

12. Text of Proposed Revised Regulation (August 2020)

a. Third Draft Proposed Regulations



Pharmaceutical and Sharps Waste Stewardship Program

Proposed Regulations
Third Draft

The following denotes proposed text:

~~Strikethrough~~ = deletions from First Draft Proposed Regulations for 45-day
Comment Period, December 2019

Underline = additions from First Draft Proposed Regulations for 45-day Comment
Period, December 2019

Double Underline = additions to First Draft Proposed Regulations for 45-day
Comment Period, December 2019

Grey highlight (no underline or strikethrough) = additions from Second Draft
Proposed Regulations, July 2020

Grey highlight with single strikethrough = deletions from Second Draft Proposed
Regulations, July 2020

1 **THIRD DRAFT**

2 **PROPOSED REGULATIONS**

3 **PHARMACEUTICAL AND SHARPS WASTE**
4 **STEWARDSHIP PROGRAM**

5 **TITLE 14. NATURAL RESOURCES**

6 **DIVISION 7. DEPARTMENT OF RESOURCES RECYCLING AND**
7 **RECOVERY**

8 **CHAPTER 11. PRODUCT STEWARDSHIP**

9 **ARTICLE 4. PHARMACEUTICAL AND SHARPS WASTE**
10 **STEWARDSHIP PROGRAM**

11 **18972. PURPOSE.**

12 The purpose of this Article is to clarify existing statute and establish administrative
13 procedures to efficiently and effectively implement the department's responsibilities
14 under the law and to provide a uniform competitive business environment to all covered
15 entities, stewardship organizations, program operators, distributors, wholesalers, retail
16 pharmacies, retail pharmacy chains, ~~other retailers, and~~ other authorized collectors, and
17 other retailers pursuant to Chapter 2 (commencing with section 42030), Part 3, Division
18 30 of the Public Resources Code.

19 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
20 Reference: Sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2,
21 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2,
22 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code.

23 **18972.1. DEFINITIONS.**

24 (a) Except as otherwise noted, the following definitions ~~of~~ shall govern the provisions of
25 this Article and supplement ~~and are governed by~~ the definitions set forth in Chapter 2,
26 (commencing with section 42030) Part 3, Division 30 of the Public Resources Code:

27 (b1) "Administrative and operational costs" means costs to implement and
28 operate a stewardship program, including, but not limited to, collection,
29 transportation, processing, disposal, and education and outreach costs, as well
30 as administrative costs of operating the stewardship organization, pursuant to
31 section 42034 of the Public Resources Code, ~~and administrative fees charged by~~
32 the department.

1 (2) “Departmental administrative fees” are fees required to be paid pursuant to
2 section 42034.2 of the Public Resources Code.

3 (e3) “Homebound” has the same meaning as defined in the Medicare Benefit
4 Policy Manual, Chapter 15, 60.4.1.

5 (e4) “Homeless” has the same meaning as “homeless individual” as defined in
6 subsection (5)(A) of subdivision (h) of section 254b of Title 42 of the U.S. Code
7 on Public Health and Welfare.

8 (e5) “Home-generated sharps consolidation point” has the same meaning as
9 defined in Division 104, Part 14, Chapter 3, section 117904 of the Health and
10 Safety Code.

11 (6) “Inert” means the covered drug or mixture of covered drugs is rendered
12 chemically inactive prior to disposal and complies with all applicable local, state
13 and federal laws and regulations, including those of the United State Drug
14 Enforcement Administration and California statutes and regulations governing
15 disposal in a municipal solid waste landfill.

16 (f7) “Local jurisdiction” and “local agency” means a California city, county, city
17 and county, a joint powers authority, or public service district responsible for
18 household hazardous waste or residential waste management planning or
19 services.

20 (g8) “Minutes, books, and records” means complete, correct, accurate and up-
21 to-date information regarding a program operator’s transactions and activities
22 related to the operation of the stewardship program.

23 (h9) “Prescription” has the same meaning as defined in Division 2, Chapter 9,
24 section 4040 of the Business and Professions Code.

25 (i10) “Point of sale” means the point in time at which an ultimate user purchases
26 a covered drug or sharp product at a checkout system utilized by pharmacies,
27 stores, or other retailer, including but not limited to an online retailer or online
28 marketplace outlets where a covered product is sold, including online sales.

29 (j11) “Provides or initiates distribution of a sharps waste container and mail-
30 back materials” means one of the following:

31 (4A) To provide a sharps waste container and mail-back materials to the
32 ultimate user, at the point of sale or prior, at no cost to the ultimate user;
33 or,

34 (2B) To arrange, at the point of sale or prior, for a sharps waste container
35 and mail-back materials to be sent to the ultimate user and arrive within

1 fivefourthree business days at no cost or inconvenience to the ultimate
2 user; or,

3 ~~(3C) Other methods of providing a sharps waste container and mail-back~~
4 ~~materials to the ultimate user at the point of sale or prior, at no cost to the~~
5 ~~ultimate user, as approved by the department in a stewardship plan, if the~~
6 ~~method identified in subpart (A4) above is not allowed by law or is not~~
7 ~~reasonably feasible, and if the method identified in subpart (B) above or (2)~~
8 ~~is are not allowed by law or is not reasonably feasible. These methods~~
9 ~~must be and approved by the department in a stewardship plan and which~~
10 ~~result in substantially the same level of convenience to the ultimate user~~
11 ~~as the methods identified in subparts (A) and (B) above.~~

12 ~~(1211) “Repeal” means to revoke or annul a law or ordinance in its entirety such~~
13 ~~that any program mandated by the law or ordinance is permanently dissolved.~~
14 ~~For the purposes of this Article, a modification of an existing law or ordinance~~
15 ~~does not constitute a repeal unless the changes fundamentally alter the program~~
16 ~~to the extent that it no longer meets the definition of a “stewardship program” as~~
17 ~~defined in subdivision (y) of section 42030 of the Public Resources Code.~~

18 ~~(k13) “Significant change” means a change that is not consistent with to an~~
19 ~~approved stewardship plan that the department determines has a material impact~~
20 ~~on the operation of a stewardship program includes, including, but is not limited~~
21 ~~to:~~

22 ~~(1A) An addition or discontinuation of a collection method, whether a mail-~~
23 ~~back program, collection receptacle program, or an alternative method of~~
24 ~~collection.~~

25 ~~(2B) Any changes to a stewardship program that are required by local,~~
26 ~~state, or federal laws and regulations.~~

27 ~~(3C) Any changes to a stewardship program necessitated by the repeal of~~
28 ~~a local ordinance for either covered drugs or home-generated sharps~~
29 ~~waste.~~

30 ~~(4D) Any changes regarding achievement of convenience standards.~~

31 ~~(5E) Any changes in of the service providers or facility(ies) facility(ies) to~~
32 ~~be used to transport, handle, process or dispose of a covered drugs or~~
33 ~~home-generated sharps waste collected through the stewardship program~~
34 ~~not identified in the approved plan.~~

35 ~~(F) Any changes necessitated by a substantial change in stewardship~~
36 ~~program funding.~~

1 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
2 Reference: Sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2,
3 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2,
4 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code;
5 Medicare Benefit Policy Manual, Chapter 15, 60.4.1; 42 U.S.C. Section 254b, U.S.
6 Code on Public Health and Welfare; Section 117904, Health and Safety Code; and
7 Section 4040, Business and Professions Code.

8 **18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.**

9 ~~(a) The department shall consider all manufacturers of covered products that are sold,~~
10 ~~offered for sale, or dispensed in California, whether they are program operators or are~~
11 ~~represented by a stewardship organization, as the covered entities.~~
12 ~~(b) The department will use the priority set forth in subsections (1)(B) (E) of subdivision~~
13 ~~(f) of section 42030 of the Public Resources Code to identify the covered entity for any~~
14 ~~covered products consistent with subdivision (f) of section 42030, which do not meet the~~
15 ~~definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public~~
16 ~~Resources Code.~~

17 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
18 Reference: Section 42030, Public Resources Code.

19 **18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM**
20 **BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

21 ~~(a) A corporate officer, acting on behalf of the program operator, shall submit to the~~
22 ~~department contact information of the corporate officer responsible for submitting and~~
23 ~~overseeing the document, including, but not limited to:~~

- 24 ~~(1) Contact name and title~~
- 25 ~~(2) Name of program operator~~
- 26 ~~(3) Mailing and physical address(es)~~
- 27 ~~(4) Phone number~~
- 28 ~~(5) Email address~~
- 29 ~~(6) Internet website address~~

30 A stewardship plan, initial program budget, annual report, annual budget, or any
31 document associated with the foregoing that is submitted to the department shall meet
32 all the following requirements outlined in subsections (a) through (e) of this section:

33 ~~(a) The document Documents are required to be in compliance with sections 7405 of~~
34 ~~the Government Code, and the Web Content Accessibility Guidelines 2.0, or a~~

1 subsequent version, published by the Web Accessibility Initiative of the World Wide
2 Web Consortium at a minimum Level AA success criteria to allow for posting on the
3 department's website.

4 ~~(b)~~ The document shall be submitted electronically ~~according to instructions provided~~
5 ~~by the department.~~ The date of electronic submittal will be considered the date of
6 receipt by the department.

7 ~~(d) A hard copy submittal letter referencing the electronically submitted document with~~
8 ~~the signature of a corporate officer shall be submitted to the department.~~

9 ~~(c)~~ Any submittals to the department that the program operator believes are
10 confidential in nature shall include a cover letter explaining the justification of
11 confidentiality. Records supplied to the department pursuant to this Article that are, at
12 the time of submission, claimed to be proprietary, confidential, or a trade secret shall be
13 subject to the provisions in Title 14, California Code of Regulations, Division 7, Chapter
14 1, Article 4 (commencing with section 17041).

15 (d) The document shall be complete and correct.

16 (e) The document shall be provided to the department under penalty of perjury. A party,
17 with signatory authority, who is responsible for the contents of the document, shall sign
18 the document and provide the following certification statement: "I hereby declare, under
19 penalty of perjury, that the information provided in this document is true and correct, to
20 the best of my knowledge."

21 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
22 Reference: Sections 42030, 42032, 42033.2 and 42036.4, Public Resources Code;
23 Section 7405, Government Code; and Section 17041, California Code of Regulations.

24 **18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM**
25 **BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

26 A program operator that submits a stewardship plan, initial program budget, annual
27 report, or annual budget to the department shall meet the following requirements:

28 (a) A program operator submitting a stewardship plan, initial program budget, annual
29 report, or annual budget shall provide to the department, upon request and by the
30 requested deadline, clarifying information that is necessary to assist the department in
31 its consideration of completeness and/or approval.

