

# 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 retailers, and 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, 42036.4, SEC. 2, and SEC. 3 Public Resources Code.

#### 18972.1. DEFINITIONS.

(a) Except as otherwise noted, the definitions of this Article supplement and are governed by the definitions set forth in Chapter 2, (commencing with section 42030) Part 3, Division 30 of the Public Resources Code.

(b) "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 and administrative fees charged by the department.

(c) "Homebound" has the same meaning as defined in the Medicare Benefit Policy Manual, Chapter 15, 60.4.1.

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

(e) "Home-generated sharps consolidation point" has the same meaning as defined in Division 104, Part 14, Chapter 3, section 117904 of the Health and Safety Code.

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

(g) "Minutes, books, and records" means accurate and up-to-date information regarding a program operator's activities.

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

(i) "Point of sale" means the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, including online sales.

(j) "Provides or initiates distribution of a sharps waste container" means:

(1) To provide a sharps waste container and mail-back materials to the ultimate user at the point of sale at no cost to the ultimate user;

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

(3) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, if (1) or (2) are not reasonably feasible, and which result in substantially the same level of convenience to the ultimate user.

(k) "Significant change" to an approved stewardship plan includes, but is not limited to:

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

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

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

(4) Any changes regarding achievement of convenience standards.

(5) Any changes in the facility(ies) to be used to process or dispose of a covered drug or home-generated sharps waste collected through the stewardship program not identified in the approved plan.

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, 42036.4, SEC. 2, and SEC. 3 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, 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

(b) Documents 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.

(c) 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.

(e) 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).

Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.  
Reference: Sections 42030, 42032, 42033.2, 42036.4, SEC 2, 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) 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 approval.

(b) The department shall determine if a document is complete and notify the submitting program operator within 30 days of receipt. If the department determines that the document is complete, the department's 90-day review period for consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt. If the department determines that the document is incomplete, the department shall identify for the program operator the required additional information and the program operator shall resubmit the document within 30 days of the department's notification that the document is incomplete. If the department determines upon resubmittal that the document is complete, the department's 90-day review period for consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt of the resubmittal.

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

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

(e) If the department disapproves a stewardship plan, the department shall identify how the stewardship plan does not comply and provide written notice to the program operator within 30 days. The program operator shall resubmit a revised stewardship plan within 60 days of the notice date and the department will review the revised stewardship plan within 90 days of resubmittal. If a revised stewardship plan is disapproved by the department, the covered entities operating under the stewardship plan are not in compliance until the program operator submits a stewardship plan the department approves.

(f) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies and the program operator shall comply with the conditions within 60 days of the notice date unless the director determines that additional time is needed. If the program operator does not comply and the conditions are not met within 60 days of the notice date for a conditional approval, the department shall disapprove the annual report or program budget.

(g) If the department disapproves an annual report or program budget, the department shall identify the deficiencies and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

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

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

A stewardship plan for covered drugs shall comply with all applicable local, state, and federal laws and regulations, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration. The stewardship plan shall include the following:

(a) Contact Information. Contact information per section 18973 of this Chapter.

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

(1) Contact name and title

- 1 (2) Name of entity
- 2 (3) Mailing and physical address(es)
- 3 (4) Email address
- 4 Upon request by the department, the internet website address and phone number of  
5 participating covered entities shall be provided, if available. The requested information  
6 shall be submitted within 30 days of the request unless extended as determined by the  
7 department.
- 8 (c) Covered Products. List of each covered drug sold or offered for sale by each  
9 participating covered entity covered by the stewardship plan.
- 10 (d) Authorized Collectors.
- 11 (1) For each participating authorized collector operating a collection site where  
12 covered drugs are collected, include, not limited to, the following:
- 13 (A) Contact name and title
- 14 (B) Name of entity
- 15 (C) Mailing and physical address(es)
- 16 (D) List of participating authorized collection sites, with name and physical  
17 address, by county
- 18 (2) List of potential authorized collectors in the counties in which the program will  
19 operate that were notified of the opportunity to serve as an authorized collector  
20 for the proposed stewardship program.
- 21 (3) Description of the process in which good faith negotiations with potential  
22 authorized collectors is conducted.
- 23 (4) Description of the conditions for excluding any potential authorized collectors,  
24 including those who requested joining the program, as applicable.
- 25 (e) Agency Determinations. Determinations of compliance from the State Board of  
26 Pharmacy and any other state agency that reviewed the plan for compliance. If a  
27 determination of noncompliance was issued, the plan shall include both the  
28 determination of noncompliance and the superseding determination of compliance.
- 29 (f) Initial Program Budget and Program Funding. Demonstration of adequate funding for  
30 all administrative and operational costs of the stewardship program, to be borne by  
31 participating covered entities for the first five calendar years of operation pursuant to  
32 section 18973.6.

