

PROPOSED REGULATIONS

PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM

TITLE 14. NATURAL RESOURCES

DIVISION 7. DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

CHAPTER 11. PRODUCT STEWARDSHIP

ARTICLE 4. PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM

18972. PURPOSE.

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

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.

18972.1. DEFINITIONS.

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

(1) "Administrative and operational costs" means costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization, pursuant to section 42034 of the Public Resources Code.

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

1 (3) "Homebound" has the same meaning as defined in the Medicare Benefit
2 Policy Manual, Chapter 15, 60.4.1 (definition issued, effective, and implemented
3 in 2014). The Medicare Benefit Policy Manual, Chapter 15, Section 60.4.1 is
4 incorporated herein by reference.

5 (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 (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) "Local jurisdiction" and "local agency" means a California city, county, city and
12 county, a joint powers authority, or public service district responsible for
13 household hazardous waste or residential waste management planning or
14 services.

15 (7) "Minutes, books, and records" means complete, correct, and up-to-date
16 information regarding a program operator's transactions and activities related to
17 the operation of the stewardship program.

18 (8) "Prescription" has the same meaning as defined in Division 2, Chapter 9,
19 section 4040 of the Business and Professions Code.

20 (9) "Point of sale" means the point in time at which an ultimate user purchases a
21 covered drug or sharp at a pharmacy or other retailer, including but not limited to
22 an online retailer.

23 (10) "Provides or initiates distribution of a sharps waste container and mail-back
24 materials" means one of the following:

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

28 (B) To arrange, at the point of sale or prior, for a sharps waste container
29 and mail-back materials to be sent to the ultimate user and arrive within
30 five business days at no cost or inconvenience to the ultimate user; or,

31 (C) Other methods of providing a sharps waste container and mail-back
32 materials to the ultimate user at the point of sale or prior, at no cost to the
33 ultimate user, if the method identified in subpart (A) above is not allowed
34 by law and if the method identified in subpart (B) above is not allowed by
35 law. These methods must be approved by the department in a
36 stewardship plan and result in substantially the same level of convenience

1 to the ultimate user as the methods identified in subparts (A) and (B)
2 above.

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

9 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
10 Reference: Sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2,
11 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2,
12 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code;
13 Medicare Benefit Policy Manual, Chapter 15, 60.4.1; 42 U.S.C. Section 254b, U.S.
14 Code on Public Health and Welfare; Section 117904, Health and Safety Code; and
15 Section 4040, Business and Professions Code.

16 **18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.**

17 The department shall identify the covered entity for any covered products consistent
18 with subdivision (f) of section 42030 of the Public Resources Code.

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

21 **18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM** 22 **BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

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

26 (a) The document is required to be in compliance with section 7405 of the Government
27 Code, and the Web Content Accessibility Guidelines 2.0 (published in 2008), or a
28 subsequent version, published by the Web Accessibility Initiative of the World Wide
29 Web Consortium at a minimum Level AA success criteria to allow for posting on the
30 department's website. The entirety of the Web Content Accessibility Guidelines 2.0
31 (published in 2008), or a subsequent version, are incorporated herein by reference.

32 (b) The document shall be submitted electronically. The date of electronic submittal will
33 be considered the date of receipt by the department.

34 (c) Any submittals to the department that the program operator believes are confidential
35 in nature shall include a cover letter explaining the justification of confidentiality.
36 Records supplied to the department pursuant to this Article that are, at the time of

1 submission, claimed to be proprietary, confidential, or a trade secret shall be subject to
2 the provisions in Title 14, California Code of Regulations, Division 7, Chapter 1, Article 4
3 (commencing with section 17041).

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

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

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

13 **18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM**
14 **BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

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

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

21 (b) Within 30 days of the department's receipt of a document, the department shall
22 determine if a document is complete or incomplete and notify the submitting program
23 operator. The department shall consider a document to be complete if it contains
24 provisions intended to meet each requirement in sections 18973, 18973.1, 18973.2,
25 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3 of this
26 Article, as applicable to each document, and if it contains sufficient detail for the
27 department to determine if the requirements in the referenced sections have been met.

