

function of the body of humans or other animals; (d) articles intended for use as a component of any of the other specified articles. (BPC § 4025)

- 7) Defines “furnish” as to supply by any means, by sale or otherwise. (BPC § 4026)
- 8) Defines “manufacturer” as every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer. (BPC § 4033(a)(1))
- 9) Defines “pharmacist” as a natural person who holds a pharmacist license issued by the CSBP and entitles the licensee to practice pharmacy within or outside of a licensed pharmacy. (BPC § 4036)
- 10) Defines “pharmacy” as an area, place, or premises licensed by the CSBP in which the profession of pharmacist is practiced and where prescriptions are compounded, including any area, place, or premises described in a CSBP license where controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. (BPC § 4037)
- 11) Defines “prescription” as an oral, written, or electronic transmission order that is given individually for the person for whom ordered that contains specified identifying and instructional information and is issued by a licensed provider authorized to issue the order. (BPC § 4040).
- 12) Defines “wholesaler” as a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device; prohibits a wholesaler from storing, warehousing, or authorizing the storage or warehousing of drugs with any person or at any location not licensed by the CSBP. (BPC § 4043)
- 13) Defines “food” as (a) articles used for food or drink for humans or animals, (b) chewing gum, and (c) articles used for components of any such article. (Health and Safety Code § 109935)
- 14) The Sherman Food, Drug, and Cosmetic Law establishes California's statutory framework governing foods, drugs, devices, and cosmetics, including provisions relating to their manufacture, packaging, labeling, distribution, and sale within the state.
- 15) Defines “drug” to include articles recognized in the official compendia, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles (other than food) intended to affect the structure or function of the body. (HSC § 109925.)
- 16) Defines “medical food” as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive

nutritional requirements, based on recognized scientific principles, are established by medical evaluation. (21 U.S.C. § 360ee(b)(3))

This bill authorizes a pharmacist, manufacturer, or wholesaler to participate in an arrangement or agreement to deliver enteral nutrition supplements or replacements directly to a patient's residence pursuant to a valid order from a prescriber acting within their scope of practice without this being considered the unlicensed practice of pharmacy. Defines "enteral nutrition supplements or replacements" as medical food used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food.

FISCAL EFFECT: This bill is keyed fiscal by Legislative Counsel. According to the Assembly Committee on Appropriations, the Board anticipates minor and absorbable costs to educate licensees through various means and to promulgate regulations.

COMMENTS:

1. **Purpose.** The California Association for Medical Product Suppliers is the sponsor of this bill. According to the Author, "AB 1794 addresses a critical but often overlooked component of healthcare: access to medically necessary enteral formulas. For many Californians living with chronic illness, neurological conditions, gastrointestinal disorders, or severe disabilities who can't consume food orally, enteral formula is life-sustaining liquid nutrition. These products are equivalent to food and prescribed by healthcare providers to keep people nourished and healthy, preventing hospitalization, and preserving their quality of life. Patients and families face unnecessary barriers to obtaining enteral formula; for medically fragile patients it can be difficult or even dangerous to make trips to the pharmacy to pick up a food product. That is an unacceptable barrier. Nutrition delivered through enteral products, defined as "medical food," should be as accessible for patients as the grocery store. AB 1794 makes access to these medically necessary formulas simple and straightforward for patients, allowing the formula to be shipped directly to their front door, because no one should struggle to obtain the nutrition they need to survive and thrive."

The Author states that "Medicare and many commercial payers allow for drop shipping as a cost-effective and efficient distribution method of enteral nutrition formulas and products as these formulas are classified as over-the-counter (OTC) items. Prior to the establishment of Medi-Cal Rx in January 2022, licensed Home Medical Device Retailers (HMDRs) were able to distribute these items under fee for service and Medi-Cal managed care in the same manner. However, once Medi-Cal RX was implemented, it limited the distribution of enteral nutrition to "by pharmacies only." Providers were recently notified by the pharmacy benefit manager (PBM) for California's Medi-Cal Rx program, that drop shipping would no longer be acceptable as dispensing of these over the counter (OTC) nutritional items would require a pharmacist or pharmacy technician to pull and label the items eliminating the possibility of drop shipping from manufacturers."

According to the Author, the sponsor states that they believe this interpretation may have occurred since the implementation of Medi-Cal RX, and that enteral nutrition is now being treated with the same caution reserved for "controlled drugs" and

“dangerous drugs” as opposed to “food.” If left unchanged, this policy poses serious repercussions for those who rely on enteral nutrition formulas for their daily nutritional needs.

