

Overview of Requirements and Regulations for Qualifying Centers and Clinics

A clinic or center that has registered with the Pharmacy Board to receive donated medications may dispense donated medications to medically indigent residents of Kansas. Medically indigent individuals include those earning under 200 percent of the federal poverty level and those eligible for public insurance programs administered by the Kansas Health Policy Authority (Medicaid/HealthWave) (KAR 28-53-3).

Participating clinics or centers may **not** charge a handling fee for medications received from The Kansas Repository.

Participating clinics or centers must comply with all applicable federal and state laws related to the storage and distribution of medications. They must inspect all medications prior to dispensing them to determine that they are not adulterated, and they must dispense prescription medications only pursuant to a prescription issued by a practitioner.

Each qualifying center or clinic must maintain all unused medications in a storage unit with controlled access.

Upon receipt of donated medications, qualifying centers or clinics must:

1. Determine the quality and suitability of each unused medication by the verification of a pharmacist or practitioner that the unused medication meets the following requirements:

- Can be identified;
- Is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer;

2. Ensure that the name of the patient or resident and all of the patient's or resident's personal identifiers have been removed in order to protect confidentiality;

3. Check each unused medication against the manifest received from The Kansas Repository in order to resolve any discrepancies;

The quality and suitability of medication received from The Kansas Repository has been verified by a pharmacist prior to its receipt by an eligible clinic.

Medications that have been donated under the auspices of the Unused Medications Act may not be resold but may be transferred to another qualifying center or clinic.

Qualifying centers or clinics receiving unused medications are required to submit an Unused Medications Annual Reporting Form by March 31 of each year with the following information to the Kansas Department of Health and Environment: the amount of donated medications distributed and the number of patients receiving donated medications.

Note: Participating clinics or centers that receive Kansas community-based primary care clinic program funding do not need to complete the annual reporting form, as the information is provided through the online DataCounts clinic data reporting process. If your clinic or center does not receive community-based primary care clinic funding, please provide the appropriate data by March 31 of each year and fax to 785-296-1231 or email to sloyd@kdheks.gov.

Recall of Unused Medications and Destruction of Outdated Medications

If The Kansas Repository has transferred an unused medication to a qualifying center or clinic and the medication is recalled, The Kansas Repository is responsible for notifying all qualifying centers that received the medication of the recall.

If an unused medication is recalled and the qualifying center or clinic does not have a lot number to differentiate between recalled medications and non-recalled medications, all of the donated medications of that type shall be destroyed.

Each qualifying center or clinic in possession of unused medication that is expired, adulterated, or recalled should make a manifest for and destroy that medication. Following the destruction of expired, adulterated, or recalled medications, the manifest must be signed by pharmacist-in-charge and a witness to verify its destruction. Each manifest for destroyed medications must be maintained for at least five years.

For matters related to the lawful donation, acceptance, or dispensing of medications under the Act, and in the absence of bad faith or gross negligence, governmental entities, donating entities, or persons donating medications as well as any qualifying center or clinic or its practitioners that dispenses donated medications under the Unused Medications Act shall not be subject to criminal or civil liability for injury other than death, or loss to a person or property, or professional disciplinary action.