

Yana Garcia
Secretary for Environmental Protection
Zoe Heller
CalRecycle Director

Sent via e-mail

July 29, 2024

Chris Smith
President
The Drug Takeback Solutions Foundation
P.O. Box 997
Winston-Salem, NC 27102

Re: Notice Regarding Disapproval of The Drug Takeback Solutions Foundation's 2023 Annual Report for Covered Drugs

Dear Mr. Smith:

On June 27, 2024, CalRecycle's director disapproved The Drug Takeback Solutions Foundation's (The Foundation) 2023 annual report for covered drugs submitted on March 29, 2024, titled, *The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2023 Annual Report (2023 Annual Report)* and directed staff to provide written notice to The Foundation within 30 days of disapproval (i.e., by July 29, 2024) identifying how the *2023 Annual Report* does not comply. The summary of CalRecycle's analysis of The Foundation's *2023 Annual Report* and its record of decision is contained in CalRecycle's Request for Action, titled, *Consideration of The Drug Takeback Solutions Foundation's 2023 Annual Report for Covered Drugs (June 2024 RFA)*, which was emailed to The Foundation on June 28, 2024.

The deficiencies of The Foundation's 2023 Annual Report are those items identified as "requirements not met" in the June 2024 RFA. This letter supplements the June 2024 RFA and provides additional information on how the 2023 Annual Report does not comply. This notice further highlights supplemental information necessary for determining compliance. Together, this notice and the June 2024 RFA satisfy the department's obligation to provide written notice to The Foundation pursuant to Public Resources Code (PRC) section 42033.2(e)(3) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(k) within 30 days of disapproval (i.e., by July 29, 2024).

In some instances, the department was not able to verify compliance due to a lack of clarity or information in The Foundation's submission. This notice identifies information that is needed to assess the compliance of The Foundation's annual report. Providing the information requested below will be necessary for the department to determine compliance, however, providing information may not be sufficient to achieve compliance.

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Pursuant to 14 CCR section 18973.1(k), The Foundation must revise and resubmit its 2023 Annual Report within 60 days of this notice (i.e., by September 27, 2024) to address the deficiencies referenced above and to meet the following requirements:

Convenience Standard - Authorized Collection Sites:

As the *June 2024 RFA* explains, there was a deficiency regarding the number of authorized collection sites meeting the convenience standard. The 2023 Annual Report provided enough information for the department to identify a deficiency and we cannot conceive of any information that might remedy the deficiency; thus, we do not provide a specific request for information in this notice. If the department is incorrect and there is information that could cure the deficiency, The Foundation should provide that information to the department.

Convenience Standard – Reasonable Geographic Spread:

1. Provide a description of how the reasonable geographic spread of authorized collection sites stated in The Foundation's approved plan was met and for which counties it was met. If reasonable geographic spread was not met, include the counties where it was not met and a description of efforts made to achieve compliance, pursuant to 14 CCR section 18973.4(c)(3).

Transportation and Disposal:

- 2. Provide the name, mailing and physical address, and the total weight of covered drugs disposed for each disposal facility pursuant to 14 CCR section 18973.4(d)(3).
- 3. Clarify whether The Foundation added a new disposal facility in 2023 and, if so, provide the required information pursuant to 14 CCR section 18973.4(d).
 - a. If applicable, provide a description and evaluation of the process that was used for selecting the new service provider pursuant to 14 CCR section 18973.4(k).

Education and Outreach:

- 4. Clarify any discrepancies among reported metrics pursuant to 14 CCR sections 18973.4(i)(2), 18973.1(a), and 18973(d). The correct number should be identified along with the reason that this number is the correct number; the reason the incorrect number was initially provided should also be noted.
- 5. Include a discussion of what the metrics, including the survey results, reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility pursuant to 14 CCR sections 18973.2(j)(5) and 18973.4(i). Describe how The Foundation will use the results to improve the program in accordance with its approved plan.
- 6. Clarify whether the "provider" survey was completed by pharmacists and healthcare professionals, in accordance with The Foundation's approved

- plan. Clarify how the survey was conducted and the methods of contact pursuant to The Foundation's approved plan and 14 CCR section 18973.1(a).
- 7. Provide the questions The Foundation used for its survey of providers and ultimate users pursuant to 14 CCR section 18973.1(a).

Actual Expenses for Department Administrative Fees:

8. Include the actual expense for the departmental administrative fee or clarify why the departmental administrative fee is listed as \$2,316,503.36, pursuant to 14 CCR sections 18973.4(n), 18973.1(a), and 18973(d). If the incorrect number was initially provided, the reason why it was included initially should also be noted.

Authorized Collectors:

- 9. Provide all mailing and physical addresses associated with each authorized collector pursuant to 14 CCR section 18973.4(j)(3).
- 10. Submit a complete and correct list of authorized collectors that are located within the statewide program pursuant to 14 CCR sections 18973.4(j)(3) and 18973(d).

Collection System:

- 11. Distinguish the potential authorized collectors from the mail-back distribution locations that were notified and include the location's county pursuant to PRC section 42030(b) and 14 CCR section 18973.4(c)(2)(A).
- 12. Consistently report metrics for the amount of potential authorized collectors notified of the opportunity to participate in the program pursuant to 14 CCR section 18973(d).

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Document Submittals:

13. Define and utilize correct and consistent terminology and metrics within the annual report, pursuant to 14 CCR section 18973(d), in a complete and correct manner, including those discrepancies noted in the *June 2024 RFA* (e.g., items noted in the "Education and Outreach" and "Document Submittals" sections of the *June 2024 RFA*). The correct number or fact should be identified along with the reason that this number or fact is correct; if an incorrect number or fact was initially provided, the reason why it was included initially should also be noted.

Questions regarding this letter may be directed to pharmasharps@calrecycle.ca.gov.

Regards,

Signed by: Zoe Heller, Director Dated: July 29, 2024

Zoe Heller Director

Cc: Heather Beckner, Supervisor, Pharmaceutical and Sharps Unit Becky Haworth, Environmental Scientist, Pharmaceutical and Sharps Unit