SESSION OF 2021

SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2280

As Amended by Senate Committee on Public Health and Welfare

Brief*

HB 2280, as amended, would create law allowing a patient desiring to be prescribed a U.S. Food and Drug Administration (FDA)-approved drug for an off-label use of such drug to sign, or have a legal representative sign, a liability waiver for such use. The bill would also amend and update the Pharmacy Act of the State of Kansas (Act) with regard to the powers, duties, and functions of the State Board of Pharmacy (Board). The bill would create new law to address the confidentiality of investigations, inspections, and audits and provide for exceptions under specific circumstances; allow for the cost of additional compliance inspections and audits required as a condition of probation or other disciplinary action to be charged to a licensee or registrant; define the practice of telepharmacy; require the Board to adopt rules and regulations for the oversight and administration of telepharmacy; and address the registration of manufacturers and virtual manufacturers. The bill would amend the Act to make modifications and add definitions; make the Board's disciplinary authority consistent across all license and registration types and include compliance with federal requirements; and address prescription adaptation and transfer. The bill would also amend the Act to provide that all civil fines assessed for violations of the Act that are collected must be credited to the State Board of Pharmacy Fee Fund (Fee Fund), instead of a portion being credited to the State General Fund.

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*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at http://www.kslegislature.org

The bill would make New Sections 2 through 5 part of and supplemental to the Act.

The bill would make technical amendments and further amendments to the Act as described below.

Off-Label Use of FDA-Approved Drugs (New Section 1)

The bill would create new law allowing a patient desiring to be prescribed an FDA-approved drug for an off-label use of such prescription drug to sign, or have a legal representative sign, a liability waiver. The waiver would relieve the physician from liability for any claims arising out of the act of prescribing such drugs for off-label use.

For the purposes of this section of the bill, "off-label use" would mean utilizing a prescription drug for treatment in a manner other than the manner approved by the FDA stated on the labeling.

The provisions of this section of the bill would not apply to "controlled substances" as defined in statute. The bill would provide that nothing in this bill would relieve a physician of the duty to receive consent from a patient or the patient's legal representative before assisting in the care or treatment of such patient.

Confidentiality of Investigations and Related Documents (New Section 2)

The bill would make confidential any complaint, investigation, report, record, or other information relating to a complaint or investigation that is received, obtained, or maintained by the Board. The bill would prohibit the Board or its employees from disclosing such information in a manner that would identify or enable identification of the person who is the subject or source of the information. The bill would allow disclosure of such information as follows:

- In any proceeding conducted by the Board 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;

- 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 a manner that would prevent identification of any other person who is the subject or source of the information; or

- 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 the Act.

The bill would prohibit an agency receiving any confidential complaint or report, record, or other information disclosed by the Board, as authorized by the bill, from disclosing such information, unless otherwise authorized by law. Except as specifically authorized in the bill, an applicant, registrant, or individual would be prohibited access to any complaint, investigation, report, record, or information concerning an investigation in progress until the investigation and enforcement action was completed.

The bill would prohibit the release of a record, report, or other information that is subject to other specific state or federal laws concerning its disclosure.

Costs of Compliance Inspections and Audits (New Section 3)

The bill would authorize the Board to charge a licensee or registrant the actual costs of additional inspections and audits that occur as a condition of probation or other

disciplinary action. The bill would allow the Board to impose additional disciplinary action if the licensee or registrant failed to comply with a Board order regarding payment of such costs.

The actual costs of inspections would include, but not be limited to: salaries and wages; travel, mileage, and lodging; subsistence allowances, document storage, shipping, and handling; or other expenses deemed reasonable and necessary by the Board. All moneys collected for the inspections would be deposited into the State Treasury to the credit of the Fee Fund.

Telepharmacy and Rules and Regulations (New Section 4)

Definitions

The bill would define the following terms:

- "Telepharmacy" would mean the practice of pharmacy by a pharmacist located in Kansas using telecommunications or other automations and technologies to deliver personalized, electronically documented, real-time 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; and

- "Telepharmacy outlet" would mean a pharmacy located in Kansas that:
    - Is registered as a pharmacy under the Act;
    - Is owned by the managing pharmacy;
    - Is connected *via* computer link, video link, audio link, or other functionally equivalent

telecommunications equipment with a supervising pharmacy located in Kansas; and

- Has a pharmacy technician on-site who performs activities under the electronic supervision of a pharmacist located in Kansas.

