

Background

New York is the latest state to enact legislation establishing a pharmaceutical donation and reuse program to allow unused prescription drugs to be donated and re-dispensed to patients. Of the 42 states that have established such programs, only 20 have programs that are currently actively collecting and redispensing donated drugs to eligible patients.

New York State Public Health Law (PHL) § 280-b, requires the Department to promulgate regulations governing the donation and dispensing process, and no donations can occur until these regulations are adopted. Specifically, the law defines several terms essential to a drug donation program: “donor entity”, “recipient entity”, “third party intermediary”, and “redispense.” The definitions are set forth as follows:

- a. "Donor entity" means a manufacturer, wholesaler, or distributor of prescription drugs; a pharmacy; or a hospital authorized under article twenty-eight of this chapter.
- b. "Recipient entity" means a manufacturer, wholesaler, or distributor of prescription drugs; a pharmacy; or a hospital authorized under article twenty-eight of this chapter.
- c. "Third party intermediary" means a not-for-profit organization that facilitates the donation or transfer of prescription drugs under this section but does not take possession or ownership of the prescription drugs.
- d. "Redispense" means to dispense a prescription drug that was donated and received under this section.

The law allows the donation of unused prescription drugs only when completed in a secure manner and upon inspection by a pharmacist or other licensed health care provider, as provided in the Commissioner’s regulations. The law prevents the donation of drugs that are not provided in tamper-evident packaging, show evidence of being adulterated and misbranded or tampering, and would expire before use by the patient. Controlled substances are ineligible for donation, as well as prescription drugs restricted to a patient registered with the drug's manufacturer under federal Food and Drug Administration requirements including, but not limited to, those relating to risk evaluation and mitigation strategies (REMS), unless the redispensing is effectively restricted to ensure that the prescription drug is only dispensed in accordance with those requirements as applicable. In addition, participation in the Program by any donor or recipient entity is voluntary, and recipient entities are required to give priority for redispensing to patients who are indigent, uninsured, or under-insured.

The Department supports the concept of providing medically-necessary drugs to patients who may not have the financial means to afford them. The New York State Health Plan Marketplace, Elderly Pharmaceutical Insurance Coverage (EPIC) program, AIDS Drug Assistance (ADAP) program, and other prescription assistance programs currently provide low-cost options for the uninsured and underinsured. As the Department begins developing the requisite regulations to guide the Program, the Department notes several considerations that must govern the rulemaking process:

- It is of vital importance that any donor entity wishing to provide for the donation and redispensing of unused prescription drugs ensure against potential diversion and adulteration of medication.

- Any entities participating in the Program must be able to protect the integrity of the redispensed drugs, as prescription drugs must be continuously maintained in proper storage conditions, with sufficient assurances of their sterility, purity, and shelf life. Many drugs are light and temperature sensitive, and overexposure to light and heat would affect the drugs' strength and effectiveness.
- The Department also seeks to identify ways to prevent the dissemination of counterfeit drugs to participating patients.

Information Requested

It is of the utmost importance to the Department that any such program established in New York State maintain appropriate safeguards to preserve the health and safety of donating and participating patients. Furthermore, the Program must be consistent with applicable federal laws and policies, including HIPAA, the FDA Compliance Policy Guide, the Prescription Drug Marketing Act of 1987, the Food, Drug, and Cosmetic Act, and 21 CFR, Part 200, as well as state laws and regulations governing the practice of pharmacy.

To better inform the rulemaking process, the Department is soliciting responses to the questions listed below. Respondents are encouraged to provide any additional observations, strategies, and recommendations to support New York's efforts to implement a safe and effective drug donation program that complies with all applicable federal and state laws, regulations, and policies. Of particular interest to the Department are recommendations from stakeholders regarding preserving drug integrity and ensuring against diversion and misuse of donated drugs. While any interested party may respond, the Department has a strong interest in obtaining information from entities that would be interested in serving as either donors, recipients, or third-party intermediaries as described in PHL § 280-b.

All responses are non-binding and will be used for informational purposes only. Information provided becomes the property of New York State, for use at the Department's discretion. The Department is not responsible for any costs associated with the development and/or submission of any responses to this RFI. In addition, responders do not need to answer all the questions below, rather, they should answer questions relevant to their unique circumstances and interests.

