REPOSITORIES

Eligible Entities who may apply to become a **Rx Connects Repository**

The following entities may participate as a repository:

- Health care practitioner's office
- Pharmacy
- Hospital with a closed drug delivery system
- Nursing home facility with a closed drug delivery system
- Free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in Florida

Becoming a Repository in the Rx Connects Program



In addition to the eligibility criteria above, **repositories must** agree to the following:

- An eligible entity must notify the Department of Health of its intent to participate in the program as a repository before accepting or dispensing any donations under the program. The notification must be made using the Florida Rx Connects Repository Participation or Withdrawal form.
- The application form must be signed and dated by the responsible pharmacist affirming that the intended repository meets the eligibility requirements of the program.
- The repository may dispense an eligible donation to a state resident who is indigent, uninsured, or underinsured who has a valid prescription for such donation.
- By the 5th of each month, a repository must submit to the department copies of each Patient Application and Dispensing form obtained during the previous month.
- A donated drug may only be dispensed to an eligible patient who has submitted a Patient Application and Dispensing form and has shown the dispenser a valid prescription for such drug.
- A claim or other reimbursement from any public or private third-party payor may not be submitted for any donated drug or supply.
- Each repository must maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program.
- Required records must be maintained in accordance with any applicable practice act.
- All required forms must be submitted monthly to the Department of Health.

Additional Repository Requirements

Upon receipt of an approved proposed donation, a licensed pharmacist employed by, or under contract with a repository, shall inspect the donation to ensure that each donation meets the requirements listed below:

Eligible Donated Drugs

The following criteria are required of all donations:

- Donations have come from eligible donors. All donors must obtain written approval (email or mail) from a participating repository prior to shipping any donated drugs or supplies.
- The donated drug is approved for medical use in the United States.
- The drug is in unopened, tamper-evident packaging.
- The drug has been stored according to manufacturer or federal storage requirements.
- The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.
- The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.



- The packaging indicates the expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed.
- The drug has an expiration date that is more than 3 months after the date on which the drug was donated.
- The drug must be donated on the premises of the property to a person designated by the repository. (Drop box may not be used to accept a donation.)
- Donated items may not be sold or resold.

Inspection and Storage

- The repository must quarantine a donation until the licensed pharmacist has inspected and approved the drug for dispensing. (A repository that has received drugs and/or supplies from another repository is not required to reinspect such drugs and supplies.)
- The inspecting pharmacist must sign an inspection record form verifying that the prescription drug or supply meets the criteria stated above, under "Eligible Donated Drugs".
- The repository must store donations in a secure area under the environmental conditions specified by the manufacturer or federal storage requirements. DONATIONS MAY NOT BE STORED WITH OTHER (non-repository) INVENTORY or must be clearly marked to indicate that the drug or supply was donated.

- The repository must maintain an inventory of donated drugs that includes the:
 - Name of drug
 - o Strength
 - Available quantity
 - Expiration date of donations
 - o Transaction date
 - o Name, street address and telephone number of the donor

An inventory form can be found on the program webpage.

By the 5th of each month, the repository must record inventory on the Repository Inventory form and submit for all drugs received. All donations received during the previous month must be included. The Donation form must be submitted to the Florida Rx Connects email address: <u>PrescriptionDrugDonationProgram@FLHealth.gov</u>.

Recalled Prescription Drugs

- Each repository shall establish and follow a protocol for notifying patients if a prescription drug donated under the program is recalled.
- A repository shall destroy all donated prescription drugs that are recalled, expired, or unsuitable for dispensing.
- A repository must complete a Destruction of Drugs form for all such destroyed drugs and submit each month to the Department of Health.

Required Repository Forms

A repository participating in Florida Rx Connects (the Prescription Drug Donation Repository Program) must submit information to the Florida Department of Health monthly.

Below is a summary of the forms required to be submitted monthly by all approved and operating repositories. Please note that all forms must be signed, dated, and submitted by the 5th of each month, even if the repository has no new donations, eligible patients or changes to inspection and storage. If there are no new donations, patients or inspection and storage information, please indicate "No information to report" on the forms.

- Copies of all Patient Application and Dispensing form received and processed in the prior month
- Destruction of Drugs form
- Donation form
- Transfer form
- Repository Inventory form

Withdrawing as a Repository

Participating repositories may withdraw from the program by providing written notice using the Florida Rx Connects Repository Participation or Withdrawal form.

Upon withdrawal, repositories must agree to the disposition of prescription drugs and supplies in their possession. Any destroyed drugs must be reported on the Destruction of Drugs form and submit to <u>PrescriptionDrugDonationProgram@FLHealth.gov</u>. Repositories withdrawing from the program are encouraged to transfer any drugs or supplies to another participating repository.

To apply to become a repository, please go to <u>Florida Rx Connects</u> | <u>Florida Department of Health</u> (<u>floridahealth.gov</u>) to access the Repository Participation or Withdrawal form.

For a list of participating repositories, go to <u>Florida Rx Connects</u> | <u>Florida Department of Health</u> (floridahealth.gov).

Questions may be sent to: <u>PrescriptionDrugDonationProgram@FLHealth.gov</u>. Please allow at least 24 hours for a response.