Date of Hearing: April 21, 2026
Fiscal: Yes

ASSEMBLY COMMITTEE ON PRIVACY AND CONSUMER PROTECTION
Rebecca Bauer-Kahan, Chair
AB 1990 (Gipson) – As Amended April 15, 2026

PROPOSED AMENDMENTS

SUBJECT: Pharmacy Law: compounded medications: consumer protection

SYNOPSIS

Glucagon-like peptide-1 receptor agonists (GLP-1s) are weight loss medications that have skyrocketed in popularity in recent years due in part to celebrity and influencer endorsements. Typically thought of by a common name brand, Ozempic, GLP-1 medications experienced a shortage in 2022 due to widespread consumption. With the shortage, compounding pharmacists – pharmacists that are not Food and Drug Administration (FDA) approved and therefore are not verified as safe and efficacious by the FDA – were able to produce and sell GLP-1s. In 2025, however, the shortage ended and compounding pharmacists were no longer allowed to participate in the lucrative weight loss market, causing concerns that bad actors would continue to try and sell compounded medications. Additionally, misleading and deceptive advertisements about compounded medications have created administrative burden for the FDA as it attempts to "crack-down" on unlawful GLP-1 advertisements.

This bill aims to place guardrails around compounding pharmacies that produce GLP-1 medications by requiring all bulk drug substances used in the compounding of GLP-1 drugs to be pharmaceutical-grade and compliant with current federal standards and requirements. This bill requires bulk drug substances used in compounded GLP-1 medications to undergo quality control testing and receive a certificate of analysis. Additionally, this bill would require that compounding pharmacies maintain records of bulk drug substances to be made available upon inspection by the Board of Pharmacists (BOP). Finally, this bill makes it unlawful for any person to promote a compounded medication unless the advertisement is truthful and not misleading – the only part of the bill that is squarely in this Committee's jurisdiction.

This author-sponsored bill has support from California Life Sciences Association, American Diabetes Association, Biocom California, and The Partnership of Safe Medicines. This bill has opposition from the Alliance for Pharmacy Compounding, the California Pharmacists Association, and Chamber of Progress.

Committee amendments, described in Comment #7, aim to address opposition's concerns about advertisement disclosure policies infringing on intellectual property.

This bill was heard previously in Business and Professions Committee, where it passed on a 17-1 vote.

EXISTING LAW:

1) Establishes the Pharmacy Law. (Bus. & Prof. Code §§ 4000 et seq.)

2) Establishes the California State Board of Pharmacy (BOP) to administer and enforce the Pharmacy Law. (Bus. & Prof. Code § 4001.)

3) Provides that protection of the public shall be the highest priority for the BOP in exercising its licensing, regulatory, and disciplinary functions. (Bus. and Prof. Code § 4001.1.)

4) Authorizes the BOP to adopt rules and regulations as may be necessary for the protection of the public. (Bus. & Prof. Code § 4005.)

5) 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 FDA and licensed by the BOP. (Bus. & Prof. Code § 4034.)

6) Defines "pharmacy" as an area, place, or premises licensed by the BOP in which the profession of pharmacist is practiced and where prescriptions are compounded. (Bus. & Prof. Code § 4037.)

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

8) Requires each pharmacy to designate a pharmacist-in-charge, subject to approval by the BOP, who is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (Bus. & Prof. Code § 4113.)

9) Requires pharmacies that contract to compound a drug for parenteral therapy to report that contractual arrangement to the BOP within 30 days of commencing the compounding. (Bus. & Prof. Code § 4123.)

10) Requires every pharmacy to establish a quality assurance program that documents medication errors attributable to the pharmacy or its personnel. (Bus. & Prof. Code § 4125.)

11) 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, including relevant testing and quality assurance; authorizes the BOP to adopt regulations to impose additional standards for compounding drug preparations. (Bus. & Prof. Code § 4126.8.)

12) 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. (Bus. & Prof. Code § 4126.9.)

13) Authorizes a pharmacy to distribute compounded human drug preparations interstate if specified conditions are met. (Bus. & Prof. Code § 4126.10.)

14) Requires a pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license. (Bus. & Prof. Code § 4127.)

15) Prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the BOP. (Bus. & Prof. Code § 4127.1.)

16) Prohibits a nonresident pharmacy from compounding sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the BOP. (Bus. & Prof. Code § 4217.2.)

