

Guidance for K-TRACS Reporting Exemptions

Approved by the Kansas Board of Pharmacy: August 25, 2022

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- I. Purpose
 - a. The purpose of this guidance is to provide clarification regarding the process for requesting and granting exemptions from reporting requirements to K-TRACS, the Kansas prescription drug monitoring program.
- II. Statutory Authority
 - a. See K.S.A. 65-1683(c) and K.A.R. 68-21-2(f)
- III. Guidance
 - a. Statutory Exemptions
 - i. Dispensers who meet the statutory exemption for reporting to the prescription monitoring program under K.S.A. 65-1682, and amendments thereto, are not required to file an exemption form with K-TRACS. "Dispenser" means a practitioner, pharmacy 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.
 - b. Exemption from All Reporting Requirements
 - i. Dispensers who meet the following conditions may apply for an exemption from all required reporting to K-TRACS using a form provided by the Board:
 1. The dispenser is a medical care facility, as defined by K.S.A. 65-1626 and amendments thereto, that provides an interim supply of a scheduled substance or drug of concern to an outpatient on an emergency basis and the interim quantity does not exceed a 48-hour supply and, as described in K.A.R. 68-7-11(d)(2)(B), is limited to an amount sufficient to supply the outpatient's needs until a prescription can be filled in accordance with K.A.R. 68-7-11. This exemption shall only apply to the outpatient emergency interim supply of drugs and not to other outpatient dispensing or supply activities of the medical care facility.
 2. The dispenser does not dispense scheduled substances or drugs of concern in the state of Kansas or to an address in Kansas, and meets the following conditions:
 - a. Has submitted required reports for at least three months or provided three months of dispensing records to the Board.
 - b. If the dispenser is a nonresident pharmacy, provides:
 - i. a list of states in which the pharmacy is registered;
 - ii. the current prescription monitoring program reporting status in each state in which the dispenser is registered;

- iii. a copy of any written reprimand, censure or other disciplinary action related to prescription monitoring program reporting the dispenser has had in any state, district or territory.

c. Zero Report Exemptions

- i. Dispensers who meet the following conditions may apply for an exemption from required zero reporting to K-TRACS using a form provided by the Board:
 - 1. does not monthly dispense more than 10 prescriptions for scheduled substances and drugs of concern in Kansas or to an address in Kansas; and
 - 2. does not have the ability to automate the submission of zero reports.
- ii. Dispensers meeting this requirement may include infusion pharmacies and pharmacies that are not computerized.
- iii. Dispensations of scheduled substances and drugs of concern must still be reported manually through the electronic data clearinghouse by the next business day after the prescription is sold.
- iv. The dispenser will only be exempt from submitting zero reports for days on which no scheduled substances and drugs of concern were dispensed.

d. Exemption Re-Certifications

- i. Exemption status must be re-certified by PICs between August 1 and August 31 of each year under a process to be defined by the Board. Exemptions will expire August 31 of each year.
- ii. Exemption status also must be re-certified in the following circumstances:
 - 1. The pharmacist-in-charge changes. The new PIC will be required to re-certify exemption status for the pharmacy in addition to the BA-50 form submitted to the Board.
 - 2. The pharmacy's registration number and/or DEA number and/or allowed schedules on its DEA permit change (for example, as a result of an ownership change). The PIC will be required to re-certify exemption status for the pharmacy after receiving the pharmacy's new registration number and/or DEA number.
 - 3. The pharmacy acquires a DEA registration after initial registration with the state.

e. Exemption Revocations

- i. Dispensers that no longer meet the criteria for an exemption shall notify the Board and begin submitting reports within 7 days.
- ii. Board staff may revoke an exemption for a Dispenser at any time or request an explanation for the exemption upon routine review of registered Dispensers.

f. Exemption requests will be reviewed by Board staff, and Dispensers will receive notice of approval or denial.