**Welcome to the Florida RxConnects Program Guide.**



**This program, also known as the Prescription Drug Donation Repository Program, is authorized by Florida Statute 465.1902.**

Florida RxConnects was established within the Florida Department of Health by the 2020 Florida Legislature to facilitate the donation of certain prescription drugs and supplies to eligible patients through the creation of repositories, where eligible organizations or facilities may make such donations. Approved donated drugs and/or supplies may be dispensed to patients with a valid prescription.

**How does Florida Rx Connects work?**

There are three key components in this program: Repositories, Donors, and Patients. Each of these components include strict guidelines as to who may be eligible to participate. The following pages contain important information and requirements for participation in this program.

**Eligible Entities that may apply to become an RxConnects Repository**

The following entities may participate as a repository:

1. A health care practitioner’s office
2. A pharmacy
3. A hospital with a closed drug delivery system
4. A nursing home facility with a closed drug delivery system
5. A free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in Florida

Please see pages 4-6 of this Guide for more information on repository requirements.

**Eligible Drug and Supply Donors**

**The Prescription Drug Donation Repository Program has three key components:**

* **Repositories**
* **Donors**
* **Patients**

The following entities are eligible to donate to an established repository under this program:

1. Nursing home facilities with closed drug delivery systems
2. Hospices that have maintained control of a patient’s prescription drugs
3. Hospitals with closed drug delivery systems
4. Pharmacies
5. Drug manufacturers or wholesale distributors
6. Medical device manufacturers or suppliers
7. Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy

Please see page 7 of this Guide for more information on how to become a donor in this program.

Note: This program is not authorized to accept donations from individuals.

**Eligible Patients**

Any patient that wishes to receive prescription drugs from this program must:

1. Have a family income that is below 200 percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United State Department of Health and Human Services *or* be uninsured *or* underinsured.
2. Be a resident of Florida
3. Have a valid prescription for a specific donated drug
4. Complete and submit a Florida Rx Connects Patient Application and Dispensing form.

Please see page 8 of this Guide for more information on how to become a patient in this program.

**Immunity from Liability and Disciplinary Action**

Any donor of prescription drugs or supplies and any participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program is immune from civil or criminal liability and professional disciplinary action by the state for any injury, death, or loss to person or property relating to such activities.

A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the donation of any prescription drug or supply under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the donated prescription drug or supply, including its expiration date**.**

Florida Rx Connects is managed by the Florida Department of Health, Division of Emergency Preparedness and Community Support, Bureau of Public Health Pharmacy. This program is authorized by F.S. 465.1902. Rules that guide the implementation of this program can be found in Chapter 64J-4, F.A.C.

Comments and questions may be sent to: PrescriptionDrugDonationProgram@FLHealth.gov. Please allow at least 24 hours for a response.



**Becoming a Repository in the Rx Connects program**

In addition to the eligibility criteria stated on pages 1 and 2 of this Guide, **repositories must agree to the following**:

1. 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.
2. 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 Application and Withdrawal form.
3. The application form must be signed and dated by the responsible pharmacist affirming that the intended repository meets the eligibility requirements of the program.
4. Participating repositories may withdraw from the program by providing written notice using the Florida Rx Connects Repository Application and Withdrawal form.
5. 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** formand submitted monthly to PrescriptionDrugDonationProgram@FLHealth.gov. Repositories withdrawing from the program are encouraged to transfer any drugs or supplies to another participating repository (Transfer form is linked here).
6. *By the 5th of each month*, a repository must submit to the department a summary of each Patient Application and Dispensing form obtained during the previous month.
7. A donated drug may only be dispensed to an eligible patient who has submitted an intake collection form and has shown the dispenser a valid prescription for such drug.
8. A claim or other reimbursement from any public or private third-party payor may not be submitted for any donated drug or supply.
9. Each repository must maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program.
10. Required records must be maintained in accordance with any applicable practice act.
11. 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:

1. 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.
2. The donated drug is approved for medical use in the United States.
3. The drug is in unopened, tamper-evident packaging.
4. The drug has been stored according to manufacturer or federal storage requirements.
5. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.
6. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.
7. The packaging indicates the expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed.
8. The drug has an expiration date that is more than 3 months after the date on which the drug was donated.
9. The drug must have been donated on the premises of the property to a person designated by the repository. (Drop box may not be used to accept a donation).
10. Donated items may not be sold or resold.