32 (b) Within 30 days of the department's receipt of a document, ~~t~~he department shall
33 determine if a document is complete or incomplete and notify the submitting program
34 operator ~~within 30 days of receipt.~~ The department shall consider a document to be
35 complete if: 1) it contains provisions intended to meet each requirement in sections
36 18973, 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1,

1 18974.2, and 18974.3 of this Article, as applicable to each document; and 2) if it
2 contains sufficient detail for the department to determine if the requirements in the
3 referenced sections listed in subpart 1) have been met.

4 (1) If the department determines that the document is complete, the department's
5 shall have 90 -days from the date of original receipt of the document to review
6 period for consideration of approval, conditionally approval, or disapproval of
7 the document will commence upon the original date of receipt.

8 (2) If the department determines that the document is incomplete, the department
9 shall identify for the program operator the required additional information and the
10 program operator shall resubmit the document within 30 days of the department's
11 notification that the document is incomplete. If the department determines, upon
12 resubmittal, that the resubmitted document is complete, the department shall
13 have ~~90~~ -days from the date of receipt of the resubmitted document to review
14 period for consideration of approval, conditionally approval, or disapproval of
15 the resubmitted document will commence upon the original date of receipt of the
16 resubmittal.

17 (c) Should it be necessary for the department to consult with or submit a stewardship
18 plan to the State Board of Pharmacy or other agencies for review of completeness or
19 approval, the duration of time this takes the department shall not count toward the 30-
20 day review to determine completeness or 90-day review to determine approval,
21 conditional approval, or disapproval.

22 (d) The department shall approve a document if it determines that the documents meets
23 all material requirements in sections 18973, 18973.1, 18973.2, 18973.3, 18973.4,
24 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3 of this Article, as applicable
25 to each document.

26 (e) The department shall conditionally approve a document if it determines that: 1) the
27 document is substantially compliant with all material requirements in sections 18973,
28 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and
29 18974.3 of this Article, as applicable to each document; but 2) additional information
30 from and/or additional actions by the program operator are necessary.

31 (f) The department shall disapprove a document if it determines that the document is
32 not substantially compliant with all material requirements in sections 18973, 18973.1,
33 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3
34 of this Article, as applicable to each document.

35 (g) If the department conditionally approves a stewardship plan, the department shall
36 identify the condition(s) to be met for approval and provide written notice to the program
37 operator within 30 days of conditional approval. The program operator shall comply with
38 the conditions in that notice as specified. If the conditions are not met, the department
39 shall notify the program operator that the plan is deemed disapproved and the covered

1 entities operating under the stewardship plan are not in compliance until the program
2 operator submits a stewardship plan the department approves.

3 (h) If the department disapproves a stewardship plan, the department shall identify
4 explain how the stewardship plan does not comply and provide written notice to the
5 program operator within 30 days of disapproval. The program operator shall resubmit a
6 revised stewardship plan within 60 days of the disapproval notice date the written notice
7 was issued, and the department will review the revised stewardship plan within 90 days
8 of resubmittal. If a revised stewardship plan is disapproved by the department, the
9 covered entities operating under the stewardship plan are not in compliance until the
10 program operator submits a stewardship plan that the department approves.

11 (i) A program operator shall submit any significant changes to a stewardship plan in
12 writing for approval by the department, and shall not implement the changes prior to that
13 approval. Any significant changes to an approved stewardship plan shall be submitted
14 to the department in accordance with the requirements of section 18973, and shall
15 follow the review process outlined in subdivisions (a) through (h) above. The program
16 operator shall also include a re-certification that the stewardship plan containing the
17 significant changes is compliant with all applicable laws and regulations, in accordance
18 with section 18973.2(e)(2) or 18973.3(d)(2), as applicable.

19 (j) If the department conditionally approves an annual report or program budget, the
20 department shall identify the condition(s) to be met for approval and provide written
21 notice to the program operator within 30 days of conditional approval. deficiencies and
22 €The program operator shall comply with the conditions in that written notice within 60
23 days of the notice date the written notice was issued, unless the Director of the
24 Department of Resources Recycling and Recovery determines that additional time is
25 needed. If the program operator does not comply and the conditions are not met within
26 60 days of the notice date the written notice was issued for a conditional approval, the
27 department shall disapprove the annual report or program budget.

28 (k) If the department disapproves an annual report or program budget, the department
29 shall identify how the annual report or program budget does not comply and provide
30 written notice to the program operator within 30 days of disapproval. the deficiencies
31 and €The program operator shall resubmit a revised annual report or program budget
32 and provide any supplemental information requested within 60 days of the notice date
33 the written notice was issued.

34 (l) The department's review of any resubmitted documents shall follow the process
35 outlined in subdivisions (a) through (k) above.

36 (m) A program operator shall fully implement operation of an approved stewardship
37 program no later than 270 days after approval by the department of the stewardship
38 plan that establishes the stewardship program.

1 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
2 Reference: Sections 42030, 42032 and 42033.2, Public Resources Code.

3 **18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.**

4 ~~A stewardship plan for covered drugs shall comply with all applicable local, state, and~~
5 ~~federal laws and regulations, including, but not limited to, regulations adopted by the~~
6 ~~United States Drug Enforcement Administration. Within six months of the adoption date~~
7 ~~of the regulations in this Article by the department, a program operator shall submit a~~
8 ~~stewardship plan to the department. To be complete, tThe stewardship plan shall~~
9 ~~include the following:~~

10 ~~(a) Contact Information. Contact information per section 18973 of this Chapter, of the~~
11 ~~corporate officer, or designee, responsible for submitting and overseeing the~~
12 ~~stewardship plan on behalf of the program operator, including, but not limited to:~~

13 ~~(1) Contact name and title~~

14 ~~(2) Name of program operator~~

15 ~~(3) Mailing and physical address(es)~~

16 ~~(4) Phone number~~

17 ~~(5) Email address~~

18 ~~(6) Internet website address~~

19 ~~(b) Covered Entity. Contact information for each covered entity participating in the~~
20 ~~stewardship plan, including, but not limited to:~~

21 ~~(1) Contact name and title~~

22 ~~(2) Name of covered entity~~

23 ~~(3) Mailing and physical address(es)~~

24 ~~(4) Covered entity Eemail address~~

25 ~~(5) Covered entity internet website address~~

26 ~~(6) Covered entity phone number~~

27 ~~Upon request by the department, the internet website address and phone number of~~
28 ~~participating covered entities shall be provided, if available. The requested information~~
29 ~~shall be submitted within 30 days of the request unless extended as determined by the~~
30 ~~department.~~

1 (c) Covered Products. List of each covered drug sold or offered for sale by each
2 participating covered entity covered by the stewardship plan.

3 (d) Authorized Collectors.

4 (1) Contact information for each participating authorized collector operating a
5 collection site where covered drugs are collected, include including, but not
6 limited to, the following:

7 (A) Contact name and title

8 (B) Name of authorized collector entity

9 (C) Mailing and physical address(es)

10 (D) List of participating authorized collection sites, with name and physical
11 address, by county

12 (2) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, list of
13 potential authorized collectors, in the counties in which the program will operate,
14 that were notified of the opportunity to serve as an authorized collector for the
15 proposed stewardship program, and the method(s) by which each potential
16 authorized collector was notified. The notification shall occur at least 120 days
17 before the stewardship plan is submitted to the department.

18 (3) Pursuant to Section 42032.2(b)(1) of the Public Resources Code,
19 description of the process by which good faith negotiations with potential
20 authorized collectors were and, if applicable, continue to be conducted.
21 Pursuant to Section 42032.2(b)(1), if a potential authorized collector expresses
22 interest in participating in a stewardship program, the program operator shall
23 commence good faith negotiations with the potential authorized collector within
24 30 days.

25 (4) Description of efforts to work with retail pharmacies and retail pharmacy
26 chains to fulfill the requirement in section 42032.2(b)(2) of the Public Resources
27 Code, if applicable.

28 (5) Description of the process to incorporate potential authorized collectors that
29 submit a written offer to join the stewardship program, in accordance with section
30 42032.2(b)(3) of the Public Resources Code. A program operator shall include
31 under its stewardship program any entity listed in subdivision (b) of section
32 42030 of the Public Resources Code that offers to participate in the stewardship
33 program, in writing and without compensation, even if the minimum convenience
34 standards set in clause (i) of subsection (1)(F) of subdivision (a) of section
35 42032.2 of the Public Resources Code have been achieved. The program
36 operator shall include the offering entity as an authorized collector in the

1 stewardship program within 90 days of receiving the written offer to participate. A
2 program operator shall not be required to respond to offers pursuant to this
3 subsection until the program operator's stewardship plan has been approved by
4 the department.

5 (46) Description of the ~~conditions~~ reasons for excluding any potential authorized
6 collectors, including those who ~~request~~ requested joining the program, as
7 applicable.

8 (57) Description of ~~the process~~ how the program operator will notify any potential
9 authorized collectors ~~can utilize to appeal a rejection, by the program operator,~~
10 ~~for~~ of the reasons they were rejected from inclusion in the stewardship program
11 and what changes the potential authorized collector can make in order to join the
12 stewardship program.

13 (e) State Agency Determinations and Compliance Certifications.

14 (1) State agency determinations, pursuant to section 42032.2(a)(1)(C) of the
15 Public Resources Code. ~~Determinations of compliance from the State Board of~~
16 ~~Pharmacy and any other state agency that reviewed the plan for compliance.~~ If a
17 determination of noncompliance was initially issued, the stewardship plan shall
18 include both the initial determination of noncompliance and the superseding
19 determination of compliance. If any state agency failed to respond to a request
20 for review within 90 days of receipt of the stewardship plan, the program operator
21 shall include documentation of this request along with a written certification,
22 signed by an authorized representative of the program operator, that, at the time
23 of submission to the department, ~~;~~ 1) the stewardship plan is consistent with all
24 laws and regulations relevant to that agency's authority, ~~;~~ and 2) the applicable
25 state agency failed to respond within 90 days of receipt of the stewardship plan.

26 (2) Written certification, by an authorized representative of the program operator,
27 that, at the time of submission to the department, the stewardship plan, including
28 all aspects of the plan related to the collection, transportation, and disposal of
29 covered drugs, is in compliance with all applicable local, state, and federal laws
30 and regulations, including, but not limited to United States Drug Enforcement
31 Administration regulations.

32 (f) Initial Program Budget and Program Funding. Demonstration of adequate funding for
33 all administrative and operational costs of the stewardship program, as well as the
34 departmental administrative fees, ~~to be borne by participating covered entities~~ for the
35 first five calendar years of operation, to be borne by participating covered entities
36 pursuant to section 18973.6.