The bill would require a pharmacist to 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 require the pharmacist be available to consult with and assist the pharmacy technician in performing activities.

Rules and Regulations for a Managing Pharmacy and Telepharmacy

The bill would require the Board to adopt rules and regulations necessary to specify additional criteria for a managing pharmacy and telepharmacy outlet not later than January 1, 2023. The criteria to be specified would include, but not be limited to:

- Application requirements;
- Structural, security, technology, and equipment requirements;
- Staffing, training, and electronic supervision requirements;
- Inventory record keeping and storage requirements;
- Labeling requirements;
- Establishment of policies and procedures;
- The number of telepharmacy outlets that may be operated by a supervising pharmacy;

- Use of automated dispensing machines; and

- Criteria for requesting exemptions or waivers from the requirements set forth in rules and regulations pertaining to the established criteria for a managing pharmacy and telepharmacy outlet.

Registration of Manufacturers and Virtual Manufacturers (New Section 5)

The bill would clarify the registration requirements for a manufacturer or virtual manufacturer. The bill would authorize the Board to require an applicant for registration as a manufacturer or virtual manufacturer, or an applicant for renewal of such registration, to provide the following information:

- The name, full business address, and telephone number of the applicant;

- All trade or business names used by the applicant;

- All addresses, telephone numbers, and the names of contact individuals for all facilities used by the applicant for storage, handling, and distribution of prescription drugs or devices;

- The type of ownership or operation of the applicant;

- The name of the owner or operator of the applicant, including:
    - If an individual, the name of the individual;
    - If a partnership, the name of each partner and the name of the partnership;
    - If a corporation, the name and title of each corporate officer and director of the

corporation, and the name of the state of incorporation; or

- If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

- Any other information the Board deems appropriate.

The bill would require changes in any of the above information be submitted to the Board in a form and manner prescribed by the Board.

Qualifications for Manufacturer and Virtual Manufacturer Applicants

The bill would require the Board consider the following factors in reviewing the qualifications for applicants for initial registration or renewal of registration as a manufacturer or virtual manufacturer:

- Any convictions of the applicant under any federal, state, or local laws relating to drug samples, manufacture of drugs or devices, wholesale or retail drug distribution, or distribution of controlled substances;

- Any felony convictions of the applicant under federal or state laws;

- The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

- The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

- Discipline, censure, warning, suspension, or revocation by federal, state, or local government of

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

- Compliance with registration requirements under previously granted registrations, if any;

- Compliance with requirements to maintain or make available to the Board or to the federal, state, or local law enforcement officials those records required by the federal Food, Drug, and Cosmetic Act, and rules and regulations adopted pursuant to such act; and

- Any other factors or qualifications deemed by the Board to be relevant to and consistent with public health and safety.

After consideration of the qualifications for applicants for registration as a manufacturer or virtual manufacturer, the bill would authorize the Board to deny an initial application for registration or application for renewal of a registration if the Board determines the granting of such registration would not be in the public interest. The authority of the Board to deny such registration as a manufacturer or virtual manufacturer would be in addition to other statutory authority of the Board pertaining to the suspension, revocation, placement on probationary status, or denial of a registration.

Rules and Regulations

The bill would require the Board, by rules and regulations, to require personnel employed by persons registered as a manufacturer or virtual manufacturer have appropriate education or experience to assume responsibility for positions related to compliance with state registration requirements.

The bill would provide that the Board, by rules and regulations, may implement the section of the bill on the registration of manufacturers and virtual manufacturers to conform with any requirements of the federal Drug Supply Chain Security Act in effect on July 1, 2021.

Inspections

The bill would require each facility that manufactures drugs or devices to undergo an inspection by the Board, or a third party recognized by the Board, prior to initial registration and periodically thereafter according to a schedule determined by the Board, but not less than once every three years. The bill would require the Board adopt rules and regulations no later than July 1, 2022, to establish standards and requirements for the issuance and maintenance of manufacturer and virtual manufacturer registration, including inspections.

