



Pharmaceutical and Sharps Waste Stewardship Program

Proposed Regulations
Second 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
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Comment Period, December 2019

1 **SECOND 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 (~~e~~3) “Homebound” has the same meaning as defined in the Medicare Benefit
4 Policy Manual, Chapter 15, 60.4.1.

5 (~~d~~4) “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 (~~e~~5) “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 (~~f~~7) “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 (~~e~~8) “Minutes, books, and records” means ~~complete, correct, accurate~~ and up-to-
21 date information regarding a program operator’s transactions and activities
22 related to the operation of the stewardship program.

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

25 (~~i~~10) “Point of sale” means the point in time at which an ultimate user purchases
26 a covered product at a ~~checkout system utilized by pharmacies, stores, or other~~
27 retailer, or online marketplace outlets where a covered product is sold, including
28 online sales.

29 (~~i~~11) “Provides or initiates distribution of a sharps waste container” means
30 ~~either one of the following:~~

31 (~~4~~A) 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 (~~2~~B) 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

four~~three~~ business days at no cost or inconvenience to the ultimate user;
or,

(3C) Other methods of providing a sharps waste container and mail-back materials, ~~as approved by the department in a stewardship plan, if the method identified in subpart (A4) above is not allowed by law or is not reasonably feasible, and if the method identified in subpart (B) above or (2) is~~ are not allowed by law or is not reasonably feasible. These methods must be~~and~~ approved by the department in a stewardship plan and which result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.

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

(~~13~~) "Significant change" means a change that is not consistent with~~to~~ an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program~~includes, including, but is not limited to:~~

(4A) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method of collection.

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

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

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

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

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

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

18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.

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

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

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

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

~~(1) Contact name and title~~

~~(2) Name of program operator~~

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

~~(4) Phone number~~

~~(5) Email address~~

~~(6) Internet website address~~

A stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet the following requirements:

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

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

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

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

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

(d) The document shall be complete and correct.

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

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

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

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

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

(b) Within 30 days of the department's receipt of a document, ~~t~~The department shall determine if a document is complete or incomplete and notify the submitting program operator ~~within 30 days of receipt~~. The department shall consider a document to be complete if: 1) it contains provisions intended to meet each requirement in sections 18973, 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3 of this Article, as applicable to each document; and 2) it contains

1 sufficient detail for the department to determine if the requirements listed in subpart 1)
2 have been met.

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

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

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

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

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

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

34 (g) If the department conditionally approves a stewardship plan, the department shall
35 identify the condition(s) to be met for approval and provide written notice to the program
36 operator within 30 days of conditional approval. The program operator shall comply with
37 the conditions in that notice as specified. If the conditions are not met, the department
38 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) Any significant changes to an approved stewardship plan shall be submitted in
12 accordance with the requirements of section 18973, and shall follow the review process
13 outlined in subdivisions (a) through (h) above.

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

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

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

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

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

1 **18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.**

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

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

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

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

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

14 ~~(4) Phone number~~

15 ~~(5) Email address~~

16 ~~(6) Internet website address~~

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

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

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

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

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

23 ~~(5) Covered entity iInternet website address~~

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

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

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

1 (d) Authorized Collectors.

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

5 (A) Contact name and title

6 (B) Name of authorized collector entity

7 (C) Mailing and physical address(es)

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

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

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

22 (4) Description of the ~~conditions~~ reasons for excluding any potential authorized
23 collectors, including those who requested joining the program, as applicable.

24 (5) Description of the process potential authorized collectors can utilize to appeal
25 a rejection, by the program operator, for inclusion in the stewardship program.

26 (e) State Agency Determinations and Compliance Certifications.

27 (1) State agency determinations, pursuant to 42032.2(a)(1)(C) of the Public
28 Resources Code. ~~Determinations of compliance from the State Board of~~
29 ~~Pharmacy and any other state agency that reviewed the plan for compliance.~~ If a
30 determination of noncompliance was initially issued, the stewardship plan shall
31 include both the initial determination of noncompliance and the superseding
32 determination of compliance. If any state agency failed to respond to a request
33 for review within 90 days of receipt of the stewardship plan, the program operator
34 shall include documentation of this request along with a written certification,
35 signed by an authorized representative of the program operator, that: 1) the

1 stewardship plan is consistent with all laws and regulations relevant to that
2 agency's authority; and 2) the applicable state agency failed to respond within 90
3 days of receipt of the stewardship plan.

