

SB 212 Informal Rulemaking Public Workshop: Informal Draft Regulatory Text

Presented at the May 17, 2019 and June 17, 2019
Public Workshops

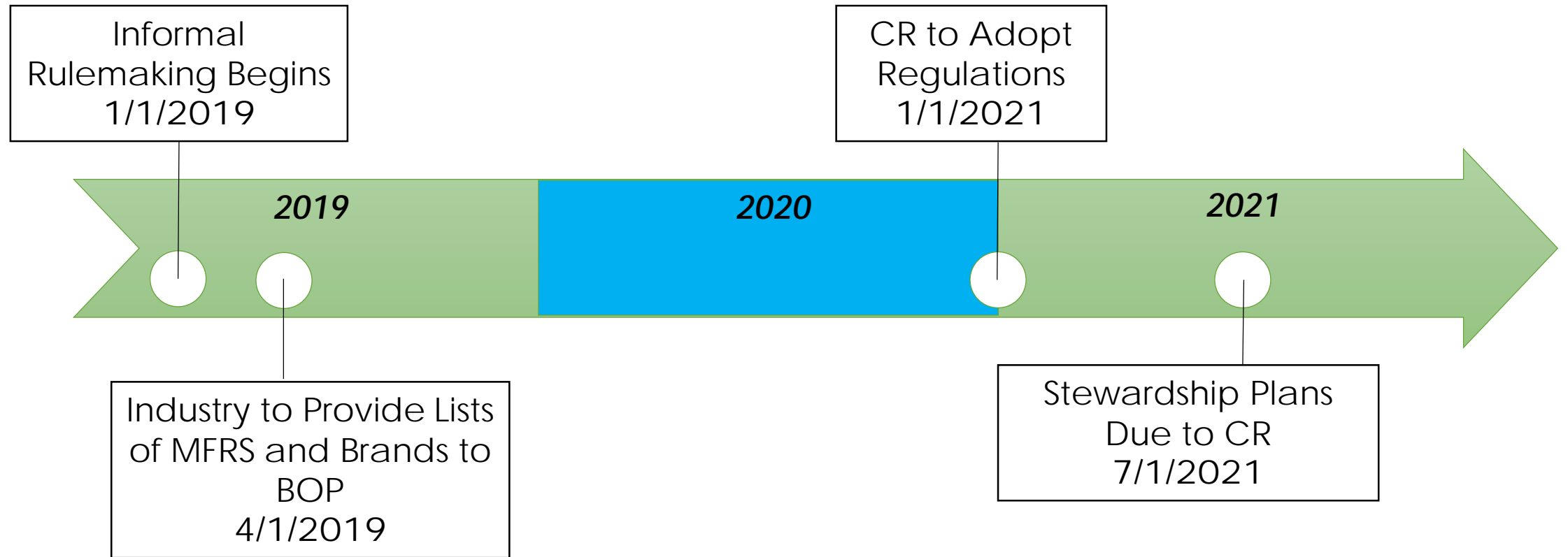


Introduction

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SB 212 Implementation Timeline



