S T A T E O F N E W Y O R K

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I N A S S E M B L Y

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Introduced by M. of A. MORELLE, LUPARDO, WRIGHT, CUSICK, SCHIMMINGER, BENEDETTO, BRONSON, CAHILL, GALEF, GUNTHER, JAFFEE, ROBERTS, SIMOTAS, WEPRIN, PEOPLES-STOKES -- Multi-Sponsored by -- M. of A. ABBATE, ABINANTI, BRAUNSTEIN, BRENNAN, HEASTIE, MAGEE, RUSSELL, SCHIMEL, 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:

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

S 6832. REPOSITORY PROGRAM; ACCEPT AND DISPENSE DONATED PRESCRIPTION DRUGS. 1. AS USED IN THIS SECTION: A. "HOSPITAL" HAS THE SAME MEANING AS IN SUBDIVISION ONE OF SECTION TWENTY-EIGHT HUNDRED ONE OF THE PUBLIC HEALTH LAW.

B. "NONPROFIT CLINIC" MEANS A CORPORATION AS DEFINED IN SUBPARAGRAPH FIVE OF PARAGRAPH (A) OF SECTION ONE HUNDRED TWO OF THE NOT-FOR-PROFIT CORPORATION LAW, OR ANY CHARITABLE ORGANIZATION NOT ORGANIZED AND NOT OPERATED FOR PROFIT, THAT PROVIDES HEALTH CARE SERVICES TO INDIGENT AND UNINSURED PERSONS. "NONPROFIT CLINIC" SHALL NOT INCLUDE A HOSPITAL OR A FACILITY AS DEFINED IN SUBDIVISION ONE OF SECTION TWENTY-EIGHT HUNDRED ONE OF THE PUBLIC HEALTH LAW.

C. "PRESCRIPTION DRUG" MEANS ANY DRUG TO WHICH THE FOLLOWING APPLIES:

(1) UNDER THE FOOD, DRUG, AND COSMETIC ACT, 52 STAT. 1040 (1938), 21 U.S.C.A. 301, AS AMENDED, THE DRUG IS REQUIRED TO BEAR A LABEL CONTAINING THE LEGEND, "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION" OR "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN" OR ANY SIMILAR RESTRICTIVE 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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(2) UNDER THIS ARTICLE, THE DRUG MAY BE DISPENSED ONLY UPON A PRESCRIPTION.

(3) DRUGS THAT CAN ONLY BE DISPENSED TO A PATIENT REGISTERED WITH THE DRUG'S MANUFACTURER IN ACCORDANCE WITH FEDERAL FOOD AND DRUG ADMINISTRATION REQUIREMENTS MAY NOT BE ACCEPTED OR DISTRIBUTED UNDER THE PROVISIONS OF THIS SECTION.

2. THE STATE BOARD OF PHARMACY SHALL ESTABLISH A DRUG REPOSITORY PROGRAM TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS DONATED FOR THE PURPOSE OF BEING DISPENSED TO INDIVIDUALS WHO ARE RESIDENTS OF THIS STATE AND MEET ELIGIBILITY STANDARDS ESTABLISHED IN RULES AND REGULATIONS ADOPTED BY THE BOARD UNDER SUBDIVISION FIVE OF THIS SECTION. ONLY PRESCRIPTION DRUGS IN THEIR ORIGINAL SEALED AND TAMPER-EVIDENT UNIT DOSE PACKAGING SHALL BE ACCEPTED AND DISPENSED. THE PACKAGING SHALL BE UNOPENED, EXCEPT THAT DRUGS PACKAGED IN SINGLE UNIT DOSES SHALL BE ACCEPTED AND DISPENSED WHEN THE OUTSIDE PACKAGING IS OPENED IF THE SINGLE UNIT DOSE PACKAGING IS UNDISTURBED. PRESCRIPTION DRUGS DONATED BY INDIVIDUALS BEARING AN EXPIRATION DATE THAT IS LESS THAN SIX MONTHS FROM THE DATE THE DRUG IS DONATED SHALL NOT BE ACCEPTED OR DISPENSED. A PRESCRIPTION DRUG SHALL NOT BE ACCEPTED OR DISPENSED IF THERE IS REASON TO BELIEVE THAT IT IS ADULTERATED AS DESCRIBED IN SECTION SIXTY-EIGHT HUNDRED FIFTEEN OF THIS ARTICLE. SUBJECT TO THE LIMITATION SPECIFIED IN THIS SUBDIVISION, UNUSED PRESCRIPTION DRUGS DISPENSED FOR PURPOSES OF THE MEDICAID PROGRAM MAY BE ACCEPTED AND DISPENSED UNDER THE DRUG REPOSITORY PROGRAM.