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

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

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

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

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

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

17 (4) Each entity to be used to transport, process, or dispose of covered drugs  
18 collected through the stewardship program, including, but not limited to:

19 (A) Name of entity

20 (B) Mailing and physical address(es)

21 (5) Mail-back services or an alternative form of collection and disposal system to  
22 be provided to ultimate users, including, but not limited to, the following:

23 (A) Locations where preaddressed, prepaid mail-back materials are  
24 distributed, if applicable.

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

29 (C) Metrics that will be used to measure the amount of materials  
30 distributed and weight of material returned.

31 (6) Any alternative form of collection and disposal system that complies with  
32 applicable local, state, and federal laws and regulations including, but not limited  
33 to, United States Drug Enforcement Administration regulations that is used as a  
34 supplemental service for any county that does not meet the minimum authorized

1 collection site threshold due to circumstances out of the program operator's  
2 control, if applicable.

3 (7) Method(s) of collection for covered drugs, other than controlled substances,  
4 that cannot be accepted or commingled with other covered drugs in secure  
5 collection receptacles or through a mail-back program.

6 (8) Process in which collection receptacles will be monitored, how service  
7 schedules are determined to ensure that collection receptacles do not reach  
8 capacity, and procedures to be followed if capacity is reached.

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

11 (10) What corrective actions will be taken if a program operator discovers an  
12 authorized collector or service provider is not maintaining compliance with all  
13 collection, transportation, and disposal standards related to the handling of  
14 covered drugs, including, but not limited to, United States Drug Enforcement  
15 Administration regulations.

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

18 (12) Standard operating procedures that address safety and security issues for  
19 an unplanned incident.

20 (h) Collection, Transportation, and Disposal System Records. Description of how and  
21 where records will be maintained on policy and procedures for collection, transportation,  
22 and disposal of covered drugs to ensure easy access for review.

23 (i) Ordinance Repeals. Description of provisions, processes, logistics, and timing of  
24 implementation that will be used to expand into jurisdictions in the event of the repeal of  
25 a local stewardship program ordinance to meet the convenience standards pursuant to  
26 subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.

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

29 (1) Any activities to promote awareness and maximize ultimate user participation  
30 in the stewardship program.

31 (2) Materials to be utilized that are distributed in languages suited to local  
32 demographics. These materials shall include, but are not limited to, signage for  
33 hospitals, pharmacies, and other locations, as necessary.



(3) Establishment of an internet website designed with functionality for mobile platforms and maintained to ensure all information is up to date and accurate. The internet website shall include, but is not limited to, the following:

(A) Authorized collection site physical addresses

(B) Authorized collection site contact telephone numbers

(C) Authorized collection site days and hours of operation

(D) Mechanism to accept requests for mail-back materials

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

(4) Establishment of a toll-free telephone number to accept requests for mail-back materials, disposal options, and other program information for ultimate users who are homeless, homebound, or disabled in addition to accepting requests through an internet website.

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

(k) 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, in the event that multiple stewardship programs for covered drugs are in operation concurrently.

(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, as 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, 42036.4, SEC 2 Public Resources Code; and Section 17041 California Code of Regulations.

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

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.

(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 entity

(3) Mailing and physical address(es)

(4) Email address

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

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

(d) Agency Determinations. Determinations of compliance from the State Board of Pharmacy and any other state agency that reviewed the plan for compliance. If a determination of noncompliance was issued, the plan shall include both the determination of noncompliance and the superseding determination of compliance.

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

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

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

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

(A) Containers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user.

(B) Mail-back materials shall include information for proper home-generated sharps waste disposal.

