

## **ARTICLE 21 – Prescription Monitoring Program**

**68-21-1. Definitions.** As used in these regulations, the following terms shall have the meanings specified in this regulation:

(a) "Authentication" means the provision of information, an electronic device, or a certificate by the board or its designee to a dispenser or prescriber that allows the dispenser or prescriber to electronically access prescription monitoring information. The authentication may include the provision of a user name, a password, or an electronic identification device or certificate.

(b) "Board" means the state board of pharmacy.

(c) "Dispenser identification number" means the drug enforcement administration (DEA) number if available or, if not available, the national provider identifier (NPI).

(d) "Drug enforcement administration number" means a unique registration number issued to an authorized prescriber of controlled substances by the drug enforcement administration, United States department of justice.

(e) "National provider identifier" and "NPI" mean a unique 10-digit number issued by the national provider identifier registry and used to identify each health care provider whose services are authorized by medicaid or medicare.

(f) "Patient identification number" means a unique number that a dispenser uses to identify a particular person.

(g) "Prescriber identification number" means the DEA number if available or, if not available, the NPI.

(h) "Program" means the Kansas prescription monitoring program.

(i) "Report" means a compilation of data concerning a dispenser, patient, drug of concern, or schedule II through IV drugs.

(j) "Stakeholder" means a person, group, or organization that could be affected by the program's actions, objectives, and policies.

(k) "Valid photographic identification" means any of the following:

(1) An unexpired permanent or temporary driver's license or instruction permit issued by any U.S. state or Canadian province;

(2) an unexpired state identification card issued by any U.S. state or Canadian province;

(3) an unexpired official passport issued by any nation;

(4) an unexpired United States armed forces identification card issued to any active duty, reserve, or retired member and the member's dependents;

(5) an unexpired merchant marine identification card issued by the United States coast guard;

(6) an unexpired state liquor control identification card issued by the liquor control authority of any U.S. state or Canadian province; or

(7) an unexpired enrollment card issued by the governing authority of a federally recognized Indian tribe located in Kansas, if the enrollment card incorporates security features comparable to those used by the Kansas department of revenue for drivers' licenses. (Authorized by and implementing K.S.A. 2009 Supp. 65-1692; effective P-\_\_\_\_\_.)

**68-21-2. Electronic reports.** (a) Each dispenser shall file a report with the board for schedule II through IV drugs and any drugs of concern dispensed in this state or to an address in this state. On and after January 1, 2013, this report shall be submitted within 24 hours of the time that the substance is dispensed, unless the board grants an extension as specified in subsection (d). During the implementation period following the effective date of this regulation and before January 1, 2013, each dispenser shall submit the report within seven days of dispensing the substance.

(b) In addition to the requirements of K.S.A. 65-1683 and amendments thereto, each dispenser shall submit the prescriber's name, the patient's telephone number, and the number of refills for the dispensed drug on the report to the board. As an alternative to reporting the dispenser identification number, any dispenser may report the pharmacy DEA number.

(c) Except as specified in K.A.R. 68-21-3, the report shall be submitted by secure file transfer protocol in the electronic format established by the American society for automation in pharmacy, dated no earlier than 2007, version 4, release 1.

(d) An extension may be granted by the board to a dispenser for the submission of a report if both of the following conditions are met:

(1)(A) The dispenser suffers a mechanical or electronic failure; or

(B) the dispenser cannot meet the deadline established by subsection (a) because of circumstances beyond the dispenser's control.

(2) The dispenser files a written application for extension on a form provided by the board within 24 hours of discovery of the circumstances necessitating the extension request or on the next day the board's administrative office is open for business.

(e) An extension for the filing of a report shall be granted to a dispenser if the board is unable to receive electronic reports submitted by the dispenser. (Authorized by K.S.A. 2009 Supp. 65-1683 and 65-1692; implementing K.S.A. 2009 Supp. 65-1683; effective P-  
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**68-21-3. Waivers for electronic reports.** (a) A waiver may be granted by the board to a dispenser who does not have an automated recordkeeping system capable of producing an electronic report as specified in K.A.R. 68-21-2(c) if the following conditions are met:

(1) The dispenser files a written application for a waiver on a form provided by the board.

(2) The dispenser agrees in writing to immediately begin filing a paper report on a form provided by the board for each drug of concern and each schedule II through IV drug dispensed in this state or dispensed to an address in this state.

