

# STATE OF NEW YORK

2301

2017-2018 Regular Sessions

## IN ASSEMBLY

January 17, 2017

Introduced by M. of A. MORELLE, LUPARDO, CUSICK, SCHIMMINGER, BENEDETTO, BRONSON, CAHILL, GALEF, GUNTHER, JAFFEE, SIMOTAS, WEPRIN, PEOPLES-STOKES, SKOUFIS -- Multi-Sponsored by -- M. of A. ABBATE, ABINANTI, BRAUNSTEIN, JENNE, MAGEE, THIELE, TITONE -- read once and referred to the Committee on Higher Education

AN ACT to amend the education law, in relation to establishing under the direction of the state board of pharmacy a drug repository program to accept and dispense donated prescription drugs

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. The education law is amended by adding a new section 6832  
2 to read as follows:

3 § 6832. Repository program; accept and dispense donated prescription  
4 drugs. 1. As used in this section: a. "Hospital" has the same meaning as  
5 in subdivision one of section twenty-eight hundred one of the public  
6 health law.

7 b. "Nonprofit clinic" means a corporation as defined in subparagraph  
8 five of paragraph (a) of section one hundred two of the not-for-profit  
9 corporation law, or any charitable organization not organized and not  
10 operated for profit, that provides health care services to indigent and  
11 uninsured persons. "Nonprofit clinic" shall not include a hospital or a  
12 facility as defined in subdivision one of section twenty-eight hundred  
13 one of the public health law.

14 c. "Prescription drug" means any drug to which the following applies:  
15 (1) Under the Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), 21  
16 U.S.C.A. 301, as amended, the drug is required to bear a label contain-  
17 ing the legend, "Caution: Federal law prohibits dispensing without  
18 prescription" or "Caution: Federal law restricts this drug to use by or  
19 on the order of a licensed veterinarian" or any similar restrictive  
20 statement, or the drug may be dispensed only upon a prescription.

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

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1     (2) Under this article, the drug may be dispensed only upon a  
2 prescription.

3     (3) Drugs that can only be dispensed to a patient registered with the  
4 drug's manufacturer in accordance with federal Food and Drug Adminis-  
5 tration requirements may not be accepted or distributed under the  
6 provisions of this section.

7     2. The state board of pharmacy shall establish a drug repository  
8 program to accept and dispense prescription drugs donated for the  
9 purpose of being dispensed to individuals who are residents of this  
10 state and meet eligibility standards established in rules and regu-  
11 lations adopted by the board under subdivision five of this section.  
12 Only prescription drugs in their original sealed and tamper-evident unit  
13 dose packaging shall be accepted and dispensed. The packaging shall be  
14 unopened, except that drugs packaged in single unit doses shall be  
15 accepted and dispensed when the outside packaging is opened if the  
16 single unit dose packaging is undisturbed. Prescription drugs donated by  
17 individuals bearing an expiration date that is less than six months from  
18 the date the drug is donated shall not be accepted or dispensed. A  
19 prescription drug shall not be accepted or dispensed if there is reason  
20 to believe that it is adulterated as described in section sixty-eight  
21 hundred fifteen of this article. Subject to the limitation specified in  
22 this subdivision, unused prescription drugs dispensed for purposes of  
23 the medicaid program may be accepted and dispensed under the drug repos-  
24 itory program.

25     3. a. Any person, including a drug manufacturer or any health care  
26 facility may donate prescription drugs to the drug repository program.  
27 The drugs shall be donated at a pharmacy, hospital or nonprofit clinic  
28 that elects to participate in the drug repository program and meets  
29 criteria for participation in the program established in rules and regu-  
30 lations adopted by the state board of pharmacy under subdivision five of  
31 this section. Participation in the program by pharmacies, hospitals and  
32 nonprofit clinics is voluntary. Nothing in this section requires a phar-  
33 macy, hospital or nonprofit clinic to participate in the program.

34     b. A pharmacy, hospital or nonprofit clinic eligible to participate in  
35 the program shall dispense prescription drugs donated under this section  
36 to individuals who are residents of this state and meet the eligibility  
37 standards established in rules and regulations adopted by the board  
38 under subdivision five of this section or to other government entities  
39 and nonprofit private entities to be dispensed to individuals who meet  
40 the eligibility standards. A prescription drug shall be dispensed only  
41 pursuant to a prescription issued by a licensed health professional  
42 authorized to prescribe drugs, as defined in section sixty-eight hundred  
43 two of this article. A pharmacy, hospital or nonprofit clinic that  
44 accepts donated drugs shall comply with all applicable federal laws and  
45 laws of this state dealing with storage and distribution of dangerous  
46 drugs and shall inspect all prescription drugs prior to dispensing them  
47 to determine that such drugs are not adulterated. The pharmacy, hospital  
48 or nonprofit clinic shall charge individuals receiving donated  
49 prescription drugs a handling fee established in accordance with rules  
50 and regulations adopted by the board under subdivision five of this  
51 section. Prescription drugs donated to the repository shall not be  
52 resold.

