) or be enrolled*
42 *and in good standing in a high school education program.* Every person
43 registered as a pharmacy technician shall pass one or more examinations

1 identified and approved by the board within the period or periods of time
2 specified by the board after becoming registered. The board shall adopt
3 rules and regulations identifying the required examinations, when they
4 must be passed and establishing the criteria for the required examinations
5 and passing scores. The board may include as a required examination any
6 national pharmacy technician certification examination. *The board shall*
7 *adopt rules and regulations restricting the tasks a pharmacy technician*
8 *may perform prior to passing any required examinations.*

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

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

16 (d) Except as otherwise provided in this subsection, each pharmacy
17 technician registration issued by the board shall expire every two years.
18 The expiration date shall be established by rules and regulations adopted
19 by the board. To provide for a system of biennial renewal of pharmacy
20 technician registrations, the board may provide by rules and regulations
21 that registrations issued or renewed may expire less than two years from
22 the date of issuance or renewal. Each applicant for renewal of a pharmacy
23 technician registration shall be made on a form prescribed and furnished
24 by the board and shall be accompanied by a renewal fee fixed by the board
25 by rule and regulation not to exceed \$25. Pharmacy technician registration
26 renewal fees may be prorated for registration periods which are less than
27 biennial in accordance with rules and regulations of the board. Except as
28 otherwise provided in this subsection, the application for registration
29 renewal, when accompanied by the renewal fee and evidence satisfactory
30 to the board that the person has successfully complied with the rules and
31 regulations of the board establishing the requirements for a program of
32 continuing pharmacy technician education and received by the ~~executive~~
33 ~~secretary of the board~~ on or before the date of expiration of the
34 registration, shall have the effect of temporarily renewing the applicant's
35 registration until actual issuance or denial of the renewal registration. If at
36 the time of filing a proceeding is pending before the board which may
37 result in the suspension, probation, revocation or denial of the applicant's
38 registration, the board may by emergency order declare that the application
39 for renewal shall not have the effect of temporarily renewing such
40 applicant's registration. If the renewal fee is not paid prior to the expiration
41 date of the renewal year, the registration is void.

42 (e) *Continuing pharmacy technician education requirements shall be*
43 *fixed by the board at not more than 20 clock hours biennially of a program*

1 *of continuing education approved by the board. Continuing education*
2 *hours may be prorated for licensure periods that are less than biennial in*
3 *accordance with rules and regulations of the board.*

4 (f) (1) The board may limit, suspend or revoke a registration or deny
5 an application for issuance or renewal of any registration as a pharmacy
6 technician on any ground, which would authorize the board to take action
7 against the license of a pharmacist under K.S.A. 65-1627, and
8 amendments thereto.

9 (2) The board may require a physical or mental examination, or both,
10 of a person applying for or registered as a pharmacy technician.

11 (3) The board may temporarily suspend or temporarily limit the
12 registration of any pharmacy technician in accordance with the emergency
13 adjudicative proceedings under the Kansas administrative procedure act if
14 the board determines that there is cause to believe that grounds exist for
15 disciplinary action under this section against the registrant and that the
16 registrant's continuation of pharmacy technician functions would constitute
17 an imminent danger to the public health and safety.

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

20 ~~(f)~~(g) Every registered pharmacy technician, within 30 days of
21 obtaining new employment or *ceasing employment as a pharmacy*
22 *technician, shall furnish notify the board's executive secretary notice* of the
23 name and address of the new employer or *cessation of employment.*

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

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

43 ~~(h)~~(j) ~~A person holding a~~Every registered pharmacy technician

1 ~~registration~~ shall display ~~such~~ *the current* registration in that part of the
2 place of business in which such person is engaged in pharmacy technician
3 activities.

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

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

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

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

14 Sec. 16. K.S.A. 2016 Supp. 65-1676 is hereby amended to read as
15 follows: 65-1676. (a) It shall be unlawful for any person to function as a
16 pharmacist intern in this state unless such person is registered with the
17 board as a pharmacist intern.

18 (b) All applications for registration shall be made on a form to be
19 prescribed and furnished by the board. Each application for registration
20 shall be accompanied by a registration fee fixed by the board by rule and
21 regulation not to exceed \$25.

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

24 (d) (1) The board may limit, suspend or revoke a registration or deny
25 an application for issuance or renewal of any registration as a pharmacist
26 intern on any ground that would authorize the board to take action against
27 the license of a pharmacist under K.S.A. 65-1627, and amendments
28 thereto.