(b) A waiver may be granted by the board to a dispenser who has an automated recordkeeping system capable of producing an electronic report as specified in K.A.R. 68-21-2(c) if both of the following conditions are met:

(1) The dispenser files a written application for a waiver on a form provided by the board.

(2)(A) A substantial hardship is created by natural disaster or other emergency beyond the dispenser's control; or

(B) the dispenser is dispensing in a controlled research project approved by a regionally accredited institution of higher education.

(c) If a medical care facility dispenses an interim supply of a drug of concern or a schedule II through IV drug to an outpatient on an emergency basis when a prescription cannot be filled as authorized by K.A.R. 68-7-11, that facility shall be exempt from the reporting requirements. The interim quantity shall not exceed a 48-hour supply and, as described in K.A.R. 68-7-11(d)(2)(B), shall be limited to an amount sufficient to supply the outpatient's needs

until a prescription can be filled. (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1683; effective P-\_\_\_\_\_.)

**68-21-4. Notice of requests for information.** Each dispenser who may access information maintained by the board on each drug of concern and schedule II through IV drug dispensed to one of the dispenser's patients for the purpose of providing medical or pharmaceutical care shall notify the patient of this access to prescription monitoring information by performing either of the following:

(a) Posting an easily viewable sign at the place where prescription orders are issued or accepted for dispensing; or

(b) providing written material about the dispenser's access to prescription monitoring information. (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1685; effective P-\_\_\_\_\_.)

**68-21-5. Access to information.** All requests for, uses of, and disclosures of prescription monitoring information by authorized persons shall meet the requirements of K.S.A. 65-1685, and amendments thereto, and this article.

(a) By patients or patient's personal representative.

(1) Any patient or that patient's personal representative may obtain a report listing all program information that pertains to the patient, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto.

(2) Each patient or the patient's personal representative seeking access to the information described in paragraph (a)(1) shall submit a written request for information in person to the board. The written request shall be in a format established by the board and shall include the following elements:

(A) The patient's name and, if applicable, the full name of the patient's personal representative;

(B) the patient's residential address and, if applicable, the complete residential address of the patient's personal representative;

(C) the patient's telephone number, if any, and, if applicable, the telephone number of the personal representative; and

(D) the time period for which information is being requested.

(3) The patient or the patient's personal representative shall produce two forms of valid photographic identification before obtaining access to the patient's information obtained by the program. The patient or the patient's personal representative shall allow photocopying of the identification.

(4) Before access to the patient's information obtained by the program is given, one of the following shall be produced if the requester is not the patient:

(A) For a personal representative, an official attested copy of the judicial order granting authority to gain access to the health care records of the patient;

(B) for a parent of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or

(C) for a person holding power of attorney, the original document establishing the power of attorney.

(5) The patient's personal representative shall allow the photocopying of the documents described in this subsection.

(6) The patient authorization may be verified by the board by any reasonable means before providing the information to the personal representative.

(b) By dispensers.

(1) Any dispenser may obtain any program information relating to a patient of the dispenser for the purpose of providing pharmaceutical care to that patient, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile transmission, or telephone.

(2) Each dispenser who seeks access to the information described in paragraph (b)(1) shall submit a written request to the board by mail, hand delivery, or electronic means in a

manner established by the board, using authentication. If the authentication is lost or missing or the security of the authentication is compromised, the dispenser shall cause the board to be

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notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request.

Each request shall be submitted in a format established by the board and shall include the following elements for each patient:

- (A) The patient's name and birth date;
- (B) if known to the dispenser, the patient's address and telephone number;
- (C) the time period for which information is being requested;
- (D) the dispenser's name;
- (E) if applicable, the name and address of the dispenser's pharmacy;
- (F) the dispenser identification number; and
- (G) the dispenser's signature.

(3) The authentication and identity of the dispenser shall be verified by the board before allowing access to any prescription monitoring information.

(c) By prescribers.

(1) Any prescriber or health care practitioner authorized by a prescriber may obtain any program information relating to a patient under the prescriber's care, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Each prescriber or health care practitioner authorized by a prescriber who seeks access to program information shall submit a written request to the board by mail, hand delivery, or electronic means in a manner established by the board, using authentication. If the authentication is lost or missing or the security of the authentication is compromised, the prescriber shall cause the board to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request.

