



Industrial and Medical Gas Safety Alert

15 Sept 2022

UPDATED: CA Pharmaceutical and Sharps Waste Stewardship Law

Recently, CAL Recycle, Department of Resource and Recovery issued letters to GAWDA members in California stating they would be in violation of the Pharmaceutical and Sharps Waste Stewardship Law, ([Public Resources Code section 42030 et seq.](#) and [Title 14 California Code of Regulations section 18972.1 et seq.](#)), unless they submitted an approved stewardship plan for the disposal of pharmaceuticals and medical sharps by September 19, 2022. Following this date, the company may be fined up to \$50,000 per day.

The Pharmaceutical and Sharps Waste Stewardship Program is a statewide pharmaceutical and home-generated sharps waste stewardship program(s) which requires the safe and convenient disposal options for pharmaceutical drugs and home-generated sharps waste. The GAWDA member companies were on a list of pharmaceutical manufacturers provided by the CA Board of Pharmacy.

When I contacted CAL recycle they requested a letter from the CA Board of Pharmacy declaring medical gases exempt from this law. CGA also contacted the CA board of Pharmacy and was of great help expediting the issue. Today, Sep 15, 2022, I received a letter from the CA Board of Pharmacy which states medical gases are not covered/ exempt from this law, please see the letter and highlighted sections below.



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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



September 15, 2022

Marilyn Dempsey

Safety Dragons Workplace Consultants, LLC GAWDA Safety Consultant

Dear Ms. Dempsey:

The Board of Pharmacy received your inquiry on August 30, 2022, asking the Board's opinion on whether medical gases are "covered drugs" subject to SB212. The analysis of whether medical gases are covered under this law is dependent on who receives the medical gas and/or the composition of the medical gas.

Pursuant to Public Resources Code section 42030(e)(1), a "covered drug" means a drug sold, offered for sale, or dispensed in the State of California. And Business and Professions Code section 4024 defines "dispense" and BPC section 4016 defines "administer". Based on the relevant sections of the law, a drug that is solely administered in doctors' offices, clinics or hospitals (Clinical Settings) within the definition of BPC section 4016, and not offered, sold or dispensed to a patient in California, would not be considered a "covered drug". Therefore, medical gases that are solely used in Clinical Settings, not offered for sale, or dispensed to ultimate users in the State of California, are not considered "covered drugs". A potential covered entity should examine its distribution chain to determine whether its medical gases are exempted under this clause.

This GAWDA Safety Alert is issued by GAWDA Consultant Marilyn Dempsey.
Please contact her at 940-999-8466 or marilyn@safetydragons.com for further information.



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Medical oxygen is a prescription drug within the meaning of section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)(1)). Thus, based on PRC 42030(e)(1)(A), medical oxygen dispensed to patients for home-use is a “covered drug”. However, medical oxygen, though a prescription drug, can be vented to the atmosphere following safety procedures. This law intends to remove unused and discarded medical products from our public spaces, municipal waste systems, and environment. According to the intent of the law, the Board considers medical oxygen not subject to SB212, since venting medical oxygen into the atmosphere will not cause any burden to the environment. The cylinder containing medical oxygen is not considered a drug, and thus does not fall under the provisions of SB212. Used oxygen tanks should not be deposited into a drug kiosk as unvented cylinders could pose a safety hazard. The Board suggests consumers contact suppliers or refer to “Management of Compressed Gas Cylinders” web page for more information regarding disposal or recycling of emptied cylinders.

This letter expresses the Board’s opinion regarding interpretation of the term “covered drug.” We note that PRC section 42031(a) also requires that covered entities submit a list of covered drugs and uncovered drugs to the Board. The Board has no authority to exempt a medical gas company from the “covered entity” definition and has no authority to interpret the requirements of such covered entities, including under Section 42031(a). Please contact CalRecycle if you have a specific question regarding the definition of a “covered entity” or their responsibilities under this Act.

Sincerely,

Lilly Fang, Pharm.D.

Inspector

California State Board of Pharmacy