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

10298

I N A S S E M B L Y

May 20, 2016

Introduced by M. of A. ENGLEBRIGHT, ROSENTHAL -- read once and referred to the Committee on Environmental Conservation

AN ACT to amend the environmental conservation law, in relation to establishing a drug stewardship program

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

Section 1. Title 27 of article 27 of the environmental conservation law, as added by chapter 625 of the laws of 2008, is amended by adding a new section 27-2705 to read as follows:

S 27-2705. DRUG STEWARDSHIP PROGRAM.

1. AS USED IN THIS SECTION, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS UNLESS THE CONTEXT CLEARLY REQUIRES OTHERWISE:

(A) "COVERED DRUG" MEANS ANY BRAND NAME OR GENERIC OPIOID DRUG PLACED IN SCHEDULE I, SCHEDULE II OR SCHEDULE III OF SECTION THIRTY-THREE HUNDRED SIX OF THE PUBLIC HEALTH LAW; PROVIDED, HOWEVER, THAT "COVERED DRUG" SHALL ALSO INCLUDE BENZODIAZEPINES; PROVIDED, FURTHER, THAT "COVERED DRUG" SHALL NOT INCLUDE: (I) DRUGS INTENDED FOR USE SOLELY IN VETERINARY CARE; (II) SUBSTANCES THAT ARE REGULATED AS COSMETIC PRODUCTS UNDER THE UNITED STATES FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. S 301 ET SEQ.; (III) HYPODERMIC NEEDLES, LANCETS OR OTHER SHARPS PRODUCTS SUBJECT TO COLLECTION AND DISPOSAL PROCEDURES ESTABLISHED IN SUBDIVISION FOUR OF SECTION THIRTEEN HUNDRED EIGHTY-NINE-DD OF THE PUBLIC HEALTH LAW, OR (IV) DRUGS APPROVED AND USE PRIMARILY FOR MEDICATION-ASSISTED SUBSTANCE USE DISORDER TREATMENT.

(B) "DRUG STEWARDSHIP PROGRAM" MEANS A PROGRAM FINANCED BY A PHARMACEUTICAL PRODUCT MANUFACTURER OR A GROUP OF MANUFACTURERS TO COLLECT, SECURE, TRANSPORT AND SAFELY DISPOSE OF UNWANTED DRUGS.

(C) "PHARMACEUTICAL PRODUCT MANUFACTURER" OR "MANUFACTURER" MEANS AN ENTITY THAT MANUFACTURES A CONTROLLED SUBSTANCE UNDER A UNITED STATES FOOD AND DRUG ADMINISTRATION MANUFACTURER'S LICENSE.

(D) "PRESCRIPTION DRUG" SHALL HAVE THE SAME MEANING AS SUBDIVISION NINE OF SECTION TWO HUNDRED SEVENTY OF THE PUBLIC HEALTH LAW.

(E) "STEWARDSHIP ORGANIZATION" MEANS AN ORGANIZATION DESIGNATED BY A MANUFACTURER OR A GROUP OF MANUFACTURERS TO ACT AS AN AGENT ON BEHALF OF

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

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THE MANUFACTURER OR THE GROUP OF MANUFACTURERS TO IMPLEMENT AND OPERATE A DRUG STEWARDSHIP PROGRAM.

(F) "UNWANTED DRUG" MEANS A COVERED DRUG: (I) THAT IS NO LONGER WANTED OR INTENDED TO BE CONSUMED, OR THAT IS ABANDONED, DISCARDED, EXPIRED OR SURRENDERED BY THE PERSON TO WHOM IT WAS PRESCRIBED; OR (II) VOLUNTARILY DEPOSITED AT COLLECTION POINTS CO-LOCATED WITH A LAW ENFORCEMENT AGENCY; PROVIDED, HOWEVER, THAT "UNWANTED DRUG" SHALL NOT INCLUDE: (A) WASTE OR UNUSED DRUG PRODUCTS FROM A PHARMACY, HOSPITAL OR HEALTH CLINIC OR OTHER COMMERCIAL SOURCES THAT THE DEPARTMENT, BASED UPON RECOMMENDATIONS FROM THE DEPARTMENT OF HEALTH, MAY DETERMINE BY REGULATION TO BE A NONRESIDENTIAL SOURCE; OR (B) DRUG PRODUCTS SEIZED BY LAW ENFORCEMENT OFFICERS IN THE COURSE OF THEIR LAW ENFORCEMENT DUTIES.