Each request shall be submitted in a format established by the board and shall include the following elements for each patient:

- (A) The patient's name and birth date;
- (B) if known to the prescriber, the patient's address and telephone number;
- (C) the time period for which information is being requested;
- (D) the prescriber's name;
- (E) the name and address of the prescriber's medical practice;
- (F) the prescriber identification number; and
- (G) the prescriber's signature.

(3) The authentication and identity of the dispenser shall be verified before allowing access to any program information.

(d) By director or board investigator of a health professional licensing, certification, or regulatory agency or entity.

(1) Any director or board investigator of a health professional licensing, certification, or regulatory agency or entity may obtain any program information needed in carrying out that individual's business, in accordance with this regulation and K.S.A. 65-1685 and amendments

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thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Each director or board investigator of a licensing board with jurisdiction over a dispenser or prescriber who seeks access to program information shall submit a written request by mail, facsimile, or electronic means to a location specified by the board. The written request shall contain a statement of facts from which the board can make a determination of reasonable cause for the request.

(e) By local, state, and federal law enforcement or prosecutorial officials.

(1) Any local, state, or federal law enforcement officer or prosecutorial official may obtain any program information as required for an ongoing case, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Each local, state, or federal law enforcement officer or prosecutorial official who seeks access to program information shall register with the board. Once registration is approved, the requester may submit a written request by mail, facsimile, or electronic means to the board. All requests for, uses of, and disclosures of prescription monitoring information by authorized persons under this subsection shall meet the requirements of K.S.A. 65-1685 (c)(4), and amendments thereto.

(f) By the Kansas health policy authority for purposes of the Kansas medicaid and state children's health insurance program (SCHIP).

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(1) An authorized representative of the Kansas health policy authority may obtain any program information regarding medicaid or SCHIP program recipients, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board.

(2) Each authorized representative of the Kansas health policy authority seeking program information regarding medicaid or SCHIP program recipients who seeks access to program information shall submit a request to the board.

(g) By any other state's prescription monitoring program.

(1) Any authorized representative from any other state's prescription monitoring program may obtain any program information for requests from within that state that do not violate the authentication and security provisions of the prescription monitoring program act, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Any authorized representative from another state's prescription monitoring program seeking access to program information shall first establish a data-sharing agreement with the board in which the states agree to share prescription monitoring information with one another. The agreement shall specify what information will be made available and to whom, how requests

will be made, how quickly requests will be processed, and in which format the information will be provided.

(h) By public or private entities for statistical, research, or educational purposes.

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(1) Any public or private entity may obtain program information, in accordance with this regulation and K.S.A. 65-1685(d) and amendments thereto. The information shall be provided in a format established by the board.

(2) Each public or private entity who seeks access to program information shall submit a written request by mail, facsimile, or electronic means to the board. The written request shall contain a statement of facts from which the board can make a determination of reasonable cause for the request. (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1685; effective P-\_\_\_\_\_.)

**68-21-6. Reciprocal agreements with other states to share information. (a)**

Reciprocal agreements with one or more states in the United States may be entered into by the board to share program information if the other state's prescription monitoring program is compatible with the program. If the board elects to evaluate the prescription monitoring program of another state, priority shall be given to a state that is contiguous to Kansas.

(b) In determining the compatibility of the other state's prescription monitoring program, the following may be considered by the board:

- (1) The safeguards for privacy of patient records and the other state's success in protecting patient privacy;
- (2) the persons authorized in the other state to view the data collected by the program;
- (3) the schedules of controlled substances monitored in the other state;
- (4) the data required by the other state to be submitted on each prescription; and
- (5) the costs and benefits to the board of mutually sharing information with the other state.

(c) Each reciprocal agreement shall be reviewed annually by the board to determine its continued compatibility with the program. (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1685; effective P-\_\_\_\_\_.)

**68-21-7. Drugs of concern.** (a) Each of the following shall be classified as a drug of concern:

(1) Any product containing all three of these drugs: butalbital, acetaminophen, and caffeine;

(2) carisoprodol; and

(3) tramadol.

(b) The stakeholders of the program shall be notified by the board if a drug is to be considered by the board for classification as a drug of concern.

(c) Any individual who wants to have a drug added to the program for monitoring may submit a written request to the board. (Authorized by K.S.A. 2009 Supp. 65-1682 and 65-1692; implementing K.S.A. 2009 Supp. 65-1682; effective P-\_\_\_\_\_.)