§ 280-b. Unused prescription drug donation and redispensing program.

1. As used in this section:

(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.

2. The commissioner shall make regulations governing the donation and redispensing of unused prescription drugs under this section.

3. A donor entity may donate unused prescription drugs to a recipient entity, directly or through a third-party intermediary, in a secure manner, ensuring the privacy of any individuals for whom the prescription drugs were initially dispensed or intended to be dispensed. Prescription drugs redispensed under this section shall be inspected by a pharmacist or other licensed health care provider as provided by regulations. The participation of any donor or recipient entity in redispensing shall be voluntary.

4. Only prescription drugs received by the recipient entity in tamper-evident packaging as defined by United States pharmacopoeia (USP) general chapter 659, or in unit-dose or multiple-dose packaging, may be redispensed. No prescription drugs may be redispensed that:

(a) show evidence of being adulterated or misbranded;

(b) show evidence of packaging having been tampered with;

(c) will expire before the use by the patient based on the prescribing practitioner's directions for use;

(d) or have been excluded from the program under regulations of the commissioner.

5. A prescription drug shall not be redispensed if it is 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.

6. A recipient entity may also be a donor entity.

7. Prescription drugs having passed inspection under subdivision three of this section may be repackaged or prepackaged by the recipient entity prior to further redispensing.

8. Recipient entities shall give priority for redispensing to patients who are indigent, uninsured, or under-insured.

9. A redispensed prescription drug shall not be resold by any person or entity. However, this subdivision does not bar the payment of reasonable processing fees.

10. No person or entity shall be subject to criminal or civil liability, or professional discipline for any action taken in reasonable good faith compliance with this section, except under otherwise applicable grounds for liability.

11. The department shall work with prospective and approved donor entities, recipient entities and third-party intermediaries to educate them about redispensing and promote participation in redispensing. The department shall maintain a list of recipient entities, and third-party intermediaries and publish it on the department's website.