1 (C) Container labels and mail-back materials shall include the stewardship  
2 program internet website and toll-free telephone number.

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

5 (3) Collection, Transportation, and Disposal System Records. Description of how  
6 and where records will be maintained on policy and procedures for collection,  
7 transportation, and disposal of home-generated sharps waste to ensure easy  
8 access for review.

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

12 (A) Name of entity

13 (B) Mailing and physical address(es) of entity

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

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

21 (A) Secure receptacle collection. If a program operator proposes to  
22 implement a receptacle-based program to supplement its mail-back  
23 program and home-generated sharps consolidation points are authorized  
24 and approved by the city, county, or state enforcement authority that  
25 provides oversight of the Medical Waste Management Act, then the  
26 following information, as applicable, shall be included, but not limited to:

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

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

32 (iii) Process in which collection receptacles will be monitored, how  
33 service schedules are determined to ensure that collection  
34 receptacles do not reach capacity, and the procedure followed if  
35 capacity is reached.

- 1 (iv) How each home-generated sharps consolidation point is  
2 notified of its responsibility to maintain and make available  
3 collection records to the department upon request.
- 4 (v) What corrective actions will be taken if a program operator  
5 discovers a home-generated sharps consolidation point or service  
6 provider is not maintaining compliance with all collection,  
7 transportation, and disposal standards related to the handling of  
8 home-generated sharps waste.
- 9 (vi) How each participating home-generated sharps consolidation  
10 point will be funded or reimbursed, if applicable.
- 11 (vii) Standard operating procedures that address safety and  
12 security issues for an unplanned incident.
- 13 (B) Take-back collection events. Date and location of events, as  
14 applicable.
- 15 (7) Metrics that will be used to measure the amount of sharps waste containers  
16 and mail-back materials distributed and the weight returned.
- 17 (8) Metrics that will be used to measure the weight of home-generated sharps  
18 waste collected through supplemental collection method(s), if applicable.
- 19 (g) Local Agency Requests.
- 20 (1) Description of the process for coordinating with local agencies, or an agent on  
21 behalf of a local agency, for the removal of home-generated sharps waste from  
22 local household hazardous waste facilities, either by reimbursement for  
23 transportation and disposal costs or removal of the home-generated sharps  
24 waste.
- 25 (2) Requests by local agencies, or an agent on behalf of a local agency, shall be  
26 submitted to the program operator as necessary. Program operators will respond  
27 to requests by local agencies in a timely manner and identify the method to  
28 resolve the request by selecting either reimbursement or removal from household  
29 hazardous waste facility(ies).
- 30 (A) A program operator that selects to resolve a request through  
31 reimbursement to a local agency shall issue payment within 45 days of the  
32 local agency providing an invoice.
- 33 (B) A program operator that provides for the removal of the home-  
34 generated sharps waste from the local household hazardous waste

1 facilities shall do so as often as required according to section 117904 of  
2 the Health and Safety Code or by the local enforcement authority.

3 (h) Ordinance Repeals. Description of provisions, processes, logistics, and timing of  
4 implementation that will be used to expand into jurisdictions in the event of the repeal of  
5 a local stewardship program ordinance.

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

8 (1) Activities to promote awareness and maximize ultimate user participation in  
9 the stewardship program.

10 (2) Materials to be utilized that are distributed in languages suited to local  
11 demographics. These materials shall include, but are not limited to, signage for  
12 hospitals, pharmacies, and other locations, as necessary.

13 (3) Establishment of an internet website designed with functionality for mobile  
14 platforms and maintained to ensure all information is up to date and accurate.  
15 The internet website shall include, but is not limited to, the following:

16 (A) A mechanism to accept requests for mail-back materials.

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

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

22 (D) Home-generated sharps consolidation point site days and hours of  
23 operation.

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

26 (4) Establishment of a toll-free telephone number to serve as an option for  
27 ultimate users to obtain information about the program including, but not limited  
28 to what is outlined in section 18973.3(i)(3)(A)-(E).

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

32 (j) Description of how the program operator will make a good faith effort to work with the  
33 other stewardship program(s) in order to most effectively achieve the requirements of

the statute and regulations, in the event that multiple stewardship programs for home-generated sharps waste are in operation concurrently.

