

## REQUEST FOR APPROVAL

**To:** Rachel Machi Wagoner  
Director

**From:** Zoe Heller  
Deputy Director, Policy Development

**Request Date:** December 8, 2021

**Decision Subject:** Consideration of MED-Project's Product Stewardship Plan for Covered Drugs from Households

**Action By:** December 13, 2021

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### **Summary of Request**

MED-Project USA (MED-Project) submitted its stewardship plan for covered drugs, which includes its initial program budget, titled, *A Product Stewardship Plan for Covered Drugs from Households* (Drugs Plan) to the Department of Resources Recycling and Recovery on September 14, 2021, pursuant to section 42032(a)(1) of the Public Resources Code. This Request for Approval presents staff's analysis and compliance recommendation regarding MED-Project's Drugs Plan.

### **Staff Analysis**

#### **Background**

Senate Bill 212 (Jackson, Chapter 1001, Statutes of 2018) established the statewide Pharmaceutical and Sharps Waste Stewardship Act (Act), requiring the first statewide stewardship program for both covered drugs and home-generated sharps waste in the country. Stewardship programs for covered drugs are primarily required to be secure collection receptacle programs supplemented with mail-back programs. Under the Act, a program operator, which is either a covered entity or a stewardship organization established on behalf of a group of covered entities, must design and operate a statewide stewardship program for the proper collection and disposal of covered products at no cost to consumers. A covered entity can be a manufacturer, distributor, wholesaler, repackager, owner or licensee of a trademark or brand, or importer as defined in Public Resources Code (PRC) section 42030(f)(1), (see Attachment 1). Additional responsibilities of program operators include operating a comprehensive education and outreach program, submitting annual reports and annual budgets to the Department of Resources Recycling and Recovery (CalRecycle), and paying CalRecycle an administrative fee every three months that covers CalRecycle's, and any other state agency's, costs of implementation related to oversight and enforcement. Because other state agencies have authority over the covered products or the handling, transport, and/or disposal of covered products, those state agencies, including, but not limited to the California State Board of Pharmacy and California Department of Public

Health, are responsible for providing program operators compliance determinations with respect to the applicable laws and regulations they oversee prior to a program operator's submittal of its stewardship plan to CalRecycle. Additionally, annually on or before January 15, a covered entity, or a stewardship organization on behalf of a group of covered entities, must submit updated covered product lists to the California State Board of Pharmacy. For covered entities to be in compliance, a covered product sold or offered for sale in or into California must be subject to an approved stewardship plan within one year of the date of adoption of the implementing regulations (i.e., January 7, 2022). The covered entity can operate a stewardship program individually or be part of a stewardship organization with an approved stewardship plan. A program operator must fully implement the program described in that plan within 270 days of CalRecycle approval of its stewardship plan.

CalRecycle adopted regulations to approve, conditionally approve, or disapprove covered drugs and sharps stewardship plans, annual reports, and annual budgets and provide oversight and enforcement of the Act. CalRecycle is also required to post a list of stewardship organizations and other entities that are in compliance with the Act and to coordinate with the California State Board of Pharmacy to obtain verified lists of covered products. Enforcement for non-compliance is addressed through administrative civil penalties, through revocation of an approved plan, and/or through other methods outlined in the implementing regulations.

PRC section 42032 requires that within six months of the adoption date of implementing regulations, a program operator shall submit to CalRecycle for approval a complete stewardship plan that meets the applicable requirements of PRC section 42030 *et seq.* and Title 14 of the California Code of Regulations (CCR) section 18972.1 *et seq.* (see Attachment 2), for the establishment and implementation of a stewardship program. CalRecycle's regulations became effective January 7, 2021. Therefore, stewardship plans were due to CalRecycle by July 7, 2021, unless the deadline was tolled by the California State Board of Pharmacy's review. CalRecycle has 90 days to review and approve, disapprove, or conditionally approve plans pursuant to PRC section 42032(d). CalRecycle's 90-day review period may be extended if CalRecycle needs to consult with another state agency.

