State of California
Department of
Industrial Relations

Date: April 30, 2026

To: Millicent Barajas, Executive Officer
Occupational Safety and Health Standards Board

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Subject: Evaluation of Petition No. 611 to protect employees from pharmaceutical exposures caused by pill crushing in healthcare facilities

1.0 INTRODUCTION

On January 20, 2026, the Division of Occupational Safety and Health (Cal/OSHA) received a petition from Barbara Sattler, a representative of the California Nurses for Environmental Health & Justice (CNEHJ; petitioner). CNEHJ operates as a non-profit organization composed of individual nurses. CNEHJ partners with communities, healthcare organizations, and non-governmental organizations (NGOs) to support environmental health and justice.

The petitioner proposes to amend California Code of Regulations title 8 by adding a requirement for the use of fume hoods and personal protective equipment in healthcare when employees crush pharmaceuticals.

Labor Code section 142.2 permits interested persons to propose new or revised standards concerning occupational safety and health and requires the Occupational Safety and Health Standards Board (Standards Board) to consider such proposals. California Labor Code section 147 requires the Standards Board to refer to Cal/OSHA for evaluation any proposed occupational safety and health standard.

2.0 PETITIONER'S REQUEST AND BASIS FOR AMENDMENT OF TITLE 8 REGULATIONS

The petitioner requests that the Standards Board establish requirements to minimize exposures to medications during pharmaceutical pill crushing.

The Petition specifically requests a requirement to install fume hoods in medication rooms and other places where medications may be prepared in healthcare facilities. Additionally, as an interim and

immediate precaution, the petitioner proposes the use of personal protective equipment such as masks and gloves when employees crush pills.

The petitioner did not offer specific regulatory text or posit an applicable title 8 regulation for this regulatory change.

3.0 APPLICABLE TITLE 8 REGULATIONS

There are no current Cal/OSHA title 8 regulations that specifically require fume hoods for pill crushing activity. However, there are current title 8 regulations in place that would protect employees from the hazards that may result from pill crushing.

Title 8 section 3203 requires every employer to establish, implement and maintain an effective Injury and Illness Prevention Program (IIPP) for employees.

Subsection 3203(a)(6) requires employers to include in their IIPP methods and/or procedures for correcting unsafe or unhealthy conditions, work practices and work procedures in a timely manner based on the severity of the hazard.

> §3203. Injury and Illness Prevention Program.
> *****
> (a)(6)
> Include methods and/or procedures for correcting unsafe or unhealthy conditions, work practices and work procedures in a timely manner based on the severity of the hazard.
> *****

Title 8 section 3384 establishes requirements for the use of hand protection.

> § 3384. Hand Protection.
>
> (a) Employers shall select, provide and require employees to use appropriate hand protection when employee's hands are exposed to hazards such as those from skin absorption of harmful substances, cuts or lacerations, abrasions, punctures, chemical burns, thermal burns, radioactive materials, and harmful temperature extremes.
> *****

Title 8 section 5141 requires that harmful exposures[1] be prevented by engineering controls whenever feasible. The standard also allows for the use of administrative controls and control by respiratory protective equipment when engineering controls are not feasible or do not achieve full compliance.

Title 8 section 5144 establishes requirements for the use of respiratory protection.

[1] Harmful exposure is defined in title 8 section 5140 as an exposure to dusts, fumes, mists, vapors, or gases:
(a) In excess of any permissible limit prescribed by (title 8) Section 5155; or
(b) Of such a nature by inhalation as to result in, or have a probability to result in, injury, illness, disease, impairment, or loss of function.

Title 8 section 5155 requires employee exposure to specifically listed airborne contaminants to be kept below specified concentration limits, referred to as permissible exposure limits (PELs).

> §5155. Airborne Contaminants.
> *****
> Table AC-1. Permissible Exposure Limits For Chemical Contaminants.
> *****
> Particulates not otherwise regulated; PEL for total dust is 10 mg/m^3; PEL for respirable fraction[2] is 5 mg/m^3

While there are existing title 8 PELs for particulate matter (i.e. particulates not otherwise regulated), these PELs are not protective for most pharmaceuticals, and it is unlikely that these PELs would be exceeded during clinical pill crushing by nurses. Furthermore, title 8 sections 5141, 5144, and 5155 would generally not be enforceable in a situation where a nurse crushes pills for a patient unless the pills were classified as hazardous drugs[3].

