SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Dr. Aisha Wahab, Chair
2025 - 2026 Regular

Bill No:	AB 1990	**Hearing Date:**	June 22, 2026
Author:	Gipson		
Version:	April 23, 2026		
Urgency:	No	**Fiscal:**	Yes
Consultant:	Sarah Mason		

Subject: Pharmacy Law: compounded medications: consumer protection

SUMMARY: Establishes additional requirements governing the compounding, distribution, and advertising of certain compounded obesity and weight-management drugs, including compounded GIP and GLP-1 receptor agonists, and prohibits false or misleading advertising of compounded medications.

NOTE: *This bill is double-referred to the Senate Committee on Judiciary, second.*

Existing law:

1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Establishes the California State Board of Pharmacy (Board) to administer and enforce the Pharmacy Law. (BPC § 4001)

3) Defines "outsourcing facility" as a facility that is engaged in the compounding of sterile drugs and nonsterile drugs in California and is both registered with the Food and Drug Administration (FDA) and licensed by the Board. (BPC § 4034)

4) Requires a pharmacy to obtain a license from the Board and establishes information to be provided by pharmacies to the Board as a condition of license renewal, including a notification to the Board regarding compounding practices, including compounded human drug preparations distributed outside of the state. (BPC § 4110)

5) Requires every pharmacy to establish a quality assurance program that documents medication errors attributable to the pharmacy or its personnel. (BPC § 4125)

6) Provides that the compounding of drug preparations by a pharmacy for furnishing, distribution, or use in California shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP), including relevant testing and quality assurance; authorizes the BOP to adopt regulations to impose additional standards for compounding drug preparations. (BPC § 4126.8)

7) Requires a pharmacy that issues a recall notice regarding a nonsterile compounded drug product to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice under specified circumstances. (BPC § 4126.9)

8) Authorizes a pharmacy to distribute compounded human drug preparations interstate if specified conditions are met. (BPC § 4126.10)

9) Requires a pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license. (BPC § 4127)

10) Prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the BOP. (BPC § 4127.1)

11) Prohibits a nonresident pharmacy from compounding sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the BOP. (BPC § 4217.2)

12) Provides that whenever the Board has a reasonable belief, based on information obtained during an inspection or investigation by the Board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the Board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. (BPC § 4127.3)

13) Authorizes the Board to issue a temporary license to compound sterile drug products upon the conditions and for any periods of time as the Board determines to be in the public interest. (BPC § 4127.7)

14) Requires a pharmacy that issues a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug as well as the Board as soon as possible within 12 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death. (BPC § 4127.8)

This bill:

1) Defines “bulk drug substance,” also known as an active pharmaceutical ingredient (API), as any substance intended for incorporation into a finished drug product and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body; excludes intermediates used in the synthesis of the substance.

2) Makes it unlawful to sell, transfer, or distribute a drug compounded under Section 503A of the federal Food, Drug, and Cosmetic Act using a drug substance that is a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist, glucagon-like peptide-1 (GLP-1) receptor agonist, or other amino acid polymer intended for human obesity or weight management use, or a drug substance that is a component of a generic equivalent approved by the federal Food and Drug Administration (FDA) for obesity or weight management, unless the compounder does all of the following:

    a) Uses bulk drug substances that comply with the following, as applicable:

i) The standards of an applicable United States Pharmacopeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding.

ii) If no such monograph exists, the bulk drug substances are drug substances that are components of drugs approved by the FDA.

iii) If no such monograph exists and the drug substance is not a component of an FDA-approved drug, the bulk drug substance appears on the list developed by the FDA pursuant to the federal Food, Drug, and Cosmetic Act.

b) Confirms that the bulk drug substance was manufactured according to the process specified in the FDA approval for the drug, if applicable.

c) Ensures that the bulk drug substance is a pharmaceutical-grade produc

d) Verifies that the bulk drug substance is accompanied by a valid certificate of analysis.

e) Conducts and documents quality control testing of any bulk drug substance before its use in a compounded drug to confirm its identity and content and the name and quantity of each impurity present in an amount exceeding 0.1%.

f) Conducts and documents quality control testing of finished drug product compounded in batches before release and at expiration for any impurities derived from the use of a bulk drug substance, including the chemical name and quantity of each impurity.

g) Obtains proof that the manufacture of the bulk drug substance took place in an establishment that:

i) Is registered with the FDA under the federal Food, Drug, and Cosmetic Act.

ii) Has undergone an FDA inspection as a human drug establishment within the preceding two years.

iii) Is not subject to an FDA import alert.

iv) Complies with the federal Food, Drug, and Cosmetic Act, including Section 503A.

