September 8, 2026

Via Email: regs@dtsc.ca.gov
Regulations Coordinator
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

Re: Petition for Rulemaking to Adopt EPA's Management Standards for Hazardous Waste Pharmaceuticals Rule, 40 C.F.R. Part 266, Subpart P, §§ 266.500–266.510 Pursuant to California Government Code Section 11340.6

I. Introduction

The California Retailers Association ("CRA") submits this Petition for Rulemaking to the Department of Toxic Substances Control ("DTSC") in accordance with Government Code Section 11340.6, requesting that the California Department of Toxic Substances Control (DTSC) adopt the federal management standards for hazardous waste pharmaceuticals, 40 C.F.R. Part 266, Subpart P, §§ 266.500–266.510 ("Subpart P" or the "Pharm Rule").

The California Retailers Association is the leading voice of California's retail industry, representing retailers of all sizes and sectors across the state. CRA advocates for public policies that support California consumers, employees, communities and a strong, competitive retail marketplace.

CRA represents all segments of the retail industry including general merchandise, department stores, mass merchandisers, on-line marketplaces, restaurants, convenience stores, supermarkets and grocery stores, chain drug and specialty retail such as auto, vision, jewelry, hardware and home stores. The California Retailers Association works on behalf of California's retail industry, a driving force of California's economy, with over 400,000 retail establishments, an annual gross domestic product of $330 billion and one fourth of California's total employment.

More than seven years ago, the United States Environmental Protection Agency ("EPA") adopted Subpart P to streamline the management standards of hazardous waste pharmaceuticals in the healthcare sector, including for many California retailers of pharmaceuticals. In short, Subpart P clarifies and establishes a regulatory structure for the reverse distribution of prescription pharmaceuticals from pharmacies across the U.S. and provides tailored and sector-specific standards for the management of hazardous waste pharmaceuticals.

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California has adopted a portion of the Rule, including the amendment to the P075 listing for nicotine (removing FDA-approved over-the-counter nicotine replacement therapies from the P075 acute hazardous-waste listing), effective March 9, 2021. However, important provisions remain outstanding, including updated regulations on treatment of empty containers, characterization of materials eligible for reverse distribution, and management standards for hazardous waste pharmaceuticals. DTSC must adopt these more stringent, federal regulations to ensure uniform and consistent treatment of hazardous waste pharmaceuticals.

II. Parties

California Retailers Association ("CRA") is a nonprofit corporation operating since 1933 that promotes, preserves, and enhances the retail industry in California by helping develop public policy and regulations that impact its retail members. Retail members span all sectors, including pharmacies. DTSC's adoption of Subpart P directly impacts CRA and its retail members. Moreover, CRA has a commitment to work on these issues, per its members' legal settlements with California district attorneys on hazardous waste management.

III. Petition for Rulemaking

Government Code Section 11340.6 authorizes interested persons to petition a state agency requesting the adoption of a regulation through the rulemaking process set forth at Cal. Gov. Code §§ 11346 *et seq.* Petitions made under this statute must include the following: "(a) The substance or nature of the regulation, amendment, or repeal requested. (b) The reason for the request. (c) Reference to the authority of the state agency to take the action requested." Cal. Gov. Code § 11340.6.

The substance or nature of the regulation requested by this Petition is a permanent regulation adopting Subpart P (40 C.F.R. §§ 266.500–266.510), which is more fully described in Sections IV and V of this Petition. EPA promulgated Subpart P as a federal rule under the Resource Conservation and Recovery Act ("RCRA") to streamline applicable regulations for hazardous waste pharmaceuticals.

The reasons for this request are multiple and are discussed further herein: first, adoption by DTSC is required to maintain its RCRA authorization by EPA, as EPA has adopted more stringent management standards for hazardous waste pharmaceuticals. Second, Subpart P provides a sector-specific regulatory framework reflective of how pharmacies and other healthcare facilities operate, rather than applying the hazardous waste rules that were designed for large-scale industrial and manufacturing facilities. This tailored approach, which has been adopted in nearly every other state, would provide clearer, workable standards for both CRA's retail members and regulators alike.

In addition, this adoption is necessary to align California's regulation of RCRA hazardous waste pharmaceuticals with AB 1442, an amendment to the California Medical Waste Management Act that passed in 2012 and authorized reverse distribution for non-RCRA hazardous waste pharmaceuticals. That 2012 amendment excluded from regulation the reverse distribution and

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shipment of pharmaceuticals that would be non-RCRA California hazardous waste in recognition of the safety and security of reverse distribution. The same authorization is needed for RCRA hazardous waste pharmaceuticals, as set forth under Subpart P.

Lastly, Section VI of this Petition describes DTSC's legal authority to take this necessary action, alongside policy principles which urge DTSC to act in accordance with this Petition.