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

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

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

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

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

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

26 (B) How frequently the convenience standards will be re-evaluated to
27 ensure compliance with the convenience standards, including updating
28 population estimates.

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

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

33 (5) Each service provider entity to be used to transport, process, or dispose of
34 covered drugs collected through the stewardship program, including, but not
35 limited to:

1 (A) Name of service provider entity

2 (B) Mailing and physical address(es)

3 (65) Mail-back services or an alternative form of collection and disposal system,
4 pursuant to section 42032.2(c) of the Public Resources Code, to be provided to
5 ultimate users, including, but not limited to, the following:

6 (A) Locations where preaddressed, prepaid mail-back materials are
7 distributed or an alternative form of collection and disposal system,
8 pursuant to section 42032.2(c)(2) of the Public Resources Code, that
9 would render the drug inert, is provided, if applicable.

10 (B) Mechanism to provide preaddressed, prepaid mail-back materials or
11 an alternative form of collection and disposal system requested by request
12 from ultimate users who are homeless, homebound, or disabled through
13 the program operator's internet website and/or toll-free telephone number.

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

18 (76) If applicable, a
19 Any alternative form of collection and disposal system that
20 complies with applicable local, state, and federal laws and regulations including,
21 but not limited to, United States Drug Enforcement Administration regulations,
22 that is used as a supplemental service for any county that does not meet the
23 minimum authorized collection site threshold due to circumstances out of the
program operator's control, if applicable.

24 (87) Method(s) of collection for covered drugs, other than controlled substances,
25 that cannot be accepted or commingled with other covered drugs in secure
26 collection receptacles or through a mail-back program, to the extent technically
27 feasible and permissible under applicable state and federal law, including, but not
28 limited to, United States Drug Enforcement Administration regulations.

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

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

1 (10) What corrective actions will be taken if a program operator discovers critical
2 deviations from stewardship plan policies and procedures, an authorized collector
3 or service provider is not maintaining compliance with all collection,
4 transportation, and disposal standards related to the handling of covered drugs,
5 including, but not limited to, United States Drug Enforcement Administration
6 regulations.

7 (11) How each participating collection site will be funded or reimbursed, if
8 applicable.

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

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

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

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

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

36 (2) Materials to be utilized that are distributed in languages suited to local
37 demographics, consistent with section 7295 of the Government Code. These
38 materials shall include, but are not limited to, signage for hospitals, pharmacies,
39 and other locations, as necessary. Signage or labeling for secure collection

1 receptacles shall be designed with explanatory graphics which are readily
2 understandable by all ultimate users.

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

8 (A) Authorized collection site physical addresses

9 (B) Authorized collection site contact telephone numbers

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

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

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

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

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

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

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

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

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

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

18973.3. STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE.

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

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

(1) Contact name and title

(2) Name of program operator

(3) Mailing and physical address(es)

(4) Phone number

(5) Email address

(6) Internet website address

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

(1) Contact name and title

(2) Name of covered entity

(3) Mailing and physical address(es)

(4) Covered entity Email address

(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: 1) the stewardship plan is consistent
18 with all laws and regulations relevant to that agency's authority; and 2) the
19 applicable agency failed to respond within 90 days of receipt of the stewardship
20 plan.

21 (2) Written certification, by an authorized representative of the program operator,
22 that: the stewardship plan, including the handling, transportation, and disposal of
23 home-generated sharps waste is in compliance with all applicable local, state, and
24 federal laws and regulations.

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

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

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

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

1 (2) How stewardship plan implementation: 1) provides or initiates distribution of
2 sharps waste containers and mail-back materials, which include mail-back
3 packaging and informational material, at no cost to ultimate users at the point of
4 sale, to the extent allowable by law, and 2) meets the following requirements:

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

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

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

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

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

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

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

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

32 ~~(5) Processes and policies to be followed by persons handling home-generated~~
33 ~~sharps waste under the stewardship plan and efforts the program operator will~~
34 ~~take to ensure that all entities participating will operate under and comply with all~~
35 ~~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 are authorized and approved by the city, county, or~~
8 ~~state enforcement authority that provides oversight of the Medical Waste~~
9 ~~Management Act,~~ then the following information, as applicable, shall be
10 included, but not be limited to:

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

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

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

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

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

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

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

1 (B) Take-back collection events. Date and location of events, if
2 applicable.

