Pharmacy Act of the State of Kansas and Emergency Medical Services Act; Sub. for SB 238

Sub. for SB 238 amends and updates 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 updates the Emergency Medical Services Act (EMS Act) to clarify the oversight provided by medical directors with regard to emergency medical services and to provide an alternate procedure for appointment of a medical director.

The bill creates 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 makes these new sections part of and supplemental to the Act.

The bill amends the Act to modify 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 requires all civil fines assessed for violations of the Act that are collected to be credited to the State Board of Pharmacy Fee Fund (Fee Fund), instead of a portion being credited to the State General Fund.

Amendments to the Act and EMS Act are described below.

Pharmacy Act of the State of Kansas

Confidentiality of Investigations and Related Documents

The bill makes 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 prohibits the Board or its employees from disclosing such information in a manner that identifies or enables identification of the person who is the subject or source of the information. The bill allows 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 prevents 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 constitute grounds for action under the Act.

The bill prohibits 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 is prohibited access to any complaint, investigation, report, record, or information concerning an investigation in progress until the investigation and enforcement action is completed.

The bill prohibits 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

The bill authorizes 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 allows the Board to impose additional disciplinary action if the licensee or registrant fails to comply with a Board order regarding payment of such costs.

The actual costs of inspections include, but are not 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 are to be deposited into the State Treasury to the credit of the Fee Fund.

Telepharmacy and Rules and Regulations

Definitions. The bill defines the following terms:

- "Telepharmacy" means 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" means 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 requires 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 requires the pharmacist to be available to consult with and assist the pharmacy technician in performing activities.

Rules and regulations for a managing pharmacy and telepharmacy. The bill requires 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 include, but are not 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

The bill clarifies the registration requirements for a manufacturer or virtual manufacturer. The bill authorizes 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 requires changes in any of the above information to be submitted to the Board in a form and manner prescribed by the Board.

Qualifications for manufacturer and virtual manufacturer applicants. The bill requires the Board to 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 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.

The bill authorizes the Board, after consideration of the qualifications for applicants for registration as a manufacturer or virtual manufacturer, to deny an initial application for registration or application for renewal of a registration if the Board determines the granting of such registration is not in the public interest. The authority of the Board to deny such registration as a manufacturer or virtual manufacturer is 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 requires the Board, by rules and regulations, to require personnel employed by any person 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 authorizes the Board, by rules and regulations, to implement this 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 [21 USC § 351 *et seq.*] in effect on July 1, 2021.

Inspections. The bill requires 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 requires the Board to 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 authorizes 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 requires 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

The bill clarifies the use or exhibition of the titles "drugstore," "pharmacy," or "apothecary" or any combination of such titles. The bill clarifies it is 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 the title is 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

The bill amends and adds definitions to the Act as follows:

- "Address" means, with respect to prescriptions, the physical address where a patient resides, including street address, city, and state;
- "Compounding" is 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" means 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" means 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" is 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" is 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" is 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" also means 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 are removed from the definition;

- "Diversion" means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use;

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

- "Interchangeable biological product" is amended to mean a biological product 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" is amended to mean the same as defined in KSA 65-425, except the term also includes psychiatric hospitals and psychiatric residential treatment facilities as defined in KSA 2020 Supp. 39-2002;

- "Medication order" is 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" is amended to mean a student currently enrolled in and in good standing with an accredited pharmacy program;

- "Pharmacy," "drugstore," or "apothecary" is amended to include any electronic medium. The definition is also 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" is amended to mean software used to process prescription information that 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" is 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" is 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" is amended to mean records kept in hard copy or by automatic data processing applications or other electronic or mechanized record-keeping systems that can be separated 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" replaces the terms "returns processor" and "reverse logistics provider," but retains the meaning of those terms;

- "Virtual manufacturer" means 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" means a wholesale distributor that sells, brokers, or transfers a drug or device but never physically possesses the product;

- "Wholesale distributor" is 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" is 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 the definition of a wholesale distribution does not include.

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

Disciplinary Action

Pharmacist. The bill modifies the disciplinary action the Board is authorized to take on an application, renewal, or license of a pharmacist. The bill authorizes the Board to also limit, condition, or place in a probationary status the license of any pharmacist upon certain findings. The bill clarifies one of the findings that warrants disciplinary action to include violations of both the federal and state Uniform Controlled Substances Act. The bill authorizes 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 authorizes 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 authorizes 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.

Provisions authorizing the above actions of the Board regarding 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 are amended to apply to a pharmacy as well as to an owner or pharmacist. Similarly, provisions regarding fraudulently claiming money for pharmaceutical services apply to pharmacies.