(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, 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, 42036.4 SEC, Public Resources Code; Section 17041 California Code of Regulations; and Section 117904, Health and Safety Code.

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

The annual report shall contain the following:

(a) Contact information. Contact information for the program operator or corporate officer responsible for annual report submittal as specified in section 18973 of this Chapter.

(b) Executive Summary. A concise summary of the information 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 (a) of section 42032.2 of the Public Resources Code, education and outreach efforts, and how challenges are being addressed.

(c) Collection System. Description of the following:

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

(2) Good faith negotiations between the program operator and potential authorized collectors to establish collection sites and the results of the negotiations, including:

(A) Efforts to notify potential authorized collectors of the opportunity to serve as an authorized collector for the stewardship program in the counties in which the program will operate.

(B) Efforts to include authorized collectors beyond the minimum convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.

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

(D) Any known reason why potential authorized collectors were excluded from participation in the stewardship program.

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

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

(A) Name and physical address

(B) Weight of material collected

(C) Number of collections and number of liners collected

(D) Total number of instances and corresponding number of business hours the authorized collection site was not available to the public

(5) Mail-back services, including, but not limited to, as applicable:

(A) Name and location of distribution facility

(B) Amount of materials distributed

(C) Mechanism of distribution

(D) Weight of material returned

(6) Alternative forms of collection and disposal, including, but not limited to, the following, as applicable:

(A) Method of collection

(B) Name and address of location

(C) Number of collections

(D) Amount of materials distributed

(E) Weight of material collected

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

3 (1) Mechanism(s) for tracking collections

4 (2) Name and mailing address of each entity used to transport or process  
5 covered drugs

6 (3) For each disposal facility, include:

7 (A) Name of entity

8 (B) Mailing and physical address

9 (C) Weight of material received

10 (e) Corrective actions taken if the program operator discovered that a service provider  
11 did not maintain compliance with all collection, transportation, and disposal standards,  
12 including, but not limited to, local, state and federal laws and regulations and United  
13 States Drug Enforcement Administration regulations.

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

18 (g) Ordinance Repeal. Description of efforts to expand into jurisdictions due to the  
19 repeal of a local stewardship program ordinance, including, but not limited to, logistics  
20 and timing of implementation of the program in the jurisdiction to meet the convenience  
21 standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the  
22 Public Resources Code.

23 (h) Safety and Security. Describe the nature of any incidents with safety or security  
24 related to collection, transportation, or disposal of collected covered drugs. Explain  
25 what corrective actions were taken to address the issue and improve safety and  
26 security. The following shall be made available to the department upon request,  
27 including, but not limited to, the following:

28 (1) Location and date

29 (2) Description of incident

30 (3) Cause(s) of incident

31 (4) Parties involved



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

(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.2(j), including electronic examples of promotional marketing materials.

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

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

(A) Name of entity

(B) Mailing and physical address

(C) Contact name and title

(D) Email address

(2) List of covered products

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

(A) Name of entity

(B) Mailing and physical address

(C) Contact name and title

(D) Email address

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

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

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

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

(n) Description of how the program operator made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, if applicable.

(o) Agency Determination. Submit all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period.

Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code. Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4, 42033.6, 42034, 42036.4, SEC 2. Public Resources Code; and Section 17041, California Code of Regulations.

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

The annual report shall contain the following:

(a) Contact information. Contact information for the program operator or corporate officer responsible for annual report submittal as specified in section 18973 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, education and outreach efforts, and how challenges are being addressed.

(c) Collection System. Description of the following:

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

(2) Amount of sharps waste containers and mail-back materials distributed, per county, through each of the following methods:

(A) Provided at point of sale

(B) Initiated at point of sale

(C) Website requests

(D) Toll-free telephone number requests

(3) Weight of material returned

(4) Supplemental collection method(s) of home generated sharps waste that were provided in addition to, but not substituted for, the mail-back program, pursuant to section 18973.3.(f)(6) and (8).

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

(1) Mechanism(s) used to track transportation and disposal.