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

6 (78) Metrics that will be used to measure the amountweight of home-generated
7 sharps waste collected through supplemental collection method(s), if applicable.

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

12 (9) Corrective actions that will be taken if a program operator discovers critical
13 deviations from stewardship plan policies and procedures.

14 (g) Local Agency Requests.

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

20 (2) Requests by local agencies, or an agent on behalf of a local agency, shall
21 include an invoice and shall be submitted to the program operator, as necessary.
22 Program operators shallwill respond to requests by local agencies within 14 days
23 of receipt of the request in a timely manner and identify the method to resolve the
24 request by selecting either reimbursement or removal from household hazardous
25 waste facility(ies).

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

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

33 (h) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public
34 Resources Code, dDescription of provisions, processes, logistics, and timing of
35 implementation that will be necessary for the stewardship programused to expand into

1 jurisdictions not previously included in the stewardship plan, in the event of the repeal of
2 a local stewardship program ordinance.

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

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

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

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

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

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

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

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

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

31 (4) Establishment of a toll-free telephone number to: 1) serve as an option for
32 ultimate users to request sharps waste containers and mail-back materials, and
33 2) to obtain information about the program, including, but not limited to what is
34 outlined in section 18973.3(i)(3)(A)-(E). The toll-free telephone number shall offer
35 language options suited to local demographics, accept calls via human

representative, and provide services for hearing-impaired and speech-impaired individuals.

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

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

(j) Coordination Efforts. Description of how the program operator will ~~make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations,~~ coordinate 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 home-generated sharps waste are in operation concurrently or new stewardship programs begin operating.

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

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

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

18973.4. ANNUAL REPORT FOR COVERED DRUGS.

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~~ the annual report shall: 1) describe how the program operator complied with all elements in its stewardship plan during the previous reporting period of one year; and 2) contain the following:

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

(b) Executive Summary. A concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, achievement of the convenience standards pursuant to subsection (1)(F) of subdivision

1 (a) of section 42032.2 of the Public Resources Code, education and outreach efforts,
2 and ~~ways in which~~ ~~how~~ challenges are being addressed.

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

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

6 (2) Good faith negotiations between the program operator and potential
7 authorized collectors to establish authorized collection sites and the results of the
8 negotiations, including, but not limited to:

9 (A) Efforts to notify potential authorized collectors of the opportunity to
10 serve as an authorized collector for the stewardship program in the
11 counties in which the program will operate, pursuant to Section
12 42032.2(b)(1) of the Public Resources Code.

13 (B) Pursuant to Section 42032.2(b)(3) of the Public Resources Code,
14 ~~e~~Efforts to include authorized collectors beyond the minimum convenience
15 standards pursuant to subsection (1)(F) of subdivision (a) of section
16 42032.2 of the Public Resources Code.

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

20 (D) Efforts between the program operator and retail pharmacy chains to
21 meet the requirement stated in subsection (2) of subdivision (b) of section
22 42032.2 of the Public Resources Code. ~~Any known reason why potential~~
23 ~~authorized collectors were excluded or rejected from participation in the~~
24 ~~stewardship program.~~

25 (E) A list of potential authorized collectors that requested joining the
26 stewardship program and were rejected, and the reason(s) for each
27 rejection.

28 (3) How the convenience standards pursuant to subsection (1)(F) of subdivision
29 (a) of section 42032.2 of the Public Resources Code were met. Include
30 necessary changes to calculations that account for changes in the number of
31 authorized collection sites and most recent publicly available population
32 calculations from the State of California Department of Finance.