Registration Requirements for Manufacturers and Virtual Manufacturers Registered in Other States

The bill would authorize the Board to register a manufacturer or virtual manufacturer licensed or registered under the laws of another state if the requirements of that state are deemed by the Board to be substantially equivalent to Kansas requirements, or the applicant is inspected by a third party recognized and approved by the Board.

Standards and Requirements for Registration

The bill would require the Board, by rules and regulations, to establish standards and requirements for the issuance and maintenance of manufacturer and virtual manufacturer registration, including, but not limited to, requirements regarding:

- An application and renewal fee;

- A surety bond;
- Registration and periodic inspections;
- Certification of a designated representative;
- Designation of a registered agent;
- Storage of drugs and devices;
- Handling, transportation, and shipment of drugs and devices;
- Security;
- Examination of drugs and devices and treatment of those found to be unacceptable as defined by the Board;
- Due diligence regarding other trading partners;
- Creation and maintenance of records, including transaction records;
- Procedures for operation; and
- Procedures for compliance with the requirements of the federal Drug Supply Chain Security Act.

Use of Titles (Section 6)

The bill would amend the Act to clarify the use or exhibition of the titles “drugstore,” “pharmacy,” or “apothecary” or any combination of such titles. The bill would clarify it would be unlawful to use such terms or any title or description of like import, or any term designed to take the place of such titles, if such title is being used in the context of health, medical, or pharmaceutical care and the individual, firm, or corporation has not provided a disclaimer sufficient to

notify customers that a pharmacist is not employed at the location.

Definitions (Section 7)

The bill would amend and add definitions to the Act as follows:

- "Address" would be added to mean, with respect to prescriptions, the physical address where a patient resides, including street address, city, and state;

- "Compounding" would be amended to clarify compounding does not include reconstituting any mixed drug according to the U.S. Food and Drug Administration (FDA)-approved labeling for the drug. [*Note:* The term "oral or topical drug" is replaced with "mixed drug," and language regarding compounding not including preparing any sterile or nonsterile preparation that is essentially a copy of a commercially available product is deleted.];

- "Current good manufacturing practices" or "CGMP" would be added to mean requirements for ensuring drugs and drug products are consistently manufactured, repackaged, produced, stored, and dispensed in accordance with 21 CFR §§ 207, 210, and 211;

- "Device" would be added to mean an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part or accessory that:

    - Is recognized in the official national formulary, or the U.S. Pharmacopoeia, or any supplement of those; is intended for use in the diagnosis of disease or other conditions; is

used for the care, mitigation, treatment, or prevention of disease in human or other animals; or is intended to affect the structure or any function of the body of human or other animals; and

- Does not achieve its primary intended purposes through chemical action within or on the body of human or other animals, and is not dependent upon being metabolized for the achievement of any of its primary intended purposes;

- "Direct supervision" would be amended to mean the process by which the responsible pharmacist shall observe and direct the activities of a pharmacist intern or pharmacy technician; be readily and immediately available at all times activities are performed; provide personal assistance, direction, and approval throughout the times the activities are performed; and complete the final check before dispensing;

- "Dispense" or "dispensing" would be amended to mean 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;

- "Dispenser" would be amended to replace the term "medication" with "drugs or devices" with regard to the items dispensed by a dispenser who is a practitioner or pharmacist. "Dispenser" would also mean a retail pharmacy, hospital pharmacy, or group of pharmacies under common ownership and control that do not act as a wholesale distributor. Affiliated warehouses or distribution

centers of such entities under common ownership and control that do not act as a wholesale distributor would be excluded from the definition;

- "Diversion" would be added to mean the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use;

- "Institutional drug room" would be amended to add residents of a juvenile correctional facility to those whose needs would be provided by an institutional drug room;

- "Interchangeable biological product" would be amended to mean a biological product that the FDA has identified in the "Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" as meeting the standards for "interchangeability" as defined in federal law regarding licensure of biological products as biosimilar or interchangeable in effect on January 1, 2017;

- "Medical care facility" would be amended to mean the same as defined in KSA 65-425, except that the term would also include psychiatric hospitals and psychiatric residential treatment facilities as defined in KSA 2020 Supp. 39-3002;

- "Medication order" would be amended to mean a written or oral order by a prescriber, or the prescriber's authorized agent, for administration of a drug or device to a patient in a Kansas licensed medical care facility or a Kansas licensed nursing facility or nursing facility for mental health, as defined by KSA 39-923;