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

18) Authorizes the BOP to issue a temporary license to compound sterile drug products upon the conditions and for any periods of time as the BOP determines to be in the public interest. (Bus. and Prof. Code § 4127.7.)

19) 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 BOP 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. (Bus. & Prof. Code § 4127.8.)

20) Requires clinics to retain a consulting pharmacist to approve policies and procedures and to certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of the Pharmacy Law. (Bus. & Prof. Code § 4192.)

21) Provides that the BOP shall take action against any licensee who is guilty of unprofessional conduct, with various specific examples provided. (Bus. & Prof. Code § 4301.)

THIS BILL:

1) Makes findings and declarations regarding the recent proliferation of inferior or contaminated active pharmaceutical ingredients, especially for use in weight loss medications. States that the intent of the Legislature is to establish safety and regulatory requirements for compounded medications.

2) Defines “bulk drug substance” also referred to as “active pharmaceutical ingredient (API)” as any substance that is intended for incorporation into a finished drug product and is 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.

3) 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 receptor or GLP-1 receptor agonist used for obesity or weight management or a drug substance that is a component of a similar drug approved by the federal FDA unless the compounder of the drug 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 Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding.

ii) If such a monograph does not exist, the bulk drug substances are drug substances that are components of drugs approved by the FDA.

iii) If such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, the bulk drug substances appear 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's approval of the drug label, if applicable.

c) Ensures that the bulk drug substance is a pharmaceutical grade product.

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 prior to its use in a compounded drug to confirm its identity and content and the name and quantity of each impurity present in the bulk drug substance in an amount that exceeds 0.1%.

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

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

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

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

iii) Is not subject to an import alert by the FDA.

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

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

5) Subjects violators of the bill's requirements to both a fine of $1,000 per dose of the illegally compounded drug sold, transferred, or distributed and revocation of the person or entity's pharmacy or business license, as applicable.

6) Requires any person or entity engaging in the sale, transfer, or distribution of compounded GLP-1 drugs to maintain all records related to the acquisition, examination, and testing of the bulk drug substance for not less than two years after the expiration date of the last lot of drug containing the bulk drug substance and, upon a request by the BOP, furnish those records

within one business day of receiving the request, or within a reasonable time as determined by the BOP based on the circumstances of the request.

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

8) Provides that refusal to permit the BOP or its duly authorized agent or third-party access to conduct an inspection constitutes a violation subject to enforcement under the bill.

9) Defines "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.

10) Provides that it is unlawful for any person to advertise or otherwise promote compounded medications unless the advertisement is truthful and not misleading. States that an advertisement is not truthful and is misleading if it includes any unsubstantiated claim with respect to the product.

11) Expressly 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 associated with active ingredients in the medication, including any noted from clinical trials, research, and other appropriate information sources.

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

    c) A clear, 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.

12) Authorizes the BOP to adopt necessary rules and regulations to implement the bill.

13) Exempts physicians and surgeons licensed, as specified, from the provisions of the bill.

COMMENTS:

1) **Author's statement**. 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.

2) **GLP-1 Medications.** GLP-1 medications are a class of prescription drugs originally intended to manage type-2 diabetes. By mimicking the action of a naturally occurring gut hormone, GLP-1, these medications help stimulate insulin release in response to food and suppress glucagon (a hormone that raises blood sugar). However, GLP-1 medications also slow digestion to prolong fullness, and act on brain appetite centers to reduce hunger and food cravings, making them effective for weight management.[1] Most FDA-approved GLP-1 medications are delivered via injection or, more recently, oral tablets.[2]

For many, GLP-1 medications are synonymous with Ozempic. Created by Novo Nordisk, a Danish Pharmaceutical company, the drug held FDA-approval as a treatment for diabetes for several years leading up to 2021 when the same drug at a different dosage, Wegovy, was approved for weight loss.[3] Weight loss is a multi-billion dollar market, valued at approximately $135 billion in 2022 and growing exponentially.[4] Production difficulties with Wegovy, however, led to public discussions of using Ozempic for the same purpose.[5] As the pandemic raged on, celebrities and influencers began posting about their weight loss journeys with Ozempic, leading to waves of interest from the general public. Views for TikTok videos tagged #Ozempic went from two million in 2021 to 1.2 billion in 2023.[6] Undoubtedly due to the widespread advertising, Ozempic would be the third best-selling drug in 2023.[7]