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

34 (A) Name and physical address

- 1 ~~(B) Weight of material collected~~
- 2 (B) Amount of covered drugs collected, as required in the stewardship
3 plan pursuant to section 18973.2(g)(4)
- 4 (C) Number of instances that collected covered drugs were picked up for
5 disposal collections and
- 6 (D) ~~n~~Number of receptacle liners picked up collected for disposal
- 7 (E) ~~N~~Total number of instances and corresponding number of business
8 hours amount of time the secure collection authorized collection site
9 receptacle was not available to the public during business hours. For each
10 instance, provide a description of why the secure collection receptacle
11 was not available.
- 12 (5) For each type of ~~M~~mail-back services utilized, include the following, including,
13 but not limited to, as applicable:
- 14 (A) Name and location of distribution facility
- 15 ~~(B) Amount of materials distributed~~
- 16 ~~(B)~~ Mechanism of distribution
- 17 ~~(C)~~ Amount of mail-back materials distributed, as required in the
18 stewardship plan pursuant to section 18973.2(g)(6)(C)
- 19 ~~(D) Weight of material returned~~
- 20 (D) Amount of mail-back material returned, as required in the stewardship
21 plan pursuant to section 18973.2(g)(6)(C)
- 22 (6) Alternative forms of collection and disposal, including, but not limited to, the
23 following, as applicable:
- 24 (A) Method of collection
- 25 (B) Name and address of location
- 26 (C) Number of collections
- 27 (D) Amount of materials distributed, as required in the stewardship plan
28 pursuant to section 18973.2(g)(6)(C)
- 29 ~~(E) Weight of material collected~~

1 (E) Amount of material collected, as required in the stewardship plan
2 pursuant to section 18973.2(g)(6)(C)

3 (d) Transportation and Disposal System. Description of the methods used for
4 transportation and disposal of covered drugs, including the following:

5 (1) Mechanism(s) for tracking the ~~collections~~ collection, transportation, and
6 disposal of covered drugs

7 (2) Name and mailing address of each ~~service provider entity~~ used to transport or
8 process covered drugs

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

10 (A) Name of ~~disposal facility~~ entity

11 (B) Mailing and physical address

12 (C) Weight of ~~material~~ covered drugs disposed~~received~~

13 (e) Corrective actions taken if the program operator discovered critical deviations from
14 stewardship plan policies and procedures and a description of each critical deviation.
15 ~~that a service provider did not maintain compliance with all collection, transportation,~~
16 ~~and disposal standards, including, but not limited to, local, state and federal laws and~~
17 ~~regulations and United States Drug Enforcement Administration regulations.~~

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

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

32 (h) Safety and Security. Describe the general nature of any incidents with safety or
33 security related to collection, transportation, or disposal of collected covered drugs.
34 Explain what corrective actions were taken to address the issue and improve safety and

1 security. The following information about any incident(s) shall be made available to the
2 department upon request, and shall include, including, but not be limited to, the following:

3 (1) Location and date

4 (2) Description of specific incident

5 (3) Cause(s) of specific incident

6 (4) Parties involved

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

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

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

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

15 (3) A discussion of what the metrics reveal about the performance of the
16 comprehensive education and outreach program, including, but not limited to,
17 ultimate user awareness, program usage, and accessibility

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

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

21 (A) Name of covered entity

22 (B) Mailing and physical address

23 (C) Contact name and title

24 (D) Email address

25 (2) A copy of the list of covered products submitted to the Board of Pharmacy
26 pursuant to subsection (2) of subdivision (a) of section 42031 of the Public
27 Resources Code. List of covered products

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

- 1 (A) Name of authorized collector~~entity~~
- 2 (B) Mailing and physical address
- 3 (C) Contact name and title
- 4 (D) Email address
- 5 ~~(4) Authorized collection sites, including the names and physical addresses of~~
- 6 ~~the sites~~
- 7 (k) Description and evaluation of ~~changes in~~ the process for selecting service providers,
- 8 if applicable.
- 9 (l) Description of ~~changes in the process for providing~~ any grants, loans, sponsorships,
- 10 reimbursements, or other incentives provided, as applicable.
- 11 (m) Description of changes in staffing of the stewardship program.
- 12 (n) Coordination Efforts. Description of how the program operator coordinated with other
- 13 program operators to avoid conflict, duplication, and confusion to the public and all
- 14 program participants in the event that multiple stewardship programs for covered drugs
- 15 are in operation concurrently or new stewardship programs begin operating. ~~made a~~
- 16 ~~good faith effort to work with any other stewardship program(s) in order to most~~
- 17 ~~effectively achieve the requirements of the statute and regulations, if applicable.~~
- 18 (o) State Agency Determinations pursuant to section 42032.2(a)(1)(C) of the Public
- 19 Resources Code. Submit all agency determination(s) of compliance, noncompliance,
- 20 and superseding determinations of compliance, if any, for the reporting period.
- 21 (p) Written certification, by an authorized representative of the program operator, that:
- 22 the stewardship plan, including the collection, transportation, and disposal of covered
- 23 drugs, is in compliance with all applicable local, state, and federal laws and regulations,
- 24 including, but not limited to United States Drug Enforcement Administration regulations.
- 25 (q) Written certification by an authorized representative for each of the authorized
- 26 collectors participating in the stewardship plan, that: the service(s) they are providing to
- 27 the program operator is compliant with applicable federal and state laws regarding
- 28 collection and transportation standards, and the handling of covered drugs, including
- 29 United States Drug Enforcement Administration regulations.
- 30 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
- 31 Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4,
- 32 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041, California
- 33 Code of Regulations.