3.1 FUTURE Cal/OSHA RULEMAKING

AB 1202 / California Labor Code §144.8

On October 9, 2013, California Assembly Bill 1202[4] was approved by the Governor and filed with the Secretary of State. AB 1202 requires the Standards Board to adopt a standard for the handling of antineoplastic drugs[5]. The standard is to apply to healthcare facilities regardless of the setting. This bill requires the standard to be consistent with and not exceed the specific recommendations of the NIOSH 2004 alert entitled "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings," as updated in 2010 and applicable updates and changes to NIOSH guidelines.

Proposed title 8 regulation for Safe Handling of Antineoplastic Drugs in Healthcare.

On June 17, 2014, a Cal/OSHA advisory meeting was held to seek public and stakeholder input on the development of the regulation to address occupational exposures to antineoplastic drugs. The meeting included a discussion of NIOSH's specific recommendations and covered possible program elements, procedures, training, and recordkeeping.

A subsequent advisory meeting was held on October 28, 2015, and included discussions on United States Pharmacopeia (USP) General Chapter 800 *Hazardous Drugs—Handling in Healthcare Settings* and the California State Board of Pharmacy's pending hazardous drugs regulations with continued public and stakeholder comments. During this meeting, the first draft regulatory proposal for Safe

[2] The concentration and percentage of the particulate used for this limit are determined from the fraction passing a size selector with certain characteristics.
[3] See part 3.1 of this evaluation for description of hazardous drugs
[4] This assembly bill was promulgated to add the associated Labor Code section 144.8.
[5] As used in this section the following definitions shall apply: "Antineoplastic drug" means a chemotherapeutic agent that controls or kills cancer cells.

Handling of Antineoplastic Drugs in Health Care[6] dated October 13, 2015, was presented. The scope of the proposed draft applied to all healthcare settings where employees have an occupational exposure to antineoplastic drugs. Healthcare settings in the draft included hospitals, pharmacies, patient treatment clinics, physicians' facilities, other healthcare institutions, and veterinarians' offices where antineoplastic drugs are handled.

Current efforts by Cal/OSHA to expand the proposal to include all hazardous drugs

In the interim since the October 2015 advisory meeting, Cal/OSHA monitored pending updates from USP regarding General Chapter 800 *Hazardous Drugs – Handling in Healthcare Settings* which became official on December 1, 2019. At that time, USP 800 was considered informational until it became compendially applicable on November 1, 2023. The General Chapter was promulgated to address the potential hazardous drugs exposure of approximately 8 million U.S. healthcare workers noting that there are published reports of adverse effects from these exposures.[7]

Correspondingly, Cal/OSHA evaluated updates to the NIOSH 2004 Alert including the most recent 2023 guidance document which builds upon the 2004 Alert. This 2023 guidance document entitled *Managing Hazardous Drug Exposures Information for Healthcare Settings*[8] addresses exposures to hazardous drugs[9] as defined by NIOSH. The guidance stresses that efforts should be made to reduce all workers' exposures to hazardous drugs. Exposure to hazardous drugs has been associated with several adverse health effects such as an increase in the risk of cancers, organ and organ system damage, and reproductive harm. The document describes risk management procedures and contains a *Table of Control Approaches* describing scenarios that workers may possibly encounter in healthcare settings when handling hazardous drugs.

As a result of the updated guidance, Cal/OSHA is currently in a pre-rulemaking period working to expand the scope of the proposal beyond the scope of antineoplastics to address all hazardous drugs as defined by NIOSH. The recommendations currently under review by Cal/OSHA include, but are not limited to:

[6] Cal/OSHA draft proposal Safe Handling of Antineoplastic Drugs in Health Care. https://www.dir.ca.gov/dosh/doshreg/Antineoplastic-Drugs/Draft-discussion-as-of-2015.10.13.pdf. Last updated October 13, 2015. Accessed on March 6, 2026.

[7] USP. Role and Applicability of USP General Chapter Related to Safe Handling of Hazardous Drugs. Updated on November 1, 2023. Accessed on March 4, 2026. go.usp.org/Compendial_Applicability_of_USP_800

[8] CDC NIOSH. Managing Hazardous Drug Exposures: Information for Healthcare Settings. Last updated April 2023. Accessed March 4, 2026

[9] Hazardous drug: A drug that is, according to the NIOSH definition, A. Approved for use in humans by FDA's Center for Drug Evaluation and Research (CDER) B. Not otherwise regulated by the U.S. Nuclear Regulatory Commission, and C. Either 1. Is accompanied by prescribing information in the "package insert" that includes manufacturer's special handling information (MSHI) or 2. Is determined to be a carcinogenic hazard, developmental hazard, reproductive hazard, genotoxic hazard, or other health hazard by exhibiting one or more of the following toxicity criteria in humans, animal models, or in vitro systems: carcinogenicity; developmental toxicity (including teratogenicity); reproductive toxicity; genotoxicity; organ toxicity at low doses; or a structure and toxicity profile that mimics existing drugs determined hazardous by exhibiting any one of the previous five toxicity types, unless the drug also exhibits a molecular property that may limit the potential for adverse health effects in healthcare workers from exposure to the drug.