2. **Background.** Nutrition therapy is a component of care used to maintain or improve nutritional status in patients with medical conditions. Nutrition therapy may be provided orally, enterally, or parenterally. Enteral nutrition involves the delivery of nutrients through the gastrointestinal tract, including through feeding tubes when a patient cannot consume adequate nutrition by mouth. Parenteral nutrition, by contrast, delivers nutrients intravenously and bypasses the gastrointestinal tract.

Certain enteral nutrition products may qualify as “medical foods” under federal law. Medical foods are defined in the Orphan Drug Act as foods formulated to be consumed or administered enterally under the supervision of a physician for the specific dietary management of a disease or condition with distinctive nutritional requirements established by medical evaluation. (21 U.S.C. § 360ee(b)(3).) Enteral nutrition products administered orally or through feeding tubes may qualify as medical foods when they are formulated and used for the specific dietary management of a disease or condition and otherwise satisfy the requirements of federal law. Thus, federal law recognizes that certain products used in connection with medical treatment and physician supervision may nonetheless be regulated as foods.

According to the U.S. Food and Drug Administration's (FDA) 2023 *Guidance for Industry, Frequently Asked Questions About Medical Foods – Third Edition*, medical foods are a distinct category of food and are not regulated as prescription drugs. FDA guidance describes medical foods as products intended for oral consumption or enteral administration by tube for patients with medically determined nutritional requirements that cannot be met by modification of the normal diet alone. FDA guidance further indicates that medical foods are not required under federal law to be dispensed solely pursuant to a prescription. Accordingly, the fact that a physician orders a medical food, or that a pharmacy processes the order for dispensing, labeling, or reimbursement purposes, does not by itself alter the product's regulatory classification as a food. A physician may prescribe or order enteral nutrition as part of a patient's medical treatment, but the product generally remains regulated as a food unless it independently satisfies the statutory definition of a drug.

The Health and Safety Code similarly defines “food” broadly to include articles used for food or drink for humans and articles used as components of such articles. Enteral nutrition products generally fall within California's food regulatory framework, although particular products may also be subject to regulation as drugs or devices depending on their composition, intended use, and applicable law. The Sherman Food, Drug, and Cosmetic Law establishes California's statutory framework governing foods, drugs, devices, and cosmetics, including provisions relating to their manufacture, packaging, labeling, advertising, distribution, and sale within the state.

Because enteral nutrition products are generally regulated as foods rather than drugs, proponents argue that existing law already permits direct delivery of

prescribed enteral nutrition products to patients, including circumstances in which a pharmacist processes the order for labeling, documentation, or reimbursement purposes. Under this interpretation, the prescription serves as evidence of medical necessity and physician supervision, but does not itself transform the enteral nutrition product into a dangerous drug subject to all provisions of Pharmacy Law.

AB 1794 appears intended to provide express statutory authority for direct-to-patient delivery arrangements involving prescribed enteral nutrition products and to clarify the permissible roles of pharmacists, wholesalers, and manufacturers in those arrangements.

- 3. Arguments in Support.** The California Association of Medical Suppliers writes that the approach in this bill “provides a safe alternative for family members and caregivers who may struggle to safely transport an individual on their own. Drop shipment allows caregivers to spend less time coordinating pharmacy trips and more time on other aspects of care. AB 1794 seeks to prioritize the needs of medically fragile individuals who already suffer from mobility issues, pain and fatigue, while maintaining appropriate clinical safeguards provided by pharmacists.”

Biocom states that “Enteral nutrition products are medically necessary for patients with serious conditions affecting their ability to eat or absorb nutrients through normal means. For these patients, consistent and timely access to enteral products is not a convenience - it is a clinical necessity. AB 1794 removes unnecessary friction by aligning the treatment of enteral nutrition products with the existing framework already in place for dialysis drugs and devices, ensuring that patients receive the nutrition they need without interruption.”

According to the California Life Sciences Association, “AB 1794 makes a simple, targeted fix; it allows enteral nutrition supplements or replacements to be delivered directly to a patient’s home pursuant to a valid order from a prescriber acting within their scope of practice, just as other essential medical and nutritional products routinely are. This change does not alter the prescriber oversight process, a valid order remains required, it simply removes a logistical intermediary that serves no clinical purpose for this category of product. The result will be greater continuity of care, reduced risk of harmful interruptions in nutrition, and improved quality of life for patients who depend on these products every day.”

SUPPORT AND OPPOSITION:

Support:

California Association of Medical Product Suppliers (sponsor)
Biocom
California Life Sciences Association

Opposition:

None received

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