1 **18973.5. ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.**

2 On or before March 31, 2022, and each year thereafter, a program operator shall
3 prepare and submit an annual report to the department. To be complete, the annual
4 report shall describe the stewardship program activities during the previous reporting
5 period of one year and shall contain the following:

6 (a) ~~Contact information.~~ Contact information for the program operator or corporate officer
7 responsible for annual report submittal as specified in pursuant to section 18973.3(a) of
8 this Chapter.

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

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

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

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

18 (A) Provided at point of sale

19 (B) Initiated at point of sale

20 (C) Website requests

21 (D) Toll-free telephone number requests

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

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

25 (4) Supplemental collection method(s) of home-generated sharps waste that
26 were provided in addition to, but not ~~substituted for~~ in lieu of, the mail-back
27 program, pursuant to section 18973.3.(f)(5) and (7)

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

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

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

(A) Name of ~~facility~~ entity

(B) Mailing and physical address

(C) Total weight of material disposed

(e) Corrective actions taken if the program operator discovered ~~critical deviations from~~ stewardship plan policies and procedures, and a description of each critical deviation, ~~that service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state and federal laws and regulations and United States Drug Enforcement Administration regulations.~~

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

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

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

(1) Location and date

(2) Description of specific incident

(3) Cause(s) of specific incident

(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 18973.3(i), 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 18973.3(i)(5)

9 (3) A discussion of what the metrics reveal about the performance of the
10 comprehensive education and outreach program, including, but not limited to,
11 ultimate user awareness, program usage, and accessibility

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

14 (1) Name of entity

15 (2) Mailing and physical address

16 (3) Contact name and title

17 (4) Email address

18 (k) A copy of the list of covered products submitted to the Board of Pharmacy pursuant
19 to subsection (2) of subdivision (a) of section 42031 of the Public Resources
20 Code. Updated list of covered products

21 (l) Description and evaluation of ~~changes to~~ the process for selecting service providers,
22 if applicable.

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

25 (n) Description of changes in staffing of the stewardship program.

26 (o) Coordination Efforts. Description of how the program operator coordinated with other
27 program operators to avoid conflict, duplication, and confusion to the public and all
28 program participants in the event that multiple stewardship programs for home-
29 generated sharps waste are in operation concurrently or new stewardship programs
30 begin operating. ~~made a good faith effort to work with any other stewardship program(s)~~
31 ~~in order to most effectively achieve the requirements of the statute and regulations.~~

1 (p) Local Agency Requests. For each local agency that has requested removal or
2 reimbursement, details including, but not limited to, the following:

3 (1) Name of local agency, or agent acting on behalf of the local agency.

4 (2) For each household hazardous waste facility:

5 (A) Facility location

6 (B) Reimbursement payment amount, as applicable

7 ~~(C) Weight of collected material~~

8 (C) Amount of home-generated sharps waste collected, as required in the
9 stewardship plan pursuant to section 18973.3(f)(9)

10 (3) Any requests that were rejected and the reason(s) each request was rejected.

11 (4) Any requests where response, removal, or reimbursement was performed
12 outside of the timelines specified in section 18973.3(g)(2).

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

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

20 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
21 Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4,
22 42033.5, 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041,
23 California Code of Regulations.

