

14. CalRecycle Adoption of Proposed Regulation  
(9-30-20)

- a. Request for Approval

# REQUEST FOR APPROVAL

**To:** Ken DaRosa  
Acting Director

**From:** Clark Williams  
Branch Chief, Materials Management and Local Assistance  
Division

**Request Date:** September 28, 2020

**Decision Subject:** Adoption of Proposed Pharmaceutical and Sharps Waste  
Stewardship Program Regulations

**Action By:** October 1, 2020

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## Summary of Request:

Staff request adoption of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations to implement the Pharmaceutical and Sharps Waste Stewardship Act [[Chapter 1004, Statutes of 2018 \(Jackson, Senate Bill 212\)](#)].

## Recommendation:

Staff recommend adoption of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations and direction to forward the regulatory package to the Office of Administrative Law for approval and publishing. Staff also recommend that the department file a Notice of Exemption with the State Clearinghouse as provided under the California Environmental Quality Act.

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## Action:

On the basis of the information and analysis in this Request for Approval, I hereby approve the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations and direct staff to forward the regulatory package to the Office of Administrative Law for approval and publishing. I also direct staff to file a Notice of Exemption with the State Clearinghouse as provided under the California Environmental Quality Act.

Signed by Ken DaRosa

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Ken DaRosa, Acting Director

September 30, 2020

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Dated

## **Attachments:**

Attachment 1 – [Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations](#)

Attachment 2 - the Pharmaceutical and Sharps Waste Stewardship Act [\[Chapter 1004, Statutes of 2018 \(Jackson, Senate Bill 212\)\]](#)

### **Background Information**

Senate Bill (SB) 212 (Jackson, Chapter 1004, Statutes of 2018) established the Pharmaceutical and Sharps Waste Stewardship Act (Act). The Act requires manufacturers or distributors of covered drugs or sharps to be covered by an approved stewardship program that provides for the safe, secure, and convenient collection and disposal of covered drugs and home-generated sharps waste.

Stewardship plans and budgets must be submitted to CalRecycle no later than July 1, 2021. The plans must be fully implemented 270 days after the department approves them. Prior to submittal to CalRecycle, stewardship plans must be submitted to the State Board of Pharmacy (BOP), and any other applicable state agency, for review with applicable rules and regulations under the purview of those respective entities. Program budgets and annual reports must be submitted to CalRecycle for review and approval on or before March 31, 2022, and each year thereafter.

A stewardship plan for covered drugs must describe the convenient collection system that will be established. A mail-back program for covered drugs must be provided for any counties where there is not a retail pharmacy operating as a collection site. Prepaid, preaddressed mail-back materials or an alternative form of collection and disposal must be provided to individuals who are homeless, homebound, or disabled. Alternative methods of collection must be provided for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs. A stewardship plan for home-generated sharps waste must describe how containers and mail-back materials will be provided at the point of sale. Stewardship plans must include a comprehensive education and outreach program. Stewardship organizations must pay a quarterly administrative fee to reimburse state agencies for any costs incurred in administering and enforcing the provisions of the law. State agencies include, but are not limited to, CalRecycle and BOP.

CalRecycle is tasked with specific oversight and enforcement responsibilities, including, but not limited to, review and approval of stewardship plans, annual budgets and reports, conducting audits of stewardship programs, and determining stewardship programs' compliance with the Act. CalRecycle must post on its website a list of all stewardship organizations, covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains in compliance with the Act and its implementing regulations. Within 12 months of a program operator's submittal of three consecutive complete annual reports, CalRecycle will publish a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of

covered drugs or home-generated sharps waste. CalRecycle is required to adopt regulations for the implementation of the Act with an effective date of no later than January 1, 2021. The proposed regulations add clarity and establish administrative procedures covering: definitions; criteria to determine a covered entity; submittal and approval instructions for stewardship plans, program budgets, and annual reports; stewardship plan and annual report components; recordkeeping requirements; administrative fees to the department; audits; product verification requirements for distributors, wholesalers, pharmacies, and retailers; criteria and procedure for imposing administrative civil penalties; and procedures for plan revocation, resubmittal, and/or additional compliance reporting.

The legislature has provided CalRecycle authority to promulgate regulations whenever there is substantial evidence that regulations are needed to implement, interpret, make specific, or to govern CalRecycle's procedure to effectuate the purpose of the statute. These regulations add clarity and establish the administrative procedures necessary for CalRecycle to fulfill its responsibilities under the Act.

### **Rulemaking Timeline**

From January through June 2019, CalRecycle staff conducted research, held internal and external scoping meetings, and conducted four informal public workshops to gather stakeholder feedback on regulatory concepts and draft informal regulatory text.

The formal rulemaking process began in December 2019. A 45-day public comment period for the First Draft of Proposed Pharmaceutical and Sharps Waste Stewardship Regulations began on January 3, 2020 and concluded with a public hearing on February 19, 2020. After considering comments received from the 45-day comment period and the public hearing, staff revised the proposed regulations and initiated a 15-day public comment period for the Second Draft of Proposed Regulations from July 15, 2020 through August 3, 2020. A second 15-day public comment period was initiated on August 21, 2020 through September 4, 2020 for the Third Draft of the Proposed Regulations. CalRecycle initiated a 15-day public comment period on August 21, 2020 through September 4, 2020 for minor changes made to the Economic and Fiscal Impact Statement and Appendix.