28 (1) If the department determines that the document is complete, the department
29 shall have 90 days from the date of original receipt of the document to approve,
30 conditionally approve, or disapprove the document.

31 (2) If the department determines that the document is incomplete, the department
32 shall identify for the program operator the required additional information and the
33 program operator shall resubmit the document within 30 days of the department's
34 notification that the document is incomplete. If the department determines, upon
35 resubmittal, that the resubmitted document is complete, the department shall
36 have 90 days from the date of receipt of the resubmitted document to approve,
37 conditionally approve, or disapprove the resubmitted document.

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

6 (d) The department shall approve a document if it determines that the documents meets
7 all material requirements in sections 18973, 18973.1, 18973.2, 18973.3, 18973.4,
8 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3 of this Article, as applicable
9 to each document.

10 (e) The department shall conditionally approve a document if it determines that the
11 document is substantially compliant with all material requirements in sections 18973,
12 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and
13 18974.3 of this Article, as applicable to each document, but additional information from
14 and/or additional actions by the program operator are necessary.

15 (f) The department shall disapprove a document if it determines that the document is
16 not substantially compliant with all material requirements in sections 18973, 18973.1,
17 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3
18 of this Article, as applicable to each document.

19 (g) If the department conditionally approves a stewardship plan, the department shall
20 identify the condition(s) to be met for approval and provide written notice to the program
21 operator within 30 days of conditional approval. The program operator shall comply with
22 the conditions in that notice as specified. If the conditions are not met, the department
23 shall notify the program operator that the plan is deemed disapproved and the covered
24 entities operating under the stewardship plan are not in compliance until the program
25 operator submits a stewardship plan the department approves.

26 (h) If the department disapproves a stewardship plan, the department shall explain how
27 the stewardship plan does not comply and provide written notice to the program
28 operator within 30 days of disapproval. The program operator shall resubmit a revised
29 stewardship plan within 60 days of the disapproval date the written notice was issued,
30 and the department will review the revised stewardship plan within 90 days of
31 resubmittal. If a revised stewardship plan is disapproved by the department, the covered
32 entities operating under the stewardship plan are not in compliance until the program
33 operator submits a stewardship plan that the department approves.

34 (i) A program operator shall submit any significant changes to a stewardship plan in
35 writing for approval by the department, and shall not implement the changes prior to that
36 approval. Any significant changes to an approved stewardship plan shall be submitted
37 to the department in accordance with the requirements of section 18973. The program
38 operator shall also include a re-certification that the stewardship plan containing the
39 significant changes is compliant with all applicable laws and regulations, in accordance
40 with section 18973.2(e)(2) or 18973.3(d)(2), as applicable.

1 (j) If the department conditionally approves an annual report or program budget, the
2 department shall identify the condition(s) to be met for approval and provide written
3 notice to the program operator within 30 days of conditional approval. The program
4 operator shall comply with the conditions in that written notice within 60 days of the date
5 the written notice was issued, unless the Director of the Department of Resources
6 Recycling and Recovery determines that additional time is needed. If the program
7 operator does not comply and the conditions are not met within 60 days of the date the
8 written notice was issued for a conditional approval, the department shall disapprove
9 the annual report or program budget.

10 (k) If the department disapproves an annual report or program budget, the department
11 shall identify how the annual report or program budget does not comply and provide
12 written notice to the program operator within 30 days of disapproval. The program
13 operator shall resubmit a revised annual report or program budget and provide any
14 supplemental information requested within 60 days of the date the written notice was
15 issued.

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

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

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

23 **18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.**

24 Within six months of the adoption date of the regulations in this Article by the
25 department, a program operator shall submit a stewardship plan to the department. To
26 be complete, the stewardship plan shall include the following:

27 (a) Contact information of the corporate officer, or designee, responsible for submitting
28 and overseeing the stewardship plan on behalf of the program operator, including, but
29 not limited to:

30 (1) Contact name and title

31 (2) Name of program operator

32 (3) Mailing and physical address(es)

33 (4) Phone number

34 (5) Email address

1 (6) Internet website address

2 (b) Contact information for each covered entity participating in the stewardship plan,
3 including, but not limited to:

4 (1) Contact name and title

5 (2) Name of covered entity

6 (3) Mailing and physical address(es)

7 (4) Covered entity email address

8 (5) Covered entity internet website address

9 (6) Covered entity phone number

10 (c) List of each covered drug sold or offered for sale by each participating covered entity
11 covered by the stewardship plan.

