



PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM GUIDE

DIVISION OF EMERGENCY PREPAREDNESS
AND COMMUNITY SUPPORT

FEBRUARY 2023



Table of Contents

	Page
General Program Information	3
Repository	4
Donor	7
Patient	9
Immunity from Liability and Disciplinary Action	10
Legal Authority	11
Contact Information	11
Appendices	12
• Repository	
○ Appendix A – Repository Application and Withdrawal Form	13
○ Appendix B – Destruction of Drugs Form	14
○ Appendix C – Transfer Form	15
○ Appendix D – Inventory Form	16
• Donor	
○ Appendix E – Donation Form	17
• Patient	
○ Appendix F – Patient Application and Dispensing Form	18

Welcome to the Florida Rx Connects Program Guide

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

Florida Rx Connects 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 who meet program eligibility and present with a valid prescription.

How does Florida Rx Connects work?

There are three key components to 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.



The Prescription Drug Donation Repository Program has three key components:

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

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
 - 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 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:

PrescriptionDrugDonationProgram@FLHealth.gov.

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 PrescriptionDrugDonationProgram@FLHealth.gov. 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 [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](https://floridahealth.gov) to access the Repository Participation or Withdrawal form.

For a list of participating repositories, go to [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](https://floridahealth.gov).

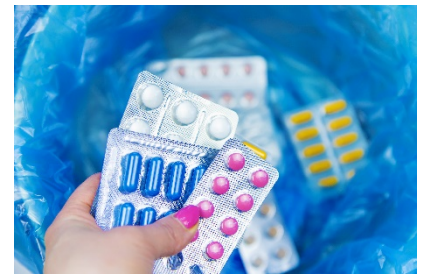
Questions may be sent to: PrescriptionDrugDonationProgram@FLHealth.gov. Please allow at least 24 hours for a response.

DONORS

Eligible Drug and Supply Donors

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

- Nursing home facilities with closed drug delivery systems
- Hospices that have maintained control of a patient's prescription drugs
- Hospitals with closed drug delivery systems
- Pharmacies
- Drug manufacturers or wholesale distributors
- Medical device manufacturers or suppliers
- Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy



Donation Requirements

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

- The donor has obtained written approval (email or US mail) from a participating repository prior to shipping any donated drugs or supplies.
- The drug is approved for medical use in the United States.
- The drug is in unopened, tamper-evident packaging.
- The drug requires storage at normal room temperature per the manufacturer or federal storage requirements.
- 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.
- 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.

Unacceptable Donations

Donations may **not** include controlled substances, cancer drugs donated under section 499.029, Florida Statutes, or drugs with an approved United States Food and Drug Administration risk evaluation and mitigation strategy.

If controlled substances are mistakenly received by a repository and it is not possible or practicable to return the controlled substances to the donor, such abandoned controlled substances must be documented and destroyed beyond reclamation pursuant to Rule 64B16-28.303, F.A.C.

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

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 by emailing PrescriptionDrugDonationProgram@FLHealth.gov and using the Transfer form which can be found on the program webpage.

If you would like additional information about becoming a donor, please go to [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](#).

PATIENTS

Eligible Patients

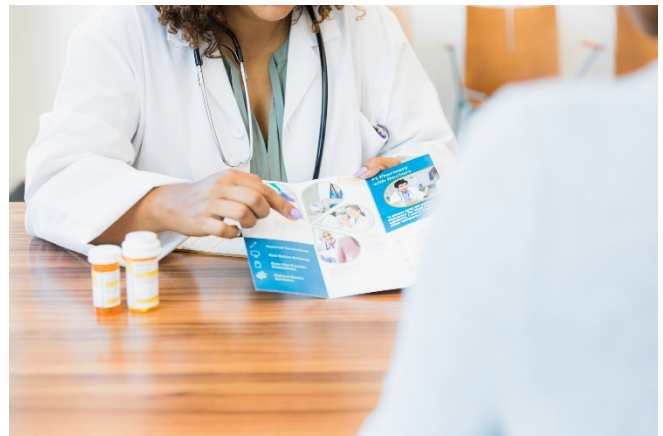
Any patient that wishes to receive prescription drugs from this program must:

- 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.
- Be a resident of Florida
- Have a valid prescription for a specific donated drug
- Complete and submit a Florida Rx Connects Patient Application and Dispensing form.

