

5903--A

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I N   S E N A T E

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Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Rules -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, passed by Senate and delivered to the Assembly, recalled, vote reconsidered, restored to third reading, amended and ordered reprinted, retaining its place in the order of third reading

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.

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

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1 3. A DONOR ENTITY MAY DONATE UNUSED PRESCRIPTION DRUGS TO A RECIPIENT  
2 ENTITY, DIRECTLY OR THROUGH A THIRD-PARTY INTERMEDIARY, IN A SECURE  
3 MANNER, ENSURING THE PRIVACY OF ANY INDIVIDUALS FOR WHOM THE  
4 PRESCRIPTION DRUGS WERE INITIALLY DISPENSED OR INTENDED TO BE DISPENSED.  
5 PRESCRIPTION DRUGS REDISPENSED UNDER THIS SECTION SHALL BE INSPECTED BY  
6 A PHARMACIST OR OTHER LICENSED HEALTH CARE PROVIDER AS PROVIDED BY REGU-  
7 LATIONS. THE PARTICIPATION OF ANY DONOR OR RECIPIENT ENTITY IN REDIS-  
8 PENSING SHALL BE VOLUNTARY.

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

13 (A) SHOW EVIDENCE OF BEING ADULTERATED OR MISBRANDED;  
14 (B) SHOW EVIDENCE OF PACKAGING HAVING BEEN TAMPERED WITH;  
15 (C) WILL EXPIRE BEFORE THE USE BY THE PATIENT BASED ON THE PRESCRIBING  
16 PRACTITIONER'S DIRECTIONS FOR USE;  
17 (D) OR HAVE BEEN EXCLUDED FROM THE PROGRAM UNDER REGULATIONS OF THE  
18 COMMISSIONER.

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

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

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

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

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

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

39 11. THE DEPARTMENT SHALL WORK WITH PROSPECTIVE AND APPROVED DONOR  
40 ENTITIES, RECIPIENT ENTITIES AND THIRD-PARTY INTERMEDIARIES TO EDUCATE  
41 THEM ABOUT REDISPENSING AND PROMOTE PARTICIPATION IN REDISPENSING. THE  
42 DEPARTMENT SHALL MAINTAIN A LIST OF RECIPIENT ENTITIES, AND THIRD-PARTY  
43 INTERMEDIARIES AND PUBLISH IT ON THE DEPARTMENT'S WEBSITE.

44 S 2. This act shall take effect immediately.