Date of Hearing: August 20, 2025

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Buffy Wicks, Chair

SB 646 (Weber Pierson) – As Amended July 10, 2025

Policy Committee: Health Vote: 15 - 0

Environmental Safety and Toxic Materials 5 - 0

Urgency: No State Mandated Local Program: Yes Reimbursable: No

SUMMARY:

This bill requires a manufacturer of prenatal multivitamins to test a sample of each lot for toxic elements and disclose specified information to the public, including the toxic element testing information. This bill also bans the manufacture, delivery, and sale of a prenatal multivitamin that does not comply with these provisions.

Please refer to the Assembly Committee on Environmental Safety and Toxic Materials analysis for definitions and further detail.

Specifically, this bill:

- 1) Defines "toxic elements" to mean arsenic, cadmium, lead, and mercury.
- 2) Requires a manufacturer of a bulk prenatal multivitamin product or a packaged prenatal multivitamin product that is sold, manufactured, delivered, held, or offered for sale in the state to test a representative sample of each lot of the manufacturer's prenatal multivitamin product at a proficient laboratory for toxic elements.
- 3) Requires a proficient laboratory, as defined, including a manufacturer's in-house laboratory that analyzes the bulk prenatal multivitamin product or packaged prenatal multivitamin product for toxic elements, meet specified criteria relating to competence of testing and calibration laboratories, testing of toxic elements, analytical methods, and quantifying toxic elements.
- 4) Requires manufacturers and brand owners to provide test results to any authorized agent of the California Department of Public Health (CDPH) upon request. Authorizes a brand owner to comply with this requirement by providing the test results of the manufacturer used to produce the bulk prenatal multivitamin product or packaged prenatal multivitamin product.
- 5) Requires, commencing January 1, 2027, a brand owner of packaged prenatal multivitamin products sold, manufactured, delivered, held, or offered for sale in the state disclose product information to the public consistent with all of the following:
 - a) Make publicly available on the brand owner's website, for the duration of the product shelf life for a packaged prenatal multivitamin product plus one month, the name and level of each toxic element present in each lot of a packaged prenatal multivitamin product. Requires the brand owner include, on the same webpage, information from the

product's supplement facts panel, including the level per serving of each nutrient ingredient, and the following statement:

Prenatal multivitamins may contain varying levels of toxic elements. Unless the ingredients come from sources with low levels of toxic elements, the prenatal multivitamins may also contain higher levels of toxic elements. The levels of toxic elements can also vary with the types of ingredients included in a prenatal multivitamin. For more information, speak with your physician about choosing a prenatal multivitamin that meets your specific nutrient needs.

- b) Make the toxic element testing information available to the public user, without the user having to provide a UPC number, lot number, or proof of purchase.
- c) Provide descriptive information on the brand owner's internet website to enable accurate identification of the packaged prenatal multivitamin product by the public, including information that makes the levels of toxic elements available to the public by lot.
- d) Provide a website link to the FDA's most recent webpage where the public can find information relating to toxic elements in food.
- e) On the brand owner's webpage describing a packaged prenatal multivitamin product, include a prominent statement that reads, "For information about toxic element testing on this product," followed by a link to the webpage containing the testing results. For products sold in retail stores, on the outermost package of any packaged prenatal multivitamin product sold, include a statement that reads: "For information about toxic element testing on this product, visit" followed by the webpage specified in this provision.
- 6) Prohibits a person from selling, manufacturing, delivering, holding, or offering for sale in the state any prenatal multivitamin that does not comply with the requirements of this bill.

FISCAL EFFECT:

The California Department of Public Health (CDPH) estimates ongoing, annual costs of \$169,000 starting in fiscal year 2026-27 to cover one full-time employee position to perform inspections and field audits, including remote inspections and desk audits, re-inspections, new license inspections, label review, and field visits to California firms holding out-of-state products (General Fund).

The Department of Justice (DOJ) anticipates increased workload for the Environmental Justice and Protection Section (EJPS) within DOJ's Public Rights Division to enforce this bill. The work anticipated by EJPS could require a significant increase in attorney hours. DOJ is unable to estimate at this time the additional number of Deputy Attorneys General, along with their legal complement, that might need to be hired. If DOJ does not pursue enforcement as authorized by this bill, DOJ would likely not incur any costs, but if DOJ hires staff to handle enforcement actions, costs could be in the low hundreds of thousands of dollars annually, at a minimum (Unfair Competition Law Fund).

COMMENTS:

1) **Purpose.** This bill is sponsored by Environmental Working Group, American College of OB/GYNs District IX (ACOG), and Unleaded Kids. According to the author:

Prenatal vitamins are essential for supplementing the nutritional needs of pregnant individuals, helping to prevent birth defects, low birth weight, and pregnancy complications. While a balanced diet is ideal, many Americans, including Californians, do not consume adequate nutrients. Prenatal vitamins commonly contain folic acid, iodine, iron, and other essential nutrients for a pregnant individual.

Recent studies highlight concerns over toxic element contamination of prenatal vitamins with lead, arsenic, cadmium, and mercury. A GAO study found lead, a heavy metal with no safe level of exposure, in half of the sampled prenatal vitamins, with some independent studies finding contamination, exceeding California's Proposition 65 limits.

Given the risks associated with heavy metal exposure and the absence of federal or state regulations specific to prenatal vitamins, legislative action is needed to enhance transparency, which allows consumers to make informed choices, incentivizes companies to reduce toxic element contamination, and, if needed, provide a basis for setting safety standards.

2) **Background.** Under the federal Food, Drug, and Cosmetic Act, as amended in 1994 by the Dietary Supplement Health and Education Act, the federal Food and Drug Administration (FDA) regulates dietary supplements—including prenatal supplements—as a special category of food. Therefore, unlike drugs, dietary supplements are subject to a limited premarket approval process and it is the responsibility of dietary supplement companies to ensure their products meet safety standards for dietary supplements and are not otherwise in violation of the law. Dietary supplement labels must have nutrition information in the form of a Supplement Facts label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. The label also must have a statement on the front of the product identifying it as a "dietary supplement" or similar descriptive term, such as "herbal supplement" or "calcium supplement." No federal statutory definition exists for a "prenatal supplement" and what it must contain. According to a 2023 report from the U.S. Government Accountability Office, there is a large and highly variable market in terms of nutrient content across prenatal supplement products.

Studies have documented the presence of heavy metals in prenatal supplements. For example, a 2025 study of a sample of 156 commercially available, over-the-counter prenatal vitamins detected lead in 83% of samples and cadmium was detected in 73% of samples. The authors of this study note that the presence of heavy metals in prenatal supplements is especially problematic because lead and cadmium have chemical similarities to calcium, allowing them to replace calcium in biological processes, which can lead to health problems such as reduced calcium and iron absorption.