

## Substitute for SENATE BILL No. 491

AN ACT concerning the board of pharmacy; relating to continuous quality improvement programs and nonresident pharmacy; enacting the prescription monitoring program act; creating the prescription monitoring program advisory committee, methamphetamine precursor scheduling task force and veterinary prescription monitoring program task force; amending K.S.A. 65-1657 and repealing the existing section.

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

New Section 1. This act shall be known and may be cited as the prescription monitoring program act.

New Sec. 2. As used in this act, unless the context otherwise requires:

- (a) "Board" means the state board of pharmacy.
- (b) "Dispenser" means a practitioner or pharmacist who delivers a scheduled substance or drug of concern to an ultimate user, but does not include:
  - (1) A licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care;
  - (2) a medical care facility as defined in K.S.A. 65-425, and amendments thereto, practitioner or other authorized person who administers such a substance;
  - (3) a registered wholesale distributor of such substances;
  - (4) a veterinarian licensed by the Kansas board of veterinary examiners who dispenses or prescribes a scheduled substance or drug of concern; or
  - (5) a practitioner who has been exempted from the reporting requirements of this act in rules and regulations promulgated by the board.
- (c) "Drug of concern" means any drug that demonstrates a potential for abuse and is designated as a drug of concern in rules and regulations promulgated by the board.
- (d) "Patient" means the person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, or both.
- (e) "Pharmacist" means an individual currently licensed by the board to practice the profession of pharmacy in this state.
- (f) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, optometrist or other person authorized by law to prescribe or dispense scheduled substances and drugs of concern.
- (g) "Scheduled substance" means controlled substances included in schedules II, III or IV of the schedules designated in K.S.A. 65-4107, 65-4109 and 65-4111, and amendments thereto, respectively, or the federal controlled substances act (21 U.S.C. 812).

New Sec. 3. (a) The board shall establish and maintain a prescription monitoring program for the monitoring of scheduled substances and drugs of concern dispensed in this state or dispensed to an address in this state.

(b) Each dispenser shall submit to the board by electronic means information required by the board regarding each prescription dispensed for a substance included under subsection (a). The board shall promulgate rules and regulations specifying the nationally recognized telecommunications format to be used for submission of information that each dispenser shall submit to the board. Such information may include, but not be limited to:

- (1) The dispenser identification number;
  - (2) the date the prescription is filled;
  - (3) the prescription number;
  - (4) whether the prescription is new or is a refill;
  - (5) the national drug code for the drug dispensed;
  - (6) the quantity dispensed;
  - (7) the number of days supply of the drug;
  - (8) the patient identification number;
  - (9) the patient's name;
  - (10) the patient's address;
  - (11) the patient's date of birth;
  - (12) the prescriber identification number;
  - (13) the date the prescription was issued by the prescriber; and
  - (14) the source of payment for the prescription.
- (c) The board shall promulgate rules and regulations specifying the transmission methods and frequency of the dispenser submissions required under subsection (b).
- (d) The board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided that all information required by rules and regulations is submitted in this alternative format.

New Sec. 4. The board shall not impose any charge for the establishment or maintenance of the prescription monitoring program database on a registered wholesale distributor, pharmacist, dispenser or other person authorized to prescribe or dispense scheduled substances and drugs of concern. The board shall not charge any fees for the transmission of data to the database or for the receipt of information from the database, except that the board may charge a fee to an individual who requests the individual's own prescription monitoring information in accordance with procedures adopted by the board.

New Sec. 5. (a) The prescription monitoring program database, all information contained therein and any records maintained by the board, or by any entity contracting with the board, submitted to, maintained or stored as a part of the database, shall be privileged and confidential, shall not be subject to subpoena or discovery in civil proceedings and may only be used for investigatory or evidentiary purposes related to violations of state or federal law and regulatory activities of entities charged with administrative oversight of those persons engaged in the prescribing or dispensing of scheduled substances and drugs of concern, shall not be a public record and shall not be subject to the Kansas open records act, K.S.A. 45-215 et seq., and amendments thereto, except as provided in subsections (c) and (d).

(b) The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided in subsections (c) and (d).

