

# PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM GUIDE

# DIVISION OF EMERGENCY PREPAREDNESS AND COMMUNITY SUPPORT

**April 2025** 



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#### 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 5<sup>th</sup> 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:
  - o Name of drug
  - 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 5<sup>th</sup> 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 5<sup>th</sup> 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 <a href="mailto:PrescriptionDrugDonationProgram@FLHealth.gov">PrescriptionDrugDonationProgram@FLHealth.gov</a>. 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 | Florida Department of Health (floridahealth.gov)</u> to access the Repository Participation or Withdrawal form.

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

Questions may be sent to: <u>PrescriptionDrugDonationProgram@FLHealth.gov</u>. 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 <a href="mailto:PrescriptionDrugDonationProgram@FLHealth.gov">PrescriptionDrugDonationProgram@FLHealth.gov</a> 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.

#### **2025 Federal Poverty Level**

2025 Family/Household Size	Fee Groups			
	100%	200%		
1	15,650	31,300		
2	21,150	42,300		
3	26,650	53,300		
4	32,150	64,300		

5	37,650	75,300
6	43,150	86,300
7	41,910	97,300
8	54,150	108,300
9	59,650	119,300
10	65,150	130,300
11+	Add \$5,500 for each	Add \$11,00 for each
	additional individual	additional individual

#### Poverty Guidelines | ASPE (hhs.gov)



If you would like additional information about becoming a patient, go to <u>Florida Rx Connects | Florida Department of Health (floridahealth.gov)</u> 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 <u>Florida Rx Connects | Florida Department of Health</u> (floridahealth.gov).

Questions may be sent to <a href="mailto:PrescriptionDrugDonationProgram@FLHealth.gov">PrescriptionDrugDonationProgram@FLHealth.gov</a>. 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 Guide

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 <u>PrescriptionDrugDonationProgram@FLHealth.gov</u>. 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) 922-9038.

Name of Pharmacy or Medical Facility (Print)  License/Registration Number (If Applicable)  License/Registration Issuing Agency  Address  City  Name-Pharmacist (Print)  Type of Facility (check one of the following): Nursing home facility with closed drug delivery systemHos  Health Care Practitioner's office	Barretta a a a a a a a a a a a a a a a a a a		ZIP Code    Description   Zip Code   Zip Cod
License/Registration Issuing Agency  Address  City  Name-Pharmacist (Print)  Type of Facility (check one of the following):  Nursing home facility with closed drug delivery system Hos	spital with closed drug delh	State Telephone Num	ZIP Code
Address  City  Name-Pharmacist (Print)  Type of Facility (check one of the following): Nursing home facility with closed drug delivery systemHos	spital with closed drug delh	Telephone Num	nber _ Pharmacy
City  Name-Pharmacist (Print)  Type of Facility (check one of the following): Nursing home facility with closed drug delivery systemHos	spital with closed drug delh	Telephone Num	nber _ Pharmacy
Name-Pharmacist (Print)  Type of Facility (check one of the following):  Nursing home facility with closed drug delivery system Hos	Barretta a a a a a a a a a a a a a a a a a a	Telephone Num	nber _ Pharmacy
Name-Pharmacist (Print)  Type of Facility (check one of the following): Nursing home facility with closed drug delivery systemHos	Barretta a a a a a a a a a a a a a a a a a a	Telephone Num	nber _ Pharmacy
Type of Facility (check one of the following):  Nursing home facility with closed drug delivery system Hos	Barretta a a a a a a a a a a a a a a a a a a	very system _	_ Pharmacy
Nursing home facility with closed drug delivery systemHos	Barretta a a a a a a a a a a a a a a a a a a		The same the same and the same a
T	Barretta a a a a a a a a a a a a a a a a a a		The same the same and the same a
Health Care Bracktionar's office Free clinic or nonnerfit he	aith clinic licensed or pem	nitted to dispens	e medicinal drugs in the state
Health Gale Flactionies o unice Hee chille of Hotologic he			
			CARTON SOCIAL SECTION SOCIAL SECTION S
attest that the above-named facility is licensed in the S federal laws and administrative rules, including the requ			
SIGNATURE- Responsible Pharmacist	Date Signed		
>	6)		
NOTICE OF WITHDRAWAL — P	HARMACY OR M Telephone Number	IEDICAL F	ACILITY
Address			
City	State		ZIP Code
attest that, as of, the pharmacy or m (Date) participating in the Prescription Drug Donation Reposito	nedical facility identific ory Program.	ed above will	no longer be
SIGNATURE- Responsible Pharmacist	Date Signed		
Submit this form to: PrescriptionDrugDonationProgram( Participation or Withdrawal Form" or mail to: DOH Bure 104-2 Hamilton Park Dr., Tallahassee, FL 32304.			
DH9006-EPCS-07/2021 Rule 64J-4.002, F.A.C.			Page 1

Effective: July 2021

#### Appendix B



### PRESCRIPTION DRUG DONATION PROGRAM DESTRUCTION OF DRUGS FORM

- Questions about completion of this form may be directed to the Bureau of Public Health
  Pharmacy at (850) 922-9036 or may be submitted to

  Proposition Proposi
- PrescriptionDruqDonationProgram@FLHealth.gov.

  Repositories are not allowed to receive monetary credit through any instrument of destruction, i.e. reverse distributor(s).

	<u> </u>	Cit. St.	
		City, Stat	te, ZIP Code
	SUPPLY INF		
ngth	NDC No.	Lot No.	Quantity Destroye
			*
	-		
	Dat	te	
Onatio Progra	nProgram@Fl am, 104-2 Hami	<u>Health.gov</u> or Iton Park Dr., T	mail to: DOH Bureau o allahassee, FL 32304
	Onatio Progra	onationProgram@FI	Date  OnationProgram@FLHealth.gov or Program, 104-2 Hamilton Park Dr., Ta

#### Appendix C



## PRESCRIPTION DRUG DONATION PROGRAM TRANSFER FORM

 Questions about completion of this form may be directed to the Bureau of Public Health Pharmacy at (850) 922-9036.