12 (d) Authorized Collectors.

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

16 (A) Contact name and title

17 (B) Name of authorized collector

18 (C) Mailing and physical address(es)

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

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

27 (3) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, description
28 of the process by which good faith negotiations with potential authorized
29 collectors were and, if applicable, continue to be conducted. If a potential
30 authorized collector expresses interest in participating in a stewardship program,

1 the program operator shall commence good faith negotiations with the potential
2 authorized collector within 30 days.

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

6 (5) Description of the process to incorporate potential authorized collectors that
7 submit a written offer to join the stewardship program, in accordance with section
8 42032.2(b)(3) of the Public Resources Code. A program operator shall include
9 under its stewardship program any entity listed in subdivision (b) of section
10 42030 of the Public Resources Code that offers to participate in the stewardship
11 program, in writing and without compensation, even if the minimum convenience
12 standards set in clause (i) of subsection (1)(F) of subdivision (a) of section
13 42032.2 of the Public Resources Code have been achieved. The program
14 operator shall include the offering entity as an authorized collector in the
15 stewardship program within 90 days of receiving the written offer to participate. A
16 program operator shall not be required to respond to offers pursuant to this
17 subsection until the program operator's stewardship plan has been approved by
18 the department.

19 (6) Description of the reasons for excluding any potential authorized collectors,
20 including those who request joining the program, as applicable.

21 (7) Description of how the program operator will notify any potential authorized
22 collectors of the reasons they were rejected from inclusion in the stewardship
23 program and what changes the potential authorized collector can make in order
24 to join the stewardship program.

25 (e) State Agency Determinations and Compliance Certifications.

26 (1) State agency determinations, pursuant to section 42032.2(a)(1)(C) of the
27 Public Resources Code. If a determination of noncompliance was initially issued,
28 the stewardship plan shall include both the initial determination of noncompliance
29 and the superseding determination of compliance. If any state agency failed to
30 respond to a request for review within 90 days of receipt of the stewardship plan,
31 the program operator shall include documentation of this request along with a
32 written certification, signed by an authorized representative of the program
33 operator, that, at the time of submission to the department, the stewardship plan
34 is consistent with all laws and regulations relevant to that agency's authority, and
35 the applicable state agency failed to respond within 90 days of receipt of the
36 stewardship plan.

37 (2) Written certification by an authorized representative of the program operator
38 that, at the time of submission to the department, the stewardship plan, including
39 all aspects of the plan related to the collection, transportation, and disposal of

covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.

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

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

(1) Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.

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

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

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

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

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

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

(A) Name of service provider

(B) Mailing and physical address(es)

(6) Mail-back services or an alternative form of collection and disposal system to be provided to ultimate users, pursuant to sections 42032.2(a)(1)(G) and 42032.2(c) of the Public Resources Code. Include, at a minimum, the following information:

(A) List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative

1 form of collection and disposal system that would render the covered drug
2 inert, if applicable.

3 (B) Pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code,
4 mechanism to provide preaddressed, prepaid mail-back materials or an
5 alternative form of collection and disposal system requested by ultimate
6 users who are homeless, homebound, or disabled through the program
7 operator's internet website and toll-free telephone number.

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

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

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

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

34 (8) What corrective actions will be taken if a program operator discovers critical
35 instances of noncompliance with stewardship plan policies and procedures.

36 (9) How each participating collection site will be funded or reimbursed, if
37 applicable.

1 (10) Standard operating procedures that will address incidents related to safety
2 and security, including processes to ensure that the department and applicable
3 local, state, and federal agencies are notified of the incident. This description
4 shall also explain the actions that will be taken to change policies, procedures,
5 and tracking mechanisms to alleviate the problems with safety and security and
6 improve safety and security.