37 (g) Collection, Transportation, and Disposal System. Descriptions of the following:

1 (1) Processes and policies that will be used to safely and securely collect, track,
2 and properly manage covered drugs from collection through final disposal. ~~to~~
3 ~~ensure all entities participating in the program will operate under and comply with~~
4 ~~all applicable local, state, and federal laws and regulations.~~

5 (2) How convenience standards pursuant to subsection (1)(F) of subdivision (a)
6 of section 42032.2 of the Public Resources Code will be met for each county,
7 including the following:

8 (A) How reasonable geographic spread is determined, including all factors
9 applied to develop the determination. Population considerations shall use
10 the most recent publicly available population calculations from the State of
11 California Department of Finance.

12 (B) How frequently the convenience standards will be re-evaluated to
13 ensure compliance with the convenience standards, including updating
14 population estimates.

15 (3) Tracking mechanism(s) for collection, transportation, and disposal.

16 (4) Metrics that will be used to measure the amount, including, but not limited to,
17 weight, of covered drugs collected from ultimate users at each authorized
18 collection site.

19 (54) Each ~~service provider~~ entity to be used to transport, process, or dispose of
20 covered drugs collected through the stewardship program, including, but not
21 limited to:

22 (A) Name of ~~service provider~~ entity

23 (B) Mailing and physical address(es)

24 (65) Mail-back services or an alternative form of collection and disposal system
25 to be provided to ultimate users, pursuant to ~~section~~ sections 42032.2(a)(1)(G)
26 and 42032.2(c) of the Public Resources Code. Include, at a minimum, the
27 following information: ~~to be provided to ultimate users, including, but not limited~~
28 ~~to, the following:~~

29 (A) List of locations and/or description of mechanisms to provide ultimate
30 users with ~~Locations where~~ preaddressed, prepaid mail-back materials are
31 ~~distributed~~ or an alternative form of collection and disposal system,
32 pursuant to section 42032.2(c)(2) of the Public Resources Code, that
33 would render the covered drug inert, ~~is provided,~~ if applicable.

34 (B) Pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code,
35 mechanism ~~Mechanism~~ to provide preaddressed, prepaid mail-back

1 materials or an alternative form of collection and disposal system
2 requested by request from ultimate users who are homeless, homebound,
3 or disabled through the program operator's internet website and a toll-free
4 telephone number.

5 (C) Metrics that will be used to measure the amount of preaddressed,
6 prepaid mail-back materials distributed or alternative form of collection and
7 disposal system provided, and the metrics used to measure the
8 amount/weight of material returned.

9 (C76) Pursuant to section 42032.2(c)(2) of the Public Resources Code,
10 description of if applicable, a Any mail-back program or alternative form of
11 collection and disposal system that complies with applicable local, state,
12 and federal laws and regulations including, but not limited to, United
13 States Drug Enforcement Administration regulations, that will be is used
14 as a supplemental service for any county that does not have not meet the
15 minimum number of authorized collection sites site threshold due to
16 circumstances beyond out of the program operator's control, if applicable.

17 (D87) Pursuant to section 42032.2(a)(1)(G)(ii) of the Public Resources
18 Code, any alternative methods Method(s) of collection for covered drugs,
19 other than controlled substances, that cannot be accepted or commingled
20 with other covered drugs in secure collection receptacles or through a
21 mail-back program, to the extent technically feasible and permissible
22 under applicable state and federal law, including, but not limited to, United
23 States Drug Enforcement Administration regulations.

24 (E) Metrics that will be used to measure the amount of preaddressed,
25 prepaid mail-back materials distributed or alternative form of collection and
26 disposal system provided, and the metrics used to measure the amount of
27 material returned.

28 (798) Description of a service schedule that meets the needs of each authorized
29 collection site. Process by in which collection receptacles will be monitored,
30 explanation of how service schedules are determined to ensure that collection
31 receptacles do not reach capacity, and procedures to be followed if capacity is
32 reached. The service schedule must meet the needs of each authorized
33 collection site, to ensure that collected covered drugs are transported to final
34 disposal in a timely manner.

35 (9) How each authorized collection site is notified of its responsibility to maintain
36 and make available collection records to the department upon request.

37 (810) What corrective actions will be taken if a program operator discovers
38 critical instances of deviations from noncompliance with nonstewardship plan
39 policies and procedures an authorized collector or service provider is not

1 ~~maintaining compliance with all collection, transportation, and disposal standards~~
2 ~~related to the handling of covered drugs, including, but not limited to, United~~
3 ~~States Drug Enforcement Administration regulations.~~

4 (911) How each participating collection site will be funded or reimbursed, if
5 applicable.

6 (1012) Standard operating procedures that will address incidents related to
7 safety and security issues for an unplanned incident, including processes to
8 ensure that the department and applicable local, state, and federal agencies are
9 notified of the incident. This description shall also explain the actions that will be
10 taken to change policies, procedures, and tracking mechanisms to alleviate the
11 problems with safety and security and improve safety and security.

12 (h) Collection, Transportation, and Disposal System Records. Description of how and
13 where the records generated during the collection, transportation, and disposal of
14 collected covered drugs will be maintained. These records include, but are not limited
15 to: collection manifests, mailer distributions, receipts of returned covered drugs, return
16 mailings, and final disposal of covered drugs, as applicable. ~~records will be maintained~~
17 ~~on policy and procedures for collection, transportation, and disposal of covered drugs to~~
18 ~~ensure easy access for review.~~

19 (i) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public
20 Resources Code, ~~Description of provisions,~~ processes, logistics, and timing of
21 implementation that will be necessary for the stewardship program that will be used
22 expand into jurisdictions not previously included in the stewardship plan, in the event of
23 the repeal of a local stewardship program ordinance. The description shall include an
24 explanation of how the stewardship program will meet ~~to meet~~ the convenience
25 standards, pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the
26 Public Resources Code.

27 (j) Education and Outreach. Description of a comprehensive education and outreach
28 program that shall include, but is not limited to, the following:

29 (1) Any activities to promote awareness and maximize ultimate user participation
30 in the stewardship program, including, but not limited to, provision of educational
31 and outreach materials for persons authorized to prescribe drugs, pharmacies,
32 pharmacists, ultimate users, and others, as necessary.

33 (2) Materials to be utilized that are distributed in languages suited to local
34 demographics, consistent with section 7295 of the Government Code. These
35 materials shall include, but are not limited to, signage for hospitals, pharmacies,
36 and other locations, as necessary. Signage or labeling for secure collection
37 receptacles shall be designed with explanatory graphics which are readily
38 understandable by all ultimate users.

1 (3) Establishment of an internet website designed with functionality for mobile
2 platforms, provided with language options suited to local demographics,
3 consistent with section 7295 of the Government Code, and maintained to ensure
4 all information is up to date and accurate. The internet website's digital content
5 and navigability must be accessible to disabled individuals. The internet website
6 shall include, but is not limited to, the following:

7 (A) Authorized collection site physical addresses

8 (B) Authorized collection site contact telephone numbers

9 (C) Authorized collection site days and hours of operation

10 (D) Mechanism to accept requests for mail-back materials from ultimate
11 users who are homeless, homebound, or disabled

12 (E) Information to promote the stewardship program, including, but not
13 limited to, instructions for safe handling and proper disposal of covered
14 drugs and information on collection options.

15 (4) Establishment of a toll-free telephone number to ~~1) accept requests for mail-~~
16 back materials from ultimate users who are homeless, homebound, or disabled,
17 and ~~2) to provide disposal options, and other program information to ultimate~~
18 users without access to the internet, ~~for ultimate users who are homeless,~~
19 ~~homebound, or disabled in addition to accepting requests through an internet~~
20 ~~website.~~ The toll-free telephone number shall offer language options suited to
21 local demographics, accept calls via human representative, and provide services
22 for hearing-impaired and speech-impaired individuals.

23 (5) Metrics to evaluate performance of the comprehensive education and
24 outreach program, including, but not limited to, ultimate user awareness, program
25 usage, and accessibility.

26 (6) How ultimate users will be encouraged to separate products that are not
27 covered products from covered products, when appropriate, before submitting
28 the covered products to an authorized collection site or mail-back program.

29 (7) How the program operator will comply with the requirement in section
30 42031.6(b) of the Public Resources Code.

31 (k) Coordination Efforts. Description of how the program operator will ~~make a good faith~~
32 ~~effort to work with the other stewardship program(s) in order to most effectively achieve~~
33 ~~the requirements of statute and regulations, coordinate with other program operators to~~
34 ~~avoid conflict, duplication, and confusion to the public and all program participants in the~~
35 event that multiple stewardship programs for covered drugs are in operation
36 concurrently or new stewardship programs begin operating.

1 (l) Process for providing grants, loans, sponsorships, reimbursements, or other
2 incentives, if applicable.

3 (m) Process for selecting service providers, including a description of any competitive
4 procedure used, if applicable.

5 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
6 Reference: Sections 42030, 42031, 42031.6, 42032, 42032.2, 42033, 42035.8, 42036.2
7 and 42036.4, Public Resources Code; and Section 17041, California Code of
8 Regulations.

9 **18973.3. STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE.**

10 Within six months of the adoption date of the regulations in this Article by the
11 department, a program operator shall submit a stewardship plan to the department. To
12 be complete, a stewardship plan for home-generated sharps waste shall comply with
13 all applicable local, state, and federal laws and regulations and include the following:

14 (a) ~~Contact information.~~ Contact information pursuant to section 18973 of this Chapter of
15 the corporate officer, or designee, responsible for submitting and overseeing the
16 stewardship plan on behalf of the program operator, including, but not limited to:

17 (1) Contact name and title

18 (2) Name of program operator

19 (3) Mailing and physical address(es)

20 (4) Phone number

21 (5) Email address

22 (6) Internet website address

23 (b) ~~Covered Entity.~~ Contact information for each covered entity participating in the
24 stewardship plan, including, but not limited to:

25 (1) Contact name and title

26 (2) Name of covered entity

27 (3) Mailing and physical address(es)

28 (4) Covered entity ~~E~~email address

29 (5) Covered entity internet website address

1 (6) Covered entity phone number

2 ~~Upon request by the department, the internet website address and phone number of~~
3 ~~participating covered entities shall be provided, if available. The requested information~~
4 ~~shall be submitted within 30 days of the request unless extended as determined by the~~
5 ~~department.~~

6 (c) Covered Products. List of sharps sold or offered for sale by each participating
7 covered entity covered by the stewardship plan.

8 (d) State Agency Determinations and Compliance Certifications.