(c) The board is hereby authorized to provide data in the prescription monitoring program to the following persons:

(1) Persons authorized to prescribe or dispense scheduled substances and drugs of concern, for the purpose of providing medical or pharmaceutical care for their patients;

(2) an individual who requests the individual's own prescription monitoring information in accordance with procedures established by the board;

(3) designated representatives from the professional licensing, certification or regulatory agencies charged with administrative oversight of those persons engaged in the prescribing or dispensing of scheduled substances and drugs of concern;

(4) local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing scheduled substances and drugs of concern subject to the requirements in K.S.A. 22-2502, and amendments thereto;

(5) designated representatives from the Kansas health policy authority regarding authorized medicaid program recipients;

(6) persons authorized by a grand jury subpoena, inquisition subpoena or court order in a criminal action;

(7) personnel of the prescription monitoring program advisory committee for the purpose of operation of the program; and

(8) personnel of the board for purposes of administration and enforcement of this act or the uniform controlled substances act, K.S.A. 65-4101 et seq., and amendments thereto.

(d) The board is hereby authorized to provide data in the prescription monitoring program to public or private entities for statistical, research or educational purposes after removing information that could be used to identify individual practitioners, dispensers, patients or persons who received prescriptions from dispensers.

New Sec. 6. The board is hereby authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in section 5, and amendments thereto, and shall be subject to the penalties specified in section 14, and amendments thereto, for unlawful acts.

New Sec. 7. All information collected for the prescription monitoring program database and any records maintained by the board, or by any entity contracting with the board, submitted to, maintained or stored as a part of the database, shall be retained for five years. Such information and records shall then be destroyed unless a law enforcement entity or an entity charged with administrative oversight of those persons engaged in the prescribing or dispensing of scheduled substances and drugs of concern has submitted a written request to the board for retention of specific information or records in accordance with procedures adopted by the board.

New Sec. 8. No person authorized to prescribe or dispense scheduled substances and drugs of concern shall be liable to any person in a civil action for damages or other relief for injury, death or loss to person or property on the basis that such person authorized to prescribe or dispense scheduled substances and drugs of concern did or did not seek or obtain information from the prescription monitoring program prior to prescribing or dispensing scheduled substances and drug of concern to a patient. Nothing in this act shall be construed to create a duty or otherwise require a person authorized to prescribe or dispense scheduled substances and drug of concern to obtain information about a patient from the prescription monitoring program prior to prescribing or dispensing scheduled substances and drug of concern to such patient.

New Sec. 9. (a) There is hereby created the prescription monitoring program advisory committee which, subject to the oversight of the board, shall be responsible for the operation of the prescription monitoring program. The advisory committee shall consist of at least nine members appointed by the board as follows:

(1) Two licensed physicians, one nominated by the Kansas medical society and one nominated by the Kansas association of osteopathic medicine;

(2) two licensed pharmacists nominated by the Kansas pharmacists association;

(3) one person representing the Kansas bureau of investigation nominated by the attorney general;

(4) one person representing the university of Kansas school of medicine nominated by the dean of such school;

(5) one person representing the university of Kansas school of pharmacy nominated by the dean of such school;

(6) one licensed dentist nominated by the Kansas dental association; and

(7) one person representing the Kansas hospital association nominated by such association. The board may also appoint other persons authorized to prescribe or dispense scheduled substances and drugs of concern, recognized experts and representatives from law enforcement.

(b) The appointments to the advisory committee shall be for terms of three years.

(c) The advisory committee shall elect a chairperson from among its members who shall serve a one-year term. The chairperson may serve consecutive terms.

(d) The advisory committee, in accordance with K.S.A. 75-4319, and amendments thereto, may recess for a closed or executive meeting when it is considering matters relating to identifiable patients or providers.

(e) Upon the expiration of the term of office of any member of the advisory committee on or after the effective date of this act, and in any case of a vacancy existing on or after the effective date of this act, a successor shall be appointed by the board pursuant to this section.

(f) All members of the advisory committee shall serve without compensation.

New Sec. 10. (a) The prescription monitoring program advisory committee shall work with each entity charged with administrative oversight of those persons engaged in the prescribing or dispensing of scheduled substances and drugs of concern to develop a continuing education program for such persons about the purposes and uses of the prescription monitoring program.

