ASSEMBLY, No. 5192

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED MARCH 18, 2019

Sponsored by:
Assemblyman ROY FREIMAN
District 16 (Hunterdon, Mercer, Middlesex and Somerset)
Assemblywoman YVONNE LOPEZ
District 19 (Middlesex)
Assemblyman P. CHRISTOPHER TULLY
District 38 (Bergen and Passaic)

Co-Sponsored by:
Assemblyman Karabinchak, Assemblywoman Swain, Assemblyman Rooney, Assemblywomen Vainieri Huttle and Murphy

SYNOPSIS

Requires pharmaceutical manufacturers to institute drug take back programs and certain pharmacies to become authorized collectors of unused drugs.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 6/7/2019)

AN ACT concerning unused drugs and supplementing Title 24 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Authorized collector" means any entity registered with the federal Drug Enforcement Administration to collect controlled dangerous substances for the purposes of safe disposal and destruction; a law enforcement agency; or an entity authorized by the division to provide alternative collection methods for covered drugs that are not controlled dangerous substances.

"Covered drug" means any substance recognized as a drug pursuant to 21 U.S.C. s.321(g)(1), or any regulations adopted pursuant to that section, that is sold, offered for sale, or dispensed in the State, whether directly or through a wholesaler, in any form, including prescription and nonprescription drugs and biological products, drugs and biological products in medical devices and combination products, brand name and generic drugs and biological products, and drugs and biological products for veterinary use. The term shall not include: vitamins or supplements; herbal-based remedies or homeopathic drugs, products, or remedies; cosmetics, soap, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the "Federal Food, Drug and Cosmetic Act," 21 U.S.C. s.301 et seq.; pesticide products for animals, which products are contained in pet collars, powders, shampoos, topical applications, or other forms; drugs and biological products for which the manufacturer already provides a take back program, including take back programs operated as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy; emptied injector products or emptied medical devices and their component parts or accessories; or drugs that are used solely in a clinical setting.

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Drug disposal product" means a nontoxic composition that can be used to permanently sequester or deactivate unused, unwanted, or expired drugs for the purpose of safely disposing of the unused drug.

"Drug take back organization" means an organization designated by a manufacturer to act as an agent on behalf of the manufacturer to implement and operate a drug take back program pursuant to this act.

"Manufacturer" means an entity engaged in the manufacture of covered drugs sold in the State. The term shall not include a repackager or wholesaler.

"Participant pharmacy" means a pharmacy practice site issued a permit under P.L.2003, c.280 (C.45:14-40 et seq.) that is part of a group of 10 or more establishments that conduct business under the same name or that operate under a common ownership or management or pursuant to a franchise agreement with the same franchisor; or an out-of-State pharmacy that ships, mails, distributes, or delivers in any manner, covered drugs into this State.

"Repackager" means an entity that owns or operates an establishment that repacks and relabels a product or package containing a covered drug for further sale or for distribution without additional transaction.

"Wholesaler" means an entity that sells or distributes drugs and covered drugs for resale to an entity in the State other than a consumer.

2. a. A manufacturer of a covered drug shall:

(1) operate, either individually or jointly with other manufacturers, a drug take back program approved by the division;

(2) enter into an agreement with a drug take back organization to implement and operate a drug take back program approved by the division on behalf of the manufacturer; or

(3) enter into an agreement with the division to operate a drug take back program on its behalf.

b. Each manufacturer, or a drug take back organization with which the manufacturer has entered into an agreement to implement and operate a drug take back program, shall, no later than 180 days after the effective date of this act, submit to the division, in a manner and form as shall be required by the division, a proposed drug take back program plan that shall, at a minimum:

(1) certify that the drug take back program will accept all covered drugs regardless of the manufacturer of the drug;

(2) provide contact information for the person designated by the drug take back program to receive and respond to inquiries and communications from the division;

(3) describe the collection system to be implemented under the program, which system shall be designed in a manner that provides convenient, ongoing access to collection services to all persons seeking to dispose of covered drugs pursuant to section 3 of this act, including individuals located in rural and underserved areas;

(4) describe any other methods by which covered drugs will be collected by authorized collectors;

(5) outline the program's security plans and protocols, including a description of how covered drugs will be safely and securely tracked and handled from collection through final disposal and

destruction at a permitted waste disposal facility meeting federal requirements;