2. (A) ANY PHARMACEUTICAL PRODUCT MANUFACTURER SELLING OR DISTRIBUTING A COVERED DRUG TO CONSUMERS IN THE STATE, WHETHER DIRECTLY OR THROUGH A WHOLESALER, RETAILER OR OTHER AGENT, SHALL: (I) OPERATE A DRUG STEWARDSHIP PROGRAM APPROVED BY THE DEPARTMENT INDIVIDUALLY OR JOINTLY WITH OTHER MANUFACTURERS; (II)ENTER INTO AN AGREEMENT WITH A STEWARDSHIP ORGANIZATION THAT SHALL OPERATE A DRUG STEWARDSHIP PROGRAM APPROVED BY THE DEPARTMENT; OR (III) ENTER INTO AN AGREEMENT WITH THE DEPARTMENT TO OPERATE AN ALTERNATIVE PLAN UNDER SUBDIVISION SIX OF THIS SECTION.

(B) THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF HEALTH, SHALL ESTABLISH A PROCESS, PURSUANT TO REGULATION, TO REVIEW APPLICATIONS FOR APPROVAL AND RENEWAL OF A MANUFACTURER'S DRUG STEWARDSHIP PROGRAM. THE DEPARTMENT SHALL CONSULT WITH THE OFFICE OF ALCOHOLISM AND SUBSTANCE ABUSE SERVICES AND OTHER INTERESTED PARTIES IN DEVELOPING THE REQUIREMENTS OF A DRUG STEWARDSHIP PROGRAM.

(C) EACH OPERATOR OF A DRUG STEWARDSHIP PROGRAM SHALL FILE AN ANNUAL WRITTEN REPORT TO THE DEPARTMENT DESCRIBING THE PROGRAM'S ACTIVITIES FOR THE PRIOR YEAR AND THE VOLUME AND TYPE OF UNWANTED DRUGS COLLECTED NOT LATER THAN MARCH FIRST.

(D) THE DEPARTMENT SHALL REVIEW FOR RENEWAL EACH DRUG STEWARDSHIP PROGRAM AT A FREQUENCY TO BE DETERMINED BY THE DEPARTMENT PURSUANT TO REGULATION.

(E) THE DEPARTMENT SHALL PUBLISH AND MAKE PUBLICLY AVAILABLE A LIST AND DESCRIPTION OF EACH APPROVED DRUG STEWARDSHIP PROGRAM AND SHALL REGULARLY UPDATE THIS LIST.

3. A MANUFACTURER OR STEWARDSHIP ORGANIZATION SEEKING APPROVAL FOR A DRUG STEWARDSHIP PROGRAM SHALL SUBMIT, IN A MANNER AND FORM DETERMINED BY THE DEPARTMENT PURSUANT TO REGULATIONS DEVELOPED, IN CONSULTATION WITH THE DEPARTMENT OF HEALTH, A PLAN THAT MEETS, BUT IS NOT LIMITED TO, THE FOLLOWING REQUIREMENTS:

(A) IDENTIFICATION OF ALL PARTICIPATING MANUFACTURERS;