29 (2) The board may temporarily suspend or temporarily limit the
30 registration of any pharmacist intern in accordance with the emergency
31 adjudicative proceedings under the Kansas administrative procedure act, if
32 the board determines that there is cause to believe that grounds exist for
33 disciplinary action under this section against the registrant and that the
34 registrant's continuation of pharmacist intern functions would constitute an
35 imminent danger to the public health and safety.

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

38 (e) Every registered pharmacist intern, within 30 days of obtaining
39 new employment, shall furnish the ~~board's~~ executive secretary notice of
40 the name and address of the new employer.

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

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

9 ~~(g)~~(h) A person holding a pharmacist intern registration shall display
10 such registration in that part of the place of business in which such person
11 is engaged in pharmacist intern activities.

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

17 ~~(i)~~(j) This section shall be part of and supplemental to the pharmacy
18 act of the state of Kansas.

19 New Sec. 17. (a) The board shall adopt rules and regulations
20 governing proper compounding practices and distribution of compounded
21 drugs by pharmacists and pharmacies.

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

24 Sec. 18. K.S.A. 65-669 is hereby amended to read as follows: 65-669.
25 A drug or device shall be deemed to be misbranded:

26 (a) If its labeling is false or misleading in any particular.

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

28 (1) The name and place of business of the manufacturer, the packer or
29 the distributor, except that in the case of a prescription drug it shall bear
30 the name and place of business of the person responsible for the
31 production of the finished dosage form of the drug, the packer and the
32 distributor; except that nothing in ~~clause (1)~~ of this paragraph shall be
33 construed to apply to wholesalers and the requirement of ~~clause (1)~~ *this*
34 *paragraph* shall be satisfied by stating such information on the label of the
35 drug and filing a statement with such information with the secretary which
36 shall be made available by the secretary on request to local, public and
37 private health agencies, poison control centers, licentiates of the healing
38 arts, the state board of pharmacy, consumers and others to promote the
39 purposes of this act; in no event, however, shall the label contain less
40 information than required under federal law; and

41 (2) an accurate statement of the quantity of the contents in terms of
42 weight, measure, or numerical count, except that under ~~clause (2)~~ of this
43 paragraph reasonable variations shall be permitted and exemptions as to

1 small packages shall be allowed, in accordance with regulations prescribed
2 by the secretary, or issued under the federal act.

3 (c) If any word, statement, or other information required by or under
4 authority of this act to appear on the label or labeling is not prominently
5 placed thereon with such conspicuousness—(, as compared with other
6 words, statements, designs or devices, in the labeling), and in such terms
7 as to render it likely to be read and understood by the ordinary individual
8 under customary conditions of purchase and use.

9 (d) If it is for use by ~~man~~ human and contains any quantity of
10 narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-
11 eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine,
12 heroin, marijuana, morphine, opium, paraldehyde, peyote, or
13 sulphonmethane, or any chemical derivative of such substance, ~~which~~
14 ~~derivative~~ that has been by the secretary after investigation, found to be,
15 and by regulations under this act, or by regulations issued pursuant to 21
16 U.S.C. § 352 (d), designated as, habit forming, unless its label bears the
17 name and quantity or proportion of such substance or derivative and in
18 juxtaposition therewith the statement "warning-may be habit forming."

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

37 (2) As used in this ~~paragraph (e) subsection~~, the term "established
38 name," with respect to a drug or ingredient thereof, means: (A) The
39 applicable official name designated pursuant to 21 U.S.C. § 358, ~~or~~; (B) if
40 there is no such name and such drug, or such ingredient, is an article
41 recognized in an official compendium, then the official title thereof in such
42 compendium; or (C) if neither ~~clause subparagraph (A) nor clause~~
43 ~~subparagraph (B) of this subparagraph~~ applies, then the common or usual

1 name, if any, of such drug or of such ingredient. Where ~~clause~~
2 ~~subsection (B) of this subsection~~ applies to an article recognized in
3 the United States ~~pharmacopoeia~~ *pharmacopeia* and in the homeopathic
4 pharmacopoeia under different official titles, the official title used in the
5 United States ~~pharmacopoeia~~ *pharmacopeia* shall apply unless it is labeled
6 and offered for sale as a homeopathic drug, in which case the official title
7 used in the homeopathic pharmacopoeia shall apply.