53     4. a. As used in this section, "health care professional" means any of  
54 the following who provide medical, dental or other health-related diag-  
55 nosis, care or treatment:

1 (1) Individuals authorized under this title to practice medicine and  
2 surgery or podiatric medicine and surgery;

3 (2) Registered professional nurses and licensed practical nurses  
4 licensed under article one hundred thirty-nine of this title;

5 (3) Physician assistants authorized to practice under article one  
6 hundred thirty-one-B of this title;

7 (4) Dentists and dental hygienists licensed under article one hundred  
8 thirty-three of this title;

9 (5) Optometrists licensed under article one hundred forty-three of  
10 this title;

11 (6) Pharmacists licensed under this article.

12 b. The state board of pharmacy; the commissioner of health; any  
13 person, including a drug manufacturer or government entity that donates  
14 prescription drugs to the repository program; any pharmacy, hospital,  
15 nonprofit clinic or health care professional that accepts or dispenses  
16 prescription drugs under the program; and any pharmacy, hospital or  
17 nonprofit clinic that employs a health care professional who, reasonably  
18 and in good faith, accepts or dispenses prescription drugs under the  
19 program shall not be subject to any of the following for matters related  
20 to donating, accepting or dispensing prescription drugs under the  
21 program: criminal prosecution; liability in tort or other civil action  
22 for injury, death or loss to person or property; or professional disci-  
23 plinary action.

24 A drug manufacturer, who acts reasonably and in good faith, shall not  
25 be subject to criminal prosecution or liability in tort or other civil  
26 action for injury, death or loss to person or property for matters  
27 related to the donation, acceptance or dispensing of a prescription drug  
28 manufactured by the drug manufacturer that is donated by any person  
29 under the program, including but not limited to liability for failure to  
30 transfer or communicate product or consumer information or the expira-  
31 tion date of the donated prescription drug.

32 5. In consultation with the commissioner of health, the state board of  
33 pharmacy shall adopt rules and regulations governing the drug repository  
34 program that establish all of the following:

35 a. Eligibility criteria for pharmacies, hospitals and nonprofit clin-  
36 ics to receive and dispense donated prescription drugs under the  
37 program;

38 b. Standards and procedures for accepting, safely storing and dispens-  
39 ing donated prescription drugs;

40 c. Standards and procedures for inspecting donated prescription drugs  
41 to determine that the original unit dose packaging is sealed and  
42 tamper-evident and that the drugs are unadulterated, safe and suitable  
43 for dispensing;

44 d. Eligibility standards based on economic need for individuals to  
45 receive prescription drugs;

46 e. A means, such as an identification card, by which an individual who  
47 is eligible to receive donated prescription drugs shall demonstrate  
48 eligibility to the pharmacy, hospital or nonprofit clinic dispensing the  
49 drugs;

50 f. A form that an individual receiving a prescription drug from the  
51 repository shall sign before receiving the drug to confirm that the  
52 individual understands the immunity provisions of the program;

53 g. A formula to determine the amount of a handling fee that pharma-  
54 cies, hospitals and nonprofit clinics shall charge to prescription drug  
55 recipients to cover restocking and dispensing costs;

1 h. In addition, for prescription drugs donated to the repository by  
2 individuals:

3 (1) A list of prescription drugs, arranged either by category or by  
4 individual drug, that the repository shall accept from individuals;

5 (2) A list of prescription drugs, arranged either by category or by  
6 individual drug, that the repository shall not accept from individuals.  
7 The list shall include but not be limited to, a statement as to why the  
8 drug is ineligible for donation.

9 (3) A form each donor shall sign stating that the donor is the owner  
10 of the prescription drugs and intends to voluntarily donate such drugs  
11 to the repository.

12 i. In addition, for prescription drugs donated to the repository by  
13 health care facilities:

14 (1) A list of prescription drugs, arranged either by category or by  
15 individual drug, that the repository shall accept from health care  
16 facilities;

17 (2) A list of prescription drugs, arranged either by category or by  
18 individual drug, that the repository shall not accept from health care  
19 facilities. The list shall include a statement as to why such drug is  
20 ineligible for donation.

21 j. Any other standards and procedures the board considers appropriate.

22 § 2. This act shall take effect on the one hundred eightieth day after  
23 it shall have become a law. Effective immediately, the addition, amend-  
24 ment and/or repeal of any rule or regulation necessary for the implemen-  
25 tation of this act on its effective date is authorized to be made on or  
26 before such effective date.