

FAQs: Pharmaceutical and Sharps Waste Stewardship Programs

Senate Bill 212 (Jackson, Chap. 1004, Statutes of 2018) was signed by Governor Newsom on September 30, 2018. This bill was codified in the California Public Resources Code, Chapter 2, sections 42030-42036.4. This bill leveraged existing law regarding drug-take back provisions established under pharmacy law and federal law and medical waste management provisions administered by the California Department of Public Health to create a new stewardship program to ensure that a “covered entity” pays for the proper disposal of “covered products” shipped into California. This Board was given certain enumerated responsibilities under the bill. The bill requires the following with respect to the Board of Pharmacy:

- “Covered entities” had to report to the Board by April 1, 2021 a list of the “covered products” and a list of drugs or sharps that are not covered products that it sells or offers for sale in California. [Pub. Resources Code section 42031\(a\)\(1\)](#).
- By January 15 each year, a “covered entity” or the stewardship program to which it belongs must update its list of “covered products” and uncovered products with Board. [Pub. Resources Code section 42031\(a\)\(2\)](#).
- Retail pharmacies that sell a covered product under its own store label were required to notify the Board of the “covered entity” that supplied the retail pharmacy with its store label covered products. [Pub. Resources Code section 42031\(b\)](#).
- The Board must verify the information received from covered entities regarding its covered products and from retail pharmacies identifying the supplier of any store label covered products. [Pub. Resources Code section 42031\(c\)](#).
- The Board also must review proposed stewardship plans for compliance with pharmacy law and make a determination whether the plan complies with pharmacy law. [Pub. Resources Code section 42032\(b\)](#).

The Board has other authorized duties under this law. However, primary oversight over the implementation of this new program lies with the California Department of Resources Recycling and Recovery (CalRecycle), including final approval of stewardship plans and enforcement of these new provisions.

1. How does a covered entity submit a list of products?

You can email the list of covered and non-covered products to BOPStewardship@dca.ca.gov. The Board provides a [template](#) to facilitate the submission and its review. Pursuant to Public Resources Code

(PRC) section 42031(a)(1), a covered entity must submit both a list of covered products, and a “a list and description of any drugs or sharps that are not covered products”, that is sells or offers for sale in California, to the Board. A covered entity is responsible for the accuracy and completeness of the list.

Reference: PRC [42031\(a\)\(1\)](#)

2. How often shall a covered entity submit the list of products?

Public Resources Code section 42031(a)(2) specifies that a covered entity or a stewardship organization on behalf of a group of covered entities shall submit an updated list with highlighted changes to the Board on or before January 15 of each year or upon request.

Reference: PRC [42031\(a\)\(2\)](#)

3. Are auto-injectors and pre-filled syringes “covered products”?

Yes. Pursuant to Public Resource Code section 42030 (g), “covered product” means a covered drug or home-generated sharps waste. Auto-injectors and prefilled syringes are “covered products” unless they meet the exclusion criteria set forth in PRC 42030(e)(2) or PRC 42030(l)(2).

Reference: PRC [42030\(g\)](#)

4. Are intramuscular injection needles used by ultimate users at home “covered products”?

Yes. Intramuscular injection needles, such as the ones for testosterone injection, are used to penetrate skin for the delivery of medication. They are “home-generated sharps waste” pursuant to Health & Safety Code (HSC) Section 117671, and thus “covered products” pursuant to Public Resource Code section 42030 (g).

Reference: PRC [42030\(g\)](#); HSC [117671](#)

5. Can an ultimate user bring sharps waste to a pharmacy or deposit sharps waste into a drug take-back kiosk?

Pursuant to California Code of Regulations (CCR), tit. 16 section 1776.1(e), medical sharps and needles shall not be deposited into a drug take-back kiosk. Under Business and Professions Code (BPC) section 4146, a pharmacy is permitted but not required to accept sharps containers.

Please check <https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/> for more information about sharps waste stewardship.

Reference: CCR [1776.1\(e\)](#); BPC [4146](#)

6. Some drugs are only being used in clinical settings. Are they “covered drugs”?

Pursuant to Public Resource Code section 42030(e)(1), a “covered drug” means a drug sold, offered for sale, or dispensed in or into the State of California. Additionally, Business and Professions Code sections 4024 and 4016 defines “dispense” and “administer”, respectively.

Based on the relevant sections of the law, a drug that is SOLELY administered in 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”. Public Resources Code section 42031(a)(1) requires that “covered entities” submit a list of covered and uncovered products, and the Board prefers that potential covered entities submit to the Board a statement why its drugs should not be considered “covered drugs” based on any such statutory interpretation. The potential covered entity is responsible for the truthfulness of such statement.

