

California’s Pharmaceutical Stewardship Annual Report Review Checklist

(Updated March 18, 2024)

By March 31 of each year, a program operator shall submit to the Department of Resources Recycling and Recovery (CalRecycle) an annual report. This checklist includes statutory and regulatory requirements that pharmaceutical stewardship annual reports must address.

Annual reports must also meet requirements specific to a program operator’s approved stewardship plan and CalRecycle Request for Action documents, which can be found on CalRecycle’s Stewardship Plan (<https://calrecycle.ca.gov/epr/pharmasharps/pharma/plan/>) and Annual Reporting (<https://calrecycle.ca.gov/epr/pharmasharps/pharma/reports/>) webpages. This checklist is not intended as a comprehensive list of all applicable legal requirements. It is provided for reference only and may not reflect recent changes in statutes and regulations.

Table 1. Statutory Requirements (Public Resources Code [PRC])

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
42033.2(a)(1)	On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department a written report describing the stewardship program activities during the previous reporting period of one year.				
42033.2(b)	An annual report submitted pursuant to section 42033.2(a)(1) shall include, at a minimum, all of the following for the prior year:				

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42033.2(b)(1)	A list of covered entities participating in the stewardship organization.				
42033.2(b)(2)	The updated and reverified list provided pursuant to section 42031(a)(2) of covered products that each covered entity subject to the stewardship plan sells or offers for sale.				
42033.2(b)(3)	The amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program.				
42033.2(b)(4)	For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
42033.2(b)(6)	Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.				
42033.2(b)(7)	Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.				
42033.2(b)(8)	How the program operator complied with all elements in its stewardship plan.				
42033.2(b)(9)	Any other information the department reasonably requires.				

Table 2. Regulatory Requirements (California Code of Regulations Title 14 [14 CCR])

14 CCR section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973(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.				
18973(b)	The document shall be submitted electronically. The date of electronic submittal will be considered the date of receipt by the department.				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973(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).				
18973(d)	The document shall be complete and correct.				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973(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."				
18973.4(a)	Contact information pursuant to section 18973.2(a), including any changes or updates to this information.				
18973.4(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 PRC section 42032.2(a)(1)(F), education and outreach efforts, and ways in which challenges are being addressed.				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(c)	Collection System. Description of the following:				
18973.4(c) (1)	How ultimate users had an opportunity to dispose of their covered drug(s) as described in the approved stewardship plan.				
18973.4(c) (2)	Efforts between the program operator and potential authorized collectors to establish authorized collection sites, including, but not limited to:				
18973.4(c) (2)(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.				
18973.4(c) (2)(B)	Pursuant to section 18973.2(d)(3), the process by which good faith negotiations with potential authorized collectors were conducted.				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(c) (2)(C)	Pursuant to section 18973.2(d)(4), efforts to work with retail pharmacies and retail pharmacy chains to fulfill the requirement in PRC section 42032.2(b)(2), if applicable.				
18973.4(c) (2)(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.				
18973.4(c) (2)(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.				
18973.4(c) (2)(F)	Description of how the program operator complied with the requirement in section 18973.2(d)(7).				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(c) (3)	How the convenience standards pursuant to PRC section 42032.2(a)(1)(F) 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.				
18973.4(c) (4)	For each participating authorized collection site, include the following:				
18973.4(c) (4)(A)	Name and physical address				
18973.4(c) (4)(B)	Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4)				
18973.4(c) (4)(C)	Number of instances that collected covered drugs were picked up for disposal				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(c) (4)(D)	Number of receptacle liners picked up for disposal				
18973.4(c) (4)(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.				
18973.4(c) (5)	For each type of mail-back service utilized, include the following, as applicable:				
18973.4(c) (5)(A)	List of distribution locations				
18973.4(c) (5)(B)	Mechanism(s) of distribution				
18973.4(c) (5)(C)	Amount of mail-back materials distributed, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)				
18973.4(c) (5)(D)	Amount of mail-back material returned, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(c)(6)	For each alternative form of collection and disposal, include the following, as applicable:				
18973.4(c)(6)(A)	Method(s) of collection				
18973.4(c)(6)(B)	Name and address of location(s)				
18973.4(c)(6)(C)	Number of collections				
18973.4(c)(6)(D)	Amount of materials distributed, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)				
18973.4(c)(6)(E)	Amount of material collected, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)				
18973.4(d)	Transportation and Disposal System. Description of the methods used for transportation and disposal of covered drugs, including the following:				

PRC section	Requirement	Complete per 14 CCR section 18973(d)? (Yes/No)	Requirement Met? (Yes/No/Partially)	Reported metric or summary of how requirement was addressed, including annual report page numbers	Comments
18973.4(d) (1)	Mechanism(s) for tracking the collection, transportation, and disposal of covered drugs				
18973.4(d) (2)	Name and mailing address of each service provider used to transport or process covered drugs				
18973.4(d) (3)(A) through (C)	For each disposal facility, include the following: (A) Name of disposal facility (B) Mailing and physical address (C) Weight of covered drugs disposed				
18973.4(e)	Policies and Procedures. Pursuant to PRC section 42033.2(b)(6) provide the following:				
18973.4(e) (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				

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18973.4(e) (2)	Description of each instance of noncompliance from stewardship plan policies and procedures, if any occurred				
18973.4(e) (3)	Corrective actions taken, or that will be taken, if the program operator discovered critical instances of noncompliance with stewardship plan policies and procedures				
18973.4(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.				

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18973.4(g)	Ordinance Repeal. Pursuant to PRC section 42032.2(e), 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 PRC section 42032.2(a)(1)(F).				

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18973.4(h) (1) through (5)	<p>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:</p> <ul style="list-style-type: none"> (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 				

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18973.4(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:				
18973.4(i)(1)	Electronic examples of promotional marketing materials				
18973.4(i)(2)	Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(j)(5)				
18973.4(i)(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				
18973.4(i)(4)	Description of how the requirement of PRC section 42031.6(b) was met.				

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18973.4(j)	Covered Entities, Covered Products, and Authorized Collectors. List of the following:				
18973.4(j)(1)(A) through (D)	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				
18973.4(j)(2)	A copy of the list of covered products submitted to the Board of Pharmacy pursuant to PRC section 42031(a)(2).				
18973.4(j)(3)(A) through (D)	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				
18973.4(k)	Description and evaluation of the process for selecting service providers, if applicable.				

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18973.4(l)	Description of any grants, loans, sponsorships, reimbursements, or other incentives provided, as applicable.				
18973.4(m)	Description of changes in staffing of the stewardship program.				
18973.4(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).				
18973.4(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.				

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18973.4(p)	State Agency Determinations pursuant to PRC section 42032.2(a)(1)(C). Submit all agency determination(s) of compliance, noncompliance, and superseding determinations of compliance, if any, for the reporting period.				