9 (1) Agency determinations pursuant to 42032.2(d)(1)(B) of the Public Resources
10 Code. ~~Determinations of compliance from the State Board of Pharmacy and any~~
11 ~~other state agency that reviewed the plan for compliance.~~ If a determination of
12 noncompliance was initially issued, the stewardship plan shall include both the initial
13 determination of noncompliance and the superseding determination of compliance.
14 If any state agency failed to respond to a request for review within 90 days of
15 receipt of the stewardship plan, the program operator shall include documentation
16 of this request along with a written certification, signed by an authorized
17 representative of the program operator, that at the time of submission to the
18 department, ~~;~~ 1) the stewardship plan is consistent with all laws and regulations
19 relevant to that agency's authority, ~~;~~ and 2) the applicable agency failed to respond
20 within 90 days of receipt of the stewardship plan.

21 (2) Written certification, by an authorized representative of the program operator,
22 that, at the time of submission to the department, ~~;~~ the stewardship plan, including all
23 aspects of the plan related to the handling, transportation, and disposal of home-
24 generated sharps waste is in compliance with all applicable local, state, and federal
25 laws and regulations.

26 (e) Initial Program Budget and Program Funding. Demonstration of adequate funding for
27 all administrative and operational costs of the stewardship program, as well as
28 departmental administrative fees, ~~to be borne by participating covered entities~~ for the
29 first five calendar years of operation, to be borne by participating covered entities
30 pursuant to section 18973.6.

31 (f) Collection, Transportation, and Disposal System. Descriptions of the following:

32 (1) Processes and policies that will be used to safely and securely collect, track,
33 and properly manage home-generated sharps waste from collection through final
34 disposal.

35 ~~Processes, policies, and metrics for the mail-back program that will be used to~~
36 ~~safely and securely collect, track, transport, and dispose of home-generated~~
37 ~~sharps waste.~~

1 (2) How stewardship plan implementation will ~~1) provide~~ or
2 initiate~~initiates~~ distribution of sharps waste containers and mail-back materials,
3 which include mail-back packaging and informational material, at no cost to
4 ultimate users at the point of sale, to the extent allowable by law.¹ In addition,
5 how stewardship plan implementation will ~~and 2) meet~~ the following
6 requirements:

7 (A) Containers and mail-back materials shall be distributed in amounts
8 sufficient to accommodate the volume of sharps purchased by the ultimate
9 user over a selected time period.

10 (B) For any sharps, the packaging, an insert or instructions, or separate
11 information provided to the ultimate user shall include all necessary
12 information on proper sharps waste disposal. ~~Mail-back materials shall~~
13 ~~include information for proper home-generated sharps waste disposal.~~

14 (C) All sharps waste containers shall include, on a label affixed to the
15 container or packaging or on a separate insert included in the container or
16 packaging, the program operator's internet website and toll-free telephone
17 number. ~~Container labels and mail-back materials shall include the~~
18 ~~stewardship program internet website and toll-free telephone number.~~

19 (D) Prepaid postage shall be affixed to the container or mail-back
20 packaging.

21 (3) Collection, Transportation, and Disposal System Records. Description of how
22 and where the records generated during the collection, transportation, and
23 disposal of collected home-generated sharps waste will be maintained. These
24 records shall include, but are not limited to: collection manifests, mailer
25 distributions, receipts of returned home-generated sharps waste return mailings,
26 and final disposal of home-generated sharps waste, as applicable. ~~records will be~~
27 ~~maintained on policy and procedures for collection, transportation, and disposal~~
28 ~~of home-generated sharps waste to ensure easy access for review.~~

29 (4) Each ~~service provider~~ entity to be used to transport, process, or dispose of
30 home-generated sharps waste collected through the stewardship program,
31 including, but not limited to:

32 (A) Name of ~~service provider~~ entity

33 (B) Mailing and physical address(es) of ~~service provider~~ entity

34 ~~(5) Processes and policies to be followed by persons handling home-generated~~
35 ~~sharps waste under the stewardship plan and efforts the program operator will~~
36 ~~take to ensure that all entities participating will operate under and comply with all~~
37 ~~applicable local, state, and federal laws and regulations.~~

1 (56) Supplemental collection method(s) for home-generated sharps waste that
2 may be provided, in addition to, but not in lieu of, the mail-back program. These
3 methods may include, but are not limited to:

4 (A) Secure receptacle collection. If a program operator proposes to
5 implement a receptacle-based program to supplement its mail back
6 program and using authorized and approved home-generated sharps
7 consolidation points under the Medical Waste Management Act are
8 authorized and approved by the city, county, or state enforcement
9 authority that provides oversight of the Medical Waste Management Act,
10 then the following information, as applicable, shall be included, but not be
11 limited to:

12 (i) Name and physical address of home-generated sharps
13 consolidation point(s).

14 (ii) Processes and policies that will be used to safely and securely
15 collect, track, and properly manage home-generated sharps waste
16 from collection through final disposal.

17 (iii) Process in by which collection receptacles will be monitored,
18 how process by which service schedules will be determined to
19 ensure that collection receptacles do not reach capacity, and the
20 procedure to be followed if capacity is reached.

21 (iv) How each home-generated sharps consolidation point is
22 notified of its responsibility to maintain and make available
23 collection records to the department upon request.

24 (v) What corrective actions will be taken if a program operator
25 discovers a home-generated sharps consolidation point or service
26 provider is not maintaining compliance with all collection,
27 transportation, and disposal standards related to the handling of
28 home-generated sharps waste.

29 (iiiiv) How each participating home-generated sharps consolidation
30 point will be funded or reimbursed, if applicable.

31 (ivvii) Standard operating procedures that will address incidents
32 related to safety and security, including processes to ensure that
33 the department and applicable local, state, and federal agencies
34 are notified of the incident. This description shall also explain the
35 actions that will be taken to change policies, procedures, and
36 tracking mechanisms to alleviate the problems with safety and
37 security and improve safety and security address safety and
38 security issues for an unplanned incident.

1 (B) Take-back collection events shall be authorized and approved as a
2 home-generated sharps consolidation point under the Medical Waste
3 Management Act. Describe when take-back events are necessary and
4 how they will be conducted Date and location of events, if applicable.

5 (67) Metrics that will be used to measure the amount of sharps waste containers
6 and mail-back materials distributed and metrics that will be used to measure the
7 weight amount of home-generated sharps waste returned.

8 (78) Metrics that will be used to measure the amount~~weight~~ of home-generated
9 sharps waste collected through supplemental collection method(s), if applicable.

10 (8) Metrics that will be used to measure the amount of home-generated sharps
11 waste collected by household hazardous waste facilities operated by local
12 agencies that request reimbursement or removal for disposal of home-generated
13 sharps waste.

14 (9) Corrective actions that will be taken if a program operator discovers critical
15 instances of ~~deviations from~~ noncompliance with stewardship plan policies and
16 procedures.

17 (g) Local Agency Requests.

18 (1) Description of the process for coordinating with local agencies, or an agent on
19 behalf of a local agency, for the removal of home-generated sharps waste from
20 local household hazardous waste facilities, either by reimbursement for
21 transportation and disposal costs or removal of the home-generated sharps
22 waste.

23 (2) Requests by local agencies, or an agent on behalf of a local agency, shall
24 include an invoice and shall be submitted to the program operator, as necessary.
25 Such requests shall comply with the requirements in subsection (1)(F)(ii) of
26 subdivision (d) of section 42032.2 of the Public Resources Code. Program
27 operators ~~shall~~ will respond to requests by local agencies within 14 days of
28 receipt of the request ~~in a timely manner~~ and identify the method to resolve the
29 request by selecting either reimbursement or removal from household hazardous
30 waste facility(ies).

31 (A) A program operator that selects to resolve a request through
32 reimbursement to a local agency shall issue payment within 45 days of ~~the~~
33 receipt of the local agency's ~~providing an~~ invoice.

34 (B) A program operator that provides for the removal of the home-
35 generated sharps waste from the local household hazardous waste
36 facilities shall do so as often as required according to section 117904 of
37 the Health and Safety Code ~~and~~ or by the local enforcement authority.

1 (h) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public
2 Resources Code, ~~d~~Description of provisions, processes, logistics, and timing of
3 implementation that will be necessary for the stewardship program used to expand into
4 jurisdictions not previously included in the stewardship plan, in the event of the repeal of
5 a local stewardship program ordinance.

6 (i) Education and Outreach. Description of a comprehensive education and outreach
7 program shall include, but is not limited to, the following:

8 (1) Activities to promote awareness and maximize ultimate user participation in
9 the stewardship program, including, but not limited to provision of educational
10 and outreach materials for persons authorized to prescribe drugs, pharmacies,
11 pharmacists, ultimate users, and others, as necessary.

12 (2) Materials to be utilized that are distributed in languages suited to local
13 demographics, consistent with section 7295 of the Government Code. These
14 materials shall include, but are not limited to, signage for hospitals, pharmacies,
15 and other locations, as necessary. Signage or labeling for secure collection
16 receptacles shall be designed with explanatory graphics which are readily
17 understandable by all ultimate users.

18 (3) Establishment of an internet website designed with functionality for mobile
19 platforms, provided with language options suited to local demographics,
20 consistent with section 7295 of the Government Code, and maintained to ensure
21 all information is up to date and accurate. The internet website's digital content
22 and navigability must be accessible to disabled individuals. The internet website
23 shall include, but is not limited to, the following:

24 (A) A mechanism to accept requests for sharps waste containers and
25 mail-back materials.

26 (B) Information to promote the stewardship program including, but not
27 limited to, instructions for safe handling and proper disposal of home-
28 generated sharps waste and information on collection options for home-
29 generated sharps waste, if applicable.

30 (C) Home-generated sharps consolidation point addresses, if applicable.

31 (D) Home-generated sharps consolidation point site days and hours of
32 operation, if applicable.

33 (E) Home-generated sharps consolidation point contact telephone
34 numbers, if applicable.

35 (4) Establishment of a toll-free telephone number to ~~1~~ serve as an option for
36 ultimate users to request sharps waste containers and mail-back materials, and

1 2) to obtain information about the program, including, but not limited to what is
2 outlined in section 18973.3(i)(3)(A)-(E). The toll-free telephone number shall offer
3 language options suited to local demographics, accept calls via human
4 representative, and provide services for hearing-impaired and speech-impaired
5 individuals.

6 (5) Metrics to evaluate performance of the comprehensive education and
7 outreach program, including, but not limited to, ultimate user awareness, program
8 usage, and accessibility.

9 (6) How ultimate users will be encouraged to separate products that are not
10 covered products from covered products, when appropriate, before submitting
11 the covered products to a home-generated sharps consolidation point or mail-
12 back program.

13 (7) How the program operator will comply with the requirement in section
14 42031.6(b) of the Public Resources Code.

