

9905--A

I N A S S E M B L Y

April 26, 2016

Introduced by M. of A. GOTTFRIED -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to unused prescription drug donation and redispensing

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1 Section 1. Title 2 of article 2-A of the public health law is amended
2 by adding a new section 280-b to read as follows:
3 S 280-B. UNUSED PRESCRIPTION DRUG DONATION AND REDISPENSING PROGRAM.
4 1. AS USED IN THIS SECTION:
5 (A) "DONOR ENTITY" MEANS A MANUFACTURER, WHOLESALER, OR DISTRIBUTOR OF
6 PRESCRIPTION DRUGS; A PHARMACY; OR A HOSPITAL AUTHORIZED UNDER ARTICLE
7 TWENTY-EIGHT OF THIS CHAPTER, APPROVED BY THE DEPARTMENT UNDER THIS
8 SECTION.
9 (B) "RECIPIENT ENTITY" MEANS A MANUFACTURER, WHOLESALER, OR DISTRIBUTOR
10 OF PRESCRIPTION DRUGS; A PHARMACY; OR A HOSPITAL AUTHORIZED UNDER
11 ARTICLE TWENTY-EIGHT OF THIS CHAPTER, APPROVED BY THE DEPARTMENT UNDER
12 THIS SECTION.
13 (C) "THIRD PARTY INTERMEDIARY" MEANS A NOT-FOR-PROFIT ORGANIZATION THAT
14 FACILITATES THE DONATION OR TRANSFER OF PRESCRIPTION DRUGS UNDER THIS
15 SECTION BUT DOES NOT TAKE POSSESSION OR OWNERSHIP OF THE PRESCRIPTION
16 DRUGS, APPROVED BY THE DEPARTMENT UNDER THIS SECTION.
17 (D) "REDISPENSE" MEANS TO DONATE, RECEIVE, PROCESS, DISTRIBUTE, OR
18 DISPENSE A PRESCRIPTION DRUG UNDER THIS SECTION.
19 2. THE COMMISSIONER SHALL MAKE REGULATIONS GOVERNING THE REDISPENSING
20 OF UNUSED PRESCRIPTION DRUGS UNDER THIS SECTION, INCLUDING THE APPROVAL
21 OF DONOR ENTITIES, RECIPIENT ENTITIES, AND THIRD-PARTY INTERMEDIARIES.
22 3. A DONOR ENTITY MAY DONATE CENTRALLY STORED UNUSED PRESCRIPTION
23 DRUGS TO A RECIPIENT ENTITY, DIRECTLY OR THROUGH A THIRD-PARTY INTERME-
24 DIARY, IN A SECURE MANNER, ENSURING THE PRIVACY OF ANY INDIVIDUALS FOR
25 WHOM THE PRESCRIPTION DRUGS WERE INITIALLY DISPENSED OR INTENDED TO BE
26 DISPENSED. PRESCRIPTION DRUGS REDISPENSED UNDER THIS SECTION SHALL BE
27 INSPECTED BY A PHARMACIST OR OTHER LICENSED HEALTH CARE PROVIDER AS

EXPLANATION--Matter in *ITALICS* (underscored) is new; matter in brackets
[] is old law to be omitted.

LBD11582-06-6

1 PROVIDED BY REGULATIONS. THE PARTICIPATION OF ANY DONOR OR RECIPIENT
2 ENTITY IN REDISPENSING SHALL BE VOLUNTARY.

3 4. ONLY PRESCRIPTION DRUGS RECEIVED BY THE RECIPIENT ENTITY IN
4 TAMPER-EVIDENT PACKAGING AS DEFINED BY UNITED STATES PHARMACOPOEIA (USP)
5 GENERAL CHAPTER 659, OR IN UNIT-DOSE OR MULTIPLE-DOSE PACKAGING, MAY BE
6 REDISPENSED. NO PRESCRIPTION DRUGS MAY BE REDISPENSED THAT:

7 (A) SHOW EVIDENCE OF BEING ADULTERATED OR MISBRANDED; OR

8 (B) SHOW EVIDENCE OF PACKAGING HAVING BEEN TAMPERED WITH; OR

9 (C) WILL EXPIRE BEFORE THE USE BY THE PATIENT BASED ON THE PRESCRIBING
10 PRACTITIONER'S DIRECTIONS FOR USE.

11 5. A PRESCRIPTION DRUG SHALL NOT BE REDISPENSED IF IT IS RESTRICTED TO
12 A PATIENT REGISTERED WITH THE DRUG'S MANUFACTURER UNDER FEDERAL FOOD AND
13 DRUG ADMINISTRATION REQUIREMENTS INCLUDING, BUT NOT LIMITED TO, THOSE
14 RELATING TO RISK EVALUATION AND MITIGATION STRATEGIES (REMS), UNLESS THE
15 REDISPENSING IS EFFECTIVELY RESTRICTED TO ENSURE THAT THE PRESCRIPTION
16 DRUG IS ONLY DISPENSED IN ACCORDANCE WITH THOSE REQUIREMENTS AS APPLICA-
17 BLE.

18 6. A RECIPIENT ENTITY MAY ALSO BE A DONOR ENTITY.

19 7. PRESCRIPTION DRUGS HAVING PASSED INSPECTION UNDER SUBDIVISION THREE
20 OF THIS SECTION MAY BE REPACKAGED OR PREPACKAGED BY THE RECIPIENT ENTITY
21 PRIOR TO FURTHER REDISPENSING.

22 8. RECIPIENT ENTITIES SHALL GIVE PRIORITY FOR REDISPENSING TO PATIENTS
23 WHO ARE INDIGENT, UNINSURED, OR UNDER-INSURED.

24 9. A REDISPENSED PRESCRIPTION DRUG SHALL NOT BE RESOLD BY ANY PERSON
25 OR ENTITY. HOWEVER, THIS SUBDIVISION DOES NOT BAR THE PAYMENT OF REASON-
26 ABLE HANDLING FEES.

27 10. NO PERSON OR ENTITY SHALL BE SUBJECT TO CRIMINAL, CIVIL OR PROFES-
28 SIONAL DISCIPLINE LIABILITY FOR ANY ACTION TAKEN IN REASONABLE GOOD
29 FAITH COMPLIANCE WITH THIS SECTION, EXCEPT UNDER OTHERWISE APPLICABLE
30 GROUNDS FOR LIABILITY.

31 11. THE DEPARTMENT SHALL WORK WITH PROSPECTIVE AND APPROVED DONOR
32 ENTITIES, RECIPIENT ENTITIES AND THIRD-PARTY INTERMEDIARIES TO EDUCATE
33 THEM ABOUT REDISPENSING AND PROMOTE PARTICIPATION IN REDISPENSING. THE
34 DEPARTMENT SHALL MAINTAIN A LIST OF RECIPIENT ENTITIES, AND THIRD-PARTY
35 INTERMEDIARIES AND PUBLISH IT ON THE DEPARTMENT'S WEBSITE.

36 S 2. This act shall take effect immediately.