- “Pharmacist intern” or “intern” would be amended to mean a student currently enrolled in and in good standing with an accredited pharmacy program;

- “Pharmacy,” “drugstore,” or “apothecary” would be amended to include any electronic medium. The definition would also be amended to clarify where the following terms could be displayed as used in the context of health, medical, or pharmaceutical care or services: “pharmacist,” “pharmaceutical chemist,” “pharmacy,” “apothecary,” “drugstore,” “druggist,” “drugs,” “drug sundries,” or any of these words or combinations of these words or words of similar import displayed in any language or on any sign containing any of these words, and the characteristic symbols of pharmacy or the characteristic prescription sign “Rx”;

- “Pharmacy prescription application” would be amended to mean software used to process prescription information and is either installed on a pharmacy’s computers or servers and is controlled by the pharmacy or is maintained on the servers of an entity that sells electronic pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its server;

- “Preceptor” would be amended to mean a licensed pharmacist who possesses at least two years’ experience as a pharmacist and who supervises and is responsible for the actions of pharmacist interns obtaining pharmaceutical experience;

- “Prescription” or “prescription order” would be amended to mean the front and back of a lawful written, electronic, or facsimile order from a prescriber or an oral order from a prescriber or the prescriber’s authorized agent that communicates

the prescriber's instructions for a prescription drug or device to be dispensed;

- "Readily retrievable" or "readily available" would be amended to mean that records kept in hard copy or by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records quickly and easily during an inspection or investigation, or within a reasonable time not to exceed 48 hours of a written request from the Board or other authorized agent;

- "Reverse distributor" would replace the terms "returns processor" and "reverse logistics provider" but would retain the meaning of those terms;

- "Virtual manufacturer" would be added to mean an entity that engages in the manufacture of a drug or device for which it:
    - Owns the new drug application or abbreviated new drug application number, if a prescription drug;
    - Owns the unique device identification number, as available, for a prescription device;
    - Contracts with a contract manufacturing organization for the physical manufacture of the drug or device;
    - Is not involved in the physical manufacture of the drug or device; and
    - Does not store or take physical possession of the drug or device;

- "Virtual wholesale distributor" would be added to mean a wholesale distributor that sells, brokers, or transfers a drug or device but never physically possesses the product;

- "Wholesale distributor" would be amended to mean any person engaged in wholesale distribution or reverse distribution of drugs or devices, other than a manufacturer, co-licensed partner, or third-party logistics provider; and

- "Wholesale distribution" would be amended to replace the term "prescription drug" with "drug or device" and "third-party returns processor" with a registered "reverse distributor" where those terms appear in the definition, to update a reference to the edition and section of the Internal Revenue Code regarding a charitable organization, and to remove multiple references to what a wholesale distribution does not include.

The bill would remove the definitions of "application service provider," "intermediary," and "return" from the Act.

Disciplinary Action (Section 8)

Pharmacist

The bill would modify the disciplinary action the Board would be authorized to take on an application, renewal, or license of a pharmacist. The bill would authorize the Board to also limit, condition, or place in a probationary status the license of any pharmacist upon certain findings. The bill would clarify one of the findings that would warrant disciplinary action to include violations of both the federal and state Uniform Controlled Substances Act. The bill would authorize the Board to take disciplinary action if the licensee has failed to keep, has failed to file with the Board, or has falsified records required to be kept or filed by the provisions of the Act, the federal or state Uniform Controlled Substances Act, or rules and regulations adopted by the Board.

Retail Dealer

The bill would authorize the Board to suspend, revoke, place in probationary status, or deny an application for a retail dealer's permit when information in the possession of the Board discloses such operations are not being conducted according to law or the rules and regulations of the Board.

Pharmacy

The bill would authorize the Board to deny an application or renewal, limit, condition, or place in a probationary status the registration of a pharmacy upon the existence of certain findings.

A conviction for a violation of the Act, the federal or state Uniform Controlled Substances Act, or the federal or state Food, Drug, and Cosmetic Act would be amended to also apply to a pharmacy. Fraudulently claiming money for pharmaceutical services would apply to pharmacies.