8 (f) Unless its labeling bears: (1) Adequate directions for use; and (2)
9 such adequate warning against use in those pathological conditions or by
10 children where its use may be dangerous to health, or against unsafe
11 dosage or methods or duration of administration or application, in such
12 manner and form; as are necessary for the protection of users. Where any
13 requirement of ~~clause paragraph (1) of this paragraph~~, as applied to any
14 drug or device, is not necessary for the protection of the public health, the
15 secretary shall promulgate regulations exempting such drug or device from
16 such requirements. Articles exempted under regulations issued under 21
17 U.S.C. § 352 (f) may also be exempt.

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

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

42 (i) (1) If it is a drug and its container is so made, formed; or filled as
43 to be misleading; ~~or~~ (2) if it is an imitation of another drug; or (3) if it is

1 offered for sale under the name of another drug.

2 (j) If it is dangerous to health when used in the dosage, or with the
3 frequency of duration prescribed, recommended; or suggested in the
4 labeling thereof.

5 (k) If it is, ~~or~~ purports to be; or is represented as a drug composed
6 wholly or partly of insulin, unless: (1) It is from a batch with respect to
7 which a certificate or release has been issued pursuant to 21 U.S.C. § 356;;
8 and (2) such certificate or release is in effect with respect to such drug.

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

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

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

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

40 (p) Drugs and devices ~~which that~~ are, in accordance with the practice
41 of the trade, to be processed, labeled or repacked in substantial quantities
42 at establishments other than those where originally processed or packed
43 shall be exempt from any labeling or packaging requirements of this act if

1 such drugs and devices are being delivered, manufactured, processed,
2 labeled, repacked or otherwise held in compliance with regulations issued
3 by the secretary or under the federal act.

4 (q) A drug intended for use by ~~man~~ which ~~(A)~~ *human that: (1)* Is a
5 habit-forming drug to which K.S.A. 65-668, *and amendments thereto*,
6 applies; or ~~(B)~~ *(2)* because of its toxicity or other potentiality for harmful
7 effect, or the method of its use, or the collateral measures necessary to its
8 use, is not safe for use except under the supervision of a practitioner
9 licensed by law to administer such drug; or ~~(C)~~ *(3)* is limited by an
10 approved application under 21 U.S.C. § 355 or K.S.A. 65-669a, *and*
11 *amendments thereto*, to use under the professional supervision of a
12 practitioner licensed by law to administer such drug, shall be dispensed
13 only ~~(i)~~: *(A)* Upon a written prescription of a practitioner licensed by law
14 to administer such drug or upon the written prescription of a mid-level
15 practitioner as defined in ~~subsection (ii)~~ of K.S.A. 65-1626, and
16 amendments thereto, ~~or (ii)~~; *(B)* upon an oral prescription of such
17 practitioner or mid-level practitioner which is reduced promptly to writing
18 and filed by the pharmacist; or ~~(iii)~~ *(C)* by refilling, any such written or
19 oral prescription if such refilling is authorized by the prescriber either in
20 the original prescription or by oral order which is reduced promptly to
21 writing and filed by the pharmacist. The act of dispensing a drug contrary
22 to the provisions of this paragraph shall be deemed to be an act which
23 results in a drug 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 (ii)~~ 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 (q) 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 regulations issued by the

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

3 (t) A drug which is subject to ~~paragraph subsection (q) 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~~ *that* 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. 19. K.S.A. 65-1660 is hereby amended to read as follows: 65-
17 1660. (a) Except as otherwise provided in this section, the provisions of
18 the pharmacy act of the state of Kansas shall not apply to dialysates,
19 devices or drugs which are designated by the board for the purposes of this
20 section relating to treatment of a person with chronic kidney failure
21 receiving dialysis and which are prescribed or ordered by a physician or a
22 mid-level practitioner for administration or delivery to a person with
23 chronic kidney failure if:

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

26 (2) the wholesale distributor: (A) Delivers the drug or device to: (i) A
27 person with chronic kidney failure for self-administration at the person's
28 home or specified address; (ii) a physician for administration or delivery to
29 a person with chronic kidney failure; or (iii) a medicare approved renal
30 dialysis facility for administering or delivering to a person with chronic
31 kidney failure; and (B) has sufficient and qualified supervision to
32 adequately protect the public health.