Patients Eligible to Participate

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

- Eligible patients must complete and submit an eligible Patient Application and Dispensing form to a participating repository to receive a donation.
- 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.
- Each eligible patient must have a valid prescription for the donated drug and present it to the repository before the drug can be dispensed.
- 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.
- 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.



2023 Federal Poverty Level

[Poverty Guidelines | ASPE \(hhs.gov\)](#)

2023 Family/Household Size	Fee Groups	
	100%	200%
1	14,580	29,160
2	19,720	39,440
3	24,860	49,720
4	30,000	60,000
5	35,140	70,280
6	40,280	80,560
7	45,420	90,840
8	50,560	101,120
9+	Add \$5,140 for each additional individual	Add \$10,280 for each additional individual



If you would like additional information about becoming a patient, go to [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](#) 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 webpage.

For a list of participating repositories, go to [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](#).

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

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 section 465.1902, Florida Statutes. Rules that guide the implementation of this program can be found in Chapter 64J-4, Florida Administrative Code.

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

LEGAL AUTHORITY

Section 465.1902, Florida Statutes - [Statutes & Constitution :View Statutes : Online Sunshine \(state.fl.us\)](#)

Chapter 64J04, Florida Administrative Code - [64J-4 : Prescription Drug Donation Repository Program - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking \(flrules.org\)](#)

CONTACT INFORMATION

Prescription Drug Donation Repository Program

Email: PrescriptionDrugDonationProgram@FLHealth.gov

Phone: 850-841-8530

Web: [Florida Rx Connects | Florida Department of Health \(floridahealth.gov\)](#)

APPENDICES

Appendix A



**PRESCRIPTION DRUG DONATION PROGRAM
REPOSITORY PARTICIPATION OR WITHDRAWAL FORM**

- Questions about completion of this form may be directed to the Bureau of Public Health Pharmacy at (850) 841-8530.

APPLICATION – PHARMACY OR MEDICAL FACILITY			
Name of Pharmacy or Medical Facility (Print)		Facility Telephone Number	
License/Registration Number (if Applicable)		Website (if Applicable)	
License/Registration Issuing Agency			
Address		Email address	
City		State	ZIP Code
Name-Pharmacist (Print)		Telephone Number	
Type of Facility (check one of the following):			
<input type="checkbox"/> Nursing home facility with closed drug delivery system <input type="checkbox"/> Hospital with closed drug delivery system <input type="checkbox"/> Pharmacy <input type="checkbox"/> Health Care Practitioner's office <input type="checkbox"/> Free clinic or nonprofit health clinic licensed or permitted to dispense medicinal drugs in the state			

I attest that the above-named facility is licensed in the State of Florida and complies with all applicable state and federal laws and administrative rules, including the requirements of section 465.1902, Florida Statutes.

SIGNATURE- Responsible Pharmacist >	Date Signed
--	-------------

NOTICE OF WITHDRAWAL – PHARMACY OR MEDICAL FACILITY		
Name of Pharmacy or Medical Facility	Telephone Number	
Address		
City	State	ZIP Code

I attest that, as of _____, the pharmacy or medical facility identified above will no longer be participating in the Prescription Drug Donation Repository Program.
(Date)

SIGNATURE- Responsible Pharmacist >	Date Signed
--	-------------

Submit this form to: PrescriptionDrugDonationProgram@FLHealth.gov and indicate in the subject line "Repository Participation or Withdrawal Form" or mail to: DOH Bureau of Public Health Pharmacy, Drug Donation Program, 104-2 Hamilton Park Dr., Tallahassee, FL 32304.

Appendix D

Florida Department of Health
 Prescription Drug Conversion Repository Program
 Repository Inventory Form

Repository Name:

	Drug Name/Medical Supply	Strength	Date of Receipt	Lot Number	Expiration Date	Available Quantity	Name of Donor	Donor's Address	Donor's Phone	Disposition Date
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										

DRP010-EPCS-1.0/001
 Rule 600-4.004, F.A.C.
 Effective December 2021

