

## 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 Home-Generated Sharps Waste

**Action By:** December 13, 2021

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### **Summary of Request**

MED-Project USA (MED-Project) submitted its stewardship plan for home-generated sharps waste, which includes its initial program budget, titled, *A Product Stewardship Plan for Home-Generated Sharps Waste* (Sharps 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 Sharps 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 home-generated sharps waste are primarily mail-back programs where ultimate users are provided sharps waste containers and mail-back materials at the point of sale. 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 more than 40 covered entities under its proposed Sharps Plan (see Attachment 4 for a list of covered entities. Attachments 3 through 5 comprise the entirety of MED-Project's Sharps Plan). MED-Project also operates covered drugs or sharps stewardship programs in 13 local jurisdictions in California. Overall, staff found MED-Project's Sharps Plan substantially compliant with all material requirements in CCR sections 18973, 18973.3 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 Sharps Plan which are deficient, and the conditions MED-Project must meet for CalRecycle to approve its Sharps Plan, pursuant to CCR section 18973.1(g), are described below.

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

### **1. Mail-back Program**

**Requirements:** A mail-back program that provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(1)(F)(i) and CCR section 18973.3(f)(2). Pursuant to CCR section 18972.1(a)(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. Provide ultimate users with necessary information on proper sharps waste disposal pursuant to PRC section 42032.2(d)(1)(F)(i)(I) and CCR section 18973.3(f)(2)(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 1.”

MED-Project proposes to execute agreements with retail pharmacies, retail pharmacy chains, online sellers, and potential non-online point of sale sites that offer to participate and meet its requirements to act as point of sale sites in its program. MED-Project proposes to allow these participating point of sale sites to either (1) provide a sharps mail-back package, (2) initiate distribution of a sharps mail-back package through MED-Project’s ordering system designed to fulfill orders within five business days, or (3) provide instructions for ordering a sharps mail-back package via MED-Project’s website or call center. Online point of sale sites would be given access to MED-Project’s ordering system designed to initiate distribution of a sharps mail-back package, instructions for ordering sharps mail-back packages, and information about proper sharps waste disposal.

MED-Project’s proposal to provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale limits the scope of statute by fulfilling this requirement only at point of sale sites with whom MED-Project contracts, rather than everywhere sharps covered under the Sharps Plan are sold, resulting in a lower convenience level than the Act requires. Furthermore, MED-Project proposes that point of sale sites, such as pharmacies, may choose whether to (1) provide a sharps mail-back package, (2) initiate distribution of a sharps mail-back package to arrive at the ultimate user’s address within five business days, or (3) provide instructions for ordering a sharps mail-back package via MED-Project’s website or call center. CCR section 18972.1(a)(10)(C) states that other methods of providing containers and mail-back materials are only allowed if providing at the point of sale or arranging for

arrival within five business days of the point of sale are illegal. MED-Project's Sharps Plan does not demonstrate how providing or arranging for arrival of containers and mail-back materials are illegal and therefore permissible to use other methods of providing containers and mail-back materials.

MED-Project proposes a point of sale approach that allows pharmacies to direct homeless individuals to a phone or website request system to obtain a sharps mail-back package, which requires an address. However, homeless individuals may not have access to a phone or internet and may not have a permanent address to receive sharps mail-back packages. Additionally, the process for returning the sharps mail-back package does not include all necessary instructions on proper sharps waste disposal, such as how to repackage and mail the sharps container and a clear description of what items are and are not accepted in mail-back packages.

