Session of 2022

## **SENATE BILL No. 381**

By Committee on Public Health and Welfare

1-24

AN ACT concerning health and healthcare; related to prescription medications; authorizing the prescribing and dispensing of drugs for off-label use to prevent and treat COVID-19 infections

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

Section 1. (a) (1) Notwithstanding any other provision of law to the contrary, a prescriber may prescribe, and a pharmacist shall dispense, in accordance with a prescription drug order, a prescription drug approved by the United States food and drug administration, including, but not limited to, hydroxychloroquine sulfate and ivermectin, for an off-label use to prevent or treat COVID-19 infection in a patient. The provisions in this paragraph shall not apply to any controlled substances described in K.S.A. 21-5705, and amendments thereto.

- (2) A prescriber may prescribe—and a pharmacist shall dispense a prescription drug pursuant to this subsection even if the patient has not been exposed to or tested positive for COVID-19.
- (b) (1) Notwithstanding any other provision of law to the contrary, a prescriber or pharmacist shall be immune from civil liability for damages, administrative fines or penalties for acts, omissions, healthcare decisions or the rendering of or the failure to render healthcare services if such prescriber or pharmacist is acting pursuant to this section. Any action taken by a prescriber or pharmacist-pursuant to this subsection shall not be considered unprofessional conduct.
- (2) (A) A recommendation, prescription, use or opinion of a prescriber or pharmacist related to a treatment for COVID-19, including a treatment that is not recommended or regulated by the licensing board, the department of health and environment or the federal food and drug administration, shall not be considered unprofessional conduct. The provisions of this paragraph shall apply retroactively to any disciplinary action accruing on or after March 12, 2020.
- (B) The licensing boards for prescribers <u>and pharmacists</u> shall independently review all disciplinary action for acts accruing from the period of March 12, 2020, through the effective date of this section. If disciplinary action was taken based on conduct described in this paragraph, in whole or in part, the board shall reconsider such action and rescind any such disciplinary action prohibited by this paragraph.

Proposed Amendments to SB 381
Senate Public Health and Welfare
Senator Steffen
February 8, 2022
Prepared by: Jenna Moyer
Office of Revisor of Statutes.

amending K.S.A. 65-1637 and repealing the existing sections

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- (c) As used in this section:
- (1) "COVID-19" means the disease caused by the novel coronavirus identified as SARS-CoV-2.
- (2) "Disciplinary action" means a licensing board's revocation, limitation, suspension or denial of license, a licensee being publicly censured or placed under probationary conditions or any other discipline issued by a licensing board for unprofessional conduct.
- (3) "Off-label use" means prescribing prescription drugs for treatments other than those stated in the labeling approved by the federal food and drug administration.
- (4) "Pharmacist" means any person licensed by the state board of pharmacy to practice pharmacy.
- (5) "Prescriber" means a person licensed by the state board of healing arts to practice medicine and surgery in this state or a "mid-level practitioner" as defined in K.S.A. 65-1626, and amendments thereto.
- (6) "Unprofessional conduct" means "professional incompetency" as defined in K.S.A. 65-1120, 65-1626 or 65-2837, and amendments thereto, and "unprofessional conduct" as defined in K.S.A. 65-1626 or 65-2837, and amendments thereto.
- Sec. 2. / This act shall take effect and be in force from and after its publication in the Kansas register.

(5)

Sec. 2 K.S.A. 65-1637 (attachment 1) Sec. 3 K.S.A. 65-1637 is hereby repealed

Sec. 4.

## Attachment 1 Section 2

- 65-1637. Prescription orders; requirements; compounding, filling and refilling of prescriptions; refusal to fill; brand exchange; interchangeable biological products. (a) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of any prescription order consistent with federal and state laws and rules and regulations. Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law, a pharmacist shall not dispense a prescription drug if the pharmacist, in the exercise of professional judgment, determines that the prescription is not a valid prescription order.
- (b) The prescriber may authorize an agent to transmit to the pharmacy a prescription order orally, by facsimile transmission or by electronic transmission, provided that the first and last names of the transmitting agent are included in the order.
- (c) (1) A new written or electronically prepared and transmitted prescription order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the first and last names of the transmitting agent shall be included in the order.
- (2) If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy.
- (3) An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to electronic transmission. An electronically prepared and transmitted prescription that is printed following electronic transmission shall be clearly labeled as a copy, not valid for dispensing.
- (4) The board is hereby authorized to conduct pilot projects related to any new technology implementation when deemed necessary and practicable, except that no state moneys shall be expended for such purpose.
- (d) An authorization to refill a prescription order or to renew or continue an existing drug therapy may be transmitted to a pharmacist through oral communication, in writing, by facsimile transmission or by electronic transmission initiated by or directed by the prescriber.
- (1) If the transmission is completed by the prescriber's agent, and the first and last names of the transmitting agent are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.
- (2) If the refill order or renewal order differs in any manner from the original order, such as a change of the drug strength, dosage form or directions for use, the prescriber shall sign the order as provided by subsection (c)(1).
- (e) Regardless of the means of transmission to a pharmacy, a pharmacist or a pharmacist intern shall be authorized to receive a new prescription order or a refill or renewal order from a prescriber or transmitting agent. A registered pharmacy technician may receive a refill, renewal or order for continuation of therapy that contains no changes from the original prescription from a prescriber or transmitting agent if such registered pharmacy technician's supervising pharmacist has authorized that function.
- (f) A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription order.

