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Pharmaceutical Drugs and MAQs

A. BACKGROUND

Are pharmaceutical products regulated as hazardous materials by the California Fire Code?

The California Fire Code (CFC) regulates storage, use and dispensing of hazardous materials, which can include some pharmaceutical products, drugs or medicines. Whether individual pharmaceutical products are regulated by the CFC depends on their specific properties, quantities, where and how they are being stored or handled, and the type of occupancy they are stored in. The CFC does have exceptions for certain items which are outlined in Section C.

Per CFC, Hazardous materials must not exceed Maximum Allowable Quantities (MAQs). To determine whether or not specific medicines are subject to these limits, it is important to exclude items that are exempt from these regulations. See Section C for CFC Exemptions. For those items that are not exempt, each pharmaceutical product must be evaluated according to CFC definitions for hazardous materials. This information can typically be located on the manufacturer's Safety Data Sheet (SDS).

B. EVALUATE WHETHER OR NOT PHARMACEUTICAL PRODUCTS ARE SUBJECT TO MAQ LIMITS

Step 1: Identify the occupancy where the drugs are handled or stored. You may need to discuss this with the Fire Marshal. Possible locations include:

- Pharmacy or retail space (Group M) open to the public: Medicines meeting these criteria are EXEMPT from CFC hazardous materials requirements when they contain no more than 50% flammable liquid and containers do not exceed 1.3 gallons.
- Patient occupied areas of a Hospital (Group I-2): These are not exempt from CFC hazardous materials requirements. Review Section C of this document for additional Exceptions.
- Compounding pharmacy (Group I-2 or Group B): These are not exempt from CFC hazardous materials requirements. Review Section C of this document for additional Exceptions.
- Laboratory (Group B or Group L): These are not exempt from CFC hazardous materials requirements. Review Section C of this document for additional Exceptions.

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- Clinical space outside of hospitals (Group B): These are not exempt from CFC hazardous materials requirements. Review Section C of this document for additional Exceptions.

Step 2: Review Hazardous Properties of Pharmaceutical Products that are <u>not</u> Exempt by occupancy. This can be done by reviewing product Safety Data Sheets (SDSs), examining Hazardous Waste Profiles, or other approved method for identifying hazardous properties.

A sample approach using <u>Hazardous Waste Profiles</u> to narrow down a list of CFC regulated hazardous materials is outlined below:

<u>Notes and Assumptions:</u>

- **California Environmental Protection Agency (Cal EPA) Waste Code:** 311 (Pharmaceutical Waste)
- **U.S. Department of Transportation (DOT) Shipping Name:** DOT hazards are similar to CFC hazard classes. The DOT shipping information can be used to highlight hazardous materials that may also be regulated by CFC.
- **Occupational Safety and Health Administration (OSHA) hazard:** OSHA hazards are closely aligned with CFC hazardous materials, particularly for physical hazards and acute health hazards. However, certain OSHA hazardous materials are not regulated by the CFC, including chronic health hazards (e.g., carcinogens, mutagens) and environmental hazards.

A representative sample approach using a list of pharmaceutical products classified as Hazardous Waste reduced the total number of regulated items from 8,960 items to 120 items (98.7% reduction). Using a list of drugs with hazardous waste profiles, one possible procedure for reducing the list to likely CFC hazardous materials is outlined below:

1. Sort the list of waste by DOT Shipping Name.
2. Include OSHA regulated items.
3. Review all OSHA regulated items for CFC Hazards by evaluating the Manufacturer's SDS. Exclude non CFC hazardous materials.
4. Exclude batteries, aerosols, and environmentally hazardous materials from DOT list.
5. Remove duplicates and non-CFC hazardous materials.

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6. Remove DOT combustible liquid and flammable liquid hazardous materials when Exception is met (CFC 5001.1 Exception 16, CFC 5701.1 Exception 8). This would apply to medicines that only contain a small percentage of flammable or combustible liquid.
7. Exclude devices and implants.
8. **The remaining items should be regulated as CFC hazardous materials when located in non-exempt locations.**

C. CALIFORNIA FIRE CODE (CFC) AND CALIFORNIA BUILDING CODE (CBC) EXCEPTIONS:

2025 CFC Table 5003.1.1(5)/CBC Table 307.1.1 (see **HazMat Exceptions Table** for full list of Exceptions)

2025 CFC 5001.1 Exception 1
In retail and wholesale sales occupancies: The quantity of medicines, foodstuffs or consumer products, and cosmetics containing not more than 50% by volume of water-miscible liquids, with the remainder of the solutions not being flammable, is not limited. To qualify for this allowance, such materials shall be packaged in individual containers not exceeding 1.3 gallons (5L).