(b) The advisory committee shall work with the Kansas bar association to develop a

continuing education program for attorneys about the purposes and uses of the prescription monitoring program.

(c) The advisory committee shall work with the Kansas bureau of investigation to develop a continuing education program for law enforcement officers about the purposes and uses of the prescription monitoring program.

New Sec. 11. In consultation with and upon recommendation of the prescription monitoring program advisory committee, the board shall review the effectiveness of the prescription monitoring program and submit an annual report to the senate standing committee on public health and welfare and the house standing committee on health and human services.

New Sec. 12. The board is hereby authorized to promulgate rules and regulations necessary to carry out the provisions of this act.

New Sec. 13. (a) A dispenser who knowingly fails to submit prescription monitoring information to the board as required by this act or knowingly submits incorrect prescription monitoring information shall be guilty of a severity level 10, nonperson felony.

(b) A person authorized to have prescription monitoring information pursuant to this act who knowingly discloses such information in violation of this act shall be guilty of a severity level 10, nonperson felony.

(c) A person authorized to have prescription monitoring information pursuant to this act who knowingly uses such information in a manner or for a purpose in violation of this act shall be guilty of a severity level 10, nonperson felony.

(d) It shall not be a violation of this act for a practitioner or dispenser to disclose or use information obtained pursuant to this act when such information is disclosed or used solely in the course of such practitioner's or dispenser's care of the patient who is the subject of the information.

New Sec. 14. (a) There is hereby established a methamphetamine precursor scheduling task force which shall study the possibility and practicability of making methamphetamine precursors schedule III or IV drugs and its impact on consumer access and cost.

(b) The task force shall consist of nine members as follows: The attorney general or the attorney general's designee, one member appointed by the Kansas health policy authority, one member appointed by the director of the Kansas bureau of investigation, one member appointed by the board of pharmacy and one member appointed by the board of healing arts. The remaining four members shall be appointed by the board of pharmacy as follows: One member nominated by the Kansas medical society; one member nominated by the Kansas association of osteopathic medicine; one member nominated by the Kansas pharmacists association; one member nominated by the Kansas task force of the pharmaceutical research and manufacturing association representing the pharmaceutical industry.

(c) The nominations and appointments shall be made within 30 days after the effective date of this act. The initial meeting of the task force shall be convened within 60 days after the effective date of this act by the board of pharmacy at a time and place designated by the board. The task force shall elect a chairperson and may elect any additional officers from among its members necessary to discharge its duties. All task force members shall serve without compensation.

(d) The task force shall report its findings and conclusions to the legislature on or before January 12, 2009.

(e) The provisions of this section shall expire on January 13, 2009.

New Sec. 15. (a) There is hereby established the veterinary prescription monitoring program task force which shall study and determine whether to require veterinarians to report to a prescription monitoring program under this act. Such study shall include appropriate methods and procedures of reporting by the veterinarians with the necessary database field information. The task force shall utilize nationally available resources afforded by the American association of veterinary state boards and the American veterinary medical association's department of state legislative and regulatory affairs in development of the plan in consultation with the advisory committee.

(b) The task force shall consist of three members as follows: One member appointed by the prescription monitoring program advisory committee, one member appointed by the Kansas board of veterinary examiners and one member nominated by the Kansas veterinary medical association and appointed by the Kansas board of veterinary examiners.

(c) Appointments shall be made within 120 days after the effective date of this act. The initial meeting of the task force shall be convened within 180 days after the effective date of this act. The task force shall elect a chairperson and may elect any additional officers from among its members. All task force members shall serve without compensation.

(d) The task force shall report its findings and progress to the prescription monitoring program advisory committee at least annually or when requested by the advisory committee. The task force shall report its progress to the senate committee on public health and welfare and the house committee on health and human services, if requested, and report its conclusions and recommendations to such committees within five years after the effective date of this act. Based on the recommendation by the task force this act shall be amended to include the veterinarians as practitioners.

New Sec. 16. (a) No later than July 1, 2009, each pharmacy shall establish a continuous quality improvement (CQI) program. The purpose of the CQI program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Reports, memoranda, proceedings, findings and other records generated as part of a pharmacy's CQI program shall be considered confidential and privileged peer review documents and not subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than an administrative proceeding initiated by the board of pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing such patient's own prescription records. Nothing in this section shall affect the discoverability of any record not solely generated for or maintained as a part of a pharmacy's CQI program.