TRANSFERR		ACT OR W	EDICAL			100
Name- Pharmacy or Medical F	Facility (Print)			Date of T	ransfer (MM/DD/YY)	(Y)
Street Address	E	Email Address				
Facility Phone Number	City	37		State	ZIP Code	
DESCRIPTION OF THE PROPERTY OF		V 00 MED		OH 1774 BU		
RECEIVING Name- Pharmacy or Medical F		Y OR MED	ICAL FA		FORMATION ransfer (MM/DD/YY)	W)
raine Frantacy of Incascal I	comy			Date of 1	raisici (minisco i i	.,
Street Address			Email Address			
Facility Phone Number	City			State	ZIP Code	
	DRUG/MED	ICAL SUP	PI Y INFO	ORMATIO	N .	
Drug Name or Medical Supply	Strength	NDC No		Lot No.	Exp. Date	Qty
	1					
					3	B.
	1		_			
	-					
attest that the above-r	named reposito	ory receiving	the transf	ferred drugs	or supplies is	а
articipant in the Presc	ription Drug Do	onation Repo	ository Dru	ug Program		
rint Name (Pharmacis	st)	Sign	ature (Pha	armacist)	Date	•
Submit this form to: Preso Transfer Form" or mail to Hamilton Park Dr., Tallah	: DOH Bureau d	of Public Heal	@FLHealth th Pharmac	n.gov and inc cy, Drug Don	dicate in the subjustion Program, 1	ect line 04-2
	20					
H9007-EPCS-07/202 Rule 64J-4.002, F.A.C. Effective: July 2021					Page 1 of _	_

Appendix D

Donor's Address Name of Donor Florida Department of Health Prescription Drug Donation Re-pository Program Re-posit ory Inventory Form Expiration Date Lot Number Strength Drug NameMedical Repository Name:

DIPOTO-EPCS-12/2021 Role 647-4 (04, F.A.C. Effective December 2021

#### Appendix E



#### PRESCRIPTION DRUG DONATION PROGRAM DONATION FORM

# All donors must obtain written approval\* from a participating repository prior to shipping any donated drugs or supplies. Hand delivery, overnight or 2-day shipping is strongly encouraged once approval is obtained. • Questions about completion of this form may be directed to the Bureau of Public Health Pharmacy at (850) 922-9036.

		DONOR INFORM	MATION			
Name-Donor (Print)					Date Dona	ted (MM/DD/YYY)
Phone Number	Street Address		Email add	dress		
Ott.			sa	Lotete	1.70	D.O-4-
City				State	2	P Code
Indicate type of facility making  Nursing Home Hospice (that have maint: Pharmacy		□ Drug l lent's Rx's) □ Medic	tal Manufacturer al Device Manufactur riber (procured from a			aier, or pharmacy)
		ECIPIENT INFOR	RMATION			
Name of Pharmacy or Medical	Facility Receiving D	onations				
		EDICAL SUPPLY	The Real Property lies and the Personal Property lies and the	-	111111	
Drug Name or Medical Supply	Strength	NDC No.	Lot No.		ration ate	Quantity
				+		
		*				
		,				
By signing below, I veri	fy that all the dr	ugs or supplies be	ing donated me	et the pro	ogram e	ligibility
equirements, including						670 W 10
	C. LLUS DON'T VAN VAN TALVA SAA	Const.	A STATE OF THE STA		(1) (1) (1)	Transition (
Print Name (Inspecting	Pharmacist)	Sign	ature (Inspectir	ng Pharm	acist)	Date
This form must be retain	ned on file by th	ne receiving reposit	tory.			
Written approval may b	oe in the form o	f an email.				
OH9008-EPCS-07/2021	1					
Rule 64J-4.004, F.A.C. Effective: July 2021				Pag	e 1 of _	-8

#### Appendix F



# PRESCRIPTION DRUG DONATION PROGRAM PATIENT APPLICATION and DISPENSING FORM

		on of this form.  PATIENT INFO	RMATION			
Name- Patient (Print)				Received (MM/DD/YY	<b>YY</b> )	
ddress		City		21F	P Code	
Telephone number (home or w	ork)	Telephone number (cell) Email Address				
Indigent (at or below Undernsured (nour pocket expenses for pocket expenses for Uninsured (no health By signing below, I affirm my eligibility changes. I a donated to the program. disciplinary action. Eligib Attestation of Recipient (Signal	or health care benefithe drug prescribed care coverage and that I meet the iso acknowledg Donors and paile patients are	Its have been exhausted) I not eligible for drug covering the eligibility requirements the following: The recipants in the properticipants in the properticipants.	erage under federal gov ents of this section a prescription drug o gram are immune fr	emment program) nd will inform the r r supply I am rece om civil or criminal	epository if iving was	
Dispenser completes the			Y INFORMATIO	ON .		
Drug Name or Medical Supply	Strength	NDC No.	Lot No.	Expiration Date	Quantity	
Print Name (Dispenser		Signature (	Dispenser)	Date		
Submit this form to: <u>Pre</u> Public Health Pharmac)	scriptionDrug , Drug Donati	DonationProgram, 104-	am@FLHealth.q 2 Hamilton Park D	OV or mail to: DO or., Tallahassee,	H Bureau o FL 32304	
DH9005-EPCS-07/2021 Rule 64J-4.005, F.A.C.				Page	1 of	