3. A. ANY PERSON, INCLUDING A DRUG MANUFACTURER OR ANY HEALTH CARE FACILITY MAY DONATE PRESCRIPTION DRUGS TO THE DRUG REPOSITORY PROGRAM. THE DRUGS SHALL BE DONATED AT A PHARMACY, HOSPITAL OR NONPROFIT CLINIC THAT ELECTS TO PARTICIPATE IN THE DRUG REPOSITORY PROGRAM AND MEETS CRITERIA FOR PARTICIPATION IN THE PROGRAM ESTABLISHED IN RULES AND REGULATIONS ADOPTED BY THE STATE BOARD OF PHARMACY UNDER SUBDIVISION FIVE OF THIS SECTION. PARTICIPATION IN THE PROGRAM BY PHARMACIES, HOSPITALS AND NONPROFIT CLINICS IS VOLUNTARY. NOTHING IN THIS SECTION REQUIRES A PHARMACY, HOSPITAL OR NONPROFIT CLINIC TO PARTICIPATE IN THE PROGRAM.

B. A PHARMACY, HOSPITAL OR NONPROFIT CLINIC ELIGIBLE TO PARTICIPATE IN THE PROGRAM SHALL DISPENSE PRESCRIPTION DRUGS DONATED UNDER THIS SECTION TO INDIVIDUALS WHO ARE RESIDENTS OF THIS STATE AND MEET THE ELIGIBILITY STANDARDS ESTABLISHED IN RULES AND REGULATIONS ADOPTED BY THE BOARD UNDER SUBDIVISION FIVE OF THIS SECTION OR TO OTHER GOVERNMENT ENTITIES AND NONPROFIT PRIVATE ENTITIES TO BE DISPENSED TO INDIVIDUALS WHO MEET THE ELIGIBILITY STANDARDS. A PRESCRIPTION DRUG SHALL BE DISPENSED ONLY PURSUANT TO A PRESCRIPTION ISSUED BY A LICENSED HEALTH PROFESSIONAL AUTHORIZED TO PRESCRIBE DRUGS, AS DEFINED IN SECTION SIXTY-EIGHT HUNDRED TWO OF THIS ARTICLE. A PHARMACY, HOSPITAL OR NONPROFIT CLINIC THAT ACCEPTS DONATED DRUGS SHALL COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND LAWS OF THIS STATE DEALING WITH STORAGE AND DISTRIBUTION OF DANGEROUS DRUGS AND SHALL INSPECT ALL PRESCRIPTION DRUGS PRIOR TO DISPENSING THEM TO DETERMINE THAT SUCH DRUGS ARE NOT ADULTERATED. THE PHARMACY, HOSPITAL OR NONPROFIT CLINIC SHALL CHARGE INDIVIDUALS RECEIVING DONATED PRESCRIPTION DRUGS A HANDLING FEE ESTABLISHED IN ACCORDANCE WITH RULES AND REGULATIONS ADOPTED BY THE BOARD UNDER SUBDIVISION FIVE OF THIS SECTION. PRESCRIPTION DRUGS DONATED TO THE REPOSITORY SHALL NOT BE RESOLD.

4. A. AS USED IN THIS SECTION, "HEALTH CARE PROFESSIONAL" MEANS ANY OF THE FOLLOWING WHO PROVIDE MEDICAL, DENTAL OR OTHER HEALTH-RELATED DIAGNOSIS, CARE OR TREATMENT:

(1) INDIVIDUALS AUTHORIZED UNDER THIS TITLE TO PRACTICE MEDICINE AND SURGERY OR PODIATRIC MEDICINE AND SURGERY;
(2) REGISTERED PROFESSIONAL NURSES AND LICENSED PRACTICAL NURSES LICENSED UNDER ARTICLE ONE HUNDRED THIRTY-NINE OF THIS TITLE;
(3) PHYSICIAN ASSISTANTS AUTHORIZED TO PRACTICE UNDER ARTICLE ONE HUNDRED THIRTY-ONE-B OF THIS TITLE;
(4) DENTISTS AND DENTAL HYGIENISTS LICENSED UNDER ARTICLE ONE HUNDRED THIRTY-THREE OF THIS TITLE;
(5) OPTOMETRISTS LICENSED UNDER ARTICLE ONE HUNDRED FORTY-THREE OF THIS TITLE;
(6) PHARMACISTS LICENSED UNDER THIS ARTICLE.

B. THE STATE BOARD OF PHARMACY; THE COMMISSIONER OF HEALTH; ANY PERSON, INCLUDING A DRUG MANUFACTURER OR GOVERNMENT ENTITY THAT DONATES PRESCRIPTION DRUGS TO THE REPOSITORY PROGRAM; ANY PHARMACY, HOSPITAL, NONPROFIT CLINIC OR HEALTH CARE PROFESSIONAL THAT ACCEPTS OR DISPENSES PRESCRIPTION DRUGS UNDER THE PROGRAM; AND ANY PHARMACY, HOSPITAL OR NONPROFIT CLINIC THAT EMPLOYS A HEALTH CARE PROFESSIONAL WHO, REASONABLY AND IN GOOD FAITH, ACCEPTS OR DISPENSES PRESCRIPTION DRUGS UNDER THE PROGRAM SHALL NOT BE SUBJECT TO ANY OF THE FOLLOWING FOR MATTERS RELATED TO DONATING, ACCEPTING OR DISPENSING PRESCRIPTION DRUGS UNDER THE PROGRAM: CRIMINAL PROSECUTION; LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY, DEATH OR LOSS TO PERSON OR PROPERTY; OR PROFESSIONAL DISCIPLINARY ACTION.