MED-Project is a stewardship organization that represents over 300 covered entities under its proposed Drugs Plan (see Attachment 4 for a list of covered entities. Attachments 3 through 7 comprise the entirety of MED-Project's Drugs Plan). MED-Project also operates covered drugs or sharps stewardship programs in 13 local jurisdictions in California. Overall, staff found MED-Project's Drugs Plan substantially compliant with all material requirements in CCR sections 18973, 18973.2, and 18973.6, but additional information from and additional actions by MED-Project are necessary (see CCR section 18973.1(e)). The components of MED-Project's Drugs Plan which are deficient, and the conditions MED-Project must meet for CalRecycle to approve its Drugs Plan, pursuant to CCR section 18973.1(g), are described below.

## **MED-Project Drugs Plan Areas of Identified Deficiencies**

### **1. Program Budget and Funding**

Requirements: Demonstrate adequate funding for all costs, including administrative and operational costs, pursuant to PRC section 42032.2(a)(1)(D). Include a description of the types of activities relative to line items outlined in CCR section 18973.6(b), pursuant to PRC section 42032.2(a)(1)(D) and CCR sections 18973.2(f) and 18973.6(e). Funding level must cover the stewardship plan's budgeted costs to operate the stewardship program over a multi-year period pursuant to PRC section 42033(b). Provide a recommended reserve amount and justification pursuant to CCR section 18973.6(c).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled "CalRecycle Condition 1."

MED-Project's Drugs Plan includes an initial five-year budget that covers anticipated costs to implement the program from October 5, 2021, through December 31, 2025, and describes the types of activities for each line-item cost category specifically listed in CCR section 18973.6(e). MED-Project does not fully demonstrate adequate funding for all administrative costs for the first five calendar years of operation pursuant to CCR section 18973.2(f). The estimates for the departmental administrative fee are not included in MED-Project's five-year budget despite CalRecycle providing the departmental administrative fee estimate to MED-Project in advance of its Drugs Plan submittal. Additionally, MED-Project's Drugs Plan states that the fiscal year budget will be prepared in advance of the calendar year. However, statute requires a calendar year budget and the Drugs Plan "fiscal year budget" does not appear to align with the statutory requirement for a calendar year budget.

MED-Project proposes a reserve level range of 25 to 75 percent of its annual program budget and to maintain available "cash and reserves" to cover six months of the annual program budget. MED-Project does not provide a specific reserve level amount or line item in the budget as required pursuant to CCR section 18973.6(c) and (e), nor does MED-Project clarify what is meant by "cash and reserves" and how it relates to the reserve range that is to be maintained in a prudent and responsible manner pursuant to CCR section 18973.6(c). MED-Project must specify a reserve level amount within its proposed reserve level range.

CalRecycle Condition 1: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Include departmental administrative fees in the initial program budget as either a separate line item or part of the administrative costs line item, pursuant to CCR section 18973.6(b). Provide an amount for the departmental administrative fees. (The requirements necessitating these conditions appear

in PRC sections 42032.2(a)(1)(D) and 42033(b), and CCR sections 18973.2(f) and 18973.6(b), (d), and (e)).

- b. Clarify the description of “fiscal year” so that it is clear that MED-Project’s fiscal year will not conflict with its obligation to submit annual calendar year budgets to CalRecycle that meet all statutory and regulatory requirements. (The requirement necessitating this condition appears in CCR section 18973.6).
- c. Include a reserve level amount in the budget. (The requirements necessitating this condition appear in CCR sections 18973.6(c) and 18973.6(e)).
- d. Clarify the meaning of “cash and reserves,” including how it relates to the reserve range and reserve amount. (The requirements necessitating these conditions appear in CCR section 18973.6(c)).

## **2. Education and Outreach**

Requirements: A comprehensive education and outreach program that includes activities to promote awareness and ultimate user participation in the stewardship program with materials distributed in languages suited to local demographics, as necessary, pursuant to PRC section 42031.6 and CCR sections 18973.2(j)(1) and (2). Signage shall be designed with explanatory graphics which are readily understandable by all ultimate users pursuant to CCR section 18973.2(j)(2). Establish a website and toll-free telephone number pursuant to CCR section 18973.2(j)(3) and (4). A program operator shall not promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program pursuant to PRC section 42031.6(b) and CCR section 18973.2(j)(7).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled “CalRecycle Condition 2.”

