Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
AB 1794 (Ransom) – As Introduced February 10, 2026

SUBJECT: Pharmacy: enteral products.

SUMMARY: Exempts manufacturers, wholesalers, and distributors that furnish enteral nutrition products to a patient's residence from the pharmacist scope of practice under the Pharmacy Law.

EXISTING LAW:

1) Defines "medical food" to mean 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. (Title 21 United States Code § 360ee(b)(3))

2) Regulates the practice of pharmacy under the Pharmacy Law and establishes the California State Board of Pharmacy (CSBP) to administer and enforce the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000-4427.8)

3) Prohibits the unlicensed practice of pharmacy, meaning the manufacturing, compounding, furnishing, selling, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription of a prescriber unless licensed as a pharmacist. (BPC § 4051(b))

4) Exempts a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients from the prohibition against unlicensed pharmacy practice. (BPC § 4054)

5) Authorizes a pharmacist, or a manufacturer or wholesaler exempted from the unlicensed practice of pharmacy for dialysis drugs, to distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the CSBP, as specified. (BPC § 4059(c))

6) Defines "dangerous drug" or "dangerous device" to mean any drug or device unsafe for self-use in humans or animals, including any drug or device that by law can be lawfully dispensed only if prescribed or furnished by an authorized licensee. (BPC § 4022)

7) Defines "device" to mean any instrument, apparatus, machine, implant, in vitro reagent, or contrivance, including its components, parts, products, or the byproducts of a device, and accessories that are used or intended for either (a) use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or any other animal or (b) affect the structure or any function of the body of a human or any other animal. (BPC § 4023)

8) Defines "drug" to mean: (a) articles recognized in the official United States Pharmacopoeia, official National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement of any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (c) articles (other than food) intended to affect the structure or any 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)

9) Defines "furnish" to mean to supply by any means, by sale or otherwise. (BPC § 4026)

10) Defines "manufacturer" to mean 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))

11) Defines "pharmacist" to mean 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)

12) Defines "pharmacy" to mean 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)

13) Defines "prescription" to mean 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).

14) Defines "wholesaler" to mean and includes 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)

15) Defines "third-party logistics provider" to means an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition. (BPC § 4045)

THIS BILL:

1) Exempts a manufacturer, wholesaler, or distributor that furnishes enteral nutrition products directly to a patient's residence pursuant to a valid order from a prescriber from the prohibition against the unlicensed practice of pharmacy.

2) Authorizes the following individuals and entities to distribute enteral nutrition products directly to patients with medically diagnosed conditions that preclude the full use of regular food pursuant to regulations adopted by the CSBP:

   a) A pharmacist.

b) A manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

c) A manufacturer, wholesaler, or distributor that furnishes enteral nutrition products directly to a patient's residence pursuant to a valid order from a prescriber.

FISCAL EFFECT: Unknown; this bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the *California Association of Medical Product Suppliers*. According to the author:

> [This bill] 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. [This bill] 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.

Background. In clinical nutrition, nutrition therapy is a component of nutrition care provided during medical treatment.[1] Nutrition therapy is provided through food replacements or nutritional supplements to maintain a healthy nutritional status when dealing with medical conditions.

Enteral nutrition is one of three forms of nutrition therapy, along with oral nutrition and parenteral nutrition. Oral nutrition involves eating or drinking the therapy by mouth. Enteral nutrition utilizes medical devices, such as nasal or stomach feeding tubes, to bypass the mouth and access the gastrointestinal (GI) tract directly. Parenteral nutrition utilizes intravenous catheters to provide the nutrients through the bloodstream, bypassing the GI tract altogether.

Direct Delivery of Prescription Enteral Nutrition. The Pharmacy Law and federal law specifically exempt food, which is defined to include enteral nutrition, from the definition of a drug. As a result, enteral nutrition is not regulated as a drug nor mentioned in the CSBP regulations. When enteral nutrition is prescribed, a pharmacist may still process the prescription for labeling or payor reimbursement purposes, but there is no Pharmacy Law impediment to delivering food directly to a consumer.

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[1] American Society for Parenteral and Enteral Nutrition, *ASPEN Definition of Terms, Style, and Conventions Used in ASPEN Board of Directors–Approved Documents*, last modified March 6, 2026, https://nutritioncare.org/definition-of-terms-style-and-conventions-used-in-aspen-board-of-directors-approved-documents/.

Prior Related Legislation. AB 1926 (Connolly) of 2024 would have required health plan contracts and insurance policies to provide coverage for dietary enteral formulas for the treatment of regional enteritis (Crohn's disease). *AB 1926 was held on the Senate Appropriations Committee suspense file*.

