STATE OF NEW YORK

6557

2017-2018 Regular Sessions

IN SENATE

June 2, 2017

Introduced by Sen. KRUEGER -- read twice and ordered printed, and when printed to be committed to the Committee on Rules

AN ACT to amend the public health law, in relation to establishing the drug stewardship program; and to amend the state finance law, in relation to establishing the substance abuse services fund

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

Section 1. Article 2-A of the public health law is amended by adding a new title 4 to read as follows:

TITLE IV

DRUG STEWARDSHIP PROGRAM

§ 290. Definitions. As used in this title, the following words shall have the following meanings unless the context clearly requires otherwise:

1. "Covered drug" means any brand name or generic opioid drug placed in Schedule I, Schedule II, Schedule III, Schedule IV and Schedule V of section thirty-three hundred six of this chapter; provided, however, that "covered drug" shall also include benzodiazepines; provided, further, that "covered drug" shall not include:

(a) drugs intended for use solely in veterinary care;

(b) substances that are regulated as cosmetic products under the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.;

(c) drugs that are compounded under a specialty license;

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

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(d) hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in section thirteen hundred eighty-nine-dd of this chapter; or

(e) drugs approved and used primarily for medication-assisted substance use disorder treatment.

2. "Department" means the department of public health.

3. "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.

4. "Pharmaceutical product manufacturer" or "manufacturer" means an entity that manufactures a controlled substance under a United States Food and Drug Administration manufacturer's license, except for a hospital pharmacy or a wholesaler.

5. "Prescription drug" means any drug product which may be dispensed under a written prescription by an authorized prescriber.

6. "Stewardship organization" means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or the group of manufacturers to implement and operate a drug stewardship program.

7. "Unwanted drug" means a covered drug: (a) 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 (b) voluntarily deposited at collection points co-located with a law enforcement agency; provided, however, that "unwanted drug" shall not include: (i) waste or unused drug products from a pharmacy, hospital or health clinic or other commercial sources that the department may determine by regulation to be a nonresidential source; or (ii) drug products seized by law enforcement officers in the course of their law enforcement duties.

8. "Wholesaler" means an entity defined in section sixty-eight hundred two of the education law.

§ 291. Drug stewardship program. 1. 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:

(a) operate a drug stewardship program approved by the department individually or jointly with other manufacturers;

(b) enter into an agreement with a stewardship organization that shall operate a drug stewardship program approved by the department; or

(c) enter into an agreement with the department to operate an alternative plan under section two hundred ninety-five of this title.

2. The department shall establish a process to review applications for approval and renewal of a manufacturer's drug stewardship plan. 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.

3. 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 of each year.

4. The department shall review for renewal each drug stewardship program at a frequency to be determined by the department.

5. The department shall publish and make publicly available a list and description of each approved drug stewardship program and shall update this list at a frequency determined by the department.

6. The department may promulgate regulations to implement this chapter.

§ 292. Plan submission. A manufacturer or stewardship organization seeking approval for a drug stewardship program shall submit, in a manner and form determined by the department, a plan that meets, but is not limited to, the following requirements:

1. 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:

(a) 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;

(b) collection kiosks;

(c) drop-off day events at regional locations;

(d) in-home disposal methods that render a product safe from misuse and that comply with applicable controlled substance regulations and environmental safety regulations; or

(e) any other method recommended pursuant to United States Drug Enforcement Administration guidelines;

2. 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;

3. A plan for public outreach and education about the drug stewardship program;

4. 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;

5. 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

6. Any other requirements established by the department for the safe and effective administration of a drug stewardship program.

§ 293. Non-compliance. 1. The department shall send a notice to a pharmaceutical product manufacturer that sells or distributes a covered drug in the commonwealth that has not submitted an application for approval under section two hundred ninety-one of this title, informing the manufacturer of the requirements to comply with this chapter. Any manufacturer in receipt of a notice shall submit an application for approval under section two hundred ninety-one of this title within one hundred eighty calendar days of receipt of such initial notice.