7 (h) Collection, Transportation, and Disposal System Records. Description of how and
8 where the records generated during the collection, transportation, and disposal of
9 collected covered drugs will be maintained. These records include, but are not limited
10 to: collection manifests, mailer distributions, receipts of returned covered drugs, return
11 mailings, and final disposal of covered drugs, as applicable.

12 (i) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public
13 Resources Code, description of processes, logistics, and timing of implementation that
14 will be necessary for the stewardship program to expand into jurisdictions not previously
15 included in the stewardship plan, in the event of the repeal of a local stewardship
16 program ordinance. The description shall include an explanation of how the stewardship
17 program will meet the convenience standards, pursuant to subsection (1)(F) of
18 subdivision (a) of section 42032.2 of the Public Resources Code.

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

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

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

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

37 (A) Authorized collection site physical addresses

38 (B) Authorized collection site contact telephone numbers

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

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

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

7 (4) Establishment of a toll-free telephone number to accept requests for mail-
8 back materials from ultimate users who are homeless, homebound, or disabled,
9 and to provide disposal options and other program information to ultimate users
10 without access to the internet. The toll-free telephone number shall offer
11 language options suited to local demographics, accept calls via human
12 representative, and provide services for hearing-impaired and speech-impaired
13 individuals.

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

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

20 (7) How the program operator will comply with the requirement in section
21 42031.6(b) of the Public Resources Code.

22 (k) Coordination Efforts. Description of how the program operator will coordinate with
23 other program operators to avoid confusion to the public and all program participants in
24 the event that multiple stewardship programs for covered drugs are in operation
25 concurrently or new stewardship programs begin operating.

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

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

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

1 **18973.3. STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE.**

2 Within six months of the adoption date of the regulations in this Article by the
3 department, a program operator shall submit a stewardship plan to the department. To
4 be complete, a stewardship plan for home-generated sharps waste shall include the
5 following:

6 (a) Contact information of the corporate officer, or designee, responsible for submitting
7 and overseeing the stewardship plan on behalf of the program operator, including, but
8 not limited to:

9 (1) Contact name and title

10 (2) Name of program operator

11 (3) Mailing and physical address(es)

12 (4) Phone number

13 (5) Email address

14 (6) Internet website address

15 (b) Contact information for each covered entity participating in the stewardship plan,
16 including, but not limited to:

17 (1) Contact name and title

18 (2) Name of covered entity

19 (3) Mailing and physical address(es)

20 (4) Covered entity email address

21 (5) Covered entity internet website address

22 (6) Covered entity phone number

23 (c) List of sharps sold or offered for sale by each participating covered entity covered by
24 the stewardship plan.

25 (d) State Agency Determinations and Compliance Certifications.

26 (1) Agency determinations pursuant to 42032.2(d)(1)(B) of the Public Resources
27 Code. If a determination of noncompliance was initially issued, the stewardship plan
28 shall include both the initial determination of noncompliance and the superseding
29 determination of compliance. If any state agency failed to respond to a request for

1 review within 90 days of receipt of the stewardship plan, the program operator shall
2 include documentation of this request along with a written certification, signed by an
3 authorized representative of the program operator, that at the time of submission to
4 the department, the stewardship plan is consistent with all laws and regulations
5 relevant to that agency's authority, and the applicable agency failed to respond
6 within 90 days of receipt of the stewardship plan.

7 (2) Written certification, by an authorized representative of the program operator,
8 that, at the time of submission to the department, the stewardship plan, including all
9 aspects of the plan related to the handling, transportation, and disposal of home-
10 generated sharps waste is in compliance with all applicable local, state, and federal
11 laws and regulations.

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

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

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

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

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

28 (B) For any sharps, the packaging, an insert or instructions, or separate
29 information provided to the ultimate user shall include all necessary
30 information on proper sharps waste disposal.

31 (C) All sharps waste containers shall include, on a label affixed to the
32 container or packaging or on a separate insert included in the container or
33 packaging, the program operator's internet website and toll-free telephone
34 number.

