

9905--B

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 -- reported and referred to the Committee on Codes -- reported and referred to the Committee on Rules -- Rules Committee discharged, bill amended, ordered reprinted as amended and recommitted to the Committee on Rules

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.

8 (B) "RECIPIENT ENTITY" MEANS A MANUFACTURER, WHOLESALER, OR DISTRIBUTOR
9 OF PRESCRIPTION DRUGS; A PHARMACY; OR A HOSPITAL AUTHORIZED UNDER
10 ARTICLE TWENTY-EIGHT OF THIS CHAPTER.

11 (C) "THIRD PARTY INTERMEDIARY" MEANS A NOT-FOR-PROFIT ORGANIZATION THAT
12 FACILITATES THE DONATION OR TRANSFER OF PRESCRIPTION DRUGS UNDER THIS
13 SECTION BUT DOES NOT TAKE POSSESSION OR OWNERSHIP OF THE PRESCRIPTION
14 DRUGS.

15 (D) "REDISPENSE" MEANS TO DISPENSE A PRESCRIPTION DRUG THAT WAS
16 DONATED AND RECEIVED UNDER THIS SECTION.

17 2. THE COMMISSIONER SHALL MAKE REGULATIONS GOVERNING THE DONATION AND
18 REDISPENSING OF UNUSED PRESCRIPTION DRUGS UNDER THIS SECTION.

19 3. A DONOR ENTITY MAY DONATE UNUSED PRESCRIPTION DRUGS TO A RECIPIENT
20 ENTITY, DIRECTLY OR THROUGH A THIRD-PARTY INTERMEDIARY, IN A SECURE
21 MANNER, ENSURING THE PRIVACY OF ANY INDIVIDUALS FOR WHOM THE
22 PRESCRIPTION DRUGS WERE INITIALLY DISPENSED OR INTENDED TO BE DISPENSED.
23 PRESCRIPTION DRUGS REDISPENSED UNDER THIS SECTION SHALL BE INSPECTED BY
24 A PHARMACIST OR OTHER LICENSED HEALTH CARE PROVIDER AS PROVIDED BY REGU-

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

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1 LATIONS. THE PARTICIPATION OF ANY DONOR OR RECIPIENT ENTITY IN REDIS-
2 PENSING 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;

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

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

11 (D) OR HAVE BEEN EXCLUDED FROM THE PROGRAM UNDER REGULATIONS OF THE
12 COMMISSIONER.

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

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

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

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

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

29 10. NO PERSON OR ENTITY SHALL BE SUBJECT TO CRIMINAL OR CIVIL LIABIL-
30 ITY, OR PROFESSIONAL DISCIPLINE FOR ANY ACTION TAKEN IN REASONABLE GOOD
31 FAITH COMPLIANCE WITH THIS SECTION, EXCEPT UNDER OTHERWISE APPLICABLE
32 GROUNDS FOR LIABILITY.

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

38 S 2. This act shall take effect immediately.