The bill would add the following findings for such purposes:

- The registrant has obtained, renewed, or attempted to obtain or renew a registration by false or fraudulent means, including misrepresentation of a material fact or falsification of any application;

- The registrant has refused to permit the Board or its duly authorized agents to inspect the registrant's establishment according to the provisions of the Act, federal or state Uniform Controlled Substances Act, or federal or state Food, Drug, and Cosmetic Act;

- The registrant has failed to keep, has failed to file with the Board, or has falsified records required to be kept or filed by the provisions of the Act, federal

or state Uniform Controlled Substances Act, or rules and regulations adopted by the Board;

- A pharmacy has been operated in such a manner that violations of the provisions of the federal or state Food, Drug, and Cosmetic Act, federal or state Uniform Controlled Substances Act, or any rule and regulation of the Board have occurred;

- A pharmacy has been operated in such a manner that violations of the Prescription Monitoring Program Act of the State of Kansas or any rules and regulations of the Board have occurred;

- The registrant has failed to furnish the Board, its investigators, or its representatives any information legally requested by the Board; or

- The registrant has violated or failed to comply with any lawful order or directive of the Board.

Other Registrations

The bill would amend law regarding disciplinary action against various other registrations to clarify such action would be allowed with regard to registrations to manufacture or repackage drugs or devices or to operate as an outsourcing facility, institutional drug room, or automated dispensing system. The bill would also add limitations and conditions of registrations and denial of applications for renewal to the actions the Board would be authorized to take against those providers and wholesale distributors, third-party logistics providers, and sellers of durable medical equipment.

The bill would authorize the Board to take such actions on applications and registrations if any of the findings specified occur. The bill would make amendments and add findings authorizing the Board to take disciplinary action if a registrant or a registrant's agent:

- Has obtained, renewed, or attempted to obtain or renew a registration by false or fraudulent means, including misrepresentation of a material fact or falsification of any application;

- Has been convicted of a felony under any federal or state law relating to the manufacture, compounding, dispensing, or distribution of drugs or devices;

- Has had any federal registration for the manufacture, compounding, dispensing, or distribution of drugs or devices suspended, limited, denied, disciplined, censured, or revoked;

- Has refused to permit the Board or its duly authorized agents to inspect the registrant's establishment according to the provisions of the Act, federal and state Uniform Controlled Substances Act, or the federal and state Food, Drug, and Cosmetic Act;

- Has failed to keep, has failed to file with the Board, or has falsified records required to be kept or filed by the provision of the Act, the federal or state Uniform Controlled Substances Act, or rules and regulations adopted by the Board;

- Has violated the federal Uniform Controlled Substances Act, has violated the federal Food, Drug, and Cosmetic Act or any rules and regulations adopted under such act;

- Has had a registration revoked, suspended, or limited; has been censured; or has had other disciplinary action taken or an application for registration denied by the proper registering authority of another state, territory, District of Columbia, or other country, a certified copy of the record of the action of the other jurisdiction being

conclusive evidence of such action. When the Board determines that action under this subsection of the bill requires the immediate protection of the public interest, the bill would require the Board to conduct an emergency proceeding under the Kansas Administrative Procedure Act;

- Has failed to furnish the Board, its investigators, or its representatives any information legally requested by the Board; or

- Has violated or failed to comply with any lawful order or directive of the Board.

Examinations (Section 9)

The bill would authorize the Board to adopt rules and regulations relating to the score an applicant must receive in order to pass the examinations required for licensure. The bill would require the Board only accept a passing score on an examination required for licensure from an applicant's first five attempts at taking such examination.

Reciprocal Licensure

The bill would allow the Board, in its discretion, to license a pharmacist, without examination, who is duly registered or licensed by examination in some other state, except the Board would be allowed to require such individual take the multi-state jurisprudence examination approved by the Board. The bill would authorize the Board to adopt rules and regulations relating to the score such individual would be required to receive in order to pass the multi-state jurisprudence examination. The bill would require the Board only accept a passing score on an examination required for licensure from an applicant's first five attempts taking such examination.

The bill would provide reciprocal licensure may be denied for any reasons set forth in statute that authorize the Board to deny an application or renewal of any pharmacist license.

The bill would remove a provision prohibiting an applicant who has taken an examination for licensure approved by the Board and failed to complete it successfully from being considered for licensure by reciprocity within one year from the date the applicant sat for the examination.