MED-Project proposes to provide hard copy educational and outreach materials in English and Spanish only. Education and outreach materials will be available online in other languages through utilization of a third-party translation tool. MED-Project states that the third-party tool can translate education and outreach materials into over 100 languages, covering 95 percent of spoken languages at the county level. However, MED-Project does not describe how non-English and non-Spanish language users will understand that education and outreach materials are available online in other languages or how users without internet access will be served. Additionally, MED-Project proposes a call center that has translators available to provide language options suited to local demographics but does not specify how the caller would know how to communicate with the call center representative to obtain information in a language other than English or Spanish.

Sample outreach materials included in the Drugs Plan that provide instructions to ultimate users are not consistent with proper disposal of covered drugs in accordance with MED-Project’s plan, statute, and regulations and may cause confusion. Sample collection receptacle signage contains graphics for items accepted in the collection receptacles, but only text is used to inform ultimate users of the items not accepted,

such as sharps. Explanatory graphics that are readily understandable by all ultimate users must be included on collection receptacle signage for items not accepted.

MED-Project proposes to include a disclaimer on all written and verbal materials distributed that claims: "This material has been supplied for the purpose of compliance with law and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Plan." Education and outreach materials should provide information, consistent with statute and regulations, about the program. MED-Project does not describe in its Drugs Plan what "views" it intends to communicate and why the disclaimer is necessary.

CalRecycle Condition 2: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Explain how non-English and non-Spanish language users will understand that education and outreach materials are available in other languages suited to local demographics and how materials are distributed to these users. (The requirements necessitating this condition appears in CCR 18973.2(j)(1), (2), and (4)).
- b. Explain how non-English and non-Spanish language users will understand that translators are available in the call center when an interactive voice response system is only provided in English and Spanish. (The requirements necessitating this condition appears in CCR 18973.2(j)(1), (2), and (4)).
- c. Clarify that signage and labeling for secure collection receptacles will contain explanatory graphics for items not accepted in the secure collection receptacle. (The requirements necessitating this condition appears in CCR 18973.2(j)(1) and (2)).

### **3. Authorized Collectors**

Requirements: Provide contact information for each participating authorized collector in the stewardship program. Provide a list of potential authorized collectors notified of the opportunity to participate and provide reasons for excluding any potential authorized collector from participating pursuant to PRC section 42032.2(a)(1)(B) and CCR section 18973.2(d).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled "CalRecycle Condition 3."

MED-Project's Drugs Plan includes a list of participating authorized collection sites (see Attachment 6) and a list of potential authorized collectors that were notified of the opportunity to serve as an authorized collector (see Attachment 7) as separate attachments submitted with the Drugs Plan.

In January 2021, MED-Project notified potential authorized collectors of the opportunity to participate in its program. MED-Project describes the proposed

process to negotiate with potential authorized collectors in order to reach an agreement but does not describe continued efforts to notify and negotiate with potential authorized collectors to participate in the program after minimum convenience standards have been achieved. MED-Project states it has not excluded potential authorized collectors from the program as of the Drugs Plan submission, but it will exclude a potential authorized collector if the potential authorized collector is unable to comply with all applicable laws, regulations, and other legal requirements or if an agreement cannot be reached. However, PRC section 42032.2(b)(3) requires inclusion of any potential authorized collectors that offer to participate in writing and without compensation. Potential authorized collectors that negotiate in good faith with MED-Project regarding the terms of agreement must not be excluded.

CalRecycle Condition 3: Pursuant to CCR section 18973.1(g) MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Describe good faith negotiations with potential authorized collectors that will continue to be conducted even after minimum convenience standards have been achieved (The requirements necessitating this condition appear in PRC section 42032.2(b)(1) and CCR section 18973.2(d)(3)).
- b. Clarify that potential authorized collectors will not be excluded from participating in the program when agreement terms cannot be reached. MED-Project's terms must be consistent with the scope of statute, which allows authorized collectors to be accepted into the program if they offer to participate, in writing and without compensation. (The requirement necessitating this condition appears in PRC section 42032.2(b)(3) and CCR section 18973.2(d)(5)).