IV. Background of Subpart P

The Resource Conservation and Recovery Act or RCRA, 42 U.S.C. § 2901 et seq., is a federal law governing the disposal of solid waste and hazardous waste and is implemented by EPA. By statute, EPA may delegate its authority to implement RCRA to a state, provided that the state maintains a regulatory scheme that is equivalent to, or more stringent than, the standards enumerated in federal law. See 42 U.S.C. § 6926. EPA has delegated its authority to implement RCRA to the State of California, and DTSC is charged with administering California's hazardous waste program. As such, California must adopt EPA-promulgated hazardous waste regulations that are more stringent than the state's existing regulations in order to maintain its authorized status to administer the program in lieu of EPA.

Subpart P was published in the federal register on February 22, 2019 and became effective August 21, 2019 as an addition to the regulations promulgated under RCRA. EPA, *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, 84 Fed. Reg. 5816 (Feb. 22, 2019). EPA adopted Subpart P to address concerns in the healthcare sector for managing hazardous waste pharmaceuticals, including difficulties obtaining RCRA-empty status for pharmaceutical containers, making appropriate hazardous waste determinations, and clarifying the regulatory status of retailers using reverse distribution. 84 Fed. Reg. at 5819–20. In its stated rationale for the final rule, EPA referenced the regulatory uncertainty present in California and stated that "California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems." *Id.* at 5820.

By way of summary, Subpart P sets forth waste-specific and sector-specific rules for the management of hazardous waste pharmaceuticals. The rule lays out definitions and applicability of the new management standards. 40 C.F.R. §§ 266.500–501. The new management standards are divided between non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. 40 C.F.R. §§ 266.502–503. The regulations provide a voluntary opt-in for very small quantity generators, discuss management of controlled substances, and implement a sewer ban for hazardous waste pharmaceuticals. 40 C.F.R. §§ 266.504–506. Subpart P creates a more appropriate method of determining whether a container is empty by providing that stock, dispensing, and unit-dose containers are considered RCRA-empty if the pharmaceuticals have been removed using standard practices. 40 C.F.R. § 266.507. Notably, such empty containers do not contribute towards a healthcare facility's generator status. *Id*. The rule also sets forth standards applicable to healthcare facilities and reverse distributors for the management of hazardous waste pharmaceuticals. 40 C.F.R. §§ 266.508–510.

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V. Procedural History of Subpart P in California

EPA considers Subpart P to be "on the whole, more stringent than the standard RCRA regulations." 84 Fed. Reg. at 5856. The agency's position is that Subpart P is not optional for authorized states to adopt.

Two provisions of the federal rule are already effective in California. First, the "sewer ban" under Subpart P, 40 C.F.R. § 266.505, which prohibits healthcare facilities and reverse distributors from sewering or flushing hazardous waste pharmaceuticals, was adopted under the Hazardous and Solid Waste Amendments and became effective with Subpart P in all states, including California, on August 21, 2019. *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Rule*, DTSC (https://dtsc.ca.gov/pharmaceutical-waste-rulemaking/).

Second, the delisting of FDA-approved nicotine patches, gums, and lozenges as acute hazardous waste was promulgated at the same time as Subpart P (see 84 Fed. Reg. at 5823) and later adopted by California through Section 100 Rulemaking, which generally allows agencies to bypass the regular rulemaking process for non-substantive regulatory changes, to amend 22 CCR 66261.33(e). See OAL Matter No. 2020-1117-02, *Notice of Approval of Changes Without Regulatory Effect* (Mar. 9, 2021).

In 2023, DTSC took steps to adopt additional portions of Subpart P but the effort was stalled and not completed. DTSC submitted a Section 100 Rulemaking package to the California Office of Administrative Law ("OAL") to adopt the empty container provision and revise standards for when certain hazardous waste pharmaceuticals are considered RCRA-empty. *Management Standards*, DTSC (https://dtsc.ca.gov/pharmaceutical-waste-rulemaking/). However, based on consultation with OAL, DTSC withdrew the empty container rulemaking package from the Section 100 process.

Instead, in 2024, DTSC announced it was changing course and would pursue adoption of the empty container provision along with the remainder of Subpart P through regular rulemaking. DTSC's 2025 rulemaking calendar (see *Figure 1* below) included adoption of Subpart P, with a projected notice publication date[1] of January 9, 2026, and a projected adoption date of December 4, 2026. Based on information and belief, and a diligent search of the OAL's Regulatory Notice Register, DTSC has not published notice of proposed action to adopt Subpart P.

[1] The notice publication date is when an agency has formally initiated rulemaking action and publishes a notice of proposed action in California's Regulatory Notice Register. Cal. Gov. Code § 11346.4(a)(5). An agency then has one year to complete the rulemaking process and submit the complete file to OAL. Cal. Gov. Code § 11346.4(b).