24 **18973.6. PROGRAM BUDGETS.**

25 A program operator must submit an initial stewardship program budget for the first five
26 calendar years of operation and an annual budget, pursuant to sections 42033 and
27 42033.2 of Chapter 2, Part 3, Division 30 of the Public Resources Code. The initial
28 stewardship program budget that covers the first five calendar years of operation and
29 the annual program budgets shall contain at a minimum, the following information:

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

1 (1) Contact name and title

2 (2) Name of program operator

3 (3) Mailing and physical address(es)

4 (4) Phone number

5 (5) Email address

6 (6) Internet website address

7 (ba) Anticipated costs to implement the stewardship program, including, but not limited
8 to, separate line items for the following:

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

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

13 (3) Transportation of covered products

14 (4) Processing of covered products

15 (5) Disposal of covered products

16 (3e) Administrative costs, including departmental administrative fee costs

17 (4f) Education and outreach costs

18 (5g) Costs related to grants, loans, sponsorships, or other incentives as part of
19 program implementation

20 (9) Reserve level

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

24 (db) Recommended funding level necessary to cover the stewardship plan's budgeted
25 costs and to operate/implement the stewardship program over a multi-year period in a
26 prudent and responsible manner. Including a description of how costs are
27 apportioned to and funds remitted from participating covered entities, in order to
28 demonstrate that the stewardship program will be operated in a prudent and responsible
29 manner.

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

3 ~~(fe)~~ Beginning with the first annual program budget, include all actual expenses incurred
4 during the previous program year. Expenses shall be summarized in accordance with
5 the budget categories specified in section 18973.6(b).

6 ~~(ge)~~ An independent financial audit of the stewardship program funded by the member
7 covered entities participating in the stewardship program or by a covered entity, if it
8 operates its own stewardship program. The audit shall be performed at least once each
9 calendar year. The audit shall be conducted in accordance with generally accepted
10 auditing standards in the United States of America, and Generally Accepted
11 Government Auditing Standards by a Certified Public Accountant. The Certified Public
12 Accountant shall not perform the non-audit services for the program operator or engage
13 in any activities that would impair independence. The independent financial audit shall
14 include, but not be limited to:

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

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

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

22 (4) Findings and recommendations as they relate to the financial aspects of the
23 stewardship organization program.

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

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

29 **18974. RECORD KEEPING REQUIREMENTS.**

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

32 (a) Maintain records to support the requirements in this Article and Chapter 2 of Part 3
33 of Division 30 of the Public Resources Code. Covered entities, stewardship
34 organizations, program operators, retail pharmacies and retail pharmacy chains must
35 maintain records to support compliance with this Article and Chapter 2 of Part 3 of

Division 30 of the Public Resources Code regulations. Retail pharmacies or retail pharmacy chains will maintain and provide access to records required by this Article and Chapter 2 of Part 3 of Division 30 of the Public Resources Code for a minimum of three years.

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

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

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

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

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

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

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

1 **18974.1. ADMINISTRATIVE AND OPERATIONAL COSTS AND DEPARTMENTAL**
2 **ADMINISTRATIVE FEE TO DEPARTMENT OF RESOURCES RECYCLING AND**
3 **RECOVERY.**

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

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

13 (c) For a stewardship organization, the departmental administrative fee paid pursuant to
14 subsection (b) shall be funded by the covered entities that make up the stewardship
15 organization. This departmental administrative fee shall be in addition to the
16 administrative and operational costs paid pursuant to subsection (a). A stewardship
17 organization may require its participating covered entities to pay the departmental
18 administrative fee and the administrative and operational costs paid pursuant to
19 subsection (a) at the same time.

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

22 **18974.2. STEWARDSHIP ORGANIZATION AUDITS OF COVERED ENTITIES OR**
23 **AUTHORIZED COLLECTORS.**

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

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

30 **18974.3. ~~DISTRIBUTOR~~RETAILER, WHOLESALER, ~~DISTRIBUTOR~~, PHARMACY,**
31 **AND RETAILER PRODUCT VERIFICATION.**

32 ~~Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or~~
33 ~~dispenses a covered product shall:~~

34 (a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or
35 dispenses a covered product shall: ~~s~~Successfully log onto the department's internet
36 Web-site to ~~verify~~ determine if that covered products to be sold, offered for sale, or

1 dispensed are in compliance with the law, by verifying that the covered entities
2 providing the covered product(s) are in compliance with the law.

3 (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated
4 responsible party for any of the foregoing identify a noncompliant covered entity, product
5 or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or
6 designated responsible party for any of the foregoing shall report the discovery to the
7 department's Enforcement Unit within 30 days.

8 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
9 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
10 Resources Code.