#### **4. Collection System**

Requirement: Describe a collection system that meets the requirements in PRC section 42032.2(a)(1)(F) for authorized collection sites in each county in which the plan will be implemented. Describe how convenience standards will be met for each county, including 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. Describe how frequently the convenience standards will be re-evaluated to ensure compliance with the convenience standards, including updating population estimates as required by CCR sections 18973.2(g)(2) and 18973.2(g)(6).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet conditions outlined below under the section titled "CalRecycle Condition 4."

MED-Project proposes to establish a system for collecting covered drugs in each county, except for counties that are excluded pursuant to PRC section 42036.2. Collection will occur through receptacles installed at authorized collection sites and

mail-back services. On page 27 of its Drugs Plan, MED-Project states it will “seek to” establish a minimum of five authorized collection sites per county or one per 50,000 ultimate users, whichever is greater. This language does not commit MED-Project to achieving the minimum convenience requirements set in statute. If MED-Project does not meet the minimum convenience requirements it will be out of compliance with PRC section 42032.2(a)(1)(F)(i).

MED-Project proposes to rely on population estimates from the State of California Department of Finance to determine the number of authorized collection sites required in each county to meet convenience standards and to reevaluate the number of authorized collection sites annually within six months of changes to the population estimates. It is unclear whether MED-Project will reevaluate the number of authorized collection sites annually in addition to within six months of changes to the Department of Finance population estimates. MED-Project must reevaluate, annually, the number of collection sites required in each county even if the Department of Finance has not released updated population estimates.

On page 27, MED-Project proposes it will “strive to” establish the geographic spread of authorized collection sites so that greater than 90 percent of ultimate users live within a 15-mile drive of an authorized collection site. This language does not commit MED-Project to its geographic spread goal. Additionally, the Drugs Plan’s description of how the proposed reasonable geographic spread is determined and the factors used to determine the spread is incomplete. The incomplete description will adversely impact both MED-Project’s and CalRecycle’s ability to evaluate whether the geographic spread goal has been achieved.

MED-Project proposes to offer prepaid, preaddressed mail-back services to all ultimate users upon request through its website and call center. The mail-back package options available to ultimate users are defined by MED-Project as standard, inhaler, and injector. The proposed mail-back package contains instructions for using and returning the mail-back package, a description of the type of accepted covered drugs, mailing restrictions, and other disposal options available through the program. To supplement counties that do not have the minimum number of authorized collection sites or where greater than 90 percent of ultimate users do not live within a 15-mile drive of an authorized collection site, MED-Project proposes to conduct additional digital media outreach to promote its mail-back services. Mail-back services are also promoted for disposal of covered drugs that cannot be comingled with other covered drugs such as inhalers and pre-filled injector products. However, MED-Project’s proposed mail-back service is only available through its website or call center. However, not all ultimate users have access to a phone or the internet to request mail-back services. The Drugs Plan does not contain sufficient detail about other mail-back service opportunities, such as mail-back packages provided at distribution locations or alternate forms of collection and disposal. Additionally, it is unclear how MED-Project proposes to accommodate ultimate users without

permanent addresses or access to a phone or internet via mail-back requests through its website and call center if other means of mail-back materials distribution are not provided.

The Drugs Plan does not state that it will provide mail-back services covering any counties where there is not an authorized retail pharmacy operating an authorized collection site, per PRC section 42032.2(a)(1)(F)(iii).

CalRecycle Condition 4: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Remove the phrasing “seek to” and “strive to” in reference to statutory minimum convenience requirements and geographic spread goal. The stewardship plan must state that MED-Project “shall” meet the reasonable geographic spread convenience goal, as defined by MED-Project. (The requirements necessitating this condition appear in PRC section 42032.2(a)(1)(F) and CCR sections 18973.2(g)(2). Clarify that authorized collection sites will be reevaluated annually to determine the number of authorized collection sites needed in each county to meet the convenience standards. (The requirement necessitating this condition appears in CCR section 18973.2(g)(2)(B)).
- b. Describe how reasonable geographic spread is determined, including all the factors applied to develop the determination. (The requirement necessitating these conditions appears in CCR section 18973.2(g)(2)(A)).
- c. Per PRC section 42032.2(c), propose distribution locations that provide prepaid, preaddressed mail-back envelopes or an alternate form of collection and disposal in counties that do not have the minimum number of Authorized Collection Sites. (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(F)(i) and (iii), 42032.2(c) and CCR section 18973.2(g)(6)(A)).
- d. Clarify how ultimate users without permanent addresses or access to a phone or internet can receive mail-back materials through the website or call center (The requirements necessitating this condition appear in PRC section 42032.2(a)(1)(G)(i) and CCR section 18973.2(g)(6)(B)).
- e. Provide mail-back services or an alternative form of collection and disposal system in counties where there is not an authorized retail pharmacy operating an authorized collection site, per PRC sections 42032.2(a)(1)(F)(iii) and 42032.2(c). (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(F)(iii) and 42032.2(c) and CCR section 18973.2(g)(6)).