CR – CalRecycle

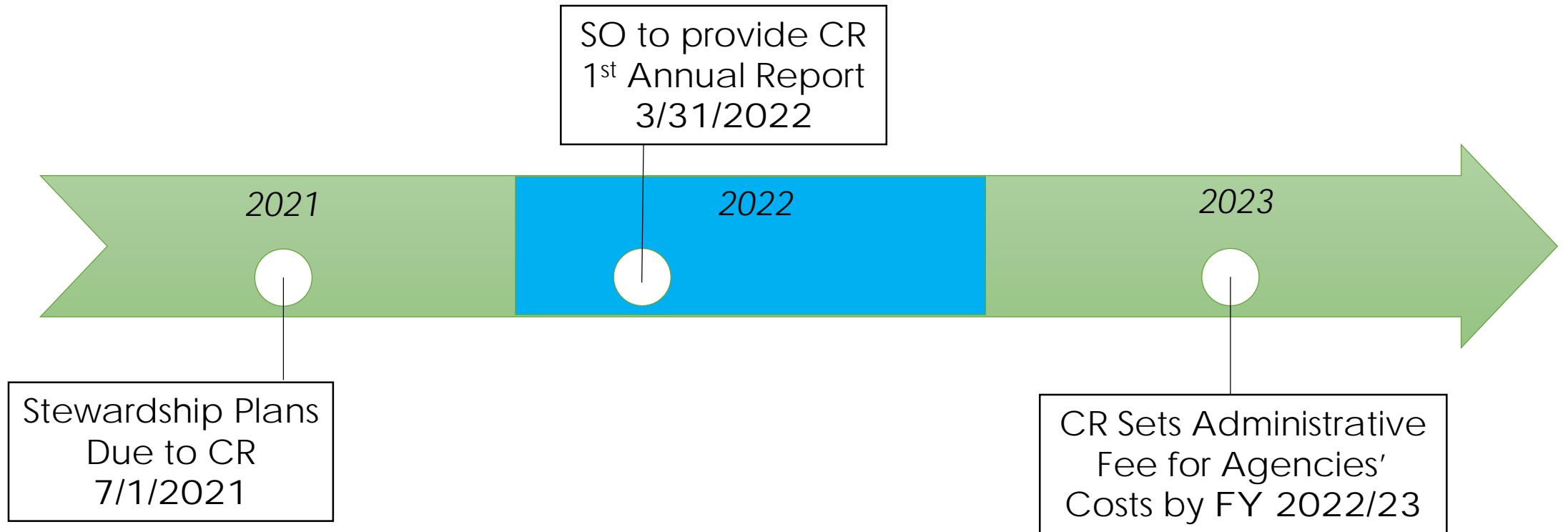
BOP – Board of Pharmacy

SO – Stewardship Organization

Text Description of the SB 212 Implementation Timeline

1. Informal Rulemaking Begins 1/1/2019
2. Industry to Provide Lists of Manufacturers and Brands to the Board of Pharmacy
3. CalRecycle to Adopt Regulations 1/1/2021
4. Stewardship Plans Due to CalRecycle 7/1/2021

SB 212 Implementation Timeline



CR – CalRecycle
BOP – Board of Pharmacy

SO – Stewardship Organization

Text Description of the SB 212 Implementation Timeline Continued

1. Stewardship Plans Due to CalRecycle 7/1/2021
2. Stewardship Organization to provide CalRecycle First Annual Report 3/31/2022
3. CalRecycle Sets Administrative Fee for Agencies' Costs by fiscal year 2022/2023

Outline of Regulation Structure

I. Purpose

II. Definitions

III. Criteria for Determining a Covered Entity

IV. Submittal of Product Lists

V. Stewardship Plan Submittal for Covered Drugs

VI. Stewardship Plan for Covered Drugs

VII. Stewardship Plan Submittal for Home-Generated Sharps Waste

VIII. Stewardship Plan for Home-Generated Sharps Waste

IX. Annual Report Submittal for Covered Drugs

X. Annual Report for Covered Drugs

XI. Annual Report Submittal for Home-Generated Sharps Waste

XII. Annual Report for Home-Generated Sharps Waste

XIII. Program Budget Submittal

Outline of Regulation Structure (continued)

XIV. Program Budgets

XV. Record Keeping Requirements

XVI. Administrative Fee to Department of Resources Recycling and Recovery

XVII. Stewardship Organization Audits of Covered Entities

XVIII. Retailer, Wholesaler, Distribution Product Verification

XIX. Criteria to Impose an Administrative Penalty

XX. Procedure for Imposing Administrative Penalties

I. Purpose

Implement Senate Bill 212 that adds Chapter 2 to Part 3 of Division 30 of the Public Resources Code

II. Definitions (b)

“Administrative and operational costs” mean costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department pursuant to subsection (1) of subdivision (a) of section 42034.2 of the Public Resources Code.

II. Definitions (c-d)

- **“Homebound”** has the same meaning as defined in the Medicare Benefit Policy Manual, Chapter 15, 60.4.1.
- **“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. (42 U.S.C. section 254b).

II. Definitions (e)

“Home-generated sharps waste,” as defined by section 117671 of the Health and Safety Code, is defined to include sharps waste that is generated from in-home medical care as well as from a Residential Care Facility for the Elderly, as defined in Title 22, Division 3, Chapter 8, section 58032 of the California Code of Regulations.

II. Definitions (f)

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

II. Definitions (g-h)

- **“Minutes, books, and records”** means accurate and up-to-date information regarding a program operator’s activities.
- **“Prescription”** has the same meaning as defined in Division 2, Chapter 9, section 4040 of the Business and Professions Code.

II. Definitions (i)

- **“Significant change”** to an approved stewardship plan includes, but is not limited to:
 - (1) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method.
 - (2) Any changes to a stewardship program that are required by federal or state laws or regulations adopted or revised after approval of the stewardship plan.
 - (3) Any changes to the convenience standards put forth in subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.

II. Definitions (j)

42030(y) of the Public Resources Code

“**Stewardship program**” means a stewardship program for the collection, transportation, and disposal of covered products.