11 ~~**18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.**~~

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

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

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

20 ~~(2) The number and severity of the violation(s)~~

21 ~~(3) Evidence that the violation was intentional, knowing, or negligent~~

22 ~~(4) The size of the violator~~

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

24 ~~(6) The willfulness of the violator's misconduct~~

25 ~~(7) Whether the violator took good faith measures to comply with this chapter and~~
26 ~~the period of time over which these measures were taken~~

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

28 ~~(9) The economic effect of the penalty on the violator~~

29 ~~(10) The deterrent effect that the imposition of the penalty would have on both~~
30 ~~the violator and the regulated community~~

31 ~~(11) Any other factor that justice may require~~

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

18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.

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

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

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

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

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

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

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

(6) The willfulness of the violator's misconduct

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

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

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

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

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

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

1 ~~**18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.**~~

2 ~~(a) Civil penalties may be administratively imposed after an informal hearing before the~~
3 ~~Director, or the Director's designee, in accordance with the procedures outlined in the~~
4 ~~Administrative Procedures Act at Article 10 of Chapter 4.5 (commencing with section~~
5 ~~11445.10) of Part 1 of Division 3 of Title 2 of the Government Code.~~

6 ~~(b) The accusation or complaint and all accompanying documents may be served on~~
7 ~~the respondent by 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: For respondents who have submitted a stewardship plan for~~
12 ~~the management of covered products, certified mail or registered mail of the~~
13 ~~letter containing the accusation or complaint and accompanying material is~~
14 ~~mailed, addressed to the respondent at the latest facility or mailing address(es)~~
15 ~~on file with the department. Proof of service of the accusation or complaint shall~~
16 ~~be the certified mail receipts or registered mail receipts proving the accusation or~~
17 ~~complaint and accompanying materials were sent to respondent by certified mail~~
18 ~~or registered mail. For respondents who have not submitted or are not required~~
19 ~~to submit a stewardship plan for the management of covered products to the~~
20 ~~department, certified mail or registered mail pursuant to the procedures indicated~~
21 ~~in the Administrative Procedure Act at subdivision (c) of section 11505 of the~~
22 ~~Government Code applies.~~

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

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

28 ~~**18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.**~~

29 ~~(a) The department shall issue a notice of violation (NOV) to the respondent if the~~
30 ~~department determines that the respondent has violated a material requirement of this~~
31 ~~Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code. The NOV~~
32 ~~shall list and describe the nature of the violation(s). The department shall issue a NOV~~
33 ~~before commencing an action to impose administrative civil penalties.~~

34 ~~(b) The department shall commence an action to impose administrative civil penalties~~
35 ~~by serving an accusation upon the respondent that includes a notice informing the~~
36 ~~respondent of their right to a hearing. The accusation shall state the legal and factual~~

1 basis for the imposition of penalties, including a description of how the department
2 applied the criteria in Section 18975(b).

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

5 (1) Personal service;

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

8 (3) Certified Mail or registered mail; or

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

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

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

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

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

28 **~~18975.2. PROCEDURE FOR REVOKING, REQUIRING RESUBMITTAL, OR~~**
29 **~~ADDITIONAL REPORTING OF AN APPROVED STEWARDSHIP PLAN FOR~~**
30 **~~FAILURE TO MEET A MATERIAL REQUIREMENT OF THE STATUTE OR~~**
31 **~~REGULATIONS.~~**

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

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

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

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

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

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

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

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

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

18975.2. PROCEDURE FOR STEWARDSHIP PLAN REVOCATION, RESUBMITTAL, OR ADDITIONAL COMPLIANCE REPORTING

~~(a) The department shall revoke a previously approved stewardship plan, require resubmittal of the stewardship plan, or require additional compliance reporting, if the department finds that a program operator has failed to meet a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.~~

~~(b) Upon making the finding in subdivision (a), the department shall issue a written notice to the program operator of the department's intent to revoke an approved stewardship plan, require resubmittal of an approved stewardship plan, require additional compliance reporting, or all three. The notice shall state the legal and factual basis for the proposed action.~~

~~(c) The notice shall be served on the respondent by one of the following means:~~

1 (1) Personal service;

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

4 (3) Certified Mail or registered mail; or

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

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

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

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

22 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
23 Reference: Sections 42030, 42032, 42033.2, 42035, 42035.2, 42035.4, 42035.6 and
24 42035.8, Public Resources Code.