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

1 (3) Collection, Transportation, and Disposal System Records. Description of how
2 and where the records generated during the collection, transportation, and
3 disposal of collected home-generated sharps waste will be maintained. These
4 records shall include, but are not limited to: collection manifests, mailer
5 distributions, receipts of returned home-generated sharps waste return mailings,
6 and final disposal of home-generated sharps waste, as applicable.

7 (4) Each service provider to be used to transport, process, or dispose of home-
8 generated sharps waste collected through the stewardship program, including,
9 but not limited to:

10 (A) Name of service provider

11 (B) Mailing and physical address(es) of service provider

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

15 (A) Secure receptacle collection. If a program operator proposes to
16 implement a receptacle-based program using authorized and approved
17 home-generated sharps consolidation points under the Medical Waste
18 Management Act, then the following information, as applicable, shall be
19 included, but not be limited to:

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

22 (ii) Process by which collection receptacles will be monitored,
23 process by which service schedules will be determined to ensure
24 that collection receptacles do not reach capacity, and the procedure
25 to be followed if capacity is reached.

26 (iii) How each participating home-generated sharps consolidation
27 point will be funded or reimbursed, if applicable.

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

35 (B) Take-back collection events shall be authorized and approved as a
36 home-generated sharps consolidation point under the Medical Waste

1 Management Act. Describe when take-back events are necessary and
2 how they will be conducted, if applicable.

3 (6) 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 amount of home-generated sharps waste returned.

6 (7) Metrics that will be used to measure the amount of home-generated sharps
7 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 instances of noncompliance with 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 Such requests shall comply with the requirements in subsection (1)(F)(ii) of
23 subdivision (d) of section 42032.2 of the Public Resources Code. Program
24 operators shall respond to requests by local agencies within 14 days of receipt of
25 the request and identify the method to resolve the request by selecting either
26 reimbursement or removal from household hazardous waste facility(ies).

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

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

34 (h) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public
35 Resources Code, description of processes, logistics, and timing of implementation that
36 will be necessary for the stewardship program to expand into jurisdictions not previously

1 included in the stewardship plan, in the event of the repeal of a local stewardship
2 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,
17 consistent with section 7295 of the Government Code, and maintained to ensure
18 all information is up to date and accurate. The internet website's digital content
19 and navigability must be accessible to disabled individuals. The internet website
20 shall include, but is not limited to, the following:

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

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

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

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

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

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

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

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

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

10 (7) How the program operator will comply with the requirement in section
11 42031.6(b) of the Public Resources Code.

12 (j) Coordination Efforts. Description of how the program operator will coordinate with
13 other program operators to avoid confusion to the public and all program participants in
14 the event that multiple stewardship programs for home-generated sharps waste are in
15 operation concurrently or new stewardship programs begin operating.

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

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

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

24 **18973.4. ANNUAL REPORT FOR COVERED DRUGS.**

25 On or before March 31, 2022, and each year thereafter, a program operator shall
26 prepare and submit an annual report to the department. To be complete, the annual
27 report shall describe how the program operator complied with all elements in its
28 stewardship plan during the previous reporting period of one year, and shall contain the
29 following:

30 (a) Contact information pursuant to section 18973.2(a), including any changes or
31 updates to this information.

32 (b) Executive Summary. A concise summary of the information contained in the report
33 that includes, but is not limited to, the highlights, outcomes and challenges,
34 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 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) Efforts between the program operator and potential authorized collectors to
7 establish authorized collection sites, including, but not limited to:

8 (A) Pursuant to section 18973.2(d)(2), efforts to notify potential authorized
9 collectors of the opportunity to serve as an authorized collector for the
10 stewardship program in the counties in which the program operated, and
11 the list of potential authorized collectors that were notified.

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

14 (C) Pursuant to section 18973.2(d)(4), efforts to work with retail
15 pharmacies and retail pharmacy chains to fulfill the requirement in section
16 42032.2(b)(2) of the Public Resources Code, if applicable.

17 (D) Pursuant to section 18973.2(d)(5), efforts to incorporate potential
18 authorized collectors that submitted a written offer to join the stewardship
19 program, and the list of potential authorized collectors that submitted
20 written offers.