Prescription Orders (Section 10)

The bill would clarify, regardless of the means of transmission to a pharmacy, a pharmacist or a pharmacist intern would be authorized to receive a new prescription order or a refill or renewal order from a prescriber or transmitting agent. The bill would authorize a registered pharmacy technician to receive a refill, renewal, or order for the 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.

Continuing law requires all prescriptions be filled or refilled in strict conformity with any directions of the prescriber but provides exceptions. The bill would amend these exceptions as follows:

- A pharmacist who receives a prescription order for a brand name product would be authorized to exercise brand exchange with a view toward achieving a lesser cost to the purchaser, unless:
    - The prescriber indicates "dispense as written" on the prescription or when communicating a prescription by oral order;
    - The FDA has determined that a biological product is not an interchangeable biological

product for the prescribed biological product [*Note:* Existing law excludes biological products from brand exchange.]; or

- The FDA has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication. [*Note:* This is continuing law.]

- Except for a prescription for a controlled substance, a pharmacist would be allowed to use professional judgment to make 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. The adaptions would include:
  - Changing the prescribed quantity if the prescribed quantity or package size is not commercially available, the change in quantity is related to a change in dosage form, or the change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program;
  - Changing 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
  - Completing missing information on the prescription order if there is evidence to support the change.

[*Note:* Continuing law allows a pharmacist to provide up to a three-month supply of a prescription that is not a controlled substance or a 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.]

The bill would increase from a maximum 7-day supply to a maximum 30-day supply the prescription amount a pharmacist would be authorized to refill 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.

Unlawful Acts (Section 11)

The bill would amend the unlawful acts under the Act as follows:

- Devices would be added to those items a person would be prohibited from distributing at wholesale without first obtaining a registration as a wholesale distributor from the Board;

- Devices would be added to the items a person would be prohibited in any manner from distributing or dispensing samples of without first having obtained a permit from the Board to do so;

- It would be unlawful for any person to manufacture in Kansas any drugs or devices except under the personal and immediate supervision of a pharmacist or such other individual approved by the Board after an investigation and determination by the Board that such individual is qualified by scientific and technical training or experience to perform such duties of supervision necessary to protect public health and safety. No individual would be authorized to manufacture any drugs or devices without first obtaining a registration to do so from the Board;

- The exceptions to the unlawful act of selling or distributing a controlled substance in a pharmacy

would be amended to require an individual purchasing, receiving, or otherwise acquiring such controlled substance to produce a valid photo identification;

- It would be unlawful for a person to supply medical-grade oxygen to an end user without first obtaining a registration from the Board. This would not apply to sales made in the regular course of the person's business or sales by charitable organizations exempt from federal income taxation pursuant to the Internal Revenue Code of 1986; and

- It would be unlawful for any person to distribute drugs or devices into Kansas as an out-of-state manufacturer of such drugs or devices without first obtaining a registration as a manufacturer from the Board.

Transfer of Prescriptions (Section 12)

The bill would allow for the filling or refilling of a valid prescription for prescription drugs not listed in Schedule II of the Uniform Controlled Substances Act that is on file in a pharmacy registered in any state and has been transferred from one pharmacy to another. [*Note:* Continuing law allows such action for licensed pharmacies only.]

The conditions and exceptions to such action would be amended as follows:

- Prior to dispensing pursuant to any such prescription:
    - The dispensing pharmacist would be required to ensure records and notifications are in compliance with rules and regulations adopted by the Board; and

- Upon receipt of a request for the transfer of a prescription record, if the requested pharmacist is satisfied in the professional judgment of the pharmacist that the request is valid and legal, the requested pharmacy would be required to:
    - Provide such information accurately and completely;
    - Ensure records and notifications are made in compliance with rules and regulations adopted by the Board; and
    - Provide information in a timely manner to avoid interruption in the medication therapy of the patient.

The bill would allow a pharmacy to forward to another pharmacy an original, unfilled prescription for a noncontrolled substance or electronically forward an original, unfilled, electronic prescription for a controlled substance, at the request of the patient, in compliance with the provisions of the federal or state Uniform Controlled Substances Act.