- Include regulations to address workplace exposures for all healthcare employees (including nurses) with occupational exposure to hazardous drugs in healthcare settings
- Include engineering controls (e.g. biological safety cabinets), administrative controls, personal protective equipment, and other strategies (e.g. medical surveillance, training, etc.) to minimize workers' exposures to hazardous drugs in healthcare settings
- Convene a future advisory meeting to discuss a new draft regulation to include occupational exposures to hazardous drugs in healthcare settings

4.0 APPLICABLE CALIFORNIA STATE BOARD OF PHARMACY REGULATIONS

The California State Board of Pharmacy promulgated regulations in title 16 *Article 4.7 Hazardous Drugs* for the compounding of hazardous drugs or crushing or splitting tablets or opening capsules of antineoplastic hazardous drugs as defined by the National Institute of Occupational Safety and Health (NIOSH) guidelines. This article references and requires compliance with United States Pharmacopeia (USP) General Chapter 800 *Hazardous Drugs-Handling in Healthcare Settings*. Article 4.7, Section 1737.5 contains requirements for containment primary engineering controls (C-PECs)[10] for compounding of hazardous drugs, however there is no requirement in the Pharmacy Law to use C-PECs for pill crushing of drugs which are not considered hazardous. Article 4.7 also addresses the hazards posed by crushing or splitting tablets or opening capsules of antineoplastic hazardous drugs in sections 1737.9 Personnel Training; 1737.15 Deactivating, Decontamination, Cleaning, and Disinfecting; and 1737.17 Documentation and Standard Operating Procedures (SOPs).

5.0 APPLICABLE FEDERAL OSHA REGULATIONS

There are no current federal OSHA regulations that specifically require fume hoods for pill crushing activity. However, OSHA enforces regulations that protect employees from hazards that may result from pill crushing.

Section 5(a)(1) of the Occupational Safety and Health Act of 1970 (General Duty Clause) requires employers to provide employees with a place of employment free from recognized hazards that may cause death or serious physical harm to these employees.

> Section 5(a)(1) of the Occupational Safety and Health Act of 1970
>
> Each employer shall furnish to each of his [sic] employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his [sic] employees…
>
> *****

Federal OSHA also has similar regulations to title 8 specific to protecting employees from harmful airborne exposures and hand protection.

[10] Containment-primary engineering control (C-PEC): A ventilated device designed and operated to minimize worker and environmental exposures to hazardous drugs by controlling emissions of airborne contaminants.

6.0 APPLICABLE GUIDANCE DOCUMENTS FROM THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

In 2004, NIOSH released the alert *Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings*. The intent of the guidance document was to increase awareness among employers and healthcare workers about the risks of exposure to hazardous drugs and to recommend methods and equipment for protecting workers' health. The alert addresses occupational exposures in healthcare settings, home healthcare agencies, retail pharmacies, veterinary medicine, and research laboratories, etc. The alert acknowledges that crushing tablets may result in employee exposure and recommends ventilated cabinets designed to prevent hazardous drug exposures, in addition to administrative controls, and personal protective equipment.

Building upon the 2004 Alert, NIOSH subsequently published *Managing Hazardous Drug Exposures Information for Healthcare Settings* in 2023. This document addresses places of employment where employees handle hazardous drugs. Identified workers with potential exposure to hazardous drugs include, but are not limited to, pharmacists, pharmacy technicians, nurses, nursing assistants, physicians, dentists, physician assistants, and others. The 2023 guidance document also acknowledges the increased potential for exposure of workers posed by cutting, crushing, or otherwise manipulating hazardous drug tablets and capsules. For crushing or manipulating hazardous drug tablets or capsules, the guidance recommends ventilated engineering controls[11]. The guidance recommends that consideration should also be given for use of a pill pouch for crushing, as well as double chemotherapy gloves and a protective gown.