(B) A COLLECTION SYSTEM TO PROVIDE CONVENIENT, ONGOING COLLECTION SERVICES TO ALL PERSONS SEEKING TO DISPOSE OF UNWANTED DRUGS; PROVIDED, HOWEVER, THAT THE COLLECTION SYSTEM MAY ACCEPT ANY COVERED DRUG AND ANY OTHER PRESCRIPTION DRUG IN A PILL FORMULATION REGARDLESS OF ITS SCHEDULE, BRAND OR SOURCE OF MANUFACTURE; PROVIDED FURTHER, THAT THE COLLECTION SYSTEM SHALL INCLUDE TWO METHODS AS RECOMMENDED BY THE DEPARTMENT, WHICH MAY INCLUDE, BUT NOT BE LIMITED TO: (I) A MAIL-BACK PROGRAM THAT PROVIDES PREPAID AND PREADDRESSED PACKAGING FOR A PHARMACY TO DISTRIBUTE WHEN FILLING A PRESCRIPTION FOR A COVERED DRUG OR UPON REQUEST BY A CONSUMER; (II) COLLECTION KIOSKS; (III) DROP-OFF DAY EVENTS AT REGIONAL LOCATIONS; OR (IV) ANY OTHER METHOD RECOMMENDED PURSUANT TO UNITED STATES DRUG ENFORCEMENT ADMINISTRATION GUIDELINES;

(C) ADEQUATE PROVISIONS FOR THE SECURITY OF UNWANTED DRUGS THROUGHOUT THE COLLECTION PROCESS AND THE SAFETY OF ANY PERSON INVOLVED IN MONITORING, STAFFING OR SERVICING THE STEWARDSHIP PROGRAM;

(D) A PLAN FOR PUBLIC OUTREACH AND EDUCATION ABOUT THE DRUG STEWARDSHIP PROGRAM;

(E) A PLAN FOR THE MANUFACTURER OR STEWARDSHIP ORGANIZATION THAT PROVIDES THE OPERATIONAL AND ADMINISTRATIVE COSTS ASSOCIATED WITH THE PROGRAM; PROVIDED, HOWEVER, THAT NO POINT-OF-SALE, POINT-OF-COLLECTION, PROCESSING FEES OR OTHER DRUG COST INCREASES MAY BE CHARGED TO INDIVIDUAL CONSUMERS TO RECOUP PROGRAM COSTS;

(F) AN ATTESTATION THAT THE PROGRAM SHALL COMPLY WITH ALL APPLICABLE STATE AND FEDERAL REQUIREMENTS FOR THE COLLECTION, SECURITY, TRANSPORT AND DISPOSAL OF DRUG PRODUCTS, INCLUDING ANY REQUIREMENTS ESTABLISHED BY RULE OR REGULATION OF EITHER THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION OR THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND

(G) ANY OTHER REQUIREMENTS ESTABLISHED BY THE DEPARTMENT PURSUANT TO REGULATION FOR THE SAFE AND EFFECTIVE ADMINISTRATION OF A DRUG STEWARDSHIP PROGRAM.

4. (A) THE DEPARTMENT SHALL SEND A NOTICE TO A PHARMACEUTICAL PRODUCT MANUFACTURER THAT SELLS OR DISTRIBUTES A COVERED DRUG IN THE STATE THAT HAS NOT SUBMITTED AN APPLICATION FOR APPROVAL UNDER SUBDIVISION TWO OF THIS SECTION, INFORMING THE MANUFACTURER OF THE REQUIREMENTS TO COMPLY WITH THIS SECTION. ANY MANUFACTURER IN RECEIPT OF A NOTICE SHALL SUBMIT AN APPLICATION FOR APPROVAL UNDER SUBDIVISION TWO OF THIS SECTION WITHIN ONE HUNDRED EIGHTY CALENDAR DAYS OF RECEIPT OF SUCH INITIAL NOTICE.

(B) UPON BECOMING AWARE THAT A PHARMACEUTICAL PRODUCT MANUFACTURER HAS DISCONTINUED ITS DRUG STEWARDSHIP PROGRAM OR HAS ALTERED THE PROGRAM SUCH THAT THE PROGRAM NO LONGER FULFILLS THE REQUIREMENTS OF THIS SECTION, THE DEPARTMENT SHALL SEND A NOTICE OF NONCOMPLIANCE TO THE MANUFACTURER. A MANUFACTURER IN RECEIPT OF A NOTICE OF NONCOMPLIANCE SHALL TAKE ALL REQUIRED CORRECTIVE STEPS TO REESTABLISH COMPLIANCE WITH THIS SECTION OR SUBMIT A WRITTEN APPEAL OF THE NOTICE OF NONCOMPLIANCE TO THE DEPARTMENT WITHIN NINETY DAYS OF RECEIPT OF THE NOTICE OF NONCOMPLIANCE.