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

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

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

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

34 (A) Name and physical address

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

3 (C) Number of instances that collected covered drugs were picked up for
4 disposal

5 (D) Number of receptacle liners picked up for disposal

6 (E) Number of instances and corresponding amount of time the secure
7 collection receptacle was not available to the public during business
8 hours. For each instance, provide a description of why the secure
9 collection receptacle was not available.

10 (5) For each type of mail-back service utilized, include the following, as
11 applicable:

12 (A) List of distribution locations

13 (B) Mechanism(s) of distribution

14 (C) Amount of mail-back materials distributed, as required in the
15 stewardship plan pursuant to section 18973.2(g)(6)(E)

16 (D) Amount of mail-back material returned, as required in the stewardship
17 plan pursuant to section 18973.2(g)(6)(E)

18 (6) For each alternative form of collection and disposal, include the following, as
19 applicable:

20 (A) Method(s) of collection

21 (B) Name and address of location(s)

22 (C) Number of collections

23 (D) Amount of materials distributed, as required in the stewardship plan
24 pursuant to section 18973.2(g)(6)(E)

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

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

29 (1) Mechanism(s) for tracking the collection, transportation, and disposal of
30 covered drugs

1 (2) Name and mailing address of each service provider used to transport or
2 process covered drugs

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

4 (A) Name of disposal facility

5 (B) Mailing and physical address

6 (C) Weight of covered drugs disposed

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

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

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

14 (3) Corrective actions taken, or that will be taken, if the program operator
15 discovered critical instances of noncompliance with stewardship plan policies and
16 procedures

17 (f) Description of updates, that have been made or will be made, to the processes and
18 policies followed to safely and securely collect, track, and properly manage covered
19 drugs from collection through final disposal.

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

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

33 (1) Location and date

34 (2) Description of specific incident

1 (3) Cause(s) of specific incident

2 (4) Parties involved

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

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

8 (1) Electronic examples of promotional marketing materials

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

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

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

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

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

20 (A) Name of covered entity

21 (B) Mailing and physical address

22 (C) Contact name and title

23 (D) Email address

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

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

29 (A) Name of authorized collector

30 (B) Mailing and physical address

1 (C) Contact name and title

2 (D) Email address

3 (k) Description and evaluation of the process for selecting service providers, if
4 applicable.

5 (l) Description of any grants, loans, sponsorships, reimbursements, or other incentives
6 provided, as applicable.

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

8 (n) A list of all actual expenses incurred during the previous reporting period. Expenses
9 shall be summarized in accordance with the budget categories specified in section
10 18973.6(b).

11 (o) Coordination Efforts. Description of how the program operator coordinated with other
12 program operators to avoid confusion to the public and all program participants in the
13 event that multiple stewardship programs for covered drugs are in operation
14 concurrently or new stewardship programs begin operating.

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

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

22 **18973.5. ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.**

23 On or before March 31, 2022, and each year thereafter, a program operator shall
24 prepare and submit an annual report to the department. To be complete, the annual
25 report shall describe how the program operator complied with all elements of the
26 stewardship plan during the previous reporting period of one year and shall contain the
27 following:

28 (a) Contact information pursuant to section 18973.3(a) including any changes or
29 updates to this information.

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

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

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

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

6 (A) Provided at point of sale

7 (B) Initiated at point of sale

8 (C) Website requests

9 (D) Toll-free telephone number requests

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

12 (4) Supplemental collection method(s) of home-generated sharps waste that
13 were provided in addition to, but not in lieu of, the mail-back program, pursuant to
14 section 18973.3(f)(5). Include a list of dates and locations of take-back events
15 that occurred pursuant to section 18973.3(f)(5)(B), if applicable

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

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

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

23 (2) Name and mailing address of each service provider used to transport or
24 process home-generated sharps waste

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

26 (A) Name of facility

27 (B) Mailing and physical address

28 (C) Total weight of material disposed

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

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

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

6 (3) Corrective actions taken, or that will be taken, if the program operator
7 discovered critical instances of noncompliance with stewardship plan policies and
8 procedures

9 (f) Description of updates, that have been made or will be made, to the processes and
10 policies followed to safely and securely collect, track, and properly manage home-
11 generated sharps waste from collection through final disposal.