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

- a. Describe how the program will: (1) provide or initiate distribution of sharps waste containers and mail-back materials at all points of sale where any sharps covered under the Sharps Plan are sold; and (2) 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 to the ultimate user within five business days of the point of sale (not just fulfill an order within five business days). (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18972.1(a)(10) and 18973.3(f)(2)).
- b. Provide circumstances and justification whereby provision and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove the option under CCR section 18972.1(a)(10)(C), described in the Sharps Plan, which provides instructions to the ultimate user at the point of sale for the ultimate user to arrange for arrival of sharps waste containers and mail-back materials. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18973.3(f)(2) and 18972.1(a)(10)).
- c. Explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through all approved options, including the option whereby ultimate users are instructed to order a mail-back package through MED-Project's website or call center. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18973.3(f)(2) and 18972.1(a)(10)).
- d. If justification for the use of the option pursuant to CCR section 18972.1(a)(10)(C), described in the Sharps Plan, is provided per CalRecycle Condition 1b, MED-Project must (1) explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through this option whereby ultimate users are instructed to

- order a mail-back package through MED-Project's website or call center; and (2) ensure the option under CCR section 18972.1(a)(10)(C) results in substantially the same level of convenience as the options under CCR sections 18972.1(a)(10)(A) and (B). (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18973.3(f)(2) and 18972.1(a)(10)).
- e. Provide all necessary information regarding proper sharps disposal to ultimate users, including but not limited to, a description of "biologics," items that are and are not accepted in mail-back packages, and instructions for repackaging and mailing a sharps container. (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(F)(i)(l) and CCR section 18973.3(f)(2)(B)).

## **2. Program Budget and Funding**

Requirements: Demonstrate adequate funding for all costs including administrative and operational costs, pursuant to PRC section 42032.2(d)(1)(C). 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(d)(1)(C) and CCR sections 18973.3(e) 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 2."

MED-Project's Sharps 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 18973.3(e). 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 Sharps Plan submittal. Additionally, MED-Project's Sharps 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 Sharps 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 sections 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 2: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Sharps 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(d)(1)(C) and 42033(b), and CCR sections 18973.3(e) and 18973.6).
- 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 MED-Project's reserve range and reserve amount. (The requirement necessitating this condition appears in CCR section 18973.6(c)).

### **3. 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 18973.3(i)(1) through (2). Signage shall be designed with explanatory graphics which are readily understandable by all ultimate users pursuant to CCR section 18973.3(i)(2). Establish a website and toll-free telephone number pursuant to CCR section 18973.3(i)(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 18973.3(i)(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 3.”

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.

The Sharps Plan contains sample point of sale site signage and informational inserts that appear to encourage dropping off sharps at local government household hazardous waste (HHW) facilities, rather than prioritizing use of the statutorily required mail-back program. MED-Project's plan shall be a mail-back program unless a supplemental collection method is identified pursuant to CCR section 18973.3(f)(5). Since promoting or prioritizing drop-off at an HHW facility is inconsistent with statute and the services offered by the program, education and outreach materials ultimately utilized by the program will need to comply with statutory requirements.

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 Sharps Plan what "views" it intends to communicate and why the disclaimer is necessary.

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

- a. Clarify that education and outreach materials utilized by the program will be consistent with the statutory and regulatory requirements. Education and outreach materials should not promote sharps disposal at HHW facilities since this is not a service offered in the proposed mail-back program. The statutory requirement is that "a stewardship program ... shall be a mail-back program for home-generated sharps waste" (see PRC section 42032.2(d)(1)(F)). Promoting disposal at HHW facilities as part of the education and outreach program is inconsistent with promoting mail-back of home-generated sharps waste (see PRC section 42031.6). (The requirements necessitating these conditions appear in PRC sections 42031.6(b) and 42032.2(d)(1)(F) and CCR section 18973.3(i)(7)).

- b. 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 18973.3(i)(1), (2), and (4)).
- c. 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 18973.3(i)(1), (2), and (4)).

#### **4. Local Agency Requests**

Requirement: Description of the process for coordinating with local agencies 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 pursuant to PRC section 42032.2(d)(1)(F)(ii) and CCR section 18973.3(g).

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 4.”

MED-Project’s Sharps Plan requires verification that an HHW facility is listed on California Department of Public Health (CDPH) and California Department of Toxic Substances Control (DTSC) websites as part of the registration process prior to the local agency receiving reimbursement. HHW facilities being listed on CDPH and DTSC websites should not be a determining factor for participation and eligibility to receive reimbursement from MED-Project. Rather than relying on CDPH and DTSC websites, the plan should state that MED-Project will provide reimbursement to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste.

