Long-Term Care Regulatory Provider Letter

**Number:** PL 19-12  
**Title:** Prescription Drug Donation Program  
**Provider Types:** Nursing Facility (NF)  
**Date Issued:** May 13, 2019

### 1.0 Subject and Purpose

The Health and Human Services Commission (HHSC) is issuing this letter to provide information on the **Prescription Drug Donation Program**. This program allows individuals to donate certain unused prescription drugs\(^1\) to participating providers\(^2\) for distribution to eligible recipients\(^3\) who would normally be unable to get these medications.

### 2.0 Policy Details & Provider Responsibilities

#### 2.1 Participating Provider

A NF that maintains a licensed pharmacy\(^4\) in the facility may elect to become a participating provider in the program. To become a participating provider, a qualifying NF needs to submit the **Prescription Drug Donation Program Participating Provider Form** to the Department of State Health Services via email at rxdrugdonation@dshs.texas.gov or by fax at 512-776-7489.

Participating providers can accept donated prescription drugs from NF residents or their representatives. Participating providers must follow all applicable federal and state laws related to proper handling and distribution of prescription drugs. The participating provider must:

\(^1\) See Title 25, Texas Administrative Code, §95.2(12)  
\(^2\) See Title 25, Texas Administrative Code, §95.2(9)  
\(^3\) See Title 25, Texas Administrative Code, §95.2(14)  
\(^4\) See Title 25, Texas Administrative Code, §95.2(11)
• have a pharmacist\(^5\) properly inspect the donated prescription drugs to determine if the drugs meet the requirements of the program and are safe and suitable for dispensing;
• maintain an inventory to include the name, strength and quantity of the prescription drug and the date of the donation;
• destroy the donated prescription drug if not suitable for dispensing and maintain record of the discarded drugs; and
• maintain separate from the non-donated inventory.

A participating provider can charge a handling fee, not to exceed $20.00, to a recipient of donated drugs to cover costs associated with inspecting, storing, labeling and dispensing donated drugs.

### 2.2 Donor and Recipient Participation

A donor may donate unused prescription drugs to a participating provider. To become a donor, a NF or NF resident must fill out and sign the [Prescription Drug Donation Program Donor Form](#) acknowledging that they are the owner, or the owner’s representative, of the prescription drug and the donation to the program is voluntary. In addition, the donor must certify that the prescription drug has been properly stored and the packaging has not been opened, tampered with, adulterated or misbranded.

To be a recipient under the program, a NF resident must have a prescription provided by a health care professional and must fill out and sign the [Prescription Drug Donation Program Recipient Form](#). By signing the form, a NF resident acknowledges that the donor is not a pharmacist, the donor took ordinary care of the prescription drug and there is no reason to believe that the prescription drug was improperly handled or stored. The NF resident must also acknowledge that by accepting the donated prescription drugs, they accept any risks an accidental mishandling might create.

### 2.3 Requirements for Donated Prescription Drugs

Eligible prescription drugs for donation, acceptance and dispensation include drugs that:

\(^5\) See Title 25, Texas Administrative Code, [§95.2(10)](#)
• are approved by the federal Food and Drug Administration (FDA);
• are labeled “Rx Only” or “Caution: Federal Law Prohibits Dispensing without Prescription”;
• are in the original, sealed and tamper-evident unit-dose packaging;
• are in a package labeled with the expiration date and are not past the expiration date;
• have no physical signs of tampering or adulteration;
• have been properly stored per manufacturer requirements; and
• are intended for human consumption.

Ineligible prescription drugs for donation, acceptance and dispensation include prescription drugs that:
• require a storage temperature other than normal room temperature;
• are controlled substances\(^6\);
• have not been stored in compliance with product labels (this includes drugs that have been tampered with or misbranded);
• are required by the FDA to have a risk evaluation and mitigation strategy; and
• prescription drugs previously purchased by Medicaid.

### 3.0 Background/History

The Prescription Drug Donation Program was created by House Bill 2561 of the 85\(^{th}\) Legislature in 2017. House Bill 2561 added Chapter 442 to the Texas Health and Safety Code.

The Department of State Health Services’ Pharmacy Branch is the administrator of the program and does not accept or dispense donated prescription drugs at its warehouse.

### 4.0 Resources

- Prescription Drug Donation Program Frequently Asked Questions
- Prescription Drug Donation Program Participating Provider Database
- Prescription Drug Donation Program Participating Provider Form
- Prescription Drug Donation Program Donor Form
- Prescription Drug Donation Program Recipient Form

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\(^6\) See Title 25, Texas Administrative Code, §95.2(2)
5.0 Contact Information

For questions regarding the Prescription Drug Donation Program, please contact the Department of State Health Services at (512) 776-2741.

If you have any questions about this letter, please contact the Policy, Rules and Training Section by email at PolicyRulesTraining@hhsc.state.tx.us or call (512) 438-3161.