42036.2(a) of the Public Resources Code

This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. If that ordinance is repealed in the jurisdiction or, if more than one ordinance is applicable, those ordinances are repealed in the jurisdiction, the drug or sharp shall be subject to this chapter in that jurisdiction within 270 days after the date on which the ordinance is, or ordinances are, repealed.

III. Criteria for Determining a Covered Entity

PRC section 42030 (f) (2) requires the development of the Criteria for determining a Covered Entity. Specifically the PRC states:

- “The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1)” of PRC section 42030 (f) (1) (A).
- The proposed language builds directly off of statute:
 - IDs the manufacturers of covered products as first to be responsible (PRC section 42030 (f) (1) (A).
 - If this entity cannot be identified, the regulations propose using the statutory priority order found in PRC section 42030(f) (1) (B)-(E).

IV. Submittal of Product Lists

Product lists shall be submitted pursuant to subdivision (a) of section 42031 of the Public Resources Code.

V. and VII. Stewardship Plan Submittals

- (a) Contact Information
- (b) Electronic/hard copy submittal letter
- (c) Accessibility standards
- (d) Hard copy submittal
- (e) Review for completeness

VI. Stewardship Plan For Covered Drugs

- (a) Plan compliance including DEA regulations
- (b) Corporate officer – contact information
- (c) Covered entities – contact information
- (d) Covered products – verified list
- (e) Authorized Collectors – contact information
- (f) Department notification of changes to (b), (c) &(e)

VI. Stewardship Plan For Covered Drugs

(g) Authorized collection sites

- (1) List of potential authorized collectors
- (2) Efforts to negotiate with collectors
- (3) Notification of retail pharmacies to serve
- (4) Retail pharmacy chain requirements
- (5) Inclusion of authorized collectors

(h) Agency determinations

(i) Program funding

VI. Stewardship Plan For Covered Drugs

(j) Handling, transportation, and disposal systems

- | | |
|-----------------------------|--|
| (1) Processes and policies | (7) Mail-back services |
| (2) Collection systems | (8) Other method(s) of collection |
| (3) Convenience standards | (9) Service schedules |
| (4) Geographic spread | (10) Process for selecting contractors |
| (5) Recalculation frequency | (11) Grants or reimbursements |
| (6) Tracking mechanism(s) | (12) Program staffing |

VI. Stewardship Plan For Covered Drugs

- (k) Collection and disposal system records
- (l) Ordinance repeals
- (m) Education and outreach
- (n) Confidentiality of policies and procedures
- (o) Clarifying information

VIII. Stewardship Plan For Home-Generated Sharps Waste

Similar to covered drugs plan

Unique components omitted in the sharps plan:

- Authorized collector contact information
- Authorized collection sites
- Minimum convenience standards

VIII. Stewardship Plan For Home-Generated Sharps Waste

(g) Handling, transportation, and disposal System – Sharps Plan has 8 components vs. 12 components in the Covered Drugs Plan

Omitted from sharps plan:

- Convenience standards
- Geographic spread
- Recalculation frequency
- Service schedule

Sharps plan combined tracking and record keeping

VIII. Stewardship Plan For Home-Generated Sharps Waste

(j) Education and outreach

- Website and toll-free phone number components
- Information on collection sites is omitted

IX and XI. Annual Report Submittal

- Similar to other submittal requirements
- Review for completeness and approval

The regulations do not currently provide additional clarification on the process for review of reports for completeness and approval as set forth in subdivision (d) & (e) of section 42033.2 of the Public Resources Code.

X. Annual Report For Covered Drugs

- (1) Contact information
- (2) Executive Summary
- (3) Collection System
 - (A) Establishment of collection sites
 - (B) Disposal opportunities for ultimate users
 - (C) Achievement of convenience standard
 - (D) Best management practices
 - (E), (F) and (G) Collection data

We are aware that the reported weight for drugs will also include the liners, bin, etc. Are there any other parameters that should be included to evaluate the achievement of the convenience standard?

X. Annual Report For Covered Drugs

(4) Transportation and Disposal

(5) Safety and Security

(6) Education and Outreach

(A) Description of activities

(B) Methods

(C) Website address and phone number

(D) Evaluation of effectiveness

X. Annual Report For Covered Drugs

(7) Policies and Procedures

(8) Verification

(9) Significant Changes

(10) Agency Determination

(11) Audits

X. Annual Report for Covered Drugs (and Sharps Waste)

Stewardship Plan requirements (j)

(10) Describe the process for selecting contractors.

(11) Explain the process for providing grants or reimbursements to local jurisdictions or service providers.

(12) Describe the staffing of the stewardship program.