7.0 APPLICABLE CONSENSUS STANDARDS - United States Pharmacopeia (USP) 800

The United States Pharmacopeia (USP) is an independent, non-profit, scientific organization focused on standard setting for medicines, food ingredients, and dietary supplements. Their USP General Chapter 800 *Hazardous Drugs-Handling in Healthcare Settings* establishes standards for the safe handling of drugs classified as hazardous according to the NIOSH definition. The standards are provided to minimize the exposure risk to healthcare employees, patients, and the environment created by handling of hazardous drugs. These standards apply to all healthcare personnel who contact (i.e. transport, receive, prepare, and administer) hazardous drugs. USP 800 identifies crushing, splitting, or opening capsules of hazardous drugs as a potential opportunity for exposure. Procedures in the document recommend that crushing tablets and opening tablets should be avoided. For exposures to powdered hazardous drugs, the standard recommends containment primary engineering control to protect personnel from exposure during these particle-generating activities in addition to personal protective equipment and the use of plastic pouches to contain any particles or dust generated.

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[11] "*When asepsis is required or recommended, use ventilated cabinets designed for both hazardous drug containment and aseptic processing…When aseptic technique is required, use one of the following types of ventilated cabinets: Class II BSCs. BSCs that exhaust filtered cabinet air to the outdoors are recommended… When asepsis is not required, a Class I BSC, a containment ventilated enclosure (CVE), or an isolator intended for containment applications (a "containment isolator") may be sufficient.*"

8.0 ANALYSIS OF PETITIONER'S BASIS

The petitioner requests a title 8 requirement for the use of fume hoods in areas of healthcare facilities where pharmaceutical pills crushing occurs. The petitioner states that nurses whose job duties include crushing pills are at risk of inhaling particulate matter (PM) which is released into the nurses' breathing zone during these operations. Petitioner argues that the PM contains the pharmaceuticals' active and inactive ingredients and inhaling such particles results in potential harmful exposures to nurses.

Although it is known that healthcare workers exposed to hazardous drugs (in particular during the crushing of hazardous drugs) may experience adverse health effects[12], the evidence for adverse health effects from airborne exposure to non-hazardous drugs and particulate matter (PM) from pharmaceuticals is limited. Currently, USP and NIOSH do not have specific guidance or requirements for fume hoods for exposure to PM from crushing drugs not classified as hazardous. Similarly, there are no specific title 8 or federal OSHA standards which cover workers who are potentially exposed to PM as a result of crushing pills.

Tavares et al. concluded in their pill crushing study that tablets are composed of various ingredients including the active pharmaceutical, binders, diluents, but it is unknown how much of the particulate contained the active drug ingredients.[13] Similarly, researchers Amiri et al. acknowledged in their 2023 pill crushing particulate matter study that their *focus was on PM size and not the chemical constituents, and there was no attempt to connect PM exposures, regardless of size, to any potential health outcomes.*[14] They concluded further that evidence of the chemical structures of the particles after medication crushing was unclear.

9.0 CONCLUSION

Cal/OSHA recommends that petition 611 be GRANTED to the extent that exposures to drugs classified as hazardous by NIOSH be considered in Cal/OSHA rulemaking already in development.

Cal/OSHA agrees that nurses (and other healthcare workers) are exposed to particulate matter (PM) during pill crushing activity which could result in health effects. The data is limited on the relationship between pharmaceutical PM and adverse health effects from drugs not classified as hazardous.

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[12] CDC NIOSH. NIOSH List of Hazardous Drugs in Healthcare Settings, 2024. Last updated December 2024. Accessed March 5, 2026. https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103

[13] Tavares, E., Loosley, B., & Shaik, A. (2025). Healthcare workers' exposure to aerosolized medications while crushing oral tablets. Journal of Occupational and Environmental Hygiene, 22(12), 939–945. https://doi.org/10.1080/15459624.2025.2544747.

[14] Amiri, A., Guess, L., Gilder, R., Showalter, D., Hart, L., & Sattler, B. (2023). Using Fume Hood to Reduce Nurses' Exposure to Particulate Matters Dispersed Into the Air During Pill Crushing. Workplace Health & Safety, 71(9), 412–418. https://doi.org/10.1177/21650799231184756.

However, it is known that healthcare workers exposed to hazardous drugs (in particular during the crushing of hazardous drugs) can experience adverse health effects.[15] Cal/OSHA is currently in a pre-rulemaking phase to address exposures to hazardous drugs in healthcare settings. Cal/OSHA encourages the petitioner to participate and provide their valuable input in that rulemaking process.

Cc: Debra Lee, Chief, Cal/OSHA

[15] CDC NIOSH. NIOSH List of Hazardous Drugs in Healthcare Settings, 2024. Last updated December 2024. Accessed March 5, 2026. https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103