A DRUG MANUFACTURER, WHO ACTS REASONABLY AND IN GOOD FAITH, SHALL NOT BE SUBJECT TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY, DEATH OR LOSS TO PERSON OR PROPERTY FOR MATTERS RELATED TO THE DONATION, ACCEPTANCE OR DISPENSING OF A PRESCRIPTION DRUG MANUFACTURED BY THE DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON UNDER THE PROGRAM, INCLUDING BUT NOT LIMITED TO LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED PRESCRIPTION DRUG.

5. IN CONSULTATION WITH THE COMMISSIONER OF HEALTH, THE STATE BOARD OF PHARMACY SHALL ADOPT RULES AND REGULATIONS GOVERNING THE DRUG REPOSITORY PROGRAM THAT ESTABLISH ALL OF THE FOLLOWING:

A. ELIGIBILITY CRITERIA FOR PHARMACIES, HOSPITALS AND NONPROFIT CLINICS TO RECEIVE AND DISPENSE DONATED PRESCRIPTION DRUGS UNDER THE PROGRAM;

B. STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY STORING AND DISPENSING DONATED PRESCRIPTION DRUGS;

C. STANDARDS AND PROCEDURES FOR INSPECTING DONATED PRESCRIPTION DRUGS TO DETERMINE THAT THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND TAMPER-EVIDENT AND THAT THE DRUGS ARE UNADULTERATED, SAFE AND SUITABLE FOR DISPENSING;

D. ELIGIBILITY STANDARDS BASED ON ECONOMIC NEED FOR INDIVIDUALS TO RECEIVE PRESCRIPTION DRUGS;

E. A MEANS, SUCH AS AN IDENTIFICATION CARD, BY WHICH AN INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE DONATED PRESCRIPTION DRUGS SHALL DEMONSTRATE ELIGIBILITY TO THE PHARMACY, HOSPITAL OR NONPROFIT CLINIC DISPENSING THE DRUGS;

F. A FORM THAT AN INDIVIDUAL RECEIVING A PRESCRIPTION DRUG FROM THE REPOSITORY SHALL SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM;

G. A FORMULA TO DETERMINE THE AMOUNT OF A HANDLING FEE THAT PHARMACIES, HOSPITALS AND NONPROFIT CLINICS SHALL CHARGE TO PRESCRIPTION DRUG RECIPIENTS TO COVER RESTOCKING AND DISPENSING COSTS;

H. IN ADDITION, FOR PRESCRIPTION DRUGS DONATED TO THE REPOSITORY BY INDIVIDUALS:

(1) A LIST OF PRESCRIPTION DRUGS, ARRANGED EITHER BY CATEGORY OR BY INDIVIDUAL DRUG, THAT THE REPOSITORY SHALL ACCEPT FROM INDIVIDUALS;

(2) A LIST OF PRESCRIPTION DRUGS, ARRANGED EITHER BY CATEGORY OR BY INDIVIDUAL DRUG, THAT THE REPOSITORY SHALL NOT ACCEPT FROM INDIVIDUALS. THE LIST SHALL INCLUDE BUT NOT BE LIMITED TO, A STATEMENT AS TO WHY THE DRUG IS INELIGIBLE FOR DONATION.

(3) A FORM EACH DONOR SHALL SIGN STATING THAT THE DONOR IS THE OWNER OF THE PRESCRIPTION DRUGS AND INTENDS TO VOLUNTARILY DONATE SUCH DRUGS TO THE REPOSITORY.

I. IN ADDITION, FOR PRESCRIPTION DRUGS DONATED TO THE REPOSITORY BY HEALTH CARE FACILITIES:

(1) A LIST OF PRESCRIPTION DRUGS, ARRANGED EITHER BY CATEGORY OR BY INDIVIDUAL DRUG, THAT THE REPOSITORY SHALL ACCEPT FROM HEALTH CARE FACILITIES;

(2) A LIST OF PRESCRIPTION DRUGS, ARRANGED EITHER BY CATEGORY OR BY INDIVIDUAL DRUG, THAT THE REPOSITORY SHALL NOT ACCEPT FROM HEALTH CARE FACILITIES. THE LIST SHALL INCLUDE A STATEMENT AS TO WHY SUCH DRUG IS INELIGIBLE FOR DONATION.

J. ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS APPROPRIATE.

S 2. This act shall take effect on the one hundred eightieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date is authorized to be made on or before such effective date.