X. Annual Report For Covered Drugs (and Sharps Waste)

- Generalized statutory requirement:
- Subdivision (b) of 42033.2 Public Resources Code
- (8) How the program operator complied with all elements in it's stewardship plan.

XII. Annual Report For Sharps Waste

(3) Collection System:

- Sharps Waste has 5 components, Covered Drugs has 7 components

Omitted requirement for:

- convenience standard requirement
- establishment of collection sites

(7) Verification is currently the same as covered drugs and includes:

- Authorized collector and authorized collection sites

XII. Annual Report For Sharps Waste

42033.5 of the Public Resources Code

For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal pursuant to Section 42032.2, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator.

XIII. Program Budget Submittal

Two types of program budgets are mentioned in statute:

1 – An initial stewardship program budget, covering the program's first five years, which is submitted along with the stewardship plan

2 – An annual program budget which is submitted on a yearly basis.

- The annual budget *may be submitted electronically per department instructions on or before March 31, 2022 and each year thereafter.
- The first annual program budget will cover two time periods:
January 1, 2021 to December 31, 2021 & January 1, 2022 to December 31, 2022
- The intent of the document is to answer two program budget questions:
 - What happened during the first year? - 2021
 - What is budgeted for this year? - 2022

Subsequent reports will cover the upcoming calendar year, i.e., the report due March 31, 2023 will cover January 1, 2023 to December 31, 2023. The audit submitted will answer the question of what financially happened during the year.

XIV. Program Budget

Annual program budgets include:

- Anticipated costs - with narrative description of the cost categories, along with the recommended funding level necessary for implementation, and
- An independent CPA financial audit of the stewardship program

XV. Record Keeping Requirements (a)(1)-(3)

- The provisions of this section require any of the following to maintain records: Covered entities, stewardship organizations, program operators, manufacturers, retail pharmacies and retail pharmacy chains
- Reasonable and timely access to facilities, operations, and relevant records must be provided to the department upon request
- Records must be kept for at least three years following the submission of an annual report that relies on the records

XV. Record Keeping Requirements (a)(4)

- Retail pharmacies and retail pharmacy chains must provide access to existing records on all covered products sold or offered for sale in the state including:
 - (i) The manufacturer of the covered product(s).
 - (ii) The date(s) the retailer purchased the covered product(s) from the manufacturer, distributor and/or wholesaler.
 - (ii) The date(s) the retailer sold the covered product(s).
 - (iii) Certification letter(s) from the department, if provided by a manufacturer, to demonstrate that a particular covered product from the manufacturer is or was subject to a department-approved covered product stewardship plan. A retail pharmacy/retail pharmacy chain must provide access to a certification letter only if it is being used as proof of compliance, pursuant to subsection (b) of section 42035 of the Public Resources Code, that a covered entity or stewardship organization not listed on the department's internet website is in compliance and may sell or offer for sale pharmaceuticals and/or sharps in California.

XVI. Administrative Fee to the Department, and XVII. Stewardship Organization Audits of Covered Entities

- **XVI.** The department will set the administrative fee pursuant to sections 42034 and 42034.2 of the Public Resources Code.
- **XVII.** Stewardship organizations may conduct an audit of covered entities pursuant to section 42034.4 of the Public Resources Code and will provide the department a copy if they do so.

XVIII. Retailer, Wholesaler, Distribution Product Verification

Requirements for each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or dispenses a covered product

- The proposed language outlines the process to obtain a “proof of website monitoring certificate” from the Department.
- The certificate is to be maintained/updated when an entity sells, offers for sale, or dispenses a new covered product/covered manufacturer.
- If a particular manufacturer or covered product cannot be verified the entity will be provided the option to report the manufacturer/covered product to the Department (consistent with PRC section 42035 (c)).

XIX. Criteria to Impose an Administrative Penalty

This section of the regulations outlines the factors that are proposed to be considered by the Department when determining the amount of a penalty

- (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 negligent
- (4) The size 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 chapter 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 that justice may require

XX. Procedure for Imposing Administrative Penalties

- The statute provides the authority to administratively issue penalties. In summary, this means the Department can have “informal administrative hearings” .
- This section outlines the process the Department will undertake to provide “due process” to any entity found to be noncompliant with the law.
- The process is consistent with the Administrative Procedures Act

Next Steps

June 17, 2019	Informal Rulemaking Workshop #4 in Diamond Bar, CA on Informal Draft Regulatory Text
October 2019	Begin Formal Rulemaking
January 1, 2021	Adopt Final Regulations

Questions?

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Website: <https://www.calrecycle.ca.gov/epr/pharmasharps/>
Listserv: <https://www2.calrecycle.ca.gov/Listservs/Subscribe/73>