(C) IF AFTER CONSIDERATION OF AN APPEAL OR IF THE MANUFACTURER DOES NOT APPEAL WITHIN NINETY DAYS OF RECEIPT OF THE NOTICE OF NONCOMPLIANCE THE DEPARTMENT DETERMINES THAT THE MANUFACTURER CONTINUES TO BE IN NONCOMPLIANCE WITH THIS SECTION, THE DEPARTMENT MAY ASSESS THE MANUFACTURER A PENALTY AFTER A HEARING AND AN OPPORTUNITY TO BE HEARD. IF THE DEPARTMENT PLANS TO ASSESS A NONCOMPLIANCE PENALTY AGAINST A MANUFACTURER PURSUANT TO THIS SUBDIVISION, THE DEPARTMENT SHALL SEND NOTICE OF THE PENALTY AND THE RIGHT TO APPEAL THE PENALTY TO THE MANUFACTURER.

5. (A) ANY REQUIREMENTS OR REGULATIONS, MAY EXCEED, BUT SHALL NOT CONFLICT WITH, ANY OBLIGATIONS IMPOSED ON A MANUFACTURER BY A RISK EVALUATION AND MITIGATION STRATEGY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(B) NOTHING IN THIS SECTION SHALL REQUIRE A PHARMACY OR A PHARMACIST PRACTICING IN A RETAIL SETTING TO PARTICIPATE IN THE COLLECTION, SECURING, TRANSPORT OR DISPOSAL OF UNWANTED DRUGS UNLESS THE PHARMACY CERTIFIES, IN WRITING, THAT THIS PARTICIPATION IS VOLUNTARY.

6. (A) THE DEPARTMENT SHALL, IN CONSULTATION WITH THE DEPARTMENT OF HEALTH AND THE OFFICE OF ALCOHOLISM AND SUBSTANCE ABUSE SERVICES PURSUANT TO RULES AND REGULATIONS, DEVELOP, PURSUANT TO REGULATION, AN ALTERNATIVE PLAN TO THE DRUG STEWARDSHIP PROGRAM ESTABLISHED UNDER SUBDIVISIONS TWO THROUGH FIVE OF THIS SECTION, INCLUSIVE. A MANUFACTURER WHO

OPTS INTO A PLAN ESTABLISHED UNDER SUCH RULES AND REGULATIONS SHALL BE EXEMPT FROM SUBDIVISION TWO THROUGH FIVE OF THIS SECTION, INCLUSIVE.

(B) A PLAN ESTABLISHED UNDER THIS SUBDIVISION MAY PERMIT CONTRIBUTIONS BY MANUFACTURERS TO THE CHEMICAL DEPENDENCE SERVICE FUND ESTABLISHED IN SECTION NINETY-SEVEN-W OF THE STATE FINANCE LAW AND THE ENVIRONMENTAL PROTECTION FUND ESTABLISHED IN SECTION NINETY-TWO-S OF THE STATE FINANCE LAW, IN A MANNER DETERMINED BY THE DEPARTMENT PURSUANT TO REGULATION; PROVIDED, HOWEVER NOT MORE THAN FIFTY PERCENT OF ANY ONE CONTRIBUTION MAY BE CONTRIBUTED TO ANY ONE FUND. A MANUFACTURER PARTICIPATING IN A PLAN ESTABLISHED UNDER THIS SUBDIVISION SHALL NOT PASS THE COST OF ANY CONTRIBUTION ON TO THE CONSUMER OR A HEALTH INSURANCE CARRIER.

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