2) Makes it unlawful for a manufacturer or wholesaler to sell, transfer, or distribute a bulk drug substance for use in compounding without providing written verification to the purchaser that the substance is pharmaceutical grade, satisfies the bill's sourcing and quality requirements, and is accompanied by a valid certificate of analysis.

3) Subjects violators to a civil penalty of $1,000 per dose of the illegally compounded drug sold, transferred, or distributed and revocation of the applicable pharmacy or business license.

4) Requires any person or entity engaged in the sale, transfer, or distribution of compounded GIP receptor agonists, GLP-1 receptor agonists, or other amino acid polymer drugs intended for obesity or weight management to maintain records relating to the acquisition, examination, and testing of the bulk drug substance for at least two years after the expiration date of the last lot containing that substance and, upon request, furnish those records to the Board of Pharmacy (BOP) within one business day or within another reasonable period determined by the BOP.

5) Authorizes the BOP, its duly authorized agent, or a duly authorized agent of a third party approved by the BOP to inspect any person or entity engaged in compounding drugs, or any domestic supplier, wholesaler, repackager, or other provider of bulk drug substances used in compounding, for compliance with the bill.

6) Provides that refusal to permit an inspection by the BOP, its agent, or an approved third-party inspector constitutes a violation subject to enforcement under the bill.

7) Defines an “unsubstantiated claim” as any statement, representation, or assertion concerning the safety, efficacy, or other attributes of a drug that is not supported by competent and reliable scientific evidence.

8) Makes it unlawful to advertise or otherwise promote compounded medications unless the advertisement is truthful and not misleading. Provides that an advertisement is misleading if it contains an unsubstantiated claim regarding the product.

9) Provides that an advertisement is misleading unless it contains all of the following:

    a) A disclosure of the potential side effects, adverse reactions, contraindications, precautions, and warnings identified in the labeling of any FDA-approved drug containing the active ingredients named in the compounded drug, unless the advertiser can demonstrate that a particular disclosure is not relevant to the compounded drug.

    b) A summary of the specified risk information contained in the labeling of an FDA-approved drug when the compounded drug contains an active ingredient that is also an active ingredient in an FDA-approved drug.

    c) A clear and conspicuous statement that the product is a compounded medication, has not been approved by the FDA, and has not been evaluated by the FDA for safety or efficacy.

10) Exempts physicians and surgeons licensed under the Medical Practice Act from the provisions of the bill, while preserving their obligations under other applicable state and federal laws.

11) Authorizes the BOP to adopt regulations necessary to implement the bill.

12) Makes legislative findings and declarations that patient safety is threatened by the use of illicit, substandard, contaminated, or otherwise noncompliant active

pharmaceutical ingredients (APIs) in compounded weight-loss medications, particularly where foreign manufacturers may circumvent FDA regulatory requirements.

13) Finds that federal enforcement alone has been insufficient to prevent potentially unsafe APIs from entering the compounding supply chain and that Californians may remain at risk of receiving compounded medications containing ingredients from manufacturers that failed to comply with federal manufacturing standards.

14) States Legislative intent to establish additional state safety and regulatory requirements to ensure that APIs used in compounded weight-loss medications are sourced from registered, inspected, and reputable establishments and meet pharmaceutical-grade quality standards.

FISCAL EFFECT: This bill is keyed fiscal by Legislative Counsel. According to the Assembly Committee on Appropriations, the bill will result in "Costs of an unknown but potentially significant amount to the [Board]. The Board anticipates this bill will result in longer and more complex inspections and investigations, potentially increasing operational costs; however, the net cost is uncertain because the bill also establishes automatic fines that could offset some expenses. The Board also notes that additional costs may arise from due process requirements for license revocations and potential legal challenges, but is unable to project the extent of these costs. The Department of Consumer Affairs, Office of Information Services estimates costs of $800 to add new enforcement codes.

COMMENTS:

1. **Purpose.** The Author is the sponsor of this bill. According to the Author, "AB 1990 protects patients by ensuring compounded GLP-1 agonist and similar drugs for weight loss are safe, high quality, and honestly marketed. As these medications-such as semaglutide and tirzepatide-have grown in popularity for weight management, demand has surged across the country. During initial supply shortages, many patients turned to compounded versions of these medications when FDA-approved products were difficult to access. These products are not reviewed or approved by the FDA and are not subject to the same rigorous standards for safety, quality, and consistency as approved medications. In some cases, compounded GLP-1 products are produced from raw active pharmaceutical ingredients imported from Chinese manufacturers that are not FDA-inspected or monitored and distributed to patients.