(c) No person in attendance at any meeting being conducted as part of a CQI program shall be compelled to testify in any civil, criminal or administrative action, other than an administrative proceeding initiated by the board of pharmacy as to any discussions or decisions which occurred as part of the CQI program.

(d) All reports and records generated as part of a pharmacy's CQI program shall be available for inspection by the board of pharmacy within a time period established by the board in rules and regulations.

(e) In conducting a disciplinary proceeding in which admission of any matters that are confidential and privileged under subsection (b) are proposed, the board of pharmacy shall hold the hearing in closed session when any report, record or testimony is disclosed. Unless otherwise provided by law, the board of pharmacy in conducting a disciplinary proceeding may close only that portion of the hearing in which disclosure of such privileged matters are proposed. In closing a portion of a hearing as provided in this subsection, the presiding officer may exclude any person from the hearing except members of the board, the licensee, the licensee's attorney, the agency's attorney, the witness, the court reporter and appropriate staff support for either counsel.

The board of pharmacy shall make the portions of the administrative record in which such privileged matters are disclosed subject to a protective order prohibiting further disclosure. Such privileged matters shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity. No person in attendance at a closed portion of a disciplinary proceeding shall be required to testify at a subsequent civil, criminal or administrative hearing regarding the privileged matters, nor shall such testimony be admitted into evidence in any subsequent civil, criminal or administrative hearing.

The board of pharmacy may review any matters that are confidential and privileged under subsection (b) in conducting a disciplinary proceeding but must prove its findings with independently obtained testimony or records which shall be presented as part of the disciplinary proceeding in an open meeting of the board of pharmacy. Offering such testimony or records in an open public hearing shall not be deemed a waiver of the peer review privilege relating to any peer review committee testimony, record or report.

(f) The board may establish by rules and regulations requirements regarding the functions and record keeping of a pharmacy CQI program.

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

Sec. 17. K.S.A. 65-1657 is hereby amended to read as follows: 65-1657. (a) No non-resident pharmacy shall ship, mail or deliver, in any manner, prescription drugs to a patient in this state unless registered under this section as a nonresident pharmacy. Applications for a nonresident pharmacy registration under this section shall be made on a form furnished by the board. A nonresident pharmacy registration shall be granted for a period of one year upon compliance by the nonresident pharmacy with the provisions of this section and rules and regulations adopted pursuant to this section and upon payment of the registration fee established under K.S.A. 65-1645, and amendments thereto, for a pharmacy registration. A nonresident pharmacy registration shall be renewed annually on forms provided by the board, upon compliance by the nonresident pharmacy with the provisions of this section and rules and regulations adopted pursuant to this section and upon payment of the renewal fee established under K.S.A. 65-1645, and amendments thereto, for the renewal of a pharmacy registration.

(b) As conditions for the granting of a registration and for the renewal of a registration for a nonresident pharmacy, the nonresident pharmacy shall comply with the following:

(1) Provide information to the board to indicate the person or persons applying for the registration, the location of the pharmacy from which the prescription drugs will be dispensed, the names and titles of all principal owners and corporate officers, if any, and the names of all pharmacists dispensing prescription drugs to residents of Kansas;

(2) be registered and in good standing in the state in which such pharmacy is located;

(3) maintain, in readily retrievable form, records of prescription drugs dispensed to Kansas patients;

(4) supply upon request, all information needed by the board to carry out the board's responsibilities under this section and rules and regulations adopted pursuant to this section;

(5) maintain pharmacy hours that permit the timely dispensing of drugs to Kansas patients and provide reasonable access for the patients to consult with a licensed pharmacist about such patients' medications;

(6) provide toll-free telephone communication consultation between a Kansas patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that the telephone number(s) will be placed upon the label affixed to each prescription drug container dispensed in Kansas; and

(7) provide to the board such other information as the board may reasonably request to administer the provisions of this section.