- 1 (2) Name and mailing address of each entity used to transport or process home-  
2 generated sharps waste.
- 3 (3) For each disposal facility, include:
- 4 (A) Name of entity
- 5 (B) Mailing and physical address
- 6 (C) Total weight of material disposed
- 7 (e) Corrective actions taken if the program operator discovered that service provider did  
8 not maintain compliance with all collection, transportation, and disposal standards,  
9 including, but not limited to, local, state and federal laws and regulations and United  
10 States Drug Enforcement Administration regulations.
- 11 (f) Description of updates to the processes and policies followed to safely and securely  
12 collect, track and properly manage covered drugs from collection through final disposal  
13 to ensure all entities are in compliance with all applicable state, local and federal laws  
14 and regulations.
- 15 (g) Ordinance Repeal. Description of efforts to expand into jurisdictions due to the  
16 repeal of a local stewardship program ordinance, including, but not limited to, logistics  
17 and timing of implementation of the program in the jurisdiction.
- 18 (h) Safety and Security. Describe the nature of any incidents with safety or security  
19 related to collection, transportation, or disposal of sharps waste. Explain the corrective  
20 actions taken to address the issue and improve safety and security. The following shall  
21 be made available to the department upon request, including, but not limited to:
- 22 (1) Location and date
- 23 (2) Description of incident
- 24 (3) Cause(s) of incident
- 25 (4) Parties involved
- 26 (5) Regulatory or law enforcement agencies involved and any litigation,  
27 arbitration, or other legal proceedings that result from each incident.
- 28 (i) Education and Outreach. Description and evaluation of the comprehensive education  
29 and outreach activities pursuant to section 18973.3(i), including electronic examples of  
30 promotional marketing materials.
- 31 (j) Covered Entities. Participating covered entities covered by the stewardship plan and  
32 their contact information, including, but not limited to, the following:

- 1 (A) Name of entity
- 2 (B) Mailing and physical address
- 3 (C) Contact name and title
- 4 (D) Email address
- 5 (k) Updated list of covered products
- 6 (l) Description of changes to the process for selecting service providers, if applicable.
- 7 (m) Description of changes in the process for providing grants, loans, sponsorships,
- 8 reimbursements, or other incentives, as applicable.
- 9 (n) Description of changes in staffing of the stewardship program.
- 10 (o) Description of how the program operator made a good faith effort to work with any
- 11 other stewardship program(s) in order to most effectively achieve the requirements of
- 12 the statute and regulations.
- 13 (p) Local Agency Requests. For each local agency that has requested removal or
- 14 reimbursement, details including, but not limited to, the following:
  - 15 (1) Name of local agency, or agency acting on behalf of the local agency.
  - 16 (2) For each household hazardous waste facility:
    - 17 (A) Facility location
    - 18 (B) Reimbursement payment amount, as applicable
    - 19 (C) Weight of collected material
- 20 (q) Agency Determination. Submit all agency determination(s) of compliance,
- 21 noncompliance and superseding determinations of compliance, if any, for the reporting
- 22 period.
- 23 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code
- 24 Reference: Sections 42030, 42031, 42031.6, 42032.2, 42033, 42033.2, 42033.4,
- 25 42033.5, 42033.6, 42034, 42036.4, SEC 2, Public Resources Code; and Section 17041,
- 26 California Code of Regulations

1    **18973.6. PROGRAM BUDGETS.**

2    The initial stewardship program budget that covers the first five calendar years of  
3    operation and annual program budgets shall contain at a minimum, the following  
4    information:

5    (a) Anticipated costs to implement the stewardship program, including, but not limited  
6    to, separate line items for the following:

7           (1) Capital costs, including but not limited to, the purchase/installation of  
8           collection receptacles, sharps waste containers, and mail-back materials, as  
9           applicable.

10          (2) Collection of covered products

11          (3) Transportation of covered products

12          (4) Processing of covered products

13          (5) Disposal of covered products

14          (6) Administrative costs

15          (7) Education and outreach

16          (8) Costs related to grants, loans, sponsorships, or other incentives as part of  
17          program implementation

18          (9) Reserve level

19    (b) Recommended funding level necessary to implement the stewardship program,  
20    including a description of how costs are apportioned to and funds remitted from  
21    participating covered entities, in order to demonstrate that the stewardship program will  
22    be operated in a prudent and responsible manner.