15 (j) ~~Coordination Efforts. Description of how the program operator will make a good faith~~
16 ~~effort to work with the other stewardship program(s) in order to most effectively achieve~~
17 ~~the requirements of the statute and regulations, coordinate with other program~~
18 ~~operators to avoid conflict, duplication, and confusion to the public and all program~~
19 ~~participants in the event that multiple stewardship programs for home-generated sharps~~
20 ~~waste are in operation concurrently or new stewardship programs begin operating.~~

21 (k) Process for providing grants, loans, sponsorships, reimbursements, or other
22 incentives, as applicable.

23 (l) Process for selecting service providers, including a description of any competitive
24 procedures used, if applicable.

25 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
26 Reference: Sections 42030, 42031, 42031.6, 42032, 42032.2, 42033, 42033.5, 42036.2
27 and 42036.4, Public Resources Code; Section 17041, California Code of Regulations;
28 and Section 117904, Health and Safety Code.

29 **18973.4. ANNUAL REPORT FOR COVERED DRUGS.**

30 On or before March 31, 2022, and each year thereafter, a program operator shall
31 prepare and submit an annual report to the department. To be complete, the annual
32 report shall: 1) describe how the program operator complied with all elements in its
33 stewardship plan during the previous reporting period of one year; and 2) shall contain
34 the following:

1 ~~(a) Contact information. Contact information for the program operator or corporate~~
2 ~~officer responsible for annual report submittal as specified in pursuant to section~~
3 ~~18973.2(a), including any changes or updates to this information of this Chapter.~~

4 ~~(b) Executive Summary. A concise summary of the information contained in the report~~
5 ~~that includes, but is not limited to, the highlights, outcomes and challenges,~~
6 ~~achievement of the convenience standards pursuant to subsection (1)(F) of subdivision~~
7 ~~(a) of section 42032.2 of the Public Resources Code, education and outreach efforts,~~
8 ~~and ways in which ~~how~~ challenges are being addressed.~~

9 ~~(c) Collection System. Description of the following:~~

10 ~~(1) How ultimate users had an opportunity to dispose of their covered drug(s) as~~
11 ~~described in the approved stewardship plan.~~

12 ~~(2) Efforts~~ ~~Good faith negotiations~~ ~~between the program operator and potential~~
13 ~~authorized collectors to establish authorized collection sites and the results of the~~
14 ~~negotiations, including, but not limited to:~~

15 ~~(A) Pursuant to section 18973.2(d)(2), efforts~~ ~~Efforts~~ ~~to notify potential~~
16 ~~authorized collectors of the opportunity to serve as an authorized collector~~
17 ~~for the stewardship program in the counties in which the program will~~
18 ~~operate~~ ~~operated,~~ ~~and the list of potential authorized collectors that were~~
19 ~~notified. pursuant to Section 42032.2(b)(1) of the Public Resources Code.~~

20 ~~(B) Pursuant to section 18973.2(d)(3), the process by which good faith~~
21 ~~negotiations with potential authorized collectors were conducted.~~

22 ~~(C) Pursuant to section 18973.2(d)(4), efforts to work with retail~~
23 ~~pharmacies and retail pharmacy chains to fulfill the requirement in section~~
24 ~~42032.2(b)(2) of the Public Resources Code, if applicable.~~

25 ~~(DB) Pursuant to section~~ ~~Section~~ ~~18973.2(d)(5), 42032.2(b)(3) of the Public~~
26 ~~Resources Code, e~~ ~~Efforts to incorporate~~ ~~include~~ ~~potential authorized~~
27 ~~collectors that submitted a written offer to join the stewardship program,~~
28 ~~and the list of potential authorized collectors that submitted written~~
29 ~~offers. beyond the minimum convenience standards pursuant to subsection~~
30 ~~(1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.~~

31 ~~(C) Efforts to achieve compliance in a county that did not achieve the~~
32 ~~minimum convenience standards pursuant to subsection (1)(F) of~~
33 ~~subdivision (a) of section 42032.2 of the Public Resources Code.~~

34 ~~(D) Efforts between the program operator and retail pharmacy chains to~~
35 ~~meet the requirement stated in subsection (2) of subdivision (b) of section~~
36 ~~42032.2 of the Public Resources Code. Any known reason why potential~~

~~authorized collectors were excluded or rejected from participation in the stewardship program.~~

(E) Pursuant to section 18973.2(d)(6), a list of potential authorized collectors that submitted a written offer requested to join joining the stewardship program and were rejected, and the reason(s) for each rejection.

(F) Description of how the program operator complied with the requirement in section 18973.2(d)(7).

(3) How the convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code were met. Include necessary changes to calculations that account for changes in the number of authorized collection sites and most recent publicly available population calculations from the State of California Department of Finance. If the convenience standards were not met, describe efforts made to achieve compliance.

(4) For each participating authorized collection site, include the following:

(A) Name and physical address

~~(B) Weight of material collected~~

(B) Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4)

(C) Number of instances that collected covered drugs were picked up for disposal collections and

~~(D) #Number of receptacle liners picked up collected for disposal~~

~~(E) #Total number of instances and corresponding number of business hours amount of time the secure collection authorized collection site receptacle was not available to the public during business hours. For each instance, provide a description of why the secure collection receptacle was not available.~~

(5) For each type of M mail-back services utilized, include the following, including, but not limited to, as applicable:

(A) List Name and location of distribution locations facility

~~(B) Amount of materials distributed~~

~~(C) Mechanism(s) of distribution~~

- 1 (C) Amount of mail-back materials distributed, as required in the
2 stewardship plan pursuant to section 18973.2(g)(6)(EG)
- 3 (D) Weight of material returned
- 4 (D) Amount of mail-back material returned, as required in the stewardship
5 plan pursuant to section 18973.2(g)(6)(EG)
- 6 (6) For each alternative form/Alternative forms of collection and disposal,
7 include/including, but not limited to, the following, as applicable:
- 8 (A) Method(s) of collection
- 9 (B) Name and address of location(s)
- 10 (C) Number of collections
- 11 (D) Amount of materials distributed, as required in the stewardship plan
12 pursuant to section 18973.2(g)(6)(EG)
- 13 (E) Weight of material collected
- 14 (E) Amount of material collected, as required in the stewardship plan
15 pursuant to section 18973.2(g)(6)(EG)
- 16 (d) Transportation and Disposal System. Description of the methods used for
17 transportation and disposal of covered drugs, including the following:
- 18 (1) Mechanism(s) for tracking the ~~collections~~collection, transportation, and
19 disposal of covered drugs
- 20 (2) Name and mailing address of each ~~service provider~~ entity used to transport or
21 process covered drugs
- 22 (3) For each disposal facility, include the following:
- 23 (A) Name of ~~disposal facility~~entity
- 24 (B) Mailing and physical address
- 25 (C) Weight of ~~material~~ covered drugs disposed/received
- 26 (e) Policies and Procedures. Pursuant to subdivision (b)(6) of section 42033.2 of the
27 Public Resources Code, provide the following:

1 (1) Description of whether policies and procedures for collecting, transporting,
2 and disposing of covered drugs, as established in the stewardship plan, were
3 followed during the reporting period

4 (2) Description of each instance of noncompliance from stewardship plan policies
5 and procedures, if any occurred

6 (3) Corrective actions taken, or that will be taken, if the program operator
7 discovered critical instances of noncompliance with stewardship plan policies and
8 procedures ~~Corrective actions taken if the program operator discovered critical~~
9 ~~deviations from stewardship plan policies and procedures and a description of~~
10 ~~each critical deviation, that a service provider did not maintain compliance with all~~
11 ~~collection, transportation, and disposal standards, including, but not limited to,~~
12 ~~local, state and federal laws and regulations and United States Drug~~
13 ~~Enforcement Administration regulations.~~

14 (f) ~~Description of updates, that have been made or will be made, to the processes and~~
15 ~~policies followed to safely and securely collect, track, and properly manage covered~~
16 ~~drugs from collection through final disposal to ensure all entities participating in the~~
17 ~~program continue to operate in compliance with all applicable state, local and federal~~
18 ~~laws and regulations.~~

19 (g) ~~Ordinance Repeal. Description of efforts to expand into jurisdictions due to the~~
20 ~~repeal of a local stewardship program ordinance. Pursuant to subdivision (e) of section~~
21 ~~42032.2 of the Public Resources Code, description of processes including, but not~~
22 ~~limited to, logistics, and timing of implementation that will be necessary for of the~~
23 ~~stewardship program to expand into jurisdictions not previously included in the~~
24 ~~stewardship plan, in the event of the repeal of a local stewardship program ordinance in~~
25 ~~the jurisdiction. The description shall include an explanation of how to meet the~~
26 ~~stewardship program will meet the convenience standards, pursuant to subsection~~
27 ~~(1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.~~

28 (h) Safety and Security. Describe the general nature of any incidents with safety or
29 security related to collection, transportation, or disposal of collected covered drugs.
30 Explain what corrective actions were taken or will be taken to address the issue and
31 improve safety and security. The following In addition, the following specific
32 information Information about any incident(s) shall be made available to the department
33 upon request, and shall include including, but not be limited to, the following:

34 (1) Location and date

35 (2) Description of specific incident

36 (3) Cause(s) of specific incident

37 (4) Parties involved

1 (5) Regulatory or law enforcement agencies involved and any litigation,
2 arbitration, or other legal proceedings that result from each incident

3 (i) Education and Outreach. Description and evaluation of the comprehensive education
4 and outreach activities pursuant to section 18973.2(j), including, but not limited to, the
5 following:

6 (1) ~~e~~Electronic examples of promotional marketing materials

7 (2) Numerical results of the education and outreach metrics outlined in the
8 stewardship plan, pursuant to section 18973.2(j)(5)

9 (3) A discussion of what the metrics, described above in section 18973.4(i)(2),
10 reveal about the performance of the comprehensive education and outreach
11 program, including, but not limited to, ultimate user awareness, program usage,
12 and accessibility

13 (4) Description of how the requirement of section 42031.6(b) of the Public
14 Resources Code was met.

