

19. Final Text

a. Proposed Regulations

CalRecycle is adding new text to the California Code of Regulations, starting with Article 4. Pharmaceutical and Sharps Waste Stewardship Program and section 18972 through section 18975.2.

ADOPTED 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

18972.1. 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.

(3) "Homebound" has the same meaning as defined in the Medicare Benefit Policy Manual, Chapter 15, 60.4.1 (Chapter revised July 12, 2019, definition issued, effective, and implemented in 2014). The Medicare Benefit Policy Manual, Chapter 15, Section 60.4.1 is incorporated herein by reference.

(4) "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.

(5) "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.

(6) "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.

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

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

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

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

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

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

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

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

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

18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.

The department shall identify the covered entity for any covered products consistent with 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 stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet all the requirements outlined in subsections (a) through (e) of this section:

(a) The document is required to be in compliance with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in 2008 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. The entirety of the Web Content Accessibility Guidelines 2.0 (published in 2008) are incorporated herein by reference.

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

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

(d) The document shall be complete and correct.

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

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

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

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

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

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

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

(2) 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 resubmitted document is complete, the department shall have 90 days from the date of receipt of the resubmitted document to approve, conditionally approve, or disapprove the resubmitted document.

(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 30-day review to determine completeness or 90-day review to determine approval, conditional approval, or disapproval.

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

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

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

(g) 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 of conditional approval. 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.

(h) If the department disapproves a stewardship plan, the department shall explain how the stewardship plan does not comply and provide written notice to the program operator within 30 days of disapproval. The program operator shall resubmit a revised stewardship plan within 60 days of the disapproval date the written notice was issued, 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 that the department approves.

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

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

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

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

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

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.

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

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

- (1) Contact name and title
- (2) Name of program operator
- (3) Mailing and physical address(es)
- (4) Phone number
- (5) Email address
- (6) Internet website address

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

- (1) Contact name and title
- (2) Name of covered entity
- (3) Mailing and physical address(es)
- (4) Covered entity email address
- (5) Covered entity internet website address
- (6) Covered entity phone number

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

(d) Authorized Collectors.

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

(A) Contact name and title

(B) Name of authorized collector

(C) Mailing and physical address(es)

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

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

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

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

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

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

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

(e) State Agency Determinations and Compliance Certifications.

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

(2) Written certification by an authorized representative of the program operator that, at the time of submission to the department, the stewardship plan, including 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 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 form of collection and disposal system that would render the covered drug inert, if applicable.

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

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

(D) Pursuant to section 42032.2(a)(1)(G)(ii) of the Public Resources Code, any alternative methods of collection for covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under

applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

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

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

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

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

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

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

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

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

(1) Any activities to promote awareness and maximize ultimate user participation in the stewardship program, including, but not limited to, provision of educational

and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

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

(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, consistent with section 7295 of the Government Code, and maintained to ensure all information is up to date and accurate. The internet website's digital content and navigability must be accessible to disabled individuals. 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 from ultimate users who are homeless, homebound, or disabled

(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 from ultimate users who are homeless, homebound, or disabled, and to provide disposal options and other program information to ultimate users without access to the internet. The toll-free telephone number shall offer language options suited to local demographics, accept calls via human representative, and provide services for hearing-impaired and speech-impaired individuals.

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

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

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

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

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

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

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

18973.3. STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE.

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

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

- (1) Contact name and title
- (2) Name of program operator
- (3) Mailing and physical address(es)
- (4) Phone number
- (5) Email address
- (6) Internet website address

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

- (1) Contact name and title
- (2) Name of covered entity
- (3) Mailing and physical address(es)
- (4) Covered entity email address

(5) Covered entity internet website address

(6) Covered entity phone number

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

(d) State Agency Determinations and Compliance Certifications.

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

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

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

(f) 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 home-generated sharps waste from collection through final disposal.

(2) How stewardship plan implementation will provide or initiate 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. In addition, how stewardship plan implementation will 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 over a selected time period.

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

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

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

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

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

(A) Name of service provider

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

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

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

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

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

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

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

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

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

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

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

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

(g) Local Agency Requests.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18973.4. ANNUAL REPORT FOR COVERED DRUGS.