23    (c) A narrative description of the types of activities within each line item cost category.

24    (d) Beginning with the first annual program budget, include all actual expenses incurred  
25    during the previous program year.

26    (e) An independent financial audit of the stewardship program funded by the covered  
27    entities participating in the stewardship program. The audit shall be conducted in  
28    accordance with generally accepted auditing standards in the United States of America,  
29    and Generally Accepted Government Auditing Standards by a Certified Public  
30    Accountant. The Certified Public Accountant shall not perform the non-audit services for  
31    the program operator or engage in any activities that would impair independence. The  
32    independent financial audit shall include, but not be limited to:

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

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

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

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

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

12 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.  
13 Reference: Sections 42030, 42033, 42033.2, 42033.4, 42034 42036.4, SEC 2, Public  
14 Resources Code; and Section 17041, California Code of Regulations

15 **18974. RECORD KEEPING REQUIREMENTS.**

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

18 (a) Maintain records to support the requirements in this Article. Covered entities,  
19 stewardship organizations, program operators, retail pharmacies and retail pharmacy  
20 chains must maintain records to support compliance with the regulations. Retail  
21 pharmacies or retail pharmacy chains will maintain and provide access to records  
22 required by this Article for 3 years.

23 (b) Provide the department with reasonable and timely access, as determined by the  
24 department, to its facilities, operations, and any relevant records necessary to  
25 determine compliance with this Article, upon request. Covered entities, stewardship  
26 organizations, and program operators will maintain and provide access to records  
27 required by this Article for three years after submission of the annual report which relies  
28 upon those records.

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

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

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

(3) The date(s) the retailer offered the covered product(s) for sale.

(4) Certification letter(s) from the department, if provided by a manufacturer, to demonstrate that a particular covered product from the manufacturer is or was subject to a department-approved covered product stewardship plan. A retail pharmacy/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 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 42036.4, SEC 2, Public Resources Code; and Section 17041, California Code of Regulations

#### **18974.1. ADMINISTRATIVE FEE TO DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY.**

The department will set the administrative fee pursuant to sections 42034 and 42034.2 of the Public Resources Code.

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

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

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

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

#### **18974.3. RETAILER, WHOLESALER, DISTRIBUTOR PRODUCT VERIFICATION.**

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

(a) Successfully log onto the department's Internet Web site to verify that covered products to be sold, offered for sale, or dispensed are in compliance with the law.

(b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party identify a noncompliant covered product, the distributor, wholesaler,

1 pharmacy, other retailer, or designated responsible party shall report the discovery to  
2 the department's Enforcement Unit.

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

6 **18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.**

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

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

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

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

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

17 (4) The size of the violator

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

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

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

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

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

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

26 (11) Any other factor that justice may require

27 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.  
28 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6, 42035.8 Public  
29 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, 42035.8 Public  
27   Resources Code; and Section 11445.10 Government 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.**

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

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

- 1 (c) The hearing shall be held before the Director, or the Director's designee, in  
2 accordance with the provisions of Article 10 of Chapter 4.5 (commencing with section  
3 11445.10) of Part 1 of Division 3 of Title 2 of the Government Code.
- 4 (d) Within thirty (30) calendar days of receipt of the notification from the Department, the  
5 program operator shall submit to the Director of the Department a clear and concise  
6 statement of the basis for objecting to revocation or resubmittal of the stewardship plan,  
7 or the additional reporting requirements.
- 8 (e) The Director shall notify the program operator of the determination on whether or not  
9 to revoke the plan, require a resubmittal of the plan, or require additional reporting, in  
10 writing within sixty (60) working days from the date the hearing is conducted.
- 11 (f) A stewardship plan requiring resubmittal shall be resubmitted pursuant to the  
12 requirements of 18973.1.
- 13 (g) For the purposes of this section, resubmittal means a revised plan to correct or  
14 address the material requirement that was not met.
- 15 (h) For the purposes of this section, additional reporting means more frequent or more  
16 detailed reports regarding the material requirement not met.
- 17 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.  
18 Reference: Sections 42030, 42032, 42033.2, 42035, 42035.2, 42035.4, 42035.6,  
19 42035.8 Public Resources Code; and Section 11445.10 Government Code