

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

Section 290. Definitions.

291. Drug stewardship program.

292. Plan submission.

293. Non-compliance.

294. Application.

295. Alternative plan.

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

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

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

7 3. "Drug stewardship program" means a program financed by a pharmaceu-
8 tical product manufacturer or a group of manufacturers to collect,
9 secure, transport and safely dispose of unwanted drugs.

10 4. "Pharmaceutical product manufacturer" or "manufacturer" means an
11 entity that manufactures a controlled substance under a United States
12 Food and Drug Administration manufacturer's license, except for a hospi-
13 tal pharmacy or a wholesaler.

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

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

20 7. "Unwanted drug" means a covered drug: (a) that is no longer wanted
21 or intended to be consumed, or that is abandoned, discarded, expired or
22 surrendered by the person to whom it was prescribed; or (b) voluntarily
23 deposited at collection points co-located with a law enforcement agency;
24 provided, however, that "unwanted drug" shall not include: (i) waste or
25 unused drug products from a pharmacy, hospital or health clinic or other
26 commercial sources that the department may determine by regulation to be
27 a nonresidential source; or (ii) drug products seized by law enforcement
28 officers in the course of their law enforcement duties.

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

31 § 291. Drug stewardship program. 1. Any pharmaceutical product
32 manufacturer selling or distributing a covered drug to consumers in the
33 state, whether directly or through a wholesaler, retailer or other
34 agent, shall:

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

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

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

41 2. The department shall establish a process to review applications for
42 approval and renewal of a manufacturer's drug stewardship plan. The
43 department shall consult with the office of alcoholism and substance
44 abuse services and other interested parties in developing the require-
45 ments of a drug stewardship program.

46 3. Each operator of a drug stewardship program shall file an annual
47 written report to the department describing the program's activities for
48 the prior year and the volume and type of unwanted drugs collected not
49 later than March first of each year.

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

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

55 6. The department may promulgate regulations to implement this chap-
56 ter.

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

5 1. A collection system to provide convenient, ongoing collection
6 services to all persons seeking to dispose of unwanted drugs; provided,
7 however, that the collection system may accept any covered drug and any
8 other prescription drug in a pill formulation regardless of its sched-
9 ule, brand or source of manufacture; provided further, that the
10 collection system shall include two methods as recommended by the
11 department, which may include, but not be limited to:

12 (a) a mail-back program that provides prepaid and preaddressed packag-
13 ing for a pharmacy to distribute when filling a prescription for a
14 covered drug or upon request by a consumer;

15 (b) collection kiosks;

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

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

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

22 2. Adequate provisions for the security of unwanted drugs throughout
23 the collection process and the safety of any person involved in monitor-
24 ing, staffing or servicing the stewardship program;

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

27 4. A plan for the manufacturer or stewardship organization that
28 provides the operational and administrative costs associated with the
29 program; provided, however, that no point-of-sale, point-of-collection,
30 processing fees or other drug cost increases may be charged to individ-
31 ual consumers to recoup program costs;

32 5. An attestation that the program shall comply with all applicable
33 state and federal requirements for the collection, security, transport
34 and disposal of drug products, including any requirements established by
35 rule or regulation of either the United States Drug Enforcement Adminis-
36 tration or the United States Environmental Protection Agency; and

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

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

47 2. Upon becoming aware that a pharmaceutical product manufacturer has
48 discontinued its drug stewardship program or has altered the program
49 such that the program no longer fulfills the requirements of this chap-
50 ter, the department shall send a notice of noncompliance to the manufac-
51 turer. A manufacturer in receipt of a notice of noncompliance shall take
52 all required corrective steps to reestablish compliance with this chap-
53 ter or submit a written appeal of the notice of noncompliance to the
54 department within ninety days of receipt of the notice of noncompliance.

55 3. If after consideration of an appeal or if the manufacturer does not
56 appeal within ninety days of receipt of the notice of noncompliance the

1 department determines that the manufacturer continues to be in noncom-
2 pliance with this chapter, the department may assess the manufacturer a
3 penalty in a manner to be determined by the department. If the depart-
4 ment plans to assess a noncompliance penalty against a manufacturer
5 pursuant to this section, the department shall send notice of the penal-
6 ty and the right to appeal the penalty to the manufacturer.

7 § 294. Application. 1. The requirements established by the department,
8 in consultation with the office of alcoholism and substance abuse
9 services and other stakeholders, may exceed, but shall not conflict
10 with, any obligations imposed on a manufacturer by a risk evaluation and
11 mitigation strategy approved by the United States Food and Drug Adminis-
12 tration.

13 2. Nothing in this chapter shall require a retail pharmacy or a phar-
14 macist practicing in a retail setting to participate in the collection,
15 securing, transport or disposal of unwanted drugs.

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

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

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

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

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

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

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

48 (c) any interest earned on such revenues; and

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

1 3. Moneys of the fund may be expended for the sole purpose of support-
2 ing the expansion of substance use disorder treatment services includ-
3 ing, but not limited to:

4 (a) detoxification services;

5 (b) clinical stabilization services;

6 (c) residential treatment services;

7 (d) outpatient treatment services;

8 (e) counseling;

9 (f) promoting the access of primary care providers, including nurse
10 practitioners and physician assistants, to available, trained and certi-
11 fied addiction physician specialists for consultation or referral; and

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

16 4. In making expenditures from the fund, the commissioner shall prior-
17 itize:

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

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

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

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

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

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

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

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

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

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