Nonresident Pharmacy (Section 13)

The bill would prohibit nonresident pharmacies from shipping, mailing, or delivering, in any manner, prescription drugs or devices to a patient, patient's agent, or prescriber's office in Kansas unless registered as a nonresident pharmacy in Kansas. [*Note:* Current law addresses only the shipping, mailing, or delivering of prescription drugs to a patient in Kansas.]

The bill would delete provisions authorizing the Board to assess civil fines, file a complaint against a nonresident pharmacy, and remit the fees for disciplinary action taken. [*Note:* Provisions addressing civil fines are addressed for all licensees and registrants in Section 14 of the bill.]

The bill would authorize the Board to limit, condition, revoke, suspend, or place in probationary status a registration or deny an application for issuance or renewal of any registration of a nonresident pharmacy on any ground that would authorize the Board to take action against the registration of a pharmacy.

Civil Fines (Section 14)

Continuing law authorizes the Board, in addition to any other penalty prescribed under the Act, to assess civil fines, after a notice and opportunity to be heard in accordance with the Kansas Administrative Procedure Act, against the following licensees and registrants: pharmacists, any licensee in accordance with emergency adjudicative proceedings under the Kansas Administrative Procedure Act, retail dealers, and pharmacies. The bill would expand the list of licensees and registrants to which the civil fine provision applies to include manufacturers or repackagers of drugs or devices, wholesale distributors, third-party logistics providers, outsourcing facilities, institutional drug rooms or automated dispensing systems, sellers of durable medical equipment, or places of business where such operations take place.

The bill would clarify, in addition to civil fines assessed in violation of the Act and rules and regulations of the Board adopted under the Act, the Board would be authorized to assess civil fines for violation of the federal or state Uniform Controlled Substances Act and rules and regulations of the Board adopted under such acts. The bill would also authorize the Board to assess civil fines for violation of the federal or state Food, Drug, and Cosmetic Act or rules and regulations adopted by the Board under such acts.

The bill would also amend provisions regarding where civil fines assessed or collected would be credited to have all fines credited to the Fee Fund instead of a portion going to the State General Fund (SGF).

Background

HB 2280 was introduced by the House Committee on Health and Human Services at the request of Representative Eplee on behalf of the State Board of Pharmacy (Board). The Senate Committee on Public Health and Welfare added the contents of SB 211, with an exception for controlled substances. SB 211 would allow a patient, or the patient's legal representative, to sign a waiver relieving a physician from liability for claims arising out of the act of prescribing FDA-approved drugs for off-label use.

[*Note:* A companion bill, SB 251, was introduced in the Senate.]

House Committee on Health and Human Services

In the House Committee hearing on HB 2280, **proponent** testimony was provided by a representative of the Board and representatives of the Kansas Association of Chain Drug Stores (KACDS) and the Kansas Pharmacists Association (KPhA). The Board representative stated the amendments proposed by the bill have been carefully crafted by the Board and vetted with the pharmacy stakeholder community. The Board representative outlined the key provisions of the bill, including language defining telepharmacy. The KPhA representative noted the work of the Telepharmacy Task Force in identifying KPhA members' concerns and recommending criteria to help provide an environment in which telepharmacy could be a positive addition. The KACDS representative indicated support for the inclusion of telepharmacy in the bill but requested the bill be amended to strike provisions regarding distance requirements and limiting the number of prescriptions dispensed, which KACDS members believe to be arbitrary limits on access for Kansas patients. The KACDS representative also recommended the definition of dispense be amended to address a distinction unique to Kansas between the method of prescription delivery allowed by a pharmacy and that

allowed for mail-order pharmacies. Written-only proponent testimony was provided by a representative of the Kansas Hospital Association.

No other testimony was provided.

The House Committee amended the bill to remove the following from the criteria for a managing pharmacy and telepharmacy: the minimum and maximum distances from the nearest pharmacy where a telepharmacy outlet may be established, if necessary and applicable, and the facilities that may be exempt; and the maximum number of prescriptions that may be dispensed by a telepharmacy outlet. The House Committee also amended the definition of "dispense" and "dispensing" in the Act, limited the number of times an applicant for a pharmacist license may take the licensing exam to obtain a passing score, and prohibited a pharmacist to exercise brand exchange when the prescriber communicates a prescription by oral order.

Senate Committee on Public Health and Welfare

In the Senate Committee hearing, **proponent** testimony was provided by a representative of the Board. Written-only **proponent** testimony was provided by KACDS and the Kansas Hospital Association.