33 (b) The wholesale distributor pursuant to subsection (a) shall be
34 supervised by a pharmacist consultant pursuant to rules and regulations
35 adopted by the board.

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

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

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

1 Sec. 20. K.S.A. 2016 Supp. 65-1669 is hereby amended to read as
2 follows: 65-1669. As used in the utilization of unused medications act:

3 (a) "Adult care home" has the same meaning as such term is defined
4 in K.S.A. 39-923, and amendments thereto.

5 (b) "Community mental health center" has the same meaning as such
6 term is defined in K.S.A. ~~75-3307e~~ 2016 Supp. 39-2002, and amendments
7 thereto.

8 (c) "Donating entities" means adult care homes, mail service
9 pharmacies, institutional drug rooms and medical care facilities who elect
10 to participate in the program.

11 (d) "Drug" has the same meaning as such term is defined in K.S.A.
12 65-1626, and amendments thereto.

13 (e) "Federally qualified health center" means a center ~~which that~~
14 meets the requirements for federal funding under 42 U.S.C. § 1396d(1) of
15 the public health service act, and amendments thereto, and ~~which that~~ has
16 been designated as a "federally qualified health center" by the federal
17 government.

18 (f) "Indigent health care clinic" has the same meaning as such term is
19 defined in K.S.A. 75-6102, and amendments thereto.

20 (g) "Institutional drug room" has the meaning as such term is defined
21 in K.S.A. 65-1626 ~~(bb)~~, and amendments thereto.

22 (h) "Mail service pharmacy" means a licensed Kansas pharmacy that
23 ships, mails or delivers by any lawful means a lawfully dispensed
24 medication in tamper-resistant packaging to residents of this state or
25 another state.

26 (i) "Medical care facility" has the same meaning as such term is
27 defined in K.S.A. 65-425, and amendments thereto.

28 (j) "Medically indigent" has the same meaning as such term is
29 defined in K.S.A. 75-6102, and amendments thereto.

30 (k) "Medication" means a prescription drug or drug as defined by this
31 section.

32 (l) "Mid-level practitioner" has the same meaning as such term is
33 defined in K.S.A. 65-1626, and amendments thereto.

34 (m) "Practitioner" has the same meaning as such term is defined in
35 K.S.A. 65-1626, and amendments thereto.

36 (n) "Prescription drug" means a drug ~~which that~~ may be dispensed
37 only upon prescription of a practitioner or mid-level practitioner
38 authorized by law and ~~which that~~ is approved for safety and effectiveness
39 as a prescription drug under section 505 or 507 of the federal food, drug
40 and cosmetic act, 52 Stat. 1040 (1938), 21 U.S.C.A. § 301.

41 (o) "Qualifying center or clinic" means an indigent health care clinic,
42 federally qualified health center or community mental health center.

43 (p) "Samples of medications or injectables" means a unit of drug that

1 is not intended to be sold and is intended to promote the sale of the drug.

2 Sec. 21. K.S.A. 2016 Supp. 65-2837a is hereby amended to read as
3 follows: 65-2837a. (a) It shall be unlawful for any person licensed to
4 practice medicine and surgery to prescribe, order, dispense, administer,
5 sell, supply or give or for a mid-level practitioner as defined in K.S.A. 65-
6 1626(ii), and amendments thereto, to prescribe, administer, supply or give
7 any amphetamine or sympathomimetic amine designated in schedule II, III
8 or IV under the uniform controlled substances act, except as provided in
9 this section. Failure to comply with this section by a licensee shall
10 constitute unprofessional conduct under K.S.A. 65-2837, and amendments
11 thereto.

12 (b) When any licensee prescribes, orders, dispenses, administers,
13 sells, supplies or gives or when any mid-level practitioner as defined in
14 K.S.A. 65-1626(ii), and amendments thereto, prescribes, administers, sells,
15 supplies or gives any amphetamine or sympathomimetic amine designated
16 in schedule II, III or IV under the uniform controlled substances act, the
17 patient's medical record shall adequately document the purpose for which
18 the drug is being given. Such purpose shall be restricted to one or more of
19 the following:

20 (1) The treatment of narcolepsy.
21 (2) The treatment of drug-induced brain dysfunction.
22 (3) The treatment of attention-deficit/hyperactivity disorder.
23 (4) The differential diagnostic psychiatric evaluation of depression.
24 (5) The treatment of depression shown by adequate medical records
25 and documentation to be unresponsive to other forms of treatment.