2. 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 chapter, 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 chapter or submit a written appeal of the notice of noncompliance to the department within ninety days of receipt of the notice of noncompliance.

3. 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 chapter, the department may assess the manufacturer a penalty in a manner to be determined by the department. If the department plans to assess a noncompliance penalty against a manufacturer pursuant to this section, the department shall send notice of the penalty and the right to appeal the penalty to the manufacturer.

§ 294. Application. 1. The requirements established by the department, in consultation with the office of alcoholism and substance abuse services and other stakeholders, 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.

2. Nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a retail setting to participate in the collection, securing, transport or disposal of unwanted drugs.

3. No stewardship program shall require an outpatient pharmacy to participate in the collection, securing, transport or disposal of unwanted drugs or to provide a space for or to maintain a collection kiosk within an outpatient pharmacy unless the pharmacy certifies, in writing, that this participation is voluntary.

§ 295. Alternative plan. 1. The department shall, in consultation with the office of alcoholism and substance abuse services and other interested parties, develop an alternative plan to the drug stewardship program established under sections two hundred ninety-one through two hundred ninety-four of this title, inclusive. A manufacturer who opts into a plan established under this section shall be exempt from the provisions of sections two hundred ninety-one through two hundred ninety-four of this title, inclusive.

2. A plan established under this section may permit contributions by manufacturers to the substance abuse services fund established in section eighty-two of the state finance law, in a manner determined by the department. A manufacturer participating in a plan established under this section shall not pass the cost of any contribution on to the consumer or a health insurance carrier.

§ 2. The state finance law is amended by adding a new section 82 to read as follows:

§ 82. Substance abuse services fund. 1. There is hereby established in the sole custody of the comptroller a special fund to be known as the "substance abuse services fund". Moneys in the fund shall be kept separate from and not commingled with other funds held in the sole custody of the comptroller.

2. Such fund shall consist of all revenues collected by the state including: (a) any revenue from appropriations or other moneys authorized by the legislature and specifically designated to be credited to the fund;

(b) any funds from public and private sources, including gifts, grants and donations to provide substance use disorder treatment services;

(c) any interest earned on such revenues; and

(d) all other money appropriated, credited, or transferred thereto from any other fund or source pursuant to law. Money remaining in the fund at the end of a fiscal year shall not revert to the general fund. Nothing contained herein shall prevent the state from receiving grants, gifts or bequests for the purposes of the fund as defined in this section and depositing them into the fund according to law.

3. Moneys of the fund may be expended for the sole purpose of supporting the expansion of substance use disorder treatment services including, but not limited to:

(a) detoxification services;

(b) clinical stabilization services;

(c) residential treatment services;

(d) outpatient treatment services;

(e) counseling;

(f) promoting the access of primary care providers, including nurse practitioners and physician assistants, to available, trained and certified addiction physician specialists for consultation or referral; and

(g) educating primary care providers, including nurse practitioners and physician assistants, about addiction prevention and treatment and encouraging primary care physicians, nurse practitioners and physician assistants to screen for signs of substance abuse.

4. In making expenditures from the fund, the commissioner shall prioritize:

(a) treatment methods that are evidence-based and cost effective;

(b) ensuring substance use disorder treatment access to historically underserved populations; and

(c) availability of a continuum of services and care for clients entering substance use disorder treatment at any level.

5. The commissioner of health shall report quarterly to the governor, the senate and assembly committees on alcoholism and drug abuse, the senate finance committee and the assembly committee on ways and means on:

(a) the way funds were spent in the previous quarter including, but not limited to, an itemized accounting of the goods and services that were procured;

(b) an accounting of substance use disorder services provided by the fund, broken down by month and type of service, from two thousand seventeen to the current quarter, inclusive;

(c) the number of clients served, by month and type of service, by the goods and services procured in the previous quarter;

(d) amounts expended by type of service for each month in the prior quarter; and

(e) procurement and service goals for the subsequent quarter.

§ 3. This act shall take effect on the one hundred eightieth day after it shall have become a law.