Proposed amendment to HB 2280

House Committee on
Health and Human Services

Session of 2021

HOUSE BILL No. 2280

By Committee on Health and Human Services

2-9

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

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

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

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

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

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

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

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

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

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

(B) is owned by the managing pharmacy;

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

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

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

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

(1) Application requirements;

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

(3) staffing, training and electronic supervision requirements;

(4) inventory record keeping and storage requirements;

(5) labeling requirements;

(6) establishment of policies and procedures;

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

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

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

(10) use of automated dispensing machines; and

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

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

New Sec. 4. (a) The board shall require an applicant for registration as a manufacturer or virtual manufacturer under K.S.A. 65-1643, and

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Stricken material in lines 29-31 and 34-35;

And by renumbering paragraphs accordingly

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

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

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

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

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

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

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

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

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

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

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

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

, including, but not limited to, delivering prescription medication to a patient by mail, common carrier, personal delivery or third-party delivery to any location requested by the patient

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

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

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