



August 21, 2025

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

Sent via e-mail

Re: Notice of Disapproval of Foundation's Proposed Changes to its Stewardship Plan for Covered Drugs

Dear Wanda Voigt:

On April 25, 2025, The Drug Takeback Solutions Foundation (Foundation) submitted proposed changes to its stewardship plan for covered drugs to CalRecycle in "Attachment A," including a cover letter, titled, *Notification of Request for Geographic Spread Plan Amendment to The Drug Take Back Solutions Foundation Stewardship Plan for Covered Drugs (Proposed Changes)*. The *Proposed Changes* describe how Foundation intends to satisfy its statutory and regulatory requirements to provide for a reasonable geographic spread of authorized collection sites. The methodology that Foundation proposes for achieving its county level reasonable geographic spread is based on the number of potential authorized collectors in each county and the population density.

CalRecycle reviewed Foundation's *Proposed Changes* and determined they are significant changes to Foundation's covered drugs stewardship plan submitted on October 15, 2022, titled, *Stewardship Plan for Covered Drugs (Plan)*. Public Resources Code (PRC) section 42032(e) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(i) require a program operator to submit any significant changes to a stewardship plan in writing to CalRecycle for approval prior to implementation.

CalRecycle determined that the *Proposed Changes* do not meet all requirements. Below is a summary of staff's analysis for those requirements where additional information from Foundation is necessary for CalRecycle to consider approval.

Foundation's *Proposed Changes* state "Foundation proposes to amend its current Stewardship Plan for Covered Drugs, October 21, 2021, Version 4 (October 15, 2022), by replacing Paragraph 2 of Subsection B (Convenience Standard) of Section VII (Collection, Transport, and Disposal)" with specified text in "Attachment A." Foundation included additional information in "Attachment A" that CalRecycle is not considering for approval, because Foundation did not indicate that this text would add to, or replace, text in its approved *Plan*.

1. PRC section 42032.2(a)(1)(F)(ii) and 14 CCR section 18973.2(g)(2) require that a stewardship plan for covered drugs provide for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread, including how reasonable geographic spread is determined and all factors applied to develop the determination. 14 CCR section 18973.2(g)(2)(B) requires that a stewardship plan for covered drugs describe how frequently the convenience standards will be re-evaluated to ensure compliance with the convenience standards, including updating population estimates.
 - a. Foundation's *Proposed Changes* include five "tiers" in Table 1 and describes how it will calculate the tier parameters by determining the number of potential authorized collection sites in each county and multiplying that number by the population density in each county. Each tier has an associated geographic spread, demonstrating how many miles a certain percentage of the population will be from an authorized collection site or "Mail-Back Site." On an annual basis, Foundation states it will "calculate the percentage of the county population that lives within a certain distance from a participating Authorized Collection Site or mail-back site."
 - i. Foundation's *Proposed Changes* do not provide an explanation for how its geographic spread for each tier is reasonable, including all factors applied to develop the determination. Foundation should provide an explanation as to why the lower levels of convenience that would result from this tiered approach are reasonable. CalRecycle recognizes a portion of Foundation's explanation for the geographic spread (e.g., rationale regarding urban and rural counties) is included in "Attachment A," but Foundation does not indicate that this text will add to, or replace, text in its approved *Plan*. See 2(a) below for significant change submittal requirements.
 - ii. Foundation's *Proposed Changes* include mail-back services in the calculation of compliance with the proposed geographic spread. Program operators are required to provide for a "reasonable geographic spread of *authorized collection sites* (emphasis added)."
 - iii. Foundation's *Proposed Changes* remove existing text in its approved *Plan* that describes how Foundation will use a "data visualization tool...to map the Authorized Collection Sites with population data to calculate the geographic spread and determine the number and location of Collection Receptacles needed per county." While the *Proposed Changes* describe how Foundation will re-evaluate the geographic standard annually by "ensuring each county continues to be serviced per the parameters discussed above utilizing the most current E-1 population data," Foundation will be unable to evaluate its compliance with reasonable geographic spread when E-1 population data does not provide any

spatial information about where the people live in that county. Additionally, without information regarding spatial analysis, Foundation cannot determine where additional authorized collection sites are necessary to meet this standard.

- b. The *Proposed Changes* state Foundation will utilize various websites and lists to determine the number of licensed pharmacies, hospitals, skilled nursing facilities, law enforcement agencies, and opioid treatment programs in “each participating county.” However, Foundation does not define what it means for a county to be “participating.”
2. 14 CCR section 18973(d) requires a document to be complete and correct.
 - a. Foundation’s *Proposed Changes* use terminology inconsistent with its *Plan*, which creates confusion about meaning. The *Proposed Changes* use the term “mail-back site,” in its description of how it calculates each tier. However, its *Plan* refers to “Mail-Back Distribution Site’ or ‘Site’” as “a physical location providing [prepaid, pre-addressed Standard Mail-Back Envelopes, Inhaler Mail-Back Envelopes, and Combination Product Mail-Back Packages] for Ultimate Users.”
 - b. Upon CalRecycle approval, the text in a significant change proposal adds to, or replaces, the text in a program operator’s stewardship plan, as specified by a program operator in its significant change proposal. As described in 1(a)(i) above, a portion of Foundation’s explanation for the geographic spread is included in “Attachment A,” but Foundation does not indicate that this text will add to, or replace, text in its approved *Plan*. Foundation must include all required information as part of the proposed changes to its stewardship plan in the appropriately identified sections.

Foundation’s *Proposed Changes* are not approved based on the information above. Foundation may choose to revise and resubmit its proposed changes for CalRecycle’s approval, pursuant to PRC section 42032(e) and 14 CCR section 18973.1(i).

Questions regarding this letter may be directed to PharmaSharps@CalRecycle.ca.gov.

Sincerely,

Signed by:
Zoe Heller
Director