12 (g) Ordinance Repeal. Pursuant to subdivision (e) of section 42032.2 of the Public
13 Resources Code, description of processes, logistics, and timing of implementation that
14 will be necessary for the stewardship program to expand into jurisdictions not previously
15 included in the stewardship plan, in the event of the repeal of a local stewardship
16 program ordinance.

17 (h) Safety and Security. Describe the general nature of any incidents with safety or
18 security related to collection, transportation, or disposal of home-generated sharps
19 waste. Explain the corrective actions taken or that will be taken to address the issue and
20 improve safety and security. Additionally, the following specific information about any
21 incident(s) shall be made available to the department, upon request, and shall include,
22 but not be limited to:

23 (1) Location and date

24 (2) Description of specific incident

25 (3) Cause(s) of specific incident

26 (4) Parties involved

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

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

32 (1) Electronic examples of promotional marketing materials

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

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

5 (4) Description of how the requirement in section 42031.6(b) of the Public
6 Resources Code was met

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

9 (1) Name of covered entity

10 (2) Mailing and physical address

11 (3) Contact name and title

12 (4) Email address

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

15 (l) Description and evaluation of the process for selecting service providers, if
16 applicable.

17 (m) Description of any grants, loans, sponsorships, reimbursements, or other incentives
18 provided, as applicable.

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

20 (o) Coordination Efforts. Description of how the program operator coordinated with other
21 program operators to avoid confusion to the public and all program participants in the
22 event that multiple stewardship programs for home-generated sharps waste are in
23 operation concurrently or new stewardship programs begin operating.

24 (p) Local Agency Requests. For each local agency that has requested removal or
25 reimbursement, pursuant to the requirements in subsection (1)(F)(ii) of subdivision (d) of
26 section 42032.2 of the Public Resources Code, provide details including, but not limited
27 to:

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

29 (2) For each household hazardous waste facility:

30 (A) Facility location

31 (B) Reimbursement payment amount, as applicable

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

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

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

6 (q) A list of all actual expenses incurred during the previous reporting period. Expenses
7 shall be summarized in accordance with the budget categories specified in section
8 18973.6(b).

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

12 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
13 Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4,
14 42033.5, 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041,
15 California Code of Regulations.

16 **18973.6. PROGRAM BUDGETS.**

17 A program operator must submit an initial stewardship program budget for the first five
18 calendar years of operation and an annual budget, pursuant to sections 42033 and
19 42033.2 of Chapter 2, Part 3, Division 30 of the Public Resources Code. The initial
20 stewardship program budget that covers the first five calendar years of operation and
21 the annual program budgets shall contain at a minimum, the following information:

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

25 (1) Contact name and title

26 (2) Name of program operator

27 (3) Mailing and physical address(es)

28 (4) Phone number

29 (5) Email address

30 (6) Internet website address

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

1 (1) Capital costs, including, but not limited to, fixed, one-time, tangible purchases

2 (2) Costs of collection, transportation, and disposal of covered products

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

4 (4) Education and outreach costs

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

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

10 (d) Recommended funding level necessary to cover the stewardship plan's budgeted
11 costs and to operate the stewardship program over a multi-year period in a prudent and
12 responsible manner. Include a description of how costs are apportioned to and funds
13 remitted from participating covered entities.

14 (e) A description of the types of activities relative to each line item cost category,
15 identified pursuant to section 18973.6(b).

16 (f) An independent financial audit of the stewardship program funded by the member
17 covered entities participating in the stewardship program or by a covered entity, if it
18 operates its own stewardship program. The audit shall be performed at least once each
19 calendar year. The audit shall be conducted in accordance with generally accepted
20 auditing standards in the United States of America by a Certified Public Accountant. The
21 Certified Public Accountant shall not perform the non-audit services for the program
22 operator or engage in any activities that would impair independence. The independent
23 financial audit shall include, but not be limited to:

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

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

28 (3) An opinion on the stewardship organization's compliance with the aspects of
29 section 42034 of the Public Resources Code and this Article.