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

- (g) All prescriptions shall be filled or refilled in strict conformity with any directions of the prescriber, except that:
- (1) A pharmacist who receives a prescription order for a brand name drug product may exercise brand exchange with a view toward achieving a lesser cost to the purchaser unless:
- (A) The prescriber indicates "dispense as written" on the prescription or when communicating a prescription by oral order;
- (B) the FDA has determined that a biological product is not an interchangeable biological product for the prescribed biological product; or
- (C) the FDA has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication;
- (2) a pharmacist may provide up to a three-month supply of a prescription drug that is not a controlled substance or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply; or
- (3) except for a prescription for a controlled substance, a pharmacist may use professional judgment to make the following adaptations to a prescription order if a patient consents, the prescriber has not indicated "dispense as written" on the prescription, the pharmacist documents the adaptation on the patient's prescription record and the pharmacist notifies the prescriber:
  - (A) Change the prescribed quantity if:
  - (i) The prescribed quantity or package size is not commercially available;
  - (ii) the change in quantity is related to a change in dosage form; or
- (iii) the change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program;
  - (B) change the prescribed dosage form, strength or directions for use if it is in the best interest of the patient and the

change achieves the intent of the prescriber; or

- (C) complete missing information on the prescription order if there is evidence to support the change.
- (h) A pharmacist who selects an interchangeable biological product shall inform the patient or the patient's representative that an interchangeable biological product has been substituted for the prescribed biological product.
- (i) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled, except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.
- (j) Prescription orders shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be dispensed by the pharmacist. This record, if telephoned by other than the prescriber, shall bear the full name of the individual so telephoning. Nothing in this section shall be construed as altering or affecting in any way laws of this state or any federal act requiring a written prescription order.
- (k) (1) Except as provided in paragraph (2), no prescription shall be refilled unless authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filled by the pharmacist.
- (2) A pharmacist may refill a prescription order issued on or after the effective date of this act for any prescription drug, except a drug listed on schedule II of the uniform controlled substances act or a narcotic drug listed on any schedule of the uniform controlled substances act, without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety and welfare. Such prescription refill shall only be in an amount judged by the pharmacist to be sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this paragraph be more than a 30-day supply or one package of the drug. However, if the prescriber states on a prescription that there shall be no emergency refilling of that prescription, then the pharmacist shall not dispense any emergency medication pursuant to that prescription. A pharmacist who refills a prescription order under this paragraph shall contact the prescriber of the prescription order on the next business day subsequent to the refill or as soon thereafter as possible. No pharmacist shall be required to refill any prescription order under this paragraph. A prescriber shall not be subject to liability for any damages resulting from the refilling of a prescription order by a pharmacist under this paragraph unless such damages are occasioned by the gross negligence or willful or wanton acts or omissions by the prescriber.
- (l) If any prescription order contains a provision that the prescription may be refilled a specific number of times within or during any particular period, such prescription shall not be refilled except in strict conformity with such requirements.
- (m) Any pharmacist who exercises brand exchange and dispenses a less expensive drug product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug.
- (n) Except as provided in K.S.A. 65-1635(e), and amendments thereto, and as may otherwise be provided by law, nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if, in the pharmacist's professional judgment and discretion, such pharmacist is of the opinion that it should not be filled or refilled.
- (o) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:
  - (1) An interoperable electronic medical records system;
  - an electronic prescribing technology;
  - (3) a pharmacy benefits management system; or
  - (4) a pharmacy record.
- (p) Entry into an electronic records system as described in subsection (o) shall be presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that communication shall not be required where:
  - (1) There is no FDA-approved interchangeable biological product for the product prescribed; or
  - (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.
  - (q) A pharmacist shall maintain a record of any biological product dispensed for at least five years.
- (r) The board shall maintain a link on its website to the current lists of all biological products that the FDA has determined to be interchangeable biological products.

, unless such prescription is being used to treat or prevent a COVID-19 infection.