

# SENATE, No. 3641

## STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED MAY 13, 2019

**Sponsored by:**

**Senator JOSEPH P. CRYAN**

**District 20 (Union)**

### **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.



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

3  
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*  
5 *of New Jersey:*

6  
7 1. As used in this act:

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

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

37 “Director” means the Director of the Division of Consumer  
38 Affairs in the Department of Law and Public Safety.

39 “Division” means the Division of Consumer Affairs in the  
40 Department of Law and Public Safety.

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

45 “Drug take back organization” means an organization designated  
46 by a manufacturer to act as an agent on behalf of the manufacturer  
47 to implement and operate a drug take back program pursuant to this  
48 act.

1 “Manufacturer” means an entity engaged in the manufacture of  
2 covered drugs sold in the State. The term shall not include a  
3 repackager or wholesaler.

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

11 “Repackager” means an entity that owns or operates an  
12 establishment that repacks and relabels a product or package  
13 containing a covered drug for further sale or for distribution without  
14 additional transaction.

15 “Wholesaler” means an entity that sells or distributes drugs and  
16 covered drugs for resale to an entity in the State other than a  
17 consumer.

18  
19 2. a. A manufacturer of a covered drug shall:

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

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

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

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

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

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

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

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

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

1 destruction at a permitted waste disposal facility meeting federal  
2 requirements;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11

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

14 (1) In-State pharmacies shall:

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

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

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

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

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

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

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

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

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

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

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

9 e. In-State participant pharmacies providing for mail-back  
10 collection as part of the drug take back program shall provide a  
11 voucher for a prepaid envelope upon dispensing a covered drug.  
12 The voucher shall include information concerning drug take back  
13 and safe drug disposal methods.  
14

15 4. Any entity that violates the provisions of this act shall be  
16 subject to a civil penalty as provided in section 12 of P.L.1978, c.73  
17 (C.45:1-25).  
18

19 5. The Director of the Division of Consumer Affairs in the  
20 Department of Law and Public Safety shall, pursuant to the  
21 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et  
22 seq.), adopt rules and regulations as shall be necessary to implement  
23 the provisions of this act.  
24

25 6. This act shall take effect 180 days after the date of  
26 enactment.  
27

28

29 STATEMENT

30

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

23 Drug take back program operators are to notify other potential  
24 authorized collectors of the opportunity to serve as an authorized  
25 collector for the drug take back program. Participation by  
26 authorized collectors, other than participant pharmacies, will be  
27 voluntary. For any municipality with a population of more than  
28 100,000 according to the last decennial census, the division is to  
29 establish a distribution plan that ensures that on-site collection  
30 receptacles are placed in a manner that provides reasonable access  
31 for all residents of the municipality while maintaining cost-  
32 effectiveness for the program.

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