(c) *When any nonresident pharmacy fails to supply requested information to the board or fails to respond to proper inquiry of the board, after receiving notice by certified mail, the board may assess a civil fine in accordance with the provisions in K.S.A. 65-1658, and amendments thereto.*

~~(d)~~ (d) Each nonresident pharmacy shall comply with the following unless compliance would be in conflict with specific laws or rules and regulations of the state in which the pharmacy is located:

(1) All statutory and regulatory requirements of Kansas for controlled substances, including those that are different from federal law;

(2) labeling of all prescriptions dispensed, to include but not be limited to identification of the product and quantity dispensed;

(3) all the statutory and regulatory requirements of Kansas for dispensing prescriptions in accordance with the quantities indicated by the prescriber; and

(4) the Kansas law regarding the maintenance and use of the patient medication profile record system.

~~(e)~~ (e) In addition to subsection ~~(d)~~ (d) requirements, each nonresident pharmacy shall

comply with all the statutory and regulatory requirements of Kansas regarding drug product selection laws whether or not such compliance would be in conflict with specific laws or rules and regulations of the state in which the pharmacy is located, except that compliance which constitutes only a minor conflict with specific laws or rules and regulations of the state in which the pharmacy is located would not be required under this subsection.

~~(e)~~ (f) Each nonresident pharmacy shall develop and provide the board with a policy and procedure manual that sets forth:

(1) Normal delivery protocols and times;

(2) the procedure to be followed if the patient's medication is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;

(3) the procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy at the earliest possible time, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and

(4) the procedure to be followed when the nonresident pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

~~(f)~~ (g) Except in emergencies that constitute an immediate threat to the public health and require prompt action by the board, the board may file a complaint against any nonresident pharmacy that violates any provision of this section. This complaint shall be filed with the regulatory or licensing agency of the state in which the nonresident pharmacy is located. If the regulatory or licensing agency of the state in which the nonresident pharmacy is located fails to resolve the violation complained of within a reasonable time, not less than 180 days from the date that the complaint is filed, disciplinary proceedings may be initiated by the board. The board also may initiate disciplinary actions against a nonresident pharmacy if the regulatory or licensing agency of the state in which the nonresident pharmacy is located lacks or fails to exercise jurisdiction.

~~(g)~~ (h) The board shall adopt rules and regulations that make exceptions to the requirement of registration by a nonresident pharmacy when the out-of-state pharmacy supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located, or when the prescriptions being mailed into the state of Kansas by a nonresident pharmacy occurs only in isolated transactions. In determining whether the prescriptions being mailed into the state of Kansas by a nonresident pharmacy are isolated transactions, the board shall consider whether the pharmacy has promoted its services in this state and whether the pharmacy has a contract with any employer or organization to provide pharmacy services to employees or other beneficiaries in this state.

~~(h)~~ (i) It is unlawful for any nonresident pharmacy which is not registered under this act to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions. A violation of this section is a class C misdemeanor.

~~(i)~~ (j) Upon request of the board, the attorney general may bring an action in a court of competent jurisdiction for injunctive relief to restrain a violation of the provisions of this section or any rules and regulations adopted by the board under authority of this section. The remedy provided under this subsection shall be in addition to any other remedy provided under this section or under the pharmacy act of the state of Kansas.

~~(j)~~ (k) The board may adopt rules and regulations as necessary and as are consistent with this section to carry out the provisions of this section.

~~(k)~~ (l) The executive secretary of the board shall remit all moneys received from fees under this section to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the manner specified under K.S.A. 74-1609, and amendments thereto.

~~(l)~~ (m) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 18. K.S.A. 65-1657 is hereby repealed.

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Sec. 19. This act shall take effect and be in force from and after its publication in the statute book.

I hereby certify that the above BILL originated in the SENATE, and passed that body

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SENATE adopted

Conference Committee Report \_\_\_\_\_

\_\_\_\_\_  
*President of the Senate.*

\_\_\_\_\_  
*Secretary of the Senate.*

Passed the HOUSE

as amended \_\_\_\_\_

HOUSE adopted

Conference Committee Report \_\_\_\_\_

\_\_\_\_\_  
*Speaker of the House.*

\_\_\_\_\_  
*Chief Clerk of the House.*

APPROVED \_\_\_\_\_

\_\_\_\_\_  
*Governor.*