   Patients seeking out GLP-1s from telehealth providers may erroneously believe they are purchasing an FDA-approved and regulated treatment. AB 1990 seeks to increase transparency and establish safeguards, so patients are appropriately informed of the unapproved status of the drugs they are purchasing and make sure they understand the differences between unapproved, compounded drugs and FDA-approved therapies. This will further protect consumers from the potential dangers of unapproved drugs made with substandard, inauthentic, or illicit ingredients."

The Author states that “Evidence shows that consumers do not understand that compounded drugs are not evaluated by FDA for safety, efficacy and quality before they are marketed. Furthermore, compounded variations of approved drugs expose patients to untested formulations that are sold at high volumes under the guise of “personalization.” For example, the combination of a GLP-1 with other vitamins (such as b12) has never been tested as a combination. There has never been a clinical trial or study to ensure that combining GLP-1s with other drugs or vitamins is safe and efficacious. Californians have become members without consent of an unregulated clinical trial – one with no outcomes tracking or adverse events reporting.”

2. **Background.**

California Regulation of Drug Compounding. The Board is the state agency responsible for licensing and regulating pharmacists, pharmacies, wholesalers, and other entities involved in the distribution and dispensing of prescription drugs. Among its responsibilities, the Board oversees the practice of drug compounding, which generally refers to the preparation of a medication by combining, mixing, or altering ingredients to create a drug tailored to the needs of an individual patient. Compounding may be used when a commercially available drug is not available in the required dosage form or strength, or when a patient cannot use an FDA-approved product because of an allergy or other clinical need.

Compounded drugs are not approved by the federal FDA for safety, effectiveness, or quality prior to being dispensed. Instead, compounding is regulated through a combination of federal and state law. Under Section 503A of the federal Food, Drug, and Cosmetic Act, licensed pharmacies may compound patient-specific medications under specified conditions and are exempt from certain federal drug approval and manufacturing requirements. Federal law also recognizes standards developed by the United States Pharmacopeia (USP), which establishes quality standards for drug ingredients, preparation, testing, storage, and handling. Compounding has traditionally existed for situations such as different dosage strengths, alternative dosage forms, removal of allergens or preservatives, or customized formulations for individual patients.

California law requires compounding to be performed consistent with applicable USP standards. Following a multistate fungal meningitis outbreak linked to contaminated compounded medications, California strengthened oversight of compounding activities and directed the Board to align state requirements with evolving national standards. Most recently, the Board completed a comprehensive update of its compounding regulations governing nonsterile compounding, sterile compounding, hazardous drugs, and radiopharmaceuticals. Those regulations became effective on October 1, 2025, and establish detailed requirements relating to facilities, personnel qualifications, ingredient sourcing, quality assurance, environmental controls, testing, recordkeeping, and compliance with USP standards. The Board's revised regulations in 16 CCR §§ 1735, 1735.1 et seq., 1736, 1737, and 1738 already regulate many of the core quality and safety issues associated with compounding, including:

- Use of appropriate ingredients and components.

- Quality assurance programs.
- Documentation and record retention.
- Beyond-use dating.
- Environmental controls and sterility requirements.
- Personnel training and competency.
- Testing requirements for compounded products.
- Inspection authority by the Board.
- Compliance with USP standards and federal compounding requirements.

As a result, California already maintains a comprehensive regulatory framework governing the sourcing, preparation, testing, documentation, and inspection of compounded medications.

GLP-1 and Related Weight-Management Medications. Glucagon-like peptide-1 (GLP-1) receptor agonists are a class of medications originally developed to treat Type 2 diabetes that are now widely prescribed for chronic weight management. These medications work by mimicking naturally occurring hormones involved in blood sugar regulation, appetite control, and digestion. More recently, newer therapies, including glucose-dependent insulinotropic polypeptide (GIP) receptor agonists and combination products that act on multiple incretin pathways, have entered the market and are commonly used for obesity treatment.

The active ingredient in a compounded product may be the same active ingredient found in an FDA-approved drug. For example:

- Semaglutide is the active ingredient in Ozempic and Wegovy.
- Tirzepatide is the active ingredient in Mounjaro and Zepbound.