## **5. Ordinance Repeals**

Requirement: Describe processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions not included in the stewardship plan in the event a jurisdiction repeals its local stewardship program ordinance pursuant to PRC section 42032.2(e) and CCR section 18973.2(i).



Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled “CalRecycle Condition 5.”

On page 38 of its Drugs Plan, MED-Project proposes to expand its stewardship program into a jurisdiction that repeals its local stewardship program ordinance “within 270 days” of the ordinance repeal. MED-Project also proposes to provide services described in the plan in a local jurisdiction that repeals an ordinance “after the end of the 270-day period;” this means that full implementation will not occur within 270 days of an ordinance repeal as required by statute.

CalRecycle Condition 5: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- a. Remove all statements that indicate expansion into a local jurisdiction will occur after (as opposed to within) 270 days from the date a jurisdiction repeals its local stewardship program ordinance. (The requirements necessitating this condition appear in PRC section 42032.2(e) and 42036.2(a), and CCR section 18973.2(i)).

## **6. Coordination Efforts**

Requirement: Coordinate with other program operators to avoid confusion to the public and all program participants pursuant to CCR section 18973.2(k).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled “CalRecycle Condition 6.”

MED-Project proposes coordination efforts with approved program operators that involve the development of a common stewardship program decal, emblem, or logo approved by CalRecycle. MED-Project’s proposal places responsibilities on CalRecycle. MED-Project, in order to avoid confusion to the public and all program participants, must work with other program operators to mutually agree to specific coordination efforts.

CalRecycle Condition 6: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- a. Propose a process to coordinate with approved program operators to avoid confusion to the public and all program participants that is not dependent upon a CalRecycle approval process. (The requirement necessitating these conditions appears in CCR section 18973.2(k)).

## **7. Handling, Transport, and Disposal System**

Requirement: Provide mailing and physical addresses for each service provider used to transport, process, or dispose of covered drugs pursuant to CCR section 18973.2(g)(5)(B).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled “CalRecycle Condition 7.”

MED-Project only provides one address for each vendor and does not specify if the address is mailing, physical, or both pursuant to CCR section 18973.2(g)(5)(B). It is important that all addresses are identified for safety and security purposes related to the handling, transportation, and disposal of covered drugs.

CalRecycle Condition 7: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- a. Include all mailing and physical addresses associated with each vendor. (The requirement necessitating this condition appears in CCR section 18973.2(g)(5)(B)).

## **8. List Submissions**

Requirement: Provide lists of participating covered entities and covered drugs pursuant to PRC section 42032.2(a)(1)(A) and CCR sections 18973.2(b) and (c).

Result: Additional information from and additional actions by MED-Project are necessary. MED-Project must meet the conditions outlined below under the section titled “CalRecycle Condition 8.”

MED-Project's Drug Plan provides a list of participating covered entities (see Attachment 4), and a list of covered drugs (see Attachment 5) as separate attachments submitted with the Drugs Plan. Some covered entities listed are missing required address and contact information pursuant to CCR section 18973.2(b).

CalRecycle Condition 8: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Drugs Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- a. Include all required information in the covered entities list (The requirement necessitating this condition appears in CCR section 18973.2(b)).

## **Stakeholder Feedback**

CalRecycle solicited public input on the MED-Project's Drugs Plan from September 15, 2021, through September 29, 2021, and received eight stakeholder comment letters. CalRecycle considered all comment letters received when reviewing MED-Project's Drugs Plan for compliance. Six of the eight comment letters articulate support for MED-

Project's Drugs Plan and were submitted by Eli Lilly, the Western Placer Waste Management Authority, the Pharmaceutical Product Stewardship Work Group, Tacoma-Pierce County Health Department, Rite Aid, and a group letter from AdvaMed, Biocom California, and California Life Sciences. The remaining two letters were submitted by the Russian River Watershed Association and the California Product Stewardship Council and articulate questions and concerns about MED-Project's Drugs Plan that generally align with CalRecycle's findings regarding insufficient detail, lack of program funding and budget clarity, and education and outreach materials and efforts.