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

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

(b) Executive Summary. A concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, achievement of the convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code, education and outreach efforts, and ways in which 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) Efforts between the program operator and potential authorized collectors to establish authorized collection sites, including, but not limited to:

(A) Pursuant to section 18973.2(d)(2), 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 operated, and the list of potential authorized collectors that were notified.

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

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

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

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

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

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

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

(A) Name and physical address

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

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

(D) Number of receptacle liners picked up for disposal

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

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

(A) List of distribution locations

(B) Mechanism(s) of distribution

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

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

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

(A) Method(s) of collection

(B) Name and address of location(s)

(C) Number of collections

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

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

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

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

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

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

(A) Name of disposal facility

(B) Mailing and physical address

(C) Weight of covered drugs disposed

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

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

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

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

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

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

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

(1) Location and date

(2) Description of specific incident

(3) Cause(s) of specific incident

(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, but not limited to, the following:

(1) Electronic examples of promotional marketing materials

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

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

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

(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 covered entity

(B) Mailing and physical address

(C) Contact name and title

(D) Email address

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

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

(A) Name of authorized collector

(B) Mailing and physical address

(C) Contact name and title

(D) Email address

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

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

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

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

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

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

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

18973.5. ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.

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

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

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

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

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

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

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

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

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

(A) Name of facility

(B) Mailing and physical address

(C) Total weight of material disposed

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

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

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

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

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

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

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

(1) Location and date

(2) Description of specific incident

(3) Cause(s) of specific incident

(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 18973.3(i), including, but not limited to, the following:

(1) Electronic examples of promotional marketing materials

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

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

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

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

(1) Name of covered entity

(2) Mailing and physical address

(3) Contact name and title

(4) Email address

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

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

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

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

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

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

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

(2) For each household hazardous waste facility:

(A) Facility location

(B) Reimbursement payment amount, as applicable

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

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

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

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

(r) State Agency Determinations pursuant to section 42032.2(d)(1)(B) of the Public Resources Code. 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, 42033.5, 42033.6, 42034 and 42036.4, Public Resources Code; and Section 17041, California Code of Regulations.

18973.6. PROGRAM BUDGETS.

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

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

(1) Contact name and title

(2) Name of program operator

(3) Mailing and physical address(es)

(4) Phone number

(5) Email address

(6) Internet website address

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

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

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

(3) Administrative costs

(4) Education and outreach costs

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

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

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

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

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

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

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

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

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

(5) Management Letter, if issued, by the stewardship organization's Certified 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) 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 stewardship organization not listed on the department's internet website is in compliance.

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

18974.1. ADMINISTRATIVE AND OPERATIONAL COSTS.

(a) Each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and

implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code. Reference: Sections 42030, 42034, and 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 and 42034.4, Public Resources Code.

18974.3. DISTRIBUTOR, WHOLESALER, PHARMACY, AND RETAILER PRODUCT VERIFICATION.

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

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

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

18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.

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

(b) In addition to the ability to impose administrative civil penalties under subdivision (a) above, the department shall, consistent with section 42035.6(d) of the Public Resources Code, take a disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain if the

department determines that any of those entities has failed to provide the department with the access to information required pursuant to section 42035.6(a) through (c) of the Public Resources Code or section 18974 of this Article. The disciplinary actions shall include one or both of the following:

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

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

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

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

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

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

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

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

(6) The willfulness of the violator's misconduct

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

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

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

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

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

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

18975.1. PROCEDURE FOR IMPOSING ADMINISTRATIVE CIVIL PENALTIES.

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

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

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

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

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

(1) Personal service;

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

(3) Certified Mail or registered mail; or

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

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

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

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

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

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

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

(a) If the department finds that a covered entity, program operator, stewardship organization, or authorized collector has failed to meet a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the department shall, in addition to imposing any civil penalties authorized under this Article and Chapter 2 of Part 3 of Division 30 of the Public Resources Code, take one or all of the following actions:

(1) Revoke a previously approved stewardship plan,

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

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

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

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

(1) Personal service;

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

(3) Certified Mail or registered mail; or

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

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

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

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

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