### **Summary of Revisions Incorporated as a Result of Comments Received During the Formal Public Comment Periods**

CalRecycle made the following substantive changes to the proposed regulations based on the formal comments received. Please refer to CalRecycle's Pharmaceutical and Sharps Waste Stewardship web page for the first, second, and third drafts of the proposed regulations at: <https://calrecycle.ca.gov/laws/rulemaking/pharmasharps>.

Section 18972.1. Definitions.

- Decided not to define “inert.” Several stakeholder comments asserted the subjective nature of this term and that, without a definition, CalRecycle may inappropriately approve the use of disposal methods that are not in compliance with local, state, and federal laws and regulations. CalRecycle does not have authority to determine if a specific disposal system would render a covered drug inert. CalRecycle decided to rely on the statutory language and to defer to agencies with direct authority to determine if a specific disposal system renders a covered drug inert.
- Clarified “provides or initiates distribution of a sharps waste container” to balance stakeholder concerns regarding the immediate distribution of sharps waste containers for consumer convenience with logistical concerns related to timing, space, and costs associated with distributing a sharps container.
- Added definition of “repeal” to clarify that the repeal of a local stewardship ordinance means that the local program established by the ordinance must be permanently “dissolved” as described in section 42032.2(c) of the statute before that local jurisdiction can participate in a department-approved stewardship program.
- Decided not to define “significant change.” This allows CalRecycle to work with program operators on a case-by-case basis to determine what constitutes a significant change to an approved stewardship plan.

#### Section 18972.2 Criteria for Determining a Covered Entity.

- Clarified that CalRecycle will utilize the statutory language in Public Resources Code section 42030(f) to determine a covered entity. Stakeholders requested additional clarity regarding the criteria the department would use for determining a covered entity. The department will continue to work with stakeholders as they determine if they are a covered entity based on the statutory tiered definition.

#### Sections 18973.2 and 18973.3 Stewardship Plans for Covered Drugs and Home-Generated Sharps Waste

- Clarified the scope of the State Agency Determinations and Compliance Certification submission requirements pursuant to the concern of some stakeholders that it is unclear what program operators are certifying and what they may be held responsible for, and that the timeframe applicable for compliance certifications is ambiguous.
- Removed “conflict” and “duplication” as reasons that require program operators to coordinate efforts in the event that multiple programs are operating concurrently to reduce the risk that coordination among program operators would be in conflict with federal and state provisions. Program operators may have

conflicts and duplicative services as each program operator works to independently satisfy statutory and regulatory requirements.

#### Sections 18973.4 and 18973.5 Annual Report for Covered Drugs and Home-Generated Sharps Waste

- Added additional requirements for the description and evaluation of the comprehensive educational and outreach activities contained within annual reports so that the department can assess the effectiveness of the activities.
- Clarified that safety and security incident descriptions included in the annual reports should be general in nature and that CalRecycle may request specific information about any incident. These changes reduce the reporting burden on program operators.

#### Section 18973.6 Program Budgets.

- Combined budget categories to minimize the burden on program operators while still allowing CalRecycle to fulfill its oversight responsibilities. Separate categories of collection, transportation, processing, and disposal costs were consolidated into one category of “costs of collection, transportation, and disposal of covered products.” This change was made in response to concerns raised by stakeholders regarding their limited ability to adequately report separate costs because service providers aggregate the costs when billing for these services.
- Removed the requirement that audits conducted by a Certified Public Accountant must be performed according to Generally Accepted Government Accounting Standards which are not applicable to non-governmental entities. Revised the regulations to require audits be conducted according to generally accepted auditing standards in the United States of America.

#### Sections 18975 Criteria to Impose Administrative Civil Penalty, 18975.1 Procedure for Imposing Administrative Civil Penalties, and Section 18975.2 Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting

- These sections were revised to clarify the procedures for imposing penalties and revoking stewardship plans. Some stakeholders asserted that: (1) CalRecycle does not have authority to issue notices of violation prior to imposition of penalties; (2) its notice and hearing procedures do not comport with minimum due process requirements; and (3) CalRecycle does not have authority under the Act to impose penalties on program operators and stewardship organizations that do not sell, offer for sale, or provide covered products or take appropriate enforcement actions based on violations of the Act and its implementing

regulations. CalRecycle declined to revise these sections for the following reasons: CalRecycle is not prohibited by statute from issuing notices of violation prior to imposition of penalties; CalRecycle is not abrogating due process rights by not explicitly mentioning them in the regulations; CalRecycle has statutory authority to impose penalties on program operators and stewardship organizations that do not sell, offer for sale, or provide covered drugs; and CalRecycle has broad authority to implement the authorizing statute, which includes ability to take enforcement actions for violations of the regulations, not only violations of the authorizing statute.

### **Compliance with the California Environmental Quality Act (CEQA)**

The adoption of the regulations is exempt from CEQA because it is not a “project,” as that term is defined in the CEQA Guidelines (Cal. Code of Regs, Title 14, Sections 15000 et seq.). A “project” is an activity “which has a potential for resulting in either a direct physical change in the environment, or a reasonably foreseeable indirect physical change in the environment...” (CEQA Guidelines, Section 15378(a).). The regulations only establish administrative procedures for CalRecycle, covered drug and sharp manufacturers, and other covered entities subject to the underlying statute.