

The Unused Medications Program/Repository

The Utilization of Unused Medications Act (KSA 65-1668 through 1675) was passed by the Kansas legislature in 2008 to allow the donation of unused medications by adult care homes, mail service pharmacies, and medical care facilities to Federally Qualified Health Centers, indigent health care clinics, and community mental health centers.

The Kansas State Board of Pharmacy has developed the Unused Medications Program regulations ([KAR 68-18-1 through 3](#)). To participate in the program, a donating or receiving entity must register with the Board of Pharmacy. Relevant statutes, regulations, forms, and a list of approved donating and receiving entities are available at the [Kansas State Board of Pharmacy](#) website.

The Unused Medications Repository, administered by Community Health Center of Southeast Kansas, provides donated medications free of charge to eligible clinics in Kansas.

Eligible Participating Entities

Adult care homes include the following: adult day care providers, assisted living facilities, boarding care homes, home plus providers, intermediate care facilities for the mentally retarded, nursing facilities, nursing facilities for mental health, residential health care facilities, Alzheimer's units, and long-term care units in hospitals. A list of these facilities by type is available on the website of the [Kansas Department on Aging](#).

Medical care facilities include the following: ambulatory surgical centers, hospitals, and psychiatric, state mental and mental retardation hospitals. A list of these facilities by type is available on the website of the [Kansas Department of Health and Environment](#).

An indigent health care clinic is a clinic that has an agreement in force with the Secretary of the Kansas Department of Health and Environment. Information on serving as an indigent health care clinic is available in the [Charitable Health Care Provider Program manual](#), which includes the [Indigent Health Care Clinic Registration Form](#).

Kansas statute ([KSA 65-1648](#)) requires that the distribution and control of prescription medications at indigent health care clinics and Federally Qualified Health Centers occur under the supervision of a pharmacist in charge. Information about these requirements and the necessary forms and materials can be obtained on the Kansas State Board of Pharmacy website. FQHCs and indigent health care clinics may obtain a [registration form](#) at the Kansas State Board of Pharmacy website.

Overview of Requirements

Medications

1. Donated medications must come from a controlled storage unit.
2. Only medications in their original or pharmacist-sealed unit dose packaging or hermetically sealed by the pharmacy in tamper-evident packaging, unit of use or sealed, unused injectables may be donated or dispensed.
3. Expired medications may not be donated.
4. A medication may not be donated or dispensed if the person accepting or dispensing the medication has reason to believe that the medication is adulterated.

5. No controlled substances may be donated.
6. Unused medications dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed.

Eligible Donating Entities (Registered with the Board of Pharmacy to Donate Unused Medications)

Mail Service Pharmacy or Medical Care Facilities: Before the transfer of unused medications, each mail service pharmacy or medical care facility must:

1. Determine the quality and suitability of each unused medication by a pharmacist's verification that the unused medication meets the following requirements:
 - Can be identified;
 - Is in the manufacturer's sealed container, a pharmacy unit-dose package, or a hermetically sealed tamper-evident package from the pharmacy;
 - Has not passed its expiration date;
 - Is not a controlled substance;
 - Has not been adulterated;
 - Is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer.
2. Remove the name of the patient or resident and all of the patient or resident's personal identifiers in order to protect confidentiality.
3. Ensure that the qualifying center or clinic is willing to accept the unused medication. And
4. Ensure that the qualifying center or clinic has a pharmacist-in-charge and is registered with the Kansas State Board of Pharmacy to receive unused medications.

Mail service pharmacies and medical care facilities may obtain a [Donating Entity Notification of Intent to Participate Form](#) at the Kansas State Board of Pharmacy website.

Adult Care Homes: Before the transfer of unused medications, each adult care home must do the following:

1. Remove the name of the patient or resident and all of the patient or resident's personal identifiers in order to protect confidentiality.
2. Ensure that the qualifying center or clinic is willing to accept the unused medication. And
3. Ensure that the qualifying center or clinic has a pharmacist-in-charge and is registered with the Kansas State Board of Pharmacy to receive unused medications.

Adult care homes may obtain a [Donating Entity Notification of Intent to Participate Form](#) at the Kansas State Board of Pharmacy.

Mail service pharmacies, medical care facilities, and adult care homes must also complete a manifest for all donated medications on the form approved by the Board of Pharmacy and provide a copy of the manifest to the qualifying center or clinic that receives the donated unused medications. The donating entity must keep a copy of the original manifest for at least five years. The donating entity must also maintain a copy of the signed and returned manifest from the qualifying center or clinic that received the medications.

Adult care homes may obtain an [Unused Medications Manifest](#) at the Kansas State Board of Pharmacy website. Mail service pharmacies and medical care facilities may obtain an [Unused](#)

[Medications Manifest](#) at the Kansas state Board of Pharmacy website.

Qualifying Centers and Clinics (Registered with Board of Pharmacy to Receive Unused Medications)

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 enrolled in public insurance programs administered by the Kansas Health Policy Authority (Medicaid/HealthWave) ([KAR 28-53-3](#)).

Participating clinics or centers may charge individuals receiving donated medications a handling fee not to exceed 200 percent of the Medicaid dispensing fee. The current Medicaid dispensing fee is \$3.40, so the maximum handling fee that may be charged is \$6.80. Clinics or centers may not charge a handling fee for medications received from the Unused Medications 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.

Clinics and qualifying centers may obtain a [Notification of Intent to Participate Form](#) at the Kansas State Board of Pharmacy. 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 donating entity in order to resolve any discrepancies;
4. Complete the manifest and return a copy to the donating entity. Each qualifying center or clinic shall maintain a copy of the manifest signed and returned to the donating entity for at least five years.

If the medication is received from an adult care home, each qualifying center or clinic must also determine the quality and suitability of each unused medication by verification of a pharmacist that the unused medication can be identified. If the medication is received through the Unused Medications Repository, from a mail order pharmacy, or a medical care facility, the quality and suitability have 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 email to kdhe.ruralhealth@ks.gov or fax to 785-296-1231.

Recall of Unused Medications and Destruction of Outdated Medications

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 the donated medications of that type shall be destroyed.

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

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.

Unused Medications Repository

The Utilization of Unused Medications Act states that, “medications donated . . . are available for transfer to another qualifying center or clinic (KSA 65-1675(d)).” Through this allowance,

KDHE funded a pilot project beginning in June, 2009 to establish a method for eligible facilities to donate medications to a central repository for distribution to eligible clinics. This pilot was initiated as a method to make clinic access to donated medications easier by allowing clinics to receive only those medications their patients need. The pilot program also allowed donating

facilities that could not donate to a local community to donate unused medications to a central location, which then sent the unused medications to clinics around the state participating in the program.

During the pilot phase of the Repository, and due to the source of funding, only state -funded primary care clinics have been able to participate in the Repository. The Repository has shown itself to be an efficient approach to facilitate the donation of unused medications to clinics and medically indigent patients in need of those medications. At present, new funding sources are being developed to allow for greater participation by both eligible donating entities and eligible clinics and centers.

Clinics that wish to receive donated medications from the Unused Medications Repository must

submit a [Receiving Facility Registration Form](#) by fax to 620-235-0869 or by email to rpoole@chcsek.org

Facilities that wish to donate unused medications to the Unused Medications Repository must submit a [Donating Facility Registration Form](#) by fax to 620-235-0869 or by email it to rpoole@chcsek.org

Beginning January 1, 2011, Community Mental Health Centers will be allowed to participate in the Utilization of Unused Medications Repository through a pilot project funded by the Kansas Department of Social and Rehabilitative Services.