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Figure 1: Excerpt from DTSC's 2025 Rulemaking Calendar

DEPARTMENT OF TOXIC SUBSTANCES CONTROL
2025 RULEMAKING CALENDAR

SCHEDULE B: PROPOSED REGULATIONS IMPLEMENTING STATUTES ENACTED PRIOR TO THE YEAR 2024

Subject:
Management Standards for Hazardous Waste Pharmaceuticals, R-2023-19N

California Code of Regulations Title and Sections Affected:
CCR, title 22, sections 66260.10, 66260.22, 66262.10, 66264.1, 66265.1, and Chapter 15, Article 5

Statute(s) Being Implemented:
Health and Safety Code section 25159

Responsible Agency Unit:
Hazardous Waste Management Program

Contact Person and Phone Number:
Liliana Cahuas – (916) 322-7636
Kareem Taylor – (916) 445-9553

Projected Notice Publication Date:
January 9, 2026

Projected Public Hearing Date:
N/A

Projected Adoption by Your Agency Date:
December 4, 2026

Projected to OAL for Review Date:
December 4, 2026

Report on the Status of all incomplete Rulemaking Described in Previous Calendars:
DTSC is preparing rulemaking documents for publication.

While DTSC staff have been responsive and assured the regulated community that DTSC still intends to adopt Subpart P, it has now been seven years since Subpart P became effective, and almost 15 years since the California Medical Waste Management Act was amended. CRA's members are unable to operate under the updated federal rules and therefore are managing hazardous waste pharmaceuticals differently in California compared to other states. Notably, California is one of only ten remaining states to not have adopted Subpart P.[2]

Further, as it stands today, DTSC's Office of Legislative Affairs webpage does not indicate a commitment to adopt Subpart P:

> DTSC has completed evaluating subpart P under 40 CFR part 266 to ***determine if any provisions or amendments are more stringent and California is statutorily required to adopt***. EPA has indicated that they intended that the subpart P

[2] *Where are the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine in Effect?*, EPA (https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075) (last updated June 30, 2026).

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> requirements be adopted in whole instead of in part, which DTSC took into consideration in its evaluation of the rule.
>
> ***DTSC has determined that California's existing generator and treatment, storage, and disposal (TSD) facility standards are equivalent, more stringent, or broader in scope, than most elements of subpart P***.

Management Standards, DTSC (https://dtsc.ca.gov/pharmaceutical-waste-rulemaking/) (emphasis added). If anything, DTSC's current website lacks a firm commitment to the regulated community to adopt Subpart P. Accordingly, CRA submits this petition to reignite the rulemaking process for Subpart P so that its retail members can operate under the updated regulations, as required by the underlying federal rule and California law.

VI. Legal Framework and Policy Rationale

Pursuant to Health and Safety Code §25150(a), "[DTSC] shall adopt, and revise when appropriate, standards and regulations for the management of hazardous wastes to protect against hazards to the public health, to domestic livestock, to wildlife, or to the environment." Thus, DTSC has clear authority to adopt Subpart P, which revises management standards for hazardous waste pharmaceuticals. And as described by the EPA, Subpart P creates "streamlined standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment." *Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, EPA (https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075) (last updated Jan. 22, 2026).

Furthermore, DTSC is required to adopt Subpart P to maintain its RCRA authorization. See Health and Safety Code § 25101(d) and 25150(d). Both EPA and DTSC have concluded that the Pharm Rule is more stringent than the existing hazardous waste standards and as such, must be adopted by authorized states. However, the start-and-stop efforts of DTSC to proceed with formal rulemaking to adopt this Rule have been ineffective to date and leave retail pharmacies in a regulatory limbo.

Unlike the existing hazardous waste rules, which were designed for large-scale industrial and manufacturing facilities, Subpart P is a sector-specific framework that reflects how pharmacies operate, providing clear, workable standards that improve compliance while maintaining strong environmental protections. Adoption would end the anomaly under which miniscule warfarin residue in otherwise empty containers pushes California pharmacies into Large Quantity Generator ("LQG") status, subjecting them to burdensome requirements never intended for the retail setting; it would streamline generator inspections through processes tailored to pharmacies, improving accuracy and reducing workload for DTSC and county-level inspectors; and it would preserve the heavily regulated reverse-distribution system (already subject to EPA registration, security, tracking, and recordkeeping controls) that minimizes the risk of drug diversion, safeguards drug supply chain integrity, and returns creditable pharmaceuticals for manufacturer credit in order to keep prescription drugs affordable and available to California residents.

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VII. Conclusion and Request for Adoption of Subpart P

For over seven years, California retailers have operated without the clarity and consistency that EPA's Subpart P was designed to provide. That delay has practical consequences: CRA's members must continue managing hazardous waste pharmaceuticals under California-specific requirements that diverge from the updated federal framework applied in most other states. CRA appreciates DTSC's efforts to evaluate and advance adoption of Subpart P, but the rulemaking process remains unfinished. CRA respectfully requests that DTSC promptly initiate rulemaking and publish a notice of proposed action in the California Regulatory Notice Register to adopt Subpart P in its entirety, which includes 40 C.F.R. §§ 266.500, 266.501, 266.502, 266.503, 266.504, 266.505, 266.506, 266.507, 266.508, 266.509, and 266.510..

Respectfully submitted by:



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