(6) describe any policies to be implemented under the program that are designed to ensure compliance with applicable State and federal laws and regulations;

(7) describe the public education and outreach activities that will be undertaken under the program, which activities shall, at a minimum, include the advertisement of collection sites using an Internet website, signage, and other written materials;

(8) describe how the program will evaluate the effectiveness of its public education and outreach activities;

(9) describe how the costs of participant pharmacies and other authorized collectors will be reimbursed. In the case of programs involving more than one manufacturer, the proposal shall include a description of how the costs will be allocated among the manufacturers in a manner that ensures that the costs paid by each manufacturer are reasonably related to the volume or value of covered drugs that the manufacturer sells or distributes in the State; and

(10) include any other information as may be required by the division.

c. No later than 30 days after the effective date of this act, each wholesaler that sells or distributes covered drugs in New Jersey shall provide the division with a list of manufacturers that produce covered drugs sold or distributed by the wholesaler in New Jersey. The lists shall be updated upon request by the division.

d. (1) Manufacturers shall pay all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting, and disposing of covered drugs from participant pharmacies and other authorized collectors, the cost of recycling or other disposal of packing, packaging, or other materials collected with the covered drug, the costs of furnishing drug disposal products to patients without cost, and any costs incurred by the State in the administration and enforcement of the drug take back program. Exclusive of fines and penalties, the State shall recover no more than its actual costs incurred in administering and enforcing the drug take back program.

(2) In instances where manufacturers jointly conduct a drug take back program, the costs of administration and enforcement shall be fairly and reasonably allocated in a manner that ensures that the share of the costs allocated to each manufacturer is reasonably related to the volume or value of covered drugs the manufacturer sells or distributes in the State.

(3) No manufacturer may charge a point-of-sale or other fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of the manufacturer’s drug take back program.

e. (1) No later than 60 days after submission of a proposed drug take back program plan, the division, in consultation with the

Department of Environmental Protection, shall determine whether the proposed program plan complies with the requirements of this section. The division may conduct a noticed public hearing prior to approval. If the program plan is approved, the division shall notify the applicant in writing. If the program plan is not approved, the division shall notify the applicant in writing, and the applicant shall have 30 days to submit a revised drug take back program plan. If the revised program plan is not approved, the manufacturer shall be deemed noncompliant with the requirements of this act and shall be subject to a civil penalty as provided in section 4 of this act. Each week during which a manufacturer does not have an approved drug take back program in place shall constitute a separate violation.

(2) At least once every three years, a manufacturer or a drug take back organization shall review its drug take back program plan and submit an updated program plan proposal to the division for approval. The division may, in its discretion, deny an updated program plan and require the manufacturer to submit a revised updated program plan for approval. The manufacturer's current drug take back program shall remain in effect until such time as the division approves an updated program plan.

(3) A manufacturer that begins to offer a covered drug in the State after the effective date of this act shall, no later than 90 days after the date the covered drug is first made available in the State, submit to the division:

(a) documentation demonstrating that the manufacturer has joined a drug take back program currently approved by the division; or

(b) a proposed drug take back program plan, which shall be subject to approval by the division as provided in paragraph (1) of this subsection.

f. The division shall publish on its Internet website a list of all drug take back programs approved pursuant to this section, which list shall, at a minimum, identify the manufacturers participating in each approved program. The division shall update the list at least annually.

g. (1) The operator or administrator of each approved drug take back program shall report to the division information concerning: the weight of covered drugs collected; the collection activities utilized and the weight of covered drugs collected using each collection method; the program's public education and outreach activities; reimbursements paid to participant pharmacies; authorized collectors, and the State; and any other information as the division may require. The division shall determine the form, manner, and frequency with which manufacturers shall be required to report the information required pursuant to this paragraph.

(2) Commencing one year after the effective date of this act, the division shall submit an annual report to the Governor and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the Legislature,

detailing all program activities, including: the weight of covered drugs collected by each program; a description of each program's collection activities; the names and locations of all collection sites; a description of the public education and outreach activities undertaken by approved programs, and an independent assessment of the effectiveness of those activities; an evaluation of the efficacy of the program and each collection method utilized; and the names of any manufacturers against which disciplinary actions were taken based on a violation of the requirements of this act, including the value of any penalties assessed pursuant to section 4 of this act.