The bill adds 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 amends law regarding disciplinary action against various other registrations to clarify such action is 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 adds limitations and conditions of registrations and

denial of applications for renewal to the actions the Board is authorized to take against those providers and wholesale distributors, third-party logistics providers, and sellers of durable medical equipment.

The bill authorizes the Board to take such actions on applications and registrations if any of the findings specified occur. The bill amends law and adds 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 provisions 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; 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 the action. When the Board determines that action under this subsection of the bill requires the immediate protection of the public interest, the bill requires 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

The bill authorizes 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 requires the Board to 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 allows 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 is allowed to require the individual to take the multi-state jurisprudence examination approved by the Board. The bill authorizes the Board to adopt rules and regulations relating to the score such individual is required to receive in order to pass the multi-state jurisprudence examination. The bill requires the Board to only accept a passing score on an examination required for licensure from an applicant's first five attempts taking the examination.

The bill provides that 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 removes 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

The bill clarifies, regardless of the means of transmission to a pharmacy, a pharmacist or a pharmacist intern is authorized to receive a new prescription order or a refill or renewal order from a prescriber or transmitting agent. The bill authorizes 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 to be filled or refilled in strict conformity with any directions of the prescriber but provides exceptions. The bill amends these exceptions as follows:

- A pharmacist who receives a prescription order for a brand-name product is 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 a biological product is not an interchangeable biological product for the prescribed biological product [*Note:* Former law excluded biological products from brand exchange.]; or
    - The FDA has determined 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 is 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 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 increases from a maximum 7-day supply to a maximum 30-day supply the prescription amount a pharmacist is 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

The bill amends the descriptions of unlawful acts under the Act as follows:

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

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

- It is 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 is authorized to manufacture any drugs or devices without first obtaining a registration to do so from the Board;

- The list of exceptions to the unlawful act of selling or distributing a controlled substance in a pharmacy is amended to require an individual purchasing, receiving, or otherwise acquiring such controlled substance to produce a photo identification that is valid;

- It is unlawful for a person to supply medical-grade oxygen to an end user without first obtaining a registration from the Board. This does 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 is 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.

Nonresident Fees

The bill requires an application for a registration or permit submitted for a facility physically located outside of Kansas to be accompanied by an additional nonresident fee prescribed by the Board through rules and regulations. The bill requires the fee to not exceed $350 for a new registration and $250 for a renewal.

Transfer of Prescriptions

The bill allows 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 are amended as follows:

- Prior to dispensing, pursuant to any such prescription, the dispensing pharmacist is 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 the request is valid and legal, the requested pharmacy is 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 allows 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

The bill prohibits 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:* Prior law addressed only the shipping, mailing, or delivering of prescription drugs to a patient in Kansas.]

The bill deletes 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 authorizes 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 authorizes the Board to take action against the registration of a pharmacy.

Civil Fines

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 expands 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 clarifies, in addition to civil fines assessed for violation of the Act and rules and regulations of the Board adopted under the Act, the Board is 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 authorizes 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 amends provisions regarding where civil fines assessed or collected are to be credited to have all fines credited to the Fee Fund instead of a portion going to the State General Fund.

Emergency Medical Services Act

The bill amends the EMS Act to clarify the oversight to be provided by medical directors with regard to emergency medical services and to provide an alternate procedure for appointment of a medical director. The bill defines "medical oversight" to mean to review, approve, and implement medical protocols and to approve and monitor the activities, competency, and education of emergency medical service providers. The term "medical oversight" replaces existing terms describing the oversight provided by a medical director.

Since the definition of medical oversight includes the approval of medical protocols, the bill amends the definition of "medical protocols" to remove language referencing the required approval of medical protocols by a county medical society or the medical staff of a hospital to which the ambulance service primarily transports patients or, if neither are able or available, by the Medical Advisory Council.

The bill clarifies that an operator is required to designate a medical director to provide medical oversight, which includes the review, approval, and implementation of medical protocols. However, the Emergency Medical Services Board is allowed to approve an alternate procedure for medical oversight by a physician if no medical director is available for designation by the operator. [*Note:* Continuing law defines "operator" as a person or municipality with a permit to operate an ambulance service.]

The bill also removes the designation of a supervising physician to clarify an emergency medical services provider is protected from liability for civil damages for implementing instructions from a physician, a physician assistant, an advanced practice registered nurse, or a licensed practical nurse when rendering emergency care. Under continuing law, emergency medical services providers are not protected from civil liability for damages resulting from their gross negligence or willful or wanton acts or omissions.