A compounding pharmacy may obtain semaglutide or tirzepatide active pharmaceutical ingredient (API) and prepare a compounded product containing that same active ingredient. However, the compounded product is not FDA-approved and may differ from the FDA-approved product with respect to formulation, concentration, inactive ingredients, packaging, delivery device, stability data, or manufacturing controls.

Federal law has long allowed compounding when FDA-approved products are unavailable due to shortages. When Wegovy, Ozempic, Mounjaro, and Zepbound experienced prolonged shortages, compounding pharmacies began preparing semaglutide and tirzepatide products for patients who could not obtain the branded products. Although several of the most prominent GLP-1 medications have since been removed from the FDA's shortage list, demand for compounded versions of these products remains substantial.

A patient generally does not walk into a pharmacy and ask for something similar to a name-brand GLP-1. A licensed prescriber evaluates the patient. The prescriber writes a prescription. The pharmacy compounds a preparation consistent with that prescription and applicable state and federal law. The patient receives the compounded medication. Not all compounding activity occurs in licensed pharmacies. Physicians may also prepare and furnish medications in connection

with the treatment of their patients, subject to applicable state and federal requirements.

In the GLP-1 context, the compounded product frequently contains semaglutide or tirzepatide itself, rather than a completely different ingredient designed to have a similar effect.

Recent Federal Enforcement Activity. Federal regulators have increasingly focused on the compounding, marketing, and distribution of GLP-1 and related weight-management medications. The FDA has issued warning letters regarding compounded products that allegedly do not comply with federal requirements and has raised concerns regarding the sourcing and quality of certain active pharmaceutical ingredients used in compounding. Federal regulators have also expressed concern regarding marketing practices that may imply compounded products are equivalent to FDA-approved medications.

In addition, the Federal Trade Commission has taken enforcement action against entities marketing weight-loss programs involving GLP-1 medications, alleging deceptive advertising and billing practices. These actions have focused on claims regarding product effectiveness, representations concerning FDA approval status, and other marketing statements directed toward consumers.

Efforts to Regulate Compounded GLP-1 Medications. In 2025, H.R. 6509, the SAFE Drugs Act of 2025, was introduced in the United States House of Representatives to increase oversight and regulation of compounding pharmacies and outsourcing facilities that compound what that bill would define as “essentially a copy” of an FDA-approved product. The legislation proposes to cap the number of drug copies that can be made each month without patient-specific justification, require reporting when pharmacists or facilities compound and ship high volumes of drugs across state lines, mandate more frequent inspections of large outsourcing facilities, and allow the federal government to adjust user fees to support enhanced oversight. A companion bill was introduced in the United States Senate in 2026, but to date, no significant federal legislation has been signed.

Legislation has been proposed in several states to crack down on the compounding of alleged “copycat” GLP-1 medications. For example, HB 2613 was introduced in the State of Washington to prohibit entities from selling, transferring, or distributing compounded drugs that use bulk drug substances unless the compounder complies with certain quality assurance requirements. Similar legislation has been introduced in Arizona, Colorado, Florida, Kentucky, Mississippi, and Virginia. The Indiana General Assembly enacted SB 282 in 2026, which both restricted the compounding of GLP-1 medications and increased state oversight of medical spas.AB 1990 would establish additional statutory requirements specific to certain compounded obesity and weight-management drugs containing GIP receptor agonists, GLP-1 receptor agonists, and other specified amino acid polymers. Among other provisions, the bill would impose additional sourcing, testing, documentation, inspection, supply-chain verification, and advertising requirements applicable to compounders, manufacturers, wholesalers, and other entities involved in the distribution of these products.

AB 1990 would establish additional statutory sourcing, testing, documentation, inspection, and advertising requirements applicable to certain compounded obesity and weight-management medications. Because the Board's updated compounding regulations became effective on October 1, 2025, the bill raises the question of whether additional statutory requirements specific to GLP-1, GIP, and related products are necessary beyond California's existing compounding framework.

The bill also expressly exempts physicians and surgeons licensed under the Medical Practice Act from its provisions.

3. **Arguments in Support.** Biocom writes that "Federal law already restricts compounding of FDA-approved versions of these drugs, but enforcement against non-compliant compounders has been limited. AB 1990 closes that gap by aligning California's standards with federal law and adding meaningful state-level enforcement. It establishes pharmaceutical-grade ingredient requirements, chain-of-custody documentation, and Board of Pharmacy inspection authority over compounders, suppliers, wholesalers, and repackagers. Per-dose penalties paired with license revocation give regulators the tools needed to deter substandard conduct, and upstream verification requirements ensure bulk drug substances meet quality standards before transfer. The bill's advertising provisions are equally sensible. Misleading claims about compounded weight-loss medications have driven patient confusion and unsafe use. Requiring disclosure of side effects, contraindications, and warnings consistent with FDA-approved labeling — along with clear notice that a product is not FDA-approved — directly addresses that harm."