3. a. Participant pharmacies shall provide for the safe collection of covered drugs as follows:

(1) In-State pharmacies shall:

(a) offer drug collection through the use of on-site receptacles that meet federal standards, mail-back collection by prepaid envelopes as authorized by federal law, or any other method of drug collection method approved by the federal Drug Enforcement Administration;

(b) offer patients a drug disposal product, which shall be furnished to the patient without cost at the patient's request; and

(c) prominently display signage advising consumers of the availability of drug collection and safe drug disposal products, which signage may identify the particular methods of drug collection and particular drug disposal products available through the pharmacy.

(2) Out-of-State pharmacies that ship, mail, distribute, or deliver in any manner, covered drugs into this State shall:

(a) offer mail-back drug collection through the use of prepaid envelopes, as authorized by federal law;

(b) offer, at the time a patient makes an order for a prescription to be dispensed to the patient by the pharmacy, to include with the dispensed drug a drug disposal product, which shall be furnished to the patient at no additional cost to the patient; and

(c) include in the packaging for each drug delivered into this State written notice advising consumers of the availability of drug collection and drug disposal products, including the use of mail-back collection using the enclosed prepaid envelope and a link to the list of collection sites operated by authorized collectors on the division's Internet website.

b. Each drug take back program operator shall notify other potential authorized collectors of the opportunity to serve as an authorized collector for the drug take back program. Participation by authorized collectors, other than participant pharmacies, shall be voluntary.

c. The costs incurred by participant pharmacies and other authorized collectors to engage in collection activities, including furnishing drug disposal products to patients at no cost to the

patient, shall be reimbursed by manufacturers as provided in subsection d. of section 2 of this act.

d. For any municipality with a population of more than 100,000 according to the last decennial census, the director shall establish, by regulation, a distribution plan that ensures that on-site collection receptacles are placed in a manner that is reasonably accessible to all residents of the municipality, and that ensures cost efficiency for the program.

e. In-State participant pharmacies providing for mail-back collection as part of the drug take back program shall provide a voucher for a prepaid envelope upon dispensing a covered drug. The voucher shall include information concerning drug take back and safe drug disposal methods.

4. Any entity that violates the provisions of this act shall be subject to a civil penalty as provided in section 12 of P.L.1978, c.73 (C.45:1-25).

5. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety shall, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt rules and regulations as shall be necessary to implement the provisions of this act.

6. This act shall take effect 180 days after the date of enactment.

STATEMENT

This bill requires drug manufacturers to establish drug take back programs, which will accept the return of covered drugs for disposal or destruction, and requires certain pharmacies to become authorized collection sites for covered drugs.

As used in the bill, "covered drug" means any substance recognized as a drug pursuant to federal law, including prescription and nonprescription drugs and biological products, drugs and biological products in medical devices and combination products, brand name and generic drugs and biological products, and drugs and biological products for veterinary use. The term will not include vitamins or supplements, herbal-based or homeopathic products, various personal care products, pesticide products for animals, emptied injector products or medical devices, drugs that are used solely in a clinical setting, or any drug or biological product for which the manufacturer already provides a take back program.

Each manufacturer will be permitted to: establish its own take back program, either on its own or jointly with other manufacturers;

enter into an agreement with a drug take back organization to implement and operate a drug take back program on behalf of the manufacturer; or enter into an agreement with the division to operate a drug take back program on its behalf.

At a minimum, each drug take back program will be required to: certify that the program will accept all covered drugs regardless of the manufacturer of the drug; designate a contact person to receive and respond to inquiries and communications; include a collection system that provides convenient, ongoing access to collection services; incorporate appropriate security plans and protocols, including tracking throughout the collection and disposal process; ensure compliance with applicable State and federal laws and regulations; include public education and outreach activities; and provide reimbursement to authorized collectors.

The bill requires manufacturers to pay all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting, and disposing of covered drugs from participant pharmacies and other authorized collectors, the cost of recycling or other disposal of packing, packaging, and other materials collected with the covered drug, and the actual costs incurred by the State in the administration and enforcement of the drug take back program. In instances where manufacturers jointly conduct a drug take back program, the costs of administration and enforcement are to be fairly and reasonably allocated in a manner that ensures that the share of the costs allocated to each manufacturer is reasonably related to the volume or value of covered drugs that the manufacturer sells or distributes in the State. Manufacturers will be prohibited from charging a point-of-sale or other fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of the manufacturer's program.