ARGUMENTS IN SUPPORT:

The *California Association of Medical Product Suppliers* (sponsor) writes in support:

> [This bill] seeks to allow for prescribed "medically necessary supplements, or enteral nutrition" to be dispensed directly to patients at their homes while maintaining pharmacist oversight to ensure that nutritionally complete and clinically appropriate products are delivered safely. "Drop shipment" of enteral nutrition formulas directly to a patient's home has provided a lifeline for medically fragile patients who would otherwise be forced to struggle with transportation due to a combination of physical, medical, sensory, and logistical challenges in order to retrieve their nutritional supports.
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> Enteral nutrition formulas are administered under medical supervision when prescribed for treatment for digestive and inherited metabolic disorders. Medicare and many commercial payers allow for shipment directly to patients' homes as a cost-effective and efficient distribution method. Once the pharmacist confirms the initial order, allowing direct shipment streamlines access and reduces overhead - especially critical for medically fragile patients who rely on consistent nutritional support.
>
> Medicare and many commercial payers allow for drop shipping as a cost-effective and efficient distribution method of enteral nutrition formulas and products. 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 Prime Therapeutics, the pharmacy benefit manager (PBM) for California's Medi-Cal Rx program, that drop shipping directly to patients' homes would no longer be acceptable as dispensing of these nutritional items would require a pharmacist or pharmacy technician to physically pull and label the items.
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> We 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.

ARGUMENTS IN OPPOSITION:

The *California Pharmacists Association* writes in opposition:

> While we appreciate the intent behind the legislation to facilitate access to enteral nutrition (EN) products, we are deeply concerned about the risks to patient safety

> that could arise from reducing or eliminating pharmacist oversight in their distribution and use.
>
> [The sponsor's] fact sheet states that, "unlike dangerous drugs that need the clinical judgment of a pharmacist when dispensed, enteral formula is prescribed as a nutritional support." While enteral nutrition products are not prescription medications, they do, however, interact with several prescription drugs and, among other things, affect absorption. Pharmacists routinely apply their expertise to identify and mitigate these risks, which can have serious clinical consequences if overlooked….
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> This could lead to subtherapeutic levels, treatment failure, or toxicity if doses are not adjusted. Pharmacists review concurrent medications to recommend timing separations (e.g., holding feeds 1–2 hours before/after certain drugs), alternative formulations, or therapeutic monitoring….
>
> Additionally, exempting manufacturers, wholesalers, and distributors that furnish enteral nutrition products directly to a patient's residence from the patient protection provisions in B&P Code Section 4051 undermines the statute's longstanding commitment to safeguarding patients. These protections exist to ensure appropriate oversight, accountability, and safe delivery, regardless of the distribution channel. Carving out such an exemption creates a gap in patient protection, potentially exposing vulnerable individuals to increased risk and weakening the integrity of a framework specifically designed to prioritize patient safety.

IMPLEMENTATION ISSUES:

Overbroad Exemption. As stated in sponsor's letter, the intent of the bill is to clarify that for delivery of enteral products directly to consumers. To accomplish this, the bill exempts manufacturers, wholesalers, and distributors who deliver enteral nutrition products from the pharmacy licensing requirements altogether. However, this exemption is overbroad for the following reasons:

1) There is no prohibition against the direct-to-consumer delivery in the pharmacy licensing requirement. There may also be unintended impacts from that exemption beyond the scope of this bill.

2) As drafted, the enteral nutrition exemption extends to dialysis manufacturers and wholesalers. Likewise, the exemption that dialysis manufacturers and wholesalers have for dangerous drugs and devices extends to enteral nutrition manufacturers and wholesalers.

3) Distributors, which are not defined, do not appear to be specifically regulated under the Pharmacy Law and it is unclear why they would need to be exempted.

4) There is no definition for enteral nutrition products, and products could mean more than the food. It could include the accompanying medical devices, such as the gastronomy access device that enters the skin to access the stomach.

Instead, the author may wish to amend the bill to remove the blanket exemption and directly state that a manufacturer or wholesaler may deliver enteral nutrition directly to a consumer.

AMENDMENTS:

1) Limit enteral nutrition products to "supplements or replacements" to exclude the medical devices and the constituent parts used to administer the nutrition, and define the products using the Medi-Cal description for enteral nutrition:

   On page 3 of the bill, line 38, insert:

   (i) *(1) For purposes of this subdivision, "enteral nutrition supplements or replacements" means 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.*

2) Limit the exemption to directly allow "drop shipping" by manufacturers and wholesalers to process prescriptions as follows:

   a) On page 2, delete section 1 from the bill:

   ~~**SECTION 1.** Section 4054 of the Business and Professions Code is amended to read:~~

   ~~**4054.** (a) Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.~~

   ~~(b) Section 4051 shall not apply to a manufacturer, wholesaler, or distributor that furnishes enteral nutrition products directly to a patient's residence pursuant to a valid order from a prescriber acting within their scope of practice.~~

   b) On page 3, line 38:

   *(2)*A pharmacist, ~~or a person exempted pursuant to Section 4054,~~ *manufacturer, or wholesaler* may ~~distribute~~ *participate in an arrangement or agreement to deliver* enteral nutrition ~~products~~ *supplements or replacements* directly to ~~patients with medically diagnosed conditions that preclude the full use of regular food pursuant to regulations adopted by the board.~~ *a patient's residence pursuant to a valid order from a prescriber acting within their scope of practice.*

REGISTERED SUPPORT:

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

REGISTERED OPPOSITION:

California Pharmacists Association

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