3) **Compounding pharmacies and GLP-1 medications.** The exponential growth of Ozempic led to nationwide shortages, and incredibly steep prices, of these medications. In 2022, Wegovy and Ozempic were both placed on the FDA's drug shortage list, as thousands of pharmacists

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[1] Radwan Darwish, G. Abu-Sharia, A. E. Butler, "History of glucagon-like peptide-1 receptor agonists," *Pharmacological Research,* Vol. 222, (Dec. 2025), https://www.sciencedirect.com/science/article/pii/S1043661825004700.
[2] Drucker, Daniel J. "Mechanisms of Action and Therapeutic Application of Glucagon-like Peptide-1." *Cell Metabolism*, vol. 27, no. 4, 2018. https://www.cell.com/cell-metabolism/fulltext/S1550-4131(18)30179-7?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1550413118301797%3Fshowall%3Dtrue.
[3] Gavin Scheldrup, "The Ozempic Era," *Medical University of South Caroline,* (Aug. 29, 2024), https://www.musc.edu/content-hub/news/2024/08/29/the-ozempic-era.
[4] Custom Market Insights, "U.S. Weight Loss Market Size/Share Worth USD 305.30 Billion by 2030 at a 9.7% CAGR: Custom Market Insights (Analysis, Outlook, Leaders, Report, Trends, Forecast, Segmentation, Growth, Growth Rate, Value)," *yahoo!finance,* (May 9, 2023), https://finance.yahoo.com/news/latest-u-weight-loss-market-170000586.html.
[5] Scheldrup, "The Ozempic Era."
[6] *Id.*
[7] *Id.*

struggled with backorders and had to turn away patients looking to refill medications.[8] In an attempt to cope with demand, the FDA temporarily allowed pharmacists to sell compounded versions of the medication. Compounded medications are not FDA-approved and therefore do not undergo the rigorous testing and quality assurance that FDA-approved medicines do. Compounding pharmacists make custom medications for people who, for whatever reason, cannot take the FDA-approved drug (e.g., people who are allergic to an ingredient in the FDA-approved medicine, people needing a specific dose, or people who need a medication that is unavailable due to shortage).[9] There are two general categories of compounding pharmacies: 503A compounding pharmacists that can compound medications based on a prescription provided by healthcare professionals and 503B compounding pharmacists that can both compound medications based on prescriptions but can also compound and sell medications in large quantities.[10]

4) **Attempts to rein in GLP-1 compounders.** In the years of the GLP-1 shortage, compounding pharmacists sold millions of near-identical copies of the medicines, often for cheaper than brand-names. However, the lack of quality assurance and testing also came with downsides. By November 2024, the FDA had received over 600 reports of adverse events related to compounded semaglutide and tirzepatide, the active ingredients in GLP-1 weight loss medications.[11]

The FDA announced the end of the GLP-1 shortage on February 21, 2025, effectively ending the reign of compounding pharmacists.[12] Without the exemptions offered by the shortage, compounders were no longer allowed to produce and sell large quantities of GLP-1 medications, and the FDA announced that it would begin taking action against compounding pharmacists that make alternatives to brand-name drugs 60 to 90 days after the shortage ended.[13]

Unsurprisingly, compounding pharmacists were hesitant to walk away from the gold-mine of GLP-1 medications, forcing the FDA to act. As stated in the Business and Professions Committee analysis:

> In December 2025, the Federal Trade Commission (FTC) approved a final order against NextMed, a telehealth company, for deceptive advertising of weight-loss programs and deceptive and unfair billing and cancellation practices related to GLP-1 weight-loss programs. The FTC alleged that NextMed took advantage of the explosion in demand for GLP-1 medications by selling weight-loss programs with undisclosed costs and unsubstantiated claims about the weight loss achieved by their clients. The FTC ordered

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[8] Emma Court, "TikTok trend wipes out Ozempic supply, leaving people with diabetes dizzy, scared," *Los Angeles Times,* (Dec. 23, 2022), https://www.latimes.com/business/story/2022-12-23/tiktok-trend-sold-out-ozempic-diabetes-drug.
[9] Joshua Murdock, "What Are Compounding Pharmacies," *GoodRx,* (Nov. 22, 2021), https://www.goodrx.com/drugs/medication-basics/what-is-compounding-pharmacy?srsltid=AfmBOoqwuh3Gaf0zSiYLQpkJk8Q8mHyPr0KX8ffBosUoNyT4anSCjkuP.
[10] *Id.*
[11] Nikhil Sood, R. Garg, "Global Rise of Compounded Weight-Loss Medicines: A Worrisome Trend," *Journal of the Endocrine Society,* vol. 9, is. 8, (June 7, 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12164287/.
[12] Robert Fischer, "Declaratory Order: Resolution of Shortages of Semaglutide Injection Products (Ozempic and Wegovy)," *U.S. Food & Drug Administration,* (Feb. 21, 2025), https://www.fda.gov/media/185526/download.
[13] *Id.*

NextMed to cease its misconduct and pay $150,000, which is expected to be used to provide refunds to consumers.[14]

In March 2026, the FDA sent 30 warning letters to telehealth companies for making false or misleading claims regarding compounded GLP-1 products offered on their websites. In a press release announcing the issuance of the letters, FDA Commissioner Marty Makary stated: "We are paying close attention to misleading claims being made by telehealth and pharma companies across all media platforms—and taking swift action. Compounded drugs can be important for overcoming shortages or meeting unique patient needs—but compounders should not try to compound drugs in a way that circumvents FDA's approval process."[15] The warning letters included specific alleged violations, including unlawful claims to consumers that compounded drugs are the same as FDA-approved products.

Similar attempts to rein in compounding pharmacists have been made in Congress with the introduction of H.R. 6509, the SAFE Drugs Act. Aimed at strengthening production standards and guardrails, and encouraging oversight of compounding pharmacists, H.R. 6509 would require compounding pharmacies to report high volume drug shipments across state to the Legislature, mandate more frequent inspections of large outsourcing facilities, and authorize the FDA to adjust outsourcing facility user fees.[16] A companion bill, S. 3794, was introduced in 2026, though neither has moved beyond the house of origin.[17]

In the states, several bills have been introduced to address compounding GLP-1 medications, including HB 2613 in Washington, SB 2544 in Mississippi, SB 860 in Florida, and HB 4036 in Arizona.[18] These bills attempt to control the quality of compounded medications by requiring that the active pharmaceutical ingredients meet quality and safety standards and obtain a certificate of analysis, as well as conduct quality control inspections. In Indiana, a similar bill passed due to a focus on medical spas, businesses that market cosmetic, wellness, or lifestyle treatments while also administering prescription drugs like Botox injects and GLP-1 medications.[19]

5) **What this bill would do.** This bill mimics similar legislation introduced across the nation attempting to establish guardrails on compounding pharmacists. Specifically, this bill requires all bulk substances used in compounded drugs containing GLP-1 drug substances to be pharmaceutical grade and comply with United States Pharmacopoeia and FDA standards. Additionally, this bill requires all GLP-1 compounded medications to undergo quality control

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[14] "FTC Approves Final Order against Telehealth Provider NextMed over Charges It Used Deceptive Advertising Claims to Sell GLP-1 Weight-Loss Programs." *Federal Trade Commission*, December 2025.
[15] U.S. Food and Drug Administration. "*FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s*." *FDA*, March 2026.
[16] H.R. 6509, 119th Cong., 1st Sess. (2025), congress.gov, https://www.congress.gov/bill/119th-congress/house-bill/6509/text.
[17] S.3794, 119th Cong., 2nd Sess. (2026), congress.gov, https://www.congress.gov/bill/119th-congress/senate-bill/3794.
[18] H.B. 2613, Washington Legislature (2026), https://www.billtrack50.com/billdetail/1942704.; S.B. 2544, Mississippi Legislature, (2026), https://billstatus.ls.state.ms.us/documents/2026/html/SB/2500-2599/SB2544IN.htm.; S.B 680, Florida Legislature (2026), https://www.flsenate.gov/Session/Bill/2026/860.; H.B. 4036, Arizona Legislature, (2026), https://legiscan.com/AZ/text/HB4036/id/3350491.
[19] Casey Smith, "Medical spas, compounded drugs in focus as Indiana lawmakers hear warnings – and pushback," *Indiana Capital Chronicle,* (Feb. 18, 2026), https://indianacapitalchronicle.com/2026/02/18/medical-spas-compounded-drugs-in-focus-as-indiana-lawmakers-hear-warnings-and-pushback/.

testing and receive valid certificates of analysis. Any person or entity engaging in the sale, transfer, or distribution of compounded drugs is required to maintain all records of the bulk drug substance testing for at least two years to be made available to the BOP upon request. This bill establishes that it is misleading to advertise a compounded medication unless the advertisement includes a disclosure regarding potential side effects and warnings associated with the active ingredients in the medication; a summary of the risk information in the labeling of the FDA-approved drug if the compounded medication has the same active ingredient that is named in an FDA-approved drug; and a clear and conspicuous statement that the drug is a compounded medication that has not been approved by the FDA for safety or efficacy. Physicians and surgeons are exempt. Violations of the bill will result in fines of $1,000 per dose of an illegally compounded drug that is sold, transferred, or distributed.

6) **Misleading advertisements for GLP-1 medications.** As the Business and Professions Committee's analysis has already evaluated the feasibility of this bill from the pharmacists' perspective, this analysis will focus on the bill's consumer protection aspects within this Committee's jurisdiction. As outlined above, the bill establishes requirements for advertisements of GLP-1 compounded medications to be considered truthful and not misleading, including providing risk information of compounded drugs made with the same active ingredient of FDA-approved drugs and providing a clear statement that the drug is not FDA-approved and not tested for safety or efficacy.

The FDA is tasked with ensuring that direct-to-consumer (DTC) drug advertising provides information that is truthful, balanced, and accurately described. Under the Federal Food, Drug, and Cosmetics Act, drug manufacturers must submit evidence of a new drug's safety and efficacy to the FDA before marketing and public distribution.[20] Unless a drug is approved to treat a specific condition, that drug cannot be promoted as safe and effective for treating that condition, including drugs that are compounded.

Despite FDA requirements for drug advertising, bad actors continue to make false or misleading claims in drug advertisements, including compounding pharmacists. The Partnership for Safe Medicines, supporters of the bill, argue:

> Businesses selling compounded medicine have omitted disclosures of dangerous side effects, and promoted doses and forms of weight loss drugs that have no scientific track record. They have also characterized products as "generics," even though compounded medicines haven't undergone the rigorous testing and approval process for actual generic products. All of these practices misrepresent products in ways that can have grave consequences for California residents.

A Presidential memorandum published September 9, 2025, directed the FDA to take action to enforce the Federal Food, Drug, and Cosmetic Act's prescription drug advertising provisions, and ensure truthful and non-misleading information in DTC prescription drug advertisements.[21]

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[20] Clinton Lam and P. Patel, "Food, Drug, and Cosmetic Act," StatPearls, (July 31, 2023), https://www.ncbi.nlm.nih.gov/books/NBK585046/.

[21] The White House. "Memorandum for the Secretary of Health and Human Services the Commissioner of the Food and Drugs" *The White House*, Sept. 9, 2025, https://www.whitehouse.gov/presidential-actions/2025/09/memorandum-for-the-secretary-of-health-and-human-services-the-commissioner-of-food-and-drugs/.

As is highlighted by supporters of the bill, the National Hispanic Health Foundation, this memorandum led the National Consumers League to petition:

> Federal regulators to investigate what it described as "pervasive, deceptive and misleading advertising practices" by telehealth platforms promoting compounded GLP-1 drugs. That letter documented misleading claims, blurred lines between FDA-approved products and compounded versions, and inadequate risk disclosures.[22] We are concerned that without clear standards, these practices will continue to proliferate in California.

Indeed, as outlined in Comment #5, GLP-1 medication manufacturers have recently come under scrutiny for making false or misleading claims. A 2026 lawsuit filed by Novo Nordisk argues that the telehealth company Hims made false and misleading statements about their GLP-1 medications.[23] NextMed faced significant fines for deceptive advertisements of GLP-1 medications, including making unfound claims about the weight loss achieved by clients, using fake testimonials, and unfairly distorting customer reviews.[24] A 2025 analysis of online marketing for compounded GLP-1 medications found that:

> Of the 79 pharmacies found, 13.9 percent did not disclose the medications for sale were compounded, and 36.7 percent claimed or implied the drugs were FDA approved. Nearly half the sites did not report harmful effects, warnings, precautions, or contraindications, and 40.5 percent claimed efficacy for something not in the label of the FDA-approved branded drugs.[25]

Despite growing evidence of deceptive advertising practices for compounded weight loss medications, the Alliance of Pharmacy Compounding, opponents of the bill, argue that:

> AB 1990 would require compounded drugs