Drug take back programs will be subject to approval by the Division of Consumer Affairs in the Department of Law and Public Safety in consultation with the Department of Environmental Protection. All manufacturers will be required to submit their proposed drug take back program plans to the division for approval no later than 180 days after the effective date of the bill. The division will provide written notice of its approval determination in writing within 60 days after the date a program plan is submitted; if a program plan is not approved, the manufacturer will have 30 days to submit a revised program plan. If the revised program plan is not approved, the manufacturer will be deemed noncompliant with the requirements of the bill. The division may hold a noticed public hearing prior to making a determination with regard to approval of a proposed program plan.

Drug take back programs are to be reviewed and updated by the manufacturer, or the manufacturer's designated drug take back program operator, at least once every three years, which updates are

subject to division approval. A manufacturer who begins to offer a covered drug in the State after the effective date of the bill will be required, within 90 days of the date the covered drug is first made available in the State, to join an existing drug take back program or submit a plan for its own drug take back program. Any proposed change to a drug take back program is to be submitted to the division in writing and will be subject to division approval.

The division is to make a list of all approved drug take back programs that identifies the manufacturers participating in each program available on its Internet website. The list is to be updated at least annually.

The operator or administrator of each drug take back program will be required to report to the division concerning the program's collection activities, including, but not limited to, the weight of covered drugs collected, the collection activities utilized and the weight of covered drugs collected using each method, the program's public education and outreach activities, and reimbursements paid to participant pharmacies, authorized collectors, and the State. The division will determine the form, manner, and frequency with which the program reports are to be submitted.

The division will be required to submit an annual report to the Governor and to the Legislature detailing all program activities, including: the weight of covered drugs collected by each program; a description of each program's collection activities; the names and locations of all collection sites; a description of all public education and outreach activities undertaken by approved programs, and an assessment of the effectiveness of the various activities; an evaluation of the efficacy of the program and each collection method utilized; and the names of, and disciplinary actions taken against, manufacturers found to be in violation of the requirements of the bill.

No later than 30 days after the effective date of the bill, each wholesaler that sells or distributes covered drugs in New Jersey is to provide the division with a list of manufacturers that produce covered drugs sold or dispensed by the wholesaler in New Jersey. The lists are to be updated upon request by the division.

The bill additionally requires pharmacies that are part of a group of 10 or more establishments that conduct business under the same name or that operate under a common ownership or management or pursuant to a franchise agreement with the same franchisor, as well as out-of-State pharmacies that ship, mail, distribute, or deliver covered drugs into New Jersey, to become authorized collectors of covered drugs.

In-State pharmacies are to offer drug collection through the use of on-site receptacles, mail-back collection using prepaid envelopes, or any other drug collection method approved by the federal Drug Enforcement Administration. In-State pharmacies providing for mail-back collection will be required to provide a

voucher for a prepaid envelope upon dispensing a covered drug, which will include information concerning drug take back and safe drug disposal methods. In-State pharmacies are to additionally offer to furnish patients with a drug disposal product, which is a nontoxic composition that can be used to permanently sequester or deactivate unused, unwanted, or expired drugs for the purpose of safely disposing of the unused drug. Drug disposal products are to be furnished upon request without cost to the patient. In-State pharmacies are to display prominent signage advising consumers of the availability of drug collection and drug disposal products, which may identify the particular collection methods available through that pharmacy.

Out-of-State pharmacies are to include a prepaid mail-back collection envelope with any drug delivered, along with written notice advising consumers of the availability of drug collection, including the use of mail-back collection using the enclosed prepaid envelope and a link to the list of collection sites on the division's Internet website. Out-of-State pharmacies will also be required to offer patients, at the time the patient orders a prescription for dispensing, to include with the dispensed drug a drug disposal product, which are to be furnished upon request at no additional cost.

Drug take back program operators are to notify other potential authorized collectors of the opportunity to serve as an authorized collector for the drug take back program. Participation by authorized collectors, other than participant pharmacies, will be voluntary. For any municipality with a population of more than 100,000 according to the last decennial census, the division is to establish a distribution plan that ensures that on-site collection receptacles are placed in a manner that provides reasonable access for all residents of the municipality while maintaining cost-effectiveness for the program.

An entity that violates the requirements of the bill will be subject to a civil penalty of $10,000 for a first violation and $20,000 for a second or subsequent violation. Each week during which a manufacturer does not have an approved program in place will constitute a separate violation.