### **California Environmental Quality Act**

Staff recommend that CalRecycle file a Notice of Exemption for the Drugs Plan with the State Clearinghouse as provided under the California Environmental Quality Act.

### **Summary of Staff Analysis**

CalRecycle staff reviewed MED-Project's Drugs Plan, to determine whether all statutory and regulatory requirements were met and found the Drugs Plan to be substantially compliant. Several components of MED-Project's Drugs Plan require additional information from and additional actions by MED-Project for CalRecycle to determine if the Drugs Plan is compliant.

### **Options**

1. Conditionally approve MED-Project's Drugs Plan, contingent upon MED-Project providing the following to CalRecycle:
  - a. A letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Drugs Plan, to meet the conditions specified in the Staff Analysis section of this Request for Approval; and
  - b. A revised Drugs Plan, within 90 days of signature on this Request for Approval, that includes the additional information to meet the conditions specified in the Staff Analysis section of this Request for Approval.
2. Disapprove MED-Project's Drugs Plan. MED-Project shall resubmit its revised Drugs Plan within 60 days of signature on this Request for Approval and CalRecycle will review the revised Drugs Plan within 90 days of resubmittal.

## **Action**

Based on MED-Project's Drugs Plan and analysis within this Request for Approval, I hereby conditionally approve MED-Project's Drugs Plan, contingent upon MED-Project (1) providing a letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Drugs Plan to meet the conditions specified in the Staff Analysis section of this Request for Approval, and (2) revising and resubmitting its Drugs Plan within 90 days as described in the Recommendation and Staff Analysis sections above. Failure to comply with all the conditions and resubmit within 90 days may result in disapproval of MED-Project's Drugs Plan. This Request for Approval shall serve as the written notice of the conditions that CalRecycle must identify pursuant to the first sentence in CCR section 18973.1(g). CalRecycle's conditional approval constitutes an approval for purposes of PRC section 42032(g). MED-Project must fully implement the Drugs Plan, revised to comply with the conditions outlined in the Staff Analysis, within 270 days from signature of this Request for Approval, titled, *Consideration of MED-Project's Product Stewardship Plan for Covered Drugs from Households*. Additionally, I hereby direct staff to file a Notice of Exemption with the State Clearinghouse for the Drugs Plan as provided under the California Environmental Quality Act.

**Dated:** December 9, 2021

**Signed by:** Rachel Machi Wagoner, Director

## **Attachments:**

Documents listed below are posted to CalRecycle's website. To request documents that are referenced in this report but are not listed below, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [Pharmaceutical and Sharps Waste Stewardship Act](#) (Public Resources Code sections 42030 *et seq*)  
[https://leginfo.legislature.ca.gov/faces/codes\\_displayexpandedbranch.xhtml?tocCode=PRC&division=30.&title=&part=3.&chapter=2.&article=](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PRC&division=30.&title=&part=3.&chapter=2.&article=)
2. [Pharmaceutical and Sharps Waste Stewardship Program Regulations](#) (California Code of Regulations sections 18972.1 *et seq*)  
[https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=\(sc.Default\)&bhcp=1](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1)
3. [A Product Stewardship Plan for Covered Drugs from Households](#)  
<https://www2.calrecycle.ca.gov/Docs/Web/119601>
4. [Appendix A - Participating Covered Entities](#)  
<https://www2.calrecycle.ca.gov/Docs/Web/119604>
5. [Appendix B - Covered Products](#)  
<https://www2.calrecycle.ca.gov/Docs/Web/119607>

6. [Appendix C - Participating Authorized Collection Sites](https://www2.calrecycle.ca.gov/Docs/Web/119610)  
<https://www2.calrecycle.ca.gov/Docs/Web/119610>
7. [Appendix E - Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/119613)  
<https://www2.calrecycle.ca.gov/Docs/Web/119613>