No other testimony was provided.

The Senate Committee amended the bill to remove the following provisions:

- The ability of the Board, upon the request of a facility that is registered or applying for registration or renewal with the Board, to conduct an inspection of the place of business where such operation is conducted, regardless of whether the facility is located in Kansas, at the request of resident and nonresident facilities registered or applying for

registration or renewal with the Board and related costs;

- The ability of the Board to create rules and regulations concerning the definition of "direct supervision";

- The reference to "publicly or privately censure" in regard to the Board's disciplinary actions;

- Provisions related to requests for expungement of minor violations and the Board's power to adopt rules and regulations to establish minor violations; and

- Provisions related to the authority of the Board to adopt rules and regulations necessary to establish the criteria for a pharmacist to be designated by the Board and act as a preceptor.

The Senate Committee also removed sections of the bill that would have amended law related to amending the fees for the issuing of licenses, registrations, or permits under the Act and increasing renewal fees for a pharmacy technician and registration fees for a pharmacist intern. Those statutory provisions would remain as continuing law.

The Senate Committee also amended the bill in regard to the maximum number of times the Board may accept a passing score on an examination required for licensure to an applicant's first five attempts for those applicants seeking reciprocal licensure.

The Senate Committee further amended the bill to add the contents of SB 211, regarding waivers for off-label use of prescription drugs, with an exception for controlled substances.

SB 211 (Waivers for Off-label Use of Prescription Drugs)

SB 211 was introduced by Senator Erickson and Senator Steffen.

Senate Committee on Public Health and Welfare

SB 211 was referred to the Senate Committee on February 11, 2021. No hearing was held on the bill.

Fiscal Information

HB 2280

According to the fiscal note prepared by the Division of the Budget on the bill, as introduced, the Board states the agency has been planning for the bulk of the changes reflected in the bill for several years. Expenses have been budgeted, and no increase in expenditures is anticipated. Any changes to the Board's current Licensing and Compliance Divisions would be offset by revenue from applications and reimbursement of actual costs of inspections and investigations. All other changes have been contemplated by the Board, incorporated into the Board's current five-year strategic plan, and could be absorbed within existing agency staff.

The Board does not anticipate there would be a significant number of telepharmacy registrations. However, those facilities would be required to apply for registration with the Board and pay application and annual renewal fees to offset agency expenditures.

The bill would require depositing administrative fine revenue to the Fee Fund rather than the SGF. The Board estimates the maximum reduction to SGF revenue and the maximum increase to Fee Fund revenue would be $80,000.

The Board estimates enactment of the bill could result in additional revenue of $399,867 for the Fee Fund. This amount includes $248,267 from planned increases to existing regulatory fees, plus $115,600 from the new nonresident facility renewal fee. The Board indicates there are currently 2,312 nonresident facilities. The estimate of revenue from the nonresident facility renewal fee assumes that all current nonresident facilities renew in FY 2022. While the bill allows a maximum renewal fee of $250, the Board plans to adopt a renewal fee of approximately $50 in FY 2022. The Board is unable to estimate the number of new nonresident facility applications and, therefore, the amount of revenue that would result from the new nonresident facility application fees is unknown. The Board notes that increases in statutory fee maximums will not have an impact on Fee Fund revenue until the Board amends current fees by rules and regulations.

Any fiscal effect associated with the bill is not reflected in *The FY 2022 Governor's Budget Report*.

SB 211

According to the fiscal note prepared by the Division of the Budget on SB 211, as introduced, the Board of Healing Arts (BOHA) estimates enactment of the bill would have no fiscal effect on the BOHA. It is possible the BOHA could receive additional complaints, but the BOHA indicates any additional workload would be managed within existing resources.

The Board of Pharmacy indicates the bill could result in additional expenditures in the form of staff time and resources to investigate any complaints; however, the Board of Pharmacy is unable to estimate the costs.

Pharmacy Act of the State of Kansas; powers, duties, and functions of the State Board of Pharmacy; confidentiality of investigations, inspections, and audits; licensing; registration and permitting requirements; exhibition of titles; fees; prescription orders; telepharmacy; rules and regulations; U.S. Food and Drug Administration; off-label use of prescription drugs