Reference: PRC [42030\(e\)\(1\)](#); BPC [4016](#), [4024](#)

7. Are APIs (Active Pharmaceutical Ingredients) “covered drugs”?

APIs are not finished drugs, thus not “covered drugs” pursuant to Public Resource Code section 42030(e).

Reference: PRC [42030\(e\)](#)

8. How do I know if I am a “covered entity”?

Please refer to Public Resource Code section 42030(f) for the definition of “covered entity”. Please contact CalRecycle at pharmasharpsenforcement@calrecycle.ca.gov for interpretive questions regarding a “covered entity”.

Reference: PRC [42030\(f\)](#)

9. Where can I find the list of “covered products” and “covered entities”?

Pursuant to California Public Resource Code 42035(a)(1), on or before June 30, 2022, CalRecycle will post on its Internet Web site (<https://www.calrecycle.ca.gov/epr/pharmasharps>) a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter. The law does not require posting of a list of “covered products”.

Reference: PRC [42035\(a\)\(1\)](#)

10. Where can I find information regarding stewardship organizations and stewardship plans?

You can find information about potential stewardship organizations at <https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities> You can find information about Pharmaceutical Stewardship Plans at <https://www.calrecycle.ca.gov/epr/pharmasharps/pharma/plan>, and Home-Generated Sharps Waste Plans at <https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/plan>.

11. What are the responsibilities of a wholesaler in compliance with SB212?

A wholesaler may be considered a “covered entity” per the tiered definition under Public Resource Code 42030(f). Wholesalers should coordinate with appropriate entities in their supply chains to determine how statutory and regulatory requirements will be met. In addition, a wholesaler has the reporting responsibility pursuant to Public Resource Code 42035(c). A wholesaler shall determine if covered products are in compliance with the law, by verifying that the covered entities providing the covered products are in compliance with the law and shall notify CalRecycle if it determines that the covered entity is not listed on CalRecycle’s Internet Web site.

Reference: PRC [42030\(f\)](#), Reference: PRC [42035\(c\)](#)

12. How can a pharmacy participate in a stewardship plan for pharmaceutical or home-generated sharps waste?

A pharmacy can contact approved stewardship plan operators for participating in the program. Please check <https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities/> for approved stewardship plans and their contact information.

13. Are compounded medications “covered drugs”?

Compounded medications are exempted from section 505 of the Federal Food, Drug and Cosmetics Act (21 U. S.C. 355). Therefore, compounded medications are not “covered drugs” under the stewardship program.

Reference: PRC [42030\(e\)\(1\)](#)

14. Can a covered entity include non-covered drugs to the covered drug list?

The intent of the SB212 is to ensure the safe disposal of pharmaceutical and home-generated sharps wastes. In the spirit of the law, the Board does not view it as a violation of law if a covered entity voluntarily elects

non-covered drugs to be covered under a stewardship plan.

15. Where can I get more information if needed?

You can find more information at CalRecycle's web site:

<https://www.calrecycle.ca.gov/epr/pharmasharps>. Questions regarding "covered drugs" or "covered products" should be directed to bopstewardship@dca.ca.gov. Questions regarding "covered entity" and other provision of SB212 should be directed to pharmasharpsenforcement@calrecycle.ca.gov

16. How do I know if an over-the-counter drug is a "covered drug"?

Public Resource Code 42030(e)(1)(B) states a drug marketed under an over-the-counter drug monograph is a "covered drug". Pursuant to Public Resource Code 42030(e)(1)(A), non-prescription drugs (over-the

counter drugs) marketed under NDA or ANDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act or Section 351 of the Federal Public Health Service Act are also "covered drugs". There are some exclusions pursuant to Public Resource Code 42030(e)(2)(C). Please note whether a product is a cosmetic or/and a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. The Board recommends potential covered entities examine their over-the-counter drugs for their intended uses and contact appropriate agents, including potentially a lawyer, for guidance of whether their particular product is a covered drug.

Reference: PRC [42030\(e\)\(1\)\(A\)](#); [42030\(e\)\(1\)\(B\)](#); [42030\(e\)\(2\)\(C\)](#); [FDA Is It a Cosmetic, or a Drug, or Both?](#)

17. If a covered entity does not offer a drug for sale, could a drug still be considered a "covered" Drug"?

Yes. Pursuant to PRC 42030(e)(1), "covered drug" includes drugs that were sold, offered for sale or dispensed in the state of California. If the drug is no longer produced or no longer for sale, it could still be considered a "covered drug" under the law.

18. If a covered entity does not currently offer a "covered drug" for sale, does the covered entity still need to report the covered drug?

No. PRC 42031(a) states a covered entity shall provide a list of covered products and a list of any drugs of sharps that are not covered products, that it sells or offers for sale in the state to the Board. While a drug may still be covered, the covered entity does not need to report it if the drug is no longer for sale in the State of California.