15 (j) Covered Entities, Covered Products, and Authorized Collectors. List of the following:

16 (1) Participating covered entities covered by the stewardship plan and their
17 contact information including, but not limited to, the following:

18 (A) Name of covered entity

19 (B) Mailing and physical address

20 (C) Contact name and title

21 (D) Email address

22 (2) A copy of the list of covered products submitted to the Board of Pharmacy
23 pursuant to subsection (2) of subdivision (a) of section 42031 of the Public
24 Resources Code. ~~List of covered products~~

25 (3) Authorized collectors and their contact information including, but not limited
26 to:

27 (A) Name of authorized collector~~entity~~

28 (B) Mailing and physical address

29 (C) Contact name and title

30 (D) Email address

~~(4) Authorized collection sites, including the names and physical addresses of the sites~~

~~(k) Description and evaluation of changes in the process for selecting service providers, if applicable.~~

~~(l) Description of changes in the process for providing any grants, loans, sponsorships, reimbursements, or other incentives provided, as applicable.~~

~~(m) Description of changes in staffing of the stewardship program.~~

~~(n) A list of all actual expenses incurred during the previous reporting period. Expenses shall be summarized in accordance with the budget categories specified in section 18973.6(b).~~

~~(o) Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating. made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, if applicable.~~

~~(p) State Agency Determinations pursuant to section 42032.2(a)(1)(C) of the Public Resources Code. Submit all agency determination(s) of compliance, noncompliance, and superseding determinations of compliance, if any, for the reporting period.~~

~~(p) Written certification, by an authorized representative of the program operator, that: the stewardship plan, including the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.~~

~~(q) Written certification by an authorized representative for each of the authorized collectors participating in the stewardship plan, that: the service(s) they are providing to the program operator is compliant with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.~~

~~Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code. Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4, 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041, California Code of Regulations.~~

18973.5. ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.

On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit an annual report to the department. To be complete, the annual

1 report shall describe how the stewardship program operator activities complied with all
2 elements of the stewardship plan during the previous reporting period of one year and
3 shall contain the following:

4 (a) ~~Contact information.~~ Contact information for the program operator or corporate officer
5 responsible for annual report submittal as specified in pursuant to section 18973.3(a)
6 including any changes or updates to this information ~~of this Chapter.~~

7 (b) Executive Summary. A concise summary of the information contained in the report
8 that includes, but is not limited to, the highlights, outcomes and challenges, education
9 and outreach efforts, and ~~how ways in which~~ challenges are being addressed.

10 (c) Collection System. Description of the following:

11 (1) How ultimate users had an opportunity to dispose of their home-generated
12 sharps waste as described in the approved stewardship plan.

13 (2) Amount of sharps waste containers and mail-back materials distributed as
14 required in the stewardship plan pursuant to section 18973.3(f)(6), per county,
15 through each of the following methods:

16 (A) Provided at point of sale

17 (B) Initiated at point of sale

18 (C) Website requests

19 (D) Toll-free telephone number requests

20 ~~(3) Weight of material returned~~

21 (3) Amount of home-generated sharps waste returned through the mail-back
22 program, as required in the stewardship plan pursuant to section 18973.3(f)(6)

23 (4) Supplemental collection method(s) of home-generated sharps waste that
24 were provided in addition to, but not substituted for in lieu of, the mail-back
25 program, pursuant to section 18973.3-(f)(5) and (7). Include a list of dates and
26 locations of take-back events that occurred pursuant to section 18973.3(f)(5)(B),
27 if applicable

28 (5) If applicable, amount of home-generated sharps waste collected through
29 supplemental collection method(s), as required in the stewardship plan pursuant
30 to section 18973.3(f)(7)

31 (d) Transportation and Disposal. Descriptions of ~~the~~ the methods used to transport and
32 dispose of consolidated home-generated sharps waste, including the following:

1 (1) Mechanism(s) used to track ~~transportation and disposal~~ the collection,
2 transportation, and disposal of home-generated sharps waste

3 (2) Name and mailing address of each ~~service provider~~ entity used to transport or
4 process home-generated sharps waste

5 (3) For each disposal facility, include the following:

6 (A) Name of ~~facility~~ entity

7 (B) Mailing and physical address

8 (C) Total weight of material disposed

9 (e) Policies and Procedures. Pursuant to subdivision (b)(6) of section 42033.2 of the
10 Public Resources Code, provide the following:

11 (1) Description of whether policies and procedures for collecting, transporting,
12 and disposing of home-generated sharps waste, as established in the
13 stewardship plan, were followed during the reporting period

14 (2) Description of each instance of noncompliance from stewardship plan policies
15 and procedures, if any occurred

16 (3) Corrective actions taken, or that will be taken, if the program operator
17 discovered critical instances of noncompliance with stewardship plan policies and
18 procedures. ~~Corrective actions taken if the program operator discovered critical~~
19 ~~deviations from stewardship plan policies and procedures, and a description of~~
20 ~~each critical deviation, that service provider did not maintain compliance with all~~
21 ~~collection, transportation, and disposal standards, including, but not limited to,~~
22 ~~local, state and federal laws and regulations and United States Drug~~
23 ~~Enforcement Administration regulations.~~

24 (f) Description of updates, that have been made or will be made, to the processes and
25 policies followed to safely and securely collect, track, and properly manage home-
26 generated sharps waste from collection through final disposal ~~to ensure all entities are~~
27 ~~in compliance with all applicable state, local and federal laws and regulations.~~

28 (g) Ordinance Repeal. ~~Description of efforts to expand into jurisdictions due to the~~
29 ~~repeal of a local stewardship program ordinance.~~ Pursuant to subdivision (e) of section
30 ~~42032.2 of the Public Resources Code, description of processes including, but not~~
31 ~~limited to, logistics, and timing of implementation that will be necessary for the~~
32 ~~stewardship program to expand into jurisdictions not previously included in the~~
33 ~~stewardship plan, in the event of the repeal of a local stewardship program ordinance.~~
34 ~~of the program in the jurisdiction.~~

1 (h) Safety and Security. Describe the general nature of any incidents with safety or
2 security related to collection, transportation, or disposal of home-generated sharps
3 waste. Explain the corrective actions taken or that will be taken to address the issue and
4 improve safety and security. Additionally, the following specific information ~~Information~~
5 about any incident(s) ~~The following~~ shall be made available to the department, upon
6 request, and shall include ~~including~~, but not be limited to:

7 (1) Location and date

8 (2) Description of specific incident

9 (3) Cause(s) of specific incident

10 (4) Parties involved

11 (5) Regulatory or law enforcement agencies involved and any litigation,
12 arbitration, or other legal proceedings that result from each incident.

13 (i) Education and Outreach. Description and evaluation of the comprehensive education
14 and outreach activities pursuant to section 18973.3(i), including, but not limited to, the
15 following:

16 (1) ~~e~~Electronic examples of promotional marketing materials.

17 (2) Numerical results of the education and outreach metrics outlined in the
18 stewardship plan, pursuant to section 18973.3(i)(5)

19 (3) A discussion of what the metrics, described above in section 18973.5(i)(2),
20 reveal about the performance of the comprehensive education and outreach
21 program, including, but not limited to, ultimate user awareness, program usage,
22 and accessibility

23 (4) Description of how the requirement in section 42031.6(b) of the Public
24 Resources Code was met.

25 (j) Covered Entities. Participating covered entities covered by the stewardship plan and
26 their contact information, including, but not limited to, the following:

27 (1) Name of covered entity

28 (2) Mailing and physical address

29 (3) Contact name and title

30 (4) Email address

- 1 (k) A copy of the list of covered products submitted to the Board of Pharmacy pursuant
2 to subsection (2) of subdivision (a) of section 42031 of the Public Resources
3 Code. ~~Updated list of covered products~~
- 4 (l) Description and evaluation of ~~changes to~~ the process for selecting service providers,
5 if applicable.
- 6 (m) Description of ~~changes in the process for providing any grants, loans, sponsorships,~~
7 reimbursements, or other incentives provided, as applicable.
- 8 (n) Description of changes in staffing of the stewardship program.
- 9 (o) Coordination Efforts. Description of how the program operator coordinated with other
10 program operators to avoid conflict, duplication, and confusion to the public and all
11 program participants in the event that multiple stewardship programs for home-
12 generated sharps waste are in operation concurrently or new stewardship programs
13 begin operating. ~~made a good faith effort to work with any other stewardship program(s)~~
14 ~~in order to most effectively achieve the requirements of the statute and regulations.~~
- 15 (p) Local Agency Requests. For each local agency that has requested removal or
16 reimbursement, pursuant to the requirements in subsection (1)(F)(ii) of subdivision (d) of
17 section 42032.2 of the Public Resources Code, provide details including, but not limited
18 to, the following:
- 19 (1) Name of local agency, or agent acting on behalf of the local agency.
- 20 (2) For each household hazardous waste facility:
- 21 (A) Facility location
- 22 (B) Reimbursement payment amount, as applicable
- 23 ~~(C) Weight of collected material~~
- 24 (C) Amount of home-generated sharps waste collected, as required in the
25 stewardship plan pursuant to section 18973.3(f)(89)
- 26 (3) Any requests that were rejected and the reason(s) each request was rejected.
- 27 (4) Any requests where response, removal, or reimbursement was performed
28 outside of the timelines specified in section 18973.3(g)(2).
- 29 (q) A list of all actual expenses incurred during the previous reporting period. Expenses
30 shall be summarized in accordance with the budget categories specified in section
31 18973.6(b).

1 (q) State Agency Determinations pursuant to section 42032.2(d)(1)(B) of the Public
2 Resources Code. Submit all agency determination(s) of compliance, noncompliance
3 and superseding determinations of compliance, if any, for the reporting period.

4 (r) Written certification, by an authorized representative of the program operator, that:
5 the stewardship plan, including the handling, transportation, and disposal of home-
6 generated sharps waste is in compliance with all applicable local, state, and federal
7 laws and regulations.

8 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
9 Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4,
10 42033.5, 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041,
11 California Code of Regulations.

12 **18973.6. PROGRAM BUDGETS.**

13 A program operator must submit an initial stewardship program budget for the first five
14 calendar years of operation and an annual budget, pursuant to sections 42033 and
15 42033.2 of Chapter 2, Part 3, Division 30 of the Public Resources Code. The initial
16 stewardship program budget that covers the first five calendar years of operation and
17 the annual program budgets shall contain at a minimum, the following information:

18 (a) Contact information of the corporate officer, or designee, responsible for submitting
19 and overseeing the program budget on behalf of the program operator, including, but
20 not limited to:

21 (1) Contact name and title

22 (2) Name of program operator

23 (3) Mailing and physical address(es)

24 (4) Phone number

25 (5) Email address

26 (6) Internet website address

27 (b) Anticipated costs to implement the stewardship program, including, but not limited
28 to, separate line items for the following:

29 (1) Capital costs, including, but not limited to, fixed, one-time, tangible purchases
30 the purchase/installation of collection receptacles, sharps waste containers, and
31 mail back materials, as applicable.