   According to the California Dermatology Advocacy Network, the bill "addresses increasing concerns regarding the sourcing and quality of active pharmaceutical ingredients used in compounded medications. Recent reports have highlighted the risk that substandard or contaminated ingredients may enter the supply chain, particularly in high-demand therapeutic categories such as weight-loss medications. AB 1990 helps safeguard patients by requiring pharmaceutical-grade ingredients, certificates of analysis, quality control testing, and verification that manufacturers meet federal regulatory standards."

   The National Hispanic Health Foundation states that "This bill is not about restricting legitimate medical compounding. Compounding plays an essential role in patient care when medications must be tailored to meet individual needs. Rather, AB 1990 is about addressing a marketplace that has expanded far beyond traditional compounding into mass production, telehealth-driven distribution, and aggressive digital marketing."

4. **Arguments in Opposition.** According to the American Pharmacists Association, "Many California patients rely on compounded medications because commercially available products may not meet their clinical needs. Patients may require individualized dosage strengths, alternative dosage forms, specific formulations, or accommodations for allergies, sensitivities, or other patient-specific factors. AB 1990 would make it more difficult for pharmacists acting in compliance with applicable compounding standards and state and federal laws to meet legitimate patient needs and force compounders to only purchase bulk drug substances from

large pharmaceutical companies. APhA is also concerned that AB 1990's penalty structure, including per-dose penalties and mandatory license revocation, could create disproportionate liability exposure for licensed pharmacies and pharmacists operating in good faith to meet California patients' needs for these prescribed medications. Policies intended to address unsafe or unlawful conduct should be carefully tailored and preserve pharmacists' ability to exercise their professional judgment in the best interests of patients.

The Alliance for Pharmacy Compounding writes that "the bill effectively bans compounded GLP-1's by requiring that all compounded GLP-1 API be manufactured in the same process as FDA approved product bulk drug substances, even though FDA does not make such a distinction. Moreover, compounders do not have access to GLP-1 API that is produced using the same process as the FDA-approved product. It also requires an FDA-registered manufacturing facility to be inspected every two years to lawfully manufacture bulk drug substances despite the requirement that the FDA conduct risk-based inspections that do not occur on a regular cadence. This may seem like good policy, but it directly conflicts with purpose of compounding therapies and with long established national policies set in the federal Food, Drug and Cosmetic Act. California should not make it harder for patients to obtain medications through licensed, regulated healthcare providers while failing to address many of the entities responsible for the conduct that prompted legislative concern. Stakeholder amendments previously submitted to the author would correct these shortcomings. Those amendments would directly address misleading advertising, establish enforceable standards that apply to the appropriate actors, prohibit inappropriate marketing practices, and preserve access to medically necessary compounded therapies. The Committee faces a straightforward choice: amend the bill so it addresses the actual problem, or advance legislation that burdens regulated pharmacies while leaving significant gaps in enforcement."

The California Pharmacists Association states that "Throughout the discussion surrounding AB 1990, proponents have repeatedly suggested that compounded medications are inherently unsafe or insufficiently regulated. Such assertions are inaccurate and risk creating unwarranted fear among patients who rely on compounded medications every day. Compounding is a well-established and highly regulated area of pharmacy practice that serves an essential role within the healthcare system. Licensed pharmacists compound medications pursuant to state and federal law, professional standards, and regulatory oversight designed to protect patient safety. Compounded medications are often the only way to meet a patient's specific medical needs. Pharmacists routinely compound medications for patients with allergies to ingredients contained in commercially manufactured products, for patients who require individualized dosages that are not otherwise available, and for patients who cannot use standard dosage forms. Compounding also plays a critical role in oncology care, where individualized chemotherapy preparations are routinely compounded to meet the unique needs of cancer patients. Suggesting that pharmacy compounding is inherently unsafe risks undermining public confidence in these essential patient care services and could discourage patients from seeking therapies that are both appropriate and necessary. The bill's restrictions are particularly troubling given the vital role compounding pharmacists play in responding to drug shortages and ensuring

continuity of care when commercially available products are unavailable. During recent shortages of GLP-1 medications and other critical therapies, compounding pharmacies helped fill gaps in access for patients under the supervision of licensed healthcare professionals. Restricting access to regulated compounding services may ultimately drive patients toward unregulated or illicit sources, undermining the very consumer protection goals the bill seeks to achieve."