30 (4) Findings and recommendations as they relate to the financial aspects of the
31 stewardship program.

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

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

18974. RECORD KEEPING REQUIREMENTS.

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

(a) Maintain records to support the requirements in this Article and Chapter 2 of Part 3 of Division 30 of the Public Resources Code. Covered entities, stewardship organizations, program operators, retail pharmacies and retail pharmacy chains must maintain records to support compliance with this Article and Chapter 2 of Part 3 of Division 30 of the Public Resources Code. 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. Covered entities, stewardship organizations, and program operators will maintain and provide access to records required to be kept or submitted pursuant to 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 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, 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 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, to demonstrate that a particular covered product from the covered entity or stewardship organization 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, or to demonstrate that a covered entity or

1 stewardship organization not listed on the department's internet website is in
2 compliance.

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

6 **18974.1. ADMINISTRATIVE AND OPERATIONAL COSTS AND DEPARTMENTAL**
7 **ADMINISTRATIVE FEE.**

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

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

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

23 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
24 Reference: Sections 42030, 42034, and 42034.2, Public Resources Code.

25 **18974.2. STEWARDSHIP ORGANIZATION AUDITS OF COVERED ENTITIES OR**
26 **AUTHORIZED COLLECTORS.**

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

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

1 **18974.3. DISTRIBUTOR, WHOLESALER, PHARMACY, AND RETAILER PRODUCT**
2 **VERIFICATION.**

3 (a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or
4 dispenses a covered product shall: successfully log onto the department's internet web
5 site to determine if covered products to be sold, offered for sale, or dispensed are in
6 compliance with the law, by verifying that the covered entities providing the covered
7 product(s) are in compliance with the law.

8 (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated
9 responsible party for any of the foregoing identify a noncompliant covered entity or
10 stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or
11 designated responsible party for any of the foregoing shall report the discovery to the
12 department within 30 days.

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

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

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

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

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

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

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

- 1 (1) The nature, circumstances, extent, and gravity of the violation(s)
- 2 (2) The number and severity of the violation(s)
- 3 (3) Evidence that the violation was intentional, knowing, or reckless
- 4 (4) The size of the violator's business and/or the financial position of the violator
- 5 (5) History of violation(s) of the same or similar nature
- 6 (6) The willfulness of the violator's misconduct
- 7 (7) Whether the violator took good faith measures to comply with this Article and
- 8 Chapter 2 of Part 3 of Division 30 of the Public Resources Code and the period
- 9 of time over which these measures were taken
- 10 (8) Evidence of any financial gain resulting from the violation(s)
- 11 (9) The economic effect of the penalty on the violator
- 12 (10) The deterrent effect that the imposition of the penalty would have on both
- 13 the violator and the regulated community
- 14 (11) Any other factor(s) that justice may require.

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

18 **18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.**

19 (a) The department shall issue a written notice of violation (NOV) before commencing
20 an action to impose administrative civil penalties. The NOV shall list and describe the
21 nature of the violation(s). The department shall issue a NOV to the respondent if the
22 department determines any of the following:

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

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

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

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

8 (1) Personal service;

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

11 (3) Certified Mail or registered mail; or

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

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

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

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

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

31 **18975.2. PROCEDURE FOR STEWARDSHIP PLAN REVOCATION, RESUBMITTAL,**
32 **OR ADDITIONAL COMPLIANCE REPORTING**

33 (a) If the department finds that a covered entity, program operator, stewardship
34 organization, or authorized collector has failed to meet a material requirement of this
35 Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the

1 department shall, in addition to imposing any civil penalties authorized under this Article
2 and Chapter 2 of Part 3 of Division 30 of the Public Resources Code, take one or all of
3 the following actions:

4 (1) Revoke a previously approved stewardship plan,

5 (2) Require resubmittal of the stewardship plan, and/or

6 (3) Require additional reporting relating to compliance with the material
7 requirement(s), of this Article or Chapter 2 of Part 3 of Division 30 of the Public
8 Resources Code, that was/were not met.

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

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

17 (1) Personal service;

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

20 (3) Certified Mail or registered mail; or

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

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

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

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

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