26 (6) The clinical investigation of the effects of such drugs or
27 compounds, in which case, before the investigation is begun, the licensee
28 shall, in addition to other requirements of applicable laws, apply for and
29 obtain approval of the investigation from the *state* board of healing arts.

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

32 (8) The treatment of binge eating disorder.

33 (9) The treatment of any other disorder or disease for which such
34 drugs or compounds have been found to be safe and effective by
35 competent scientific research ~~which findings have~~ *that has* been generally
36 accepted by the scientific community, in which case, the licensee before
37 prescribing, ordering, dispensing, administering, selling, supplying or
38 giving the drug or compound for a particular condition, or the licensee
39 before authorizing a mid-level practitioner to prescribe the drug or
40 compound for a particular condition, shall obtain a determination from the
41 board of healing arts that the drug or compound can be used for that
42 particular condition.

43 Sec. 22. K.S.A. 2016 Supp. 65-4202 is hereby amended to read as

1 follows: 65-4202. As used in this act: (a) "Board" means the ~~state~~ board of
2 nursing.

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

8 (1) Involve responsible nursing and therapeutic procedures for
9 patients with mental illness or intellectual disability requiring interpersonal
10 and technical skills in the observations and recognition of symptoms and
11 reactions of such patients, the accurate recording of such symptoms and
12 reactions and the carrying out of treatments and medications as prescribed
13 by a licensed physician or a mid-level practitioner as defined in ~~subsection~~
14 ~~(ii)~~ of K.S.A. 65-1626, and amendments thereto; ~~and~~

15 (2) require an application of techniques and procedures that involve
16 understanding of cause and effect and the safeguarding of life and health
17 of the patient and others; and

18 (3) require the performance of duties that are necessary to facilitate
19 rehabilitation of the patient or are necessary in the physical, therapeutic
20 and psychiatric care of the patient and require close work with persons
21 licensed to practice medicine and surgery, psychiatrists, psychologists,
22 rehabilitation therapists, social workers, registered nurses, and other
23 professional personnel.

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

26 (d) An "approved course in mental health technology" means a
27 program of training and study including a basic curriculum which shall be
28 prescribed and approved by the board in accordance with the standards
29 prescribed herein, the successful completion of which shall be required
30 before licensure as a mental health technician, except as hereinafter
31 provided.

32 Sec. 23. K.S.A. 65-7007 is hereby amended to read as follows: 65-
33 7007. (a) Each regulated chemical distributor and retailer shall submit to
34 the bureau:

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

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

42 (3) Any unusual or excessive loss or disappearance of a regulated
43 chemical under the control of the regulated chemical distributor or retailer.

1 The regulated person responsible for reporting a loss in-transit is the
2 distributor.

3 (b) Each report submitted pursuant to subsection (a), whenever
4 possible shall be made orally to the bureau at the earliest practicable
5 opportunity after the regulated chemical distributor or retailer becomes
6 aware of the circumstances involved and as much in advance of the
7 conclusion of the transaction as possible. Written reports of these
8 transactions shall subsequently be filed within 15 days after the regulated
9 chemical distributor or retailer becomes aware of the circumstances of the
10 event. A transaction may not be completed with a person whose
11 description or identifying characteristics have previously been furnished to
12 the regulated distributor by the bureau unless the transaction is approved
13 by the bureau.

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

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

19 (2) any practitioner as defined under ~~subsection (x)~~ of K.S.A. 65-
20 1626, and amendments thereto, who administers, dispenses or furnishes a
21 substance listed in ~~subsection (1)~~ of K.S.A. 65-7003(1), and amendments
22 thereto, to such patients within the scope of a practitioner's professional
23 practice. Such administration or dispensing shall be in the patient record;

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

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

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

34 (B) liquid cold or cough medicines;

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

36 (D) nasal drops or sprays.

37 Sec. 24. K.S.A. 65-669, 65-1633, 65-1635, 65-1648, 65-1660 and 65-
38 7007 and K.S.A. 2016 Supp. 65-1626, 65-1627, 65-1636, 65-1637, 65-
39 1642, 65-1643, 65-1645, 65-1655, 65-1663, 65-1669, 65-1676, 65-2837a
40 and 65-4202 are hereby repealed.

41 Sec. 25. This act shall take effect and be in force from and after its
42 publication in the Kansas register.