32 (2) Costs of cCollection, transportation, and disposal of covered products

- 1 ~~(3) Transportation of covered products~~
- 2 ~~(4) Processing of covered products~~
- 3 ~~(5) Disposal of covered products~~
- 4 ~~(36) Administrative costs, including departmental administrative fee costs~~
- 5 ~~(47) Education and outreach costs~~
- 6 ~~(58) Costs related to grants, loans, sponsorships, or other incentives as part of~~
- 7 ~~program implementation~~
- 8 ~~(9) Reserve level~~

9 (c) Recommended reserve level amount and description justifying the reserve level
 10 amount indicated. The program operator shall maintain reserves in a prudent and
 11 responsible manner.

12 ~~(d)~~ Recommended funding level necessary to cover the stewardship plan's budgeted
 13 costs and to operate~~implement~~ the stewardship program over a multi-year period in a
 14 prudent and responsible manner, including a description of how costs are
 15 apportioned to and funds remitted from participating covered entities, in order to
 16 demonstrate that the stewardship program will be operated in a prudent and responsible
 17 manner.

18 ~~(e)~~ A narrative description of the types of activities relative to within each line item cost
 19 category, identified pursuant to section 18973.6(b).

20 ~~(f)~~ Beginning with the first annual program budget, include all actual expenses incurred
 21 during the previous program year. Expenses shall be summarized in accordance with
 22 the budget categories specified in section 18973.6(b).

23 ~~(g)~~ An independent financial audit of the stewardship program funded by the member
 24 covered entities participating in the stewardship program or by a covered entity, if it
 25 operates its own stewardship program. The audit shall be performed at least once each
 26 calendar year. The audit shall be conducted in accordance with generally accepted
 27 auditing standards in the United States of America, and ~~Generally Accepted~~
 28 ~~Government Auditing Standards~~ by a Certified Public Accountant. The Certified Public
 29 Accountant shall not perform the non-audit services for the program operator or engage
 30 in any activities that would impair independence. The independent financial audit shall
 31 include, but not be limited to:

32 (1) Minutes, books, and records that clearly reflect the activities and transactions
 33 of the program operator's stewardship program.

1 (2) Stewardship program financial statements, as required by Generally
2 Accepted Accounting Principles.

3 (3) An opinion on the stewardship organization's compliance with the aspects of
4 section 42034 of the Public Resources Code and this Article ~~Title 14, Division 7,~~
5 ~~Chapter 11 Article 4 of the California Code of Regulations.~~

6 (4) Findings and recommendations as they relate to the financial aspects of the
7 stewardship ~~organization~~ program.

8 (5) Management Letter, if issued, by the stewardship organization's Certified
9 Public Accountant.

10 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
11 Reference: Sections 42030, 42033, 42033.2, 42033.4, 42034 and 42036.4, Public
12 Resources Code; and Section 17041, California Code of Regulations.

13 **18974. RECORD KEEPING REQUIREMENTS.**

14 Each party required to comply with Chapter 2 (commencing with section 42030, Part 3,
15 Division 30 of the Public Resources Code) shall:

16 (a) Maintain records to support the requirements in this Article and Chapter 2 of Part 3
17 of Division 30 of the Public Resources Code. Covered entities, stewardship
18 organizations, program operators, retail pharmacies and retail pharmacy chains must
19 maintain records to support compliance with this Article and Chapter 2 of Part 3 of
20 Division 30 of the Public Resources Code ~~and regulations.~~ Retail pharmacies or retail
21 pharmacy chains will maintain and provide access to records required by this Article
22 and Chapter 2 of Part 3 of Division 30 of the Public Resources Code for a minimum of
23 three years.

24 (b) Upon request, ~~provide~~ provide the department with reasonable and timely access, as
25 determined by the department, to its facilities, operations, and any relevant records
26 necessary to determine compliance with this Article and Chapter 2 of Part 3 of Division
27 30 of the Public Resources Code, ~~upon request.~~ Covered entities, stewardship
28 organizations, and program operators will maintain and provide access to records
29 required to be kept or submitted pursuant to ~~by~~ this Article and Chapter 2 of Part 3 of
30 Division 30 of the Public Resources Code for a minimum of three years after submission
31 of ~~the annual report~~ a document which relies upon those records.

32 (c) Retail pharmacies and retail pharmacy chains that are participating in the
33 stewardship program must provide access to existing records on all covered products
34 sold, ~~or~~ offered for sale, or dispensed in the state, including:

35 (1) The manufacturer of the covered product(s).

1 (2) The date(s) the retailer purchased the covered product(s) from the
2 manufacturer, distributor, and/or wholesaler.

3 (3) The date(s) the retailer sold, offered ~~the covered product(s)~~ for sale, or
4 dispensed the covered product(s).

5 (4) Certification letter(s) from the department, pursuant to subdivision (b) of
6 section 42035 of the Public Resources Code, if provided by a covered entity or
7 stewardship organization~~manufacturer~~, to demonstrate that a particular covered
8 product from the covered entity or stewardship organization~~manufacturer~~ is or
9 was subject to a department-approved covered product stewardship plan. A retail
10 pharmacy and ~~retail pharmacy chain~~ must provide access to a certification letter
11 only if it is being used as proof of compliance, ~~pursuant to subdivision (b) of~~
12 ~~section 42035 of the Public Resources Code, or to demonstrate that a covered~~
13 entity or stewardship organization not listed on the department's internet website
14 is in compliance, ~~and may sell or offer for sale pharmaceuticals and/or sharps in~~
15 California.

16 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
17 Reference: Sections 42030, 42033.4, 42035, 42035.6 and 42036.4, Public Resources
18 Code; and Section 17041, California Code of Regulations.

19 **18974.1. ADMINISTRATIVE AND OPERATIONAL COSTS AND DEPARTMENTAL**
20 **ADMINISTRATIVE FEE ~~TO DEPARTMENT OF RESOURCES RECYCLING AND~~**
21 **RECOVERY.**

22 (a) Each covered entity, either individually or through a stewardship organization, shall
23 pay all administrative and operational costs associated with establishing and
24 implementing the stewardship program in which it participates, including the cost of
25 collecting, transporting, and disposing of covered products.

26 (b) On or before the end of the 2022-23 fiscal year, and once every three (3) months
27 thereafter, a program operator shall pay to the department a departmental
28 administrative fee. The department will set the departmental administrative fee pursuant
29 to subsection (1) of subdivision (a) of sections ~~42034.4 and~~ 42034.2 of the Public
30 Resources Code.

31 (c) For a stewardship organization, the departmental administrative fee paid pursuant to
32 subsection (b) shall be funded by the covered entities that make up the stewardship
33 organization. This departmental administrative fee shall be in addition to the
34 administrative and operational costs paid pursuant to subsection (a). A stewardship
35 organization may require its participating covered entities to pay the departmental
36 administrative fee and the administrative and operational costs paid pursuant to
37 subsection (a) at the same time.

1 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
2 Reference: Sections 42030, ~~42034~~ and, 42034.2, Public Resources Code.

3 **18974.2. STEWARDSHIP ORGANIZATION AUDITS OF COVERED ENTITIES OR**
4 **AUTHORIZED COLLECTORS.**

5 If a stewardship organization conducts an audit of covered entities or authorized
6 collectors pursuant to section 42034.4 of the Public Resources Code, the stewardship
7 organization shall provide a copy of the audit to the department within 30 days of its
8 completion.

9 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
10 Reference: Sections 42030 and 42034.4, Public Resources Code.

11 **18974.3. ~~DISTRIBUTOR, RETAILER, WHOLESALER, DISTRIBUTOR, PHARMACY,~~**
12 **AND RETAILER PRODUCT VERIFICATION.**

13 ~~Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or~~
14 ~~dispenses a covered product shall:~~(a) Each distributor, wholesaler, pharmacy, and
15 retailer that sells, offers for sale, or dispenses a covered product shall: sSuccessfully log
16 onto the department's ~~internet~~ ~~web-site~~ to ~~verify~~ ~~determine if~~ that covered products to
17 be sold, offered for sale, or dispensed are in compliance with the law, by verifying that
18 the covered entities providing the covered product(s) are in compliance with the law.

19 (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated
20 responsible party for any of the foregoing identify a noncompliant covered entity~~product~~
21 or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or
22 designated responsible party for any of the foregoing shall report the discovery to the
23 department's ~~Enforcement Unit~~ within 30 days.

24 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
25 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
26 Resources Code.

27 **18975. ~~CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.~~**

28 ~~(a) A covered entity is not in compliance with this chapter and is subject to~~
29 ~~administrative penalties if it sells or offers for sale a covered product which is not~~
30 ~~subject to an approved stewardship plan that has been submitted by the covered entity~~
31 ~~or by a stewardship organization that includes the covered entity.~~

32 ~~(b) In assessing or reviewing the amount of an administrative penalty imposed for a~~
33 ~~violation of this Article, the department shall consider the totality of the circumstances,~~
34 ~~which may include, but is not limited to, the following:~~

35 ~~(1) The nature, circumstances, extent, and gravity of the violation(s)~~

- 1 ~~(2) The number and severity of the violation(s)~~
- 2 ~~(3) Evidence that the violation was intentional, knowing, or negligent~~
- 3 ~~(4) The size of the violator~~
- 4 ~~(5) History of violation(s) of the same or similar nature~~
- 5 ~~(6) The willfulness of the violator's misconduct~~
- 6 ~~(7) Whether the violator took good faith measures to comply with this chapter and~~
- 7 ~~the period of time over which these measures were taken~~
- 8 ~~(8) Evidence of any financial gain resulting from the violation(s)~~
- 9 ~~(9) The economic effect of the penalty on the violator~~
- 10 ~~(10) The deterrent effect that the imposition of the penalty would have on both~~
- 11 ~~the violator and the regulated community~~
- 12 ~~(11) Any other factor that justice may require~~

13 ~~Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.~~
14 ~~Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public~~
15 ~~Resources Code.~~

16 **18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.**

17 (a) The department shall impose an administrative civil penalty if it determines that any
18 covered entity, program operator, stewardship organization, or authorized collector that
19 sells, offers for sale, or provides a covered product in California has violated~~violation of~~
20 this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.

21 (b) In addition to the ability to impose administrative civil penalties under subdivision (a)
22 above, the department shall, consistent with section 42035.6(d) of the Public Resources
23 Code, take a disciplinary action against a covered entity, stewardship organization,
24 program operator, pharmacy, retail pharmacy, or retail pharmacy chain if the
25 department determines that any of those entities has failed to provide the department
26 with the access to information required pursuant to section 42035.6(a) through (c) of the
27 Public Resources Code or section 18974 of this Article. The disciplinary actions shall
28 include one or both of the following:

29 (1) Imposition of an administrative civil penalty by the department

30 (2) Posting of a notice in accordance with section 42035.6(d)(2) of the Public
31 Resources Code.