**Inspection and Storage**

1. The repository must quarantine a donation until the licensed pharmacist has inspected and approved drug for dispensing. (A repository that has received drugs and/or supplies from another repository is not required to reinspect such drugs and supplies.)
2. The inspecting pharmacist must sign an inspection record form verifying that the prescription drug or supply meets the criteria stated in items a. through i. above, under “Eligible Donated Drugs”.
3. 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.
4. The repository must maintain an inventory of donated drugs that includes the:
	* Name of drug
	* Strength
	* Available quantity
	* Expiration date of donations
	* Transaction date
	* Name, street address and telephone number of the donor

An inventory form can be found on the program webpages.

*By the 5th of each month,* the repository must also record inventory on the Donation Form and submit for all drugs received*.* All donations received during the previous month must be included. The Inspection Record Form must be submitted to the Florida Rx Connects email address: PrescriptionDrugDonationProgram@FLHealth.gov.

**Recalled Prescription Drugs**

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

If you would like to apply to become a repository, please go the PrescriptionDrugDonationProgram@FLHealth.gov to access the Repository Application or Withdrawal form.

Please go to the program webpage for a link to the Repository Application or Withdrawal form.

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

**Donors: Donating Drugs and Supplies**

In addition to the eligibility criteria stated on pages 1 and 2 of this Guide, donors **must agree to the following**:

An eligible donor may only donate a prescription drug or supply to a repository if:

1. The donor has obtained written approval (email or US mail) from a participating repository prior to shipping any donated drugs or supplies.
2. The drug is approved for medical use in the United States.
3. The drug is in unopened, tamper-evident packaging.
4. The drug requires storage at normal room temperature per the manufacturer or federal storage requirements.
5. The drug has been stored according to manufacturer or federal storage requirements.
6. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.
7. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.
8. The packaging indicates the expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed.
9. The drug has an expiration date that is more than 3 months after the date on which the drug was donated.
10. Donations are made on the premises of a repository to a person designated by the repository. A drop box may not be used to accept donations. Donations may also be shipped with a donation form and prior approval from the receiving repository.

A prescription drug or supply may not be donated to a specific patient.

The Department of Health may facilitate the redistribution of donations between repositories. A participating repository that wishes to transfer approved donated drugs to another repository must notify the Department and can do so by emailing PrescriptionDrugDonationProgram@FLHealth.gov and using the Transfer form which can be found on the program webpages.

If you would like additional information about becoming a donor, please go to PrescriptionDrugDonationProgram@FLHealth.gov. The Donor Form may also be accessed there.

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

**Patients Eligible to Participate**

In addition to the eligibility criteria stated on page 2 of this Guide, **patients must agree to the following**:

1. Eligible patients must complete and submit an eligible Patient Application and Dispensing form to a participating repository to receive a donation.
2. A repository may only dispense eligible donated drugs or supplies to Florida residents who are indigent, uninsured, or underinsured. Indigent is defined as at or below 200% of the federal poverty level.
3. Each eligible patient must have a valid prescription for the donated drug and present it to the Repository before the drug can be dispensed.
4. Each patient must submit a signed and dated statement affirming that the patient meets the eligibility requirements and will inform the repository if the patient’s eligibility changes.
5. A statement signed and dated by the eligible patient acknowledging receipt of notice that the prescription drug or supply was donated to the program, that the donors and participants in the program are immune from civil or criminal liability or disciplinary action, and that the eligible patient is not required to pay for the prescription drug or supply.

If you would like additional information about becoming a patient/recipient, go to the [program webpage](http://www.floridahealth.gov/licensing-and-regulation/florida-rx-repository-program/index.html)s for the Patient Application and Dispensing Form.

Patients are responsible for contacting a participating repository to inquire about available drugs. Participating repositories and available drugs and supplies can be found on the Participating Repository Spreadsheet linked on the program webpages.

Repositories can transfer drugs or supplies to other repositories participating in RxConnects by using the Transfer form found on the PrescriptionDrugDonationProgram@FLHealth.gov

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

**Required Repository Forms**

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

Below is a summary of the forms that are 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 form.

1. Summary of each Patient Application and Dispensing form received and processed in the prior month
2. Destruction of Drugs form
3. Donation form
4. Transfer form

For a list of participating repositories, go to the [program website](http://www.floridahealth.gov/licensing-and-regulation/florida-rx-repository-program/index.html).

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