Midi Health writes that "While the vast majority of our prescriptions are for mass-marketed pharmaceutical drugs, we believe that clinicians, not rigid legislative mandates, are best suited to judge when a patient's individual biological needs warrant a compounded solution."

According to the California Society for Health System Pharmacists, "By making compounding operationally and legally untenable, AB 1990 will eliminate access for these patients and shut them out of needed therapies used not only for weight management, but also for diabetes, sleep apnea, and complex metabolic disorders. Additionally, although AB 1990 currently targets obesity-related therapies, it establishes a precedent that could readily expand to other therapeutic categories, further eroding access to individualized care."

5. **Policy Concerns.** While compounded drugs are not FDA-approved, the absence of FDA approval does not mean that compounding is inherently unsafe or outside the law. Federal law expressly recognizes compounding under Section 503A of the federal Food, Drug, and Cosmetic Act, and FDA acknowledges that compounded drugs can serve an important medical need for patients when an approved drug cannot meet the patient's clinical needs.

   Existing federal and state law already place meaningful limits on compounding. Section 503A restricts compounding drugs that are "essentially copies" of commercially available drugs, while FDA guidance recognizes that certain amounts may still be permissible if compounding is not done "regularly or in inordinate amounts." FDA also states that a drug on the FDA shortage list is not considered commercially available for purposes of that restriction. The Board's updated compounding regulations align state rules with current USP standards, include testing and quality-assurance requirements, and impose additional standards above the national USP minimums.

   Compounded GLP-1 medications are already subject to extensive federal and state regulation. The bill's drug-specific statutory requirements may not be necessary on top of the state's newly updated compounding framework, particularly where those regulations already address ingredient sourcing, compounding records, quality assurance, testing, sterile preparation standards, environmental controls, and Board enforcement authority.

   The compliance framework outlined in the bill coupled with steep penalties has the potential to reduce the number of pharmacies willing or able to provide these medications, which could affect patient access and cost, especially for patients who cannot obtain or afford FDA-approved branded products. The market for FDA-approved GLP-1 and related weight-management drugs is dominated by a small number of branded products. While supporters argue that additional oversight is

necessary to ensure the quality and integrity of active pharmaceutical ingredients used in compounded weight-management medications, compounded GLP-1 products have also served as a lower-cost alternative for some patients, particularly during periods of drug shortages and for patients without insurance coverage for FDA-approved products.

Recent litigation has highlighted the extent to which disputes over compounded GLP-1 medications involve issues of competition and access in addition to patient safety. In January 2026, a compounding pharmacy filed a federal antitrust lawsuit alleging that Eli Lilly and Novo Nordisk used their market positions to restrict access to lawful compounded alternatives and suppress competition; the manufacturers deny those allegations. More broadly, ongoing litigation and regulatory actions involving manufacturers, telehealth companies, and compounders reflect competing views regarding patient safety, market competition, and consumer access to lower-cost treatment options. To the extent the bill increases compliance costs or limits the availability of compounded products, it is important to consider whether the resulting impact on access and affordability is justified by any demonstrated gap in California's existing compounding framework. The bill may have the practical effect of limiting lawful lower-cost alternatives in a market where affordability and access are already significant concerns.

The bill also does not apply uniformly to every setting where medication preparation may occur. The bill expressly exempts physicians and surgeons licensed under the Medical Practice Act, even though physician practices may prepare or furnish medications in connection with patient care subject to other applicable laws. If the bill is intended to address risks associated with compounded weight-management medications, it is unclear why its requirements would apply to pharmacies and supply-chain entities that are already subject to extensive regulation, but not to physician office settings where patients may also receive prepared medications.

SUPPORT AND OPPOSITION:

Support:

American Diabetes Association
Biocom
California Dermatology Advocacy Network
California Life Sciences Association
Diabetes Patient Advocacy Coalition
National Association for the Advancement of Orthotics and Prosthetics
National Consumers League
National Hispanic Health Foundation
Partnership for Safe Medicines

Opposition:

Alliance for Pharmacy Compounding
American Pharmacists Association
California Pharmacists Association
California Society of Health-system Pharmacists

Chamber of Progress
Midi Health
Netchoice

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