Commentary: Pharmaceutical products in pharmacies, drug stores, medical/veterinary supply stores, or any area open to retail sales are exempt from CFC Hazardous Materials regulations. Compounding pharmacies, laboratories, hospitals, clinical trial facilities, drug manufacturing sites, veterinary/dental/medical offices or clinics would not fall under this exception.

2025 CFC 5001.1 Exception 14

Storage and display of aerosol products complying with Chapter 51.

Commentary: Pharmaceutical products that are aerosols are not subject to CFC Chapter 50 (Hazardous Materials) requirements or typical MAQ limits. They are, however, subject to CFC Chapter 51 (Aerosols) requirements for storage.

2025 CBC 307.11 Exception 12
Buildings and structures occupied for aerosol product storage, aerosol cooking spray products or plastic aerosol products shall be classified as Group S-1, provided that such buildings conform to the requirements of the CFC.

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Commentary: Similar to the CFC Exception 14 (above), Pharmaceutical products that are aerosols are not subject to CFC Chapter 50 (Hazardous Materials) requirements or typical MAQ limits. They are, however, subject to CFC Chapter 51 (Aerosols) requirements for storage.

2025 CFC 5001.1 Exception 15
Storage and use of flammable or combustible liquids that do not have a fire point when tested in accordance with ASTM D92, not otherwise regulated by this code.

Commentary: Certain pharmaceutical products which are barely flammable could fall into this category.

2025 CFC 5001.1 Exception 16
Flammable or combustible liquids with a flash point greater than 95ºF (35ºC) in a water-miscible solution or dispersion with a water and inert (noncombustible) solids content of more than 80 percent by weight, which do not sustain combustion, not otherwise regulated by this code.

Commentary: Certain pharmaceutical products could fall into this category, including combustible liquid mixtures.

2025 CFC 5003.1.1 (Exceptions)
Medical gases used for patient care used within patient areas of a Group I-2 occupancy when the applicable requirements of NFPA 99 Chapter 5 and Chapter 11 have been met.

Commentary: Though medical gases are not drugs, this exception is included due to relevance in hospital settings. This only applies to medical gas cylinders in-use for patient care in hospitals (Group I-2 occupancies) when NFPA 99 conditions are met. It does not apply to storage of medical gas cylinders, regardless of occupancy type. See document on **medical gases** for more information.

2025 CFC 5601.1 (Exception 2)
Explosives in forms prescribed by the official United States Pharmacopoeia.

Commentary: An example includes nitrogylcerin, which can be used as a vasodilator to treat or prevent angina, heart failure, or hypertension.

2025 CFC 5701.1 (Exception 2)
Medicines, foodstuffs, cosmetics and commercial or institutional products containing not more than 50 percent by volume of water-miscible liquids and with the remainder of the solution not

being flammable, provided that such materials are packaged in individual containers not exceeding 1.3 gallons (5 L).

Commentary: Pharmaceutical products that have a flammable component (such as ethanol or isopropanol) of no more than 50% of the mixture can be exempt from Flammable liquid requirements (Chapter 57) in the CFC in all occupancies. These are still subject to MAQ limits, however.

2025 CFC 5701.1 (Exception 7)
Storage and use of liquids that do not have a fire point when tested in accordance with ASTM D92.

Commentary: Identical to CFC Exception 15 (above).

2025 CFC 5701.1 (Exception 8)
Liquids with a flash point greater than 95°F (35°C) in a water-miscible solution or dispersion with a water and inert (noncombustible) solids content of more than 80 percent by weight, which do not sustain combustion.

Commentary: Identical to CFC Exception 16 (above).

D. ADDITIONAL RELEVANT REGULATIONS

Other requirements that may impact regulation of pharmaceutical products include Federal OSHA (CFR, Title 29, Section 1910.1200) and California OSHA (CCR, Title 8, Section 5194) requirements.

OSHA requirements for labeling: 29 CFR 1910.1200 Hazard Communication Standard
1910.1200 (b)(5) This section does not require labeling of the following chemicals:

(iii) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (*e.g.*, flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration of the Department of Agriculture.

Commentary: Many pharmaceutical products are not required to have hazard labels, include pictograms, or provide hazard statements for their products. Fortunately, the products often do still have a Safety Data Sheet where the hazard information can be located.

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OSHA Hazard Communication exceptions

1910.1200 (b)(6) This section does not apply to:

(vii) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)

Commentary: Certain drugs in solid, final form (tablets or pills), medicines for sale in retail occupancies (such as pharmacies) and personal drugs that employees have on hand while in the workplace are not subject to OSHA workplace requirements. Drugs in liquid form or solid drugs being crushed or handled would not be exempt from OSHA workplace requirements. These OSHA exceptions do not impact CFC regulations. That is, these drugs would still be subject to CFC hazardous materials requirements (unless they meet CFC or CBC exceptions).