General Inquiries:

1. Describe how you or your organization may be affected by the Program's implementation.
2. Identify and describe your or your organization's primary concerns with the development of the Program.
3. Identify and describe the possible risks of implementing the Program in New York State, as well as strategies to mitigate those risks.
4. Identify and describe the possible benefits of implementing the Program in New York State and describe what steps the Department can take to ensure the program is administered in an efficient manner that can best serve the intended recipients.
5. Identify any federal laws, regulations, or policies that may have a direct impact on the Program. Describe how the Department, in developing Program regulations, can ensure consistency with any applicable federal laws, regulations, and policies.

6. Would your organization be interested in becoming a donor or recipient entity? If so, why?
7. What should be the primary focus of the Program in terms of the types of individuals served and the types of drugs to be donated?
8. What are potential barriers to implementing the Program and what program features would be useful to overcome these barriers?
9. Should the Department set geographic limitations in developing regulations for the Program? For instance, should drug donation be limited to entities within the same county or local region?

Questions for Prospective Third-Party Intermediaries:

1. Please describe your organization, including its history, mission, structure, size, staff, and any other characteristics that demonstrate the organization's ability to appropriately serve as a third-party intermediary.
2. Identify and describe the parameters that should govern the physical transport of donated drugs between entities.
3. Identify specific steps that your organization would take to ensure that the integrity of donated drugs remains uncompromised. More specifically, please identify how participating entities can successfully determine whether a drug has been exposed to light, heat, or other conditions that may impact the efficacy of the donated drugs.
4. Identify and describe the appropriate safeguards to ensure the privacy of individuals for whom the donated drugs were initially prescribed.
5. From your or your organization's perspective, what types of criteria should be considered to determine eligibility for drug donation?
6. Please provide any other comments, recommendations, concerns, or feedback that you or your organization believe are worthy of consideration by the Department in developing Program regulations.
7. Identify and describe the parameters that should govern the physical transport of donated drugs from one entity to another.
8. Identify and describe record keeping requirements for participating entities that would protect against diversion of donated drugs.
9. Identify and describe any training requirements for individuals that participate in the management and donation of unused drugs under the Program.
10. Please provide any other comments, recommendations, concerns, or feedback that you or your organization believe are worthy of consideration by the Department in developing Program regulations.

Questions for Prospective Donor Entities:

1. Please describe your organization and how it meets the statutory definition of a "donor entity."
2. Identify specific steps that your organization would take to ensure that the integrity of donated drugs remains uncompromised prior to distribution to a third-party intermediary.
3. Identify and describe the parameters that should govern the physical transport of donated drugs between your organization and a third-party intermediary.
4. Identify and describe how your organization would ensure the privacy of individuals for whom the donated drugs were initially prescribed before distribution to a third-party intermediary.

5. From the perspective of your organization, what types of drugs would be most suitable for donation?
6. From the perspective of your organization, what types of drugs would be least suitable for donation?
7. Identify and describe how your organization would maintain appropriate records of donated drugs to prevent abuse or diversion.
8. What types of training, if any, would your organization recommend implementing for donor entity employees involved in the donation of unused drugs?
9. From your or your organization's perspective, what would be potential incentives to participating as a donor entity?
10. From your or your organization's perspective, what would be potential drawbacks to participating as a donor entity?
11. Please provide any other comments, recommendations, concerns, or feedback that you or your organization believe are worthy of consideration by the Department in developing Program regulations.

Questions for Prospective Recipient Entities:

1. Please describe your organization and how it meets the statutory definition of a "recipient entity."
2. Identify specific steps that your organization would take to ensure that the integrity of donated drugs remains uncompromised after the drugs are dispensed to you or your organization from the third-party intermediary.
3. From the perspective of your organization, what types of drugs would be most suitable for donation?
4. From the perspective of your organization, what types of drugs would be least suitable for donation?
5. Identify and describe how your organization would maintain appropriate records of donated drugs to prevent abuse or diversion.
6. What types of training, if any, would your organization recommend implementing for recipient entity employees involved in the receipt of donated unused drugs?
7. From your or your organization's perspective, what would be potential incentives to participating as a recipient entity?
8. From your or your organization's perspective, what would be potential drawbacks to participating as a recipient entity?
9. Please provide any other comments, recommendations, concerns, or feedback that you or your organization believe are worthy of consideration by the Department in developing Program regulations.

Who May Respond:

The RFI seeks input from all interested parties, including, but not limited to:

- Pharmacists;
- Article 28 facilities authorized to participate in the Program;
- Patient advocacy groups; and
- Organizations who have participated in the implementation of similar drug donation programs.