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

- a. Remove reference to website listings as a determining factor for HHW facilities to be eligible for reimbursement and provide reimbursement to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste. (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(F)(ii) and CCR section 18973.3(g)).

#### **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 18973.3(h).

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 33 of its Sharps 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 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 ordinance repeal as required by statute.

CalRecycle Condition 5: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Sharps 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. (The requirements necessitating this condition appear in PRC section 42032.2(e), 42036.2(a), and CCR section 18973.3(h)).

## **6. Coordination Efforts**

Requirement: Coordinate with other program operators to avoid confusion to the public and all program participants pursuant to CCR section 18973.3(j).

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 Sharps 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 18973.3(j)).

## 7. Handling, Transport, and Disposal System

Requirements: Provide mailing and physical addresses for each service provider used to transport, process, or dispose of home-generated sharps waste pursuant to CCR section 18973.3(f)(4)(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 18973.3(f)(4)(B). It is important that all addresses are identified for safety and security purposes related to the handling, transportation, and disposal of home-generated sharps waste.

CalRecycle Condition 7: Pursuant to CCR section 18973.1(g), MED-Project must revise and resubmit its Sharps 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 18973.3(f)(4)(B)).

## 8. Compliance Certifications

Requirement: Include a certification statement that the Sharps Plan, including all aspects related to handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations pursuant to CCR section 18973.3(d)(2).

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.”

The certification statement provided on page 65 of MED-Project’s Sharps Plan refers to covered drugs rather than home-generated sharps waste.

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

- a. Remove the reference to covered drugs on page 65 and provide a certification statement referencing home-generated sharps waste. (The requirement necessitating this condition appears in CCR section 18973.3(d)(2)).

## Stakeholder Feedback

CalRecycle solicited public input on MED-Project’s Sharps 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 Sharps Plan for compliance. Five of the eight comment letters articulate support for MED-Project's Sharps Plan and were from the Pharmaceutical Product Stewardship Work Group, the Western Placer Waste Management Authority, Eli Lilly, Rite Aid, and a group letter from AdvaMed, Biocom California, and California Life Sciences. The remaining three letters were submitted by UltiMed, Inc., the Russian River Watershed Association, and San Mateo County Environmental Department and articulate questions and concerns about MED-Project's Sharps Plan that generally align with CalRecycle's findings regarding point of sale site provisions, insufficient detail, lack of program funding and budget clarity, and lack of metrics.

### **California Environmental Quality Act**

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

### **Summary of Staff Analysis**

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

### **Options**

1. Conditionally approve MED-Project's Sharps 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 Sharps Plan, to meet the conditions specified in the Staff Analysis section of this Request for Approval; and
  - b. A revised Sharps 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 Sharps Plan. MED-Project shall resubmit its revised Sharps Plan within 60 days of signature on this Request for Approval and CalRecycle will review the revised Sharps Plan within 90 days of resubmittal.

### **Action**

Based on MED-Project's Sharps Plan and analysis within this Request for Approval, I hereby conditionally approve MED-Project's Sharps 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 Sharps Plan to meet the conditions specified in the Staff Analysis section of this Request for Approval, and (2) revising and resubmitting its Sharps 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 Sharps 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 its Sharps 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 Home-Generated Sharps Waste*. Additionally, I hereby direct staff to file a Notice of Exemption with the State Clearinghouse for the Sharps 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](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PRC&division=30.&title=&part=3.&chapter=2.&article=) (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](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1) (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 Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/119592)  
<https://www2.calrecycle.ca.gov/Docs/Web/119592>
4. [Appendix A - Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/119595)  
<https://www2.calrecycle.ca.gov/Docs/Web/119595>
5. [Appendix B - Covered Products](https://www2.calrecycle.ca.gov/Docs/Web/119598)  
<https://www2.calrecycle.ca.gov/Docs/Web/119598>