1 (c) In assessing or reviewing the amount of an administrative penalty imposed for a
2 violation of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources
3 Code, the department shall consider the totality of the circumstances, which may
4 include, but is not limited to, the following:

5 (1) The nature, circumstances, extent, and gravity of the violation(s)

6 (2) The number and severity of the violation(s)

7 (3) Evidence that the violation was intentional, knowing, or reckless

8 (4) The size of the violator's business and/or the financial position of the violator

9 (5) History of violation(s) of the same or similar nature

10 (6) The willfulness of the violator's misconduct

11 (7) Whether the violator took good faith measures to comply with this Article and
12 Chapter 2 of Part 3 of Division 30 of the Public Resources Code and the period
13 of time over which these measures were taken

14 (8) Evidence of any financial gain resulting from the violation(s)

15 (9) The economic effect of the penalty on the violator

16 (10) The deterrent effect that the imposition of the penalty would have on both
17 the violator and the regulated community

18 (11) Any other factor(s) that justice may require.

19 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
20 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
21 Resources Code.

22 ~~**18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.**~~

23 ~~(a) Civil penalties may be administratively imposed after an informal hearing before the~~
24 ~~Director, or the Director's designee, in accordance with the procedures outlined in the~~
25 ~~Administrative Procedures Act at Article 10 of Chapter 4.5 (commencing with section~~
26 ~~11445.10) of Part 1 of Division 3 of Title 2 of the Government Code.~~

27 ~~(b) The accusation or complaint and all accompanying documents may be served on~~
28 ~~the respondent by the following means:~~

29 ~~(1) Personal service.~~

1 ~~(2) Substitute service by using the same service procedures as described in~~
2 ~~section 415.20 of the Code of Civil Procedure.~~

3 ~~(3) Certified Mail: For respondents who have submitted a stewardship plan for~~
4 ~~the management of covered products, certified mail or registered mail of the~~
5 ~~letter containing the accusation or complaint and accompanying material is~~
6 ~~mailed, addressed to the respondent at the latest facility or mailing address(es)~~
7 ~~on file with the department. Proof of service of the accusation or complaint shall~~
8 ~~be the certified mail receipts or registered mail receipts proving the accusation or~~
9 ~~complaint and accompanying materials were sent to respondent by certified mail~~
10 ~~or registered mail. For respondents who have not submitted or are not required~~
11 ~~to submit a stewardship plan for the management of covered products to the~~
12 ~~department, certified mail or registered mail pursuant to the procedures indicated~~
13 ~~in the Administrative Procedure Act at subdivision (c) of section 11505 of the~~
14 ~~Government Code applies.~~

15 ~~(c) Civil penalties may be imposed pursuant to subsection (2) of subdivision (a) of~~
16 ~~section 42035.2 of the Public Resources Code.~~

17 ~~Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.~~
18 ~~Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public~~
19 ~~Resources Code; and Section 11445.10, Government Code.~~

20 **18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.**

21 (a) The department shall issue a written notice of violation (NOV) before commencing
22 an action to impose administrative civil penalties. The NOV shall list and describe the
23 nature of the violation(s). The department shall issue a notice of violation (NOV) to the
24 respondent if the department determines any of the following: that the respondent has
25 violated a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the
26 Public Resources Code. The NOV shall list and describe the nature of the violation(s).
27 The department shall issue a NOV before commencing an action to impose
28 administrative civil penalties.

29 (1) That any covered entity, program operator, stewardship organization, or
30 authorized collector that sells, offers for sale, or provides a covered product in
31 California has violated this Article or Chapter 2 of Part 3 of Division 30 of the
32 Public Resources Code.

33 (2) That a covered entity, stewardship organization, program operator, pharmacy,
34 retail pharmacy, or retail pharmacy chain failed to provide the department with
35 the access to information required pursuant to section 42035.6(a) through (c) of
36 the Public Resources Code or section 18974 of this Article.

1 (b) The department shall commence an action to impose administrative civil penalties
2 by serving an accusation upon the respondent that includes a notice informing the
3 respondent of their right to a hearing. The accusation shall state the legal and factual
4 basis for the imposition of penalties, including a description of how the department
5 applied the criteria in Section 18975(c).

6 (c) The accusation and all accompanying documents shall be served on the respondent
7 by one of the following means:

8 (1) Personal service;

9 (2) Substitute service by using the same service procedures as described in
10 Section 415.20 of the Code of Civil Procedure;

11 (3) Certified Mail or registered mail; or

12 (4) Electronically, with the consent of the respondent.

13 (d) A request for hearing to contest the proposed action shall be submitted to the
14 department within thirty (30) days of receipt of the accusation. The hearing request shall
15 be in writing and shall state the basis for objecting to the department's action. Upon a
16 failure to submit a timely hearing request under this subdivision, the respondent shall be
17 deemed to have waived its right to hearing and the department shall issue a penalty
18 order to the respondent requiring payment of penalties at the levels described in the
19 accusation.

20 (e) The hearing shall be held before the Director of the Department of Resources
21 Recycling and Recovery. A party shall be afforded the opportunity to present evidence
22 and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the
23 sort of evidence on which responsible persons are accustomed to rely in the conduct of
24 serious affairs, regardless of the existence of any common law or statutory rule which
25 might make improper the admission of the evidence over objection in civil actions.

26 (f) The Director of the Department of Resources Recycling and Recovery shall issue a
27 written decision within sixty (60) days from the date the hearing is concluded.

28 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
29 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
30 Resources Code.

1 ~~**18975.2. PROCEDURE FOR REVOKING, REQUIRING RESUBMITTAL, OR**~~
2 ~~**ADDITIONAL REPORTING OF AN APPROVED STEWARDSHIP PLAN FOR**~~
3 ~~**FAILURE TO MEET A MATERIAL REQUIREMENT OF THE STATUTE.**~~

4 ~~(a) The Department may, after holding a public hearing, revoke a previously approved~~
5 ~~stewardship plan, require a resubmittal of the plan, or require additional reporting~~
6 ~~related to compliance, for failure to meet a material requirement of the statute.~~

7 ~~(b) Notice shall be given to the program operator of the Department's intent to consider~~
8 ~~revocation, resubmittal, or additional reporting of an approved stewardship plan at least~~
9 ~~sixty (60) days prior to the hearing.~~

10 ~~(c) The hearing shall be held before the Director, or the Director's designee, in~~
11 ~~accordance with the provisions of Article 10 of Chapter 4.5 (commencing with section~~
12 ~~11445.10) of Part 1 of Division 3 of Title 2 of the Government Code.~~

13 ~~(d) Within thirty (30) calendar days of receipt of the notification from the Department, the~~
14 ~~program operator shall submit to the Director of the Department a clear and concise~~
15 ~~statement of the basis for objecting to revocation or resubmittal of the stewardship plan,~~
16 ~~or the additional reporting requirements.~~

17 ~~(e) The Director shall notify the program operator of the determination on whether or not~~
18 ~~to revoke the plan, require a resubmittal of the plan, or require additional reporting, in~~
19 ~~writing within sixty (60) working days from the date the hearing is conducted.~~

20 ~~(f) A stewardship plan requiring resubmittal shall be resubmitted pursuant to the~~
21 ~~requirements of 18973.1.~~

22 ~~(g) For the purposes of this section, resubmittal means a revised plan to correct or~~
23 ~~address the material requirement that was not met.~~

24 ~~(h) For the purposes of this section, additional reporting means more frequent or more~~
25 ~~detailed reports regarding the material requirement not met.~~

26 ~~Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.~~
27 ~~Reference: Sections 42030, 42032, 42033.2, 42035, 42035.2, 42035.4, 42035.6 and~~
28 ~~42035.8, Public Resources Code; and Section 11445.10, Government Code.~~

29 ~~**18975.2. PROCEDURE FOR STEWARDSHIP PLAN REVOCATION, RESUBMITTAL,**~~
30 ~~**OR ADDITIONAL COMPLIANCE REPORTING**~~

31 ~~(a) If the department finds that a covered entity, program operator, stewardship~~
32 ~~organization, or authorized collector has failed to meet a material requirement of this~~
33 ~~Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the~~
34 ~~department shall, in addition to imposing any civil penalties authorized under this Article~~

1 and Chapter 2 of Part 3 of Division 30 of the Public Resources Code, take one or all of
2 the following actions:

3 (1) Revoke ~~revoke~~ a previously approved stewardship plan.

4 (2) Require ~~require~~ resubmittal of the stewardship plan, and/or

5 (3) Require ~~require~~ additional ~~compliance~~ reporting, relating to compliance with
6 the material requirement(s), of this Article or Chapter 2 of Part 3 of Division 30
7 of the Public Resources Code, that was/were not met. ~~if the department finds~~
8 ~~that a program operator has failed to meet a material requirement of this Article~~
9 ~~or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.~~

10 (b) Before revoking a previously approved plan, requiring resubmittal of an approved
11 stewardship plan, and/or requiring additional compliance reporting ~~Upon making the~~
12 ~~finding in subdivision (a), the department shall issue a written notice to the program~~
13 ~~operator, respondent of the department's intent to revoke an approved stewardship plan,~~
14 ~~require resubmittal of an approved stewardship plan, require additional compliance~~
15 ~~reporting, or all three. The notice shall state the legal and factual basis for the proposed~~
16 ~~action.~~

17 (c) The notice described in subdivision (b) shall be served on the respondent by one of
18 the following means:

19 (1) Personal service;

20 (2) Substitute service by using the same service procedures as described in
21 Section 415.20 of the Code of Civil Procedure;

22 (3) Certified Mail or registered mail; or

23 (4) Electronically, with the consent of the respondent.

24 (d) A program operator may submit to the department a request for hearing to contest
25 the proposed action within thirty (30) days of receipt of the notice issued pursuant to
26 subdivision (b). The hearing request shall be in writing and shall state the basis for
27 objecting to the department's action. Upon a failure to submit a timely hearing request
28 under this subdivision, the program operator shall be deemed to have waived its right to
29 hearing and the department may revoke an approved stewardship plan, require
30 resubmittal of an approved stewardship plan, require additional compliance reporting, or
31 all three.

32 (e) The hearing shall be held before the Director of the Department of Resources
33 Recycling and Recovery. A party shall be afforded the opportunity to present evidence
34 and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the
35 sort of evidence on which responsible persons are accustomed to rely in the conduct of

1 serious affairs, regardless of the existence of any common law or statutory rule which
2 might make improper the admission of the evidence over objection in civil actions.

3 (f) The Director of the Department of Resources Recycling and Recovery shall issue a
4 written decision within sixty (60) days from the date the hearing is concluded.

5 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
6 Reference: Sections 42030, 42032, 42033.2, 42035, 42035.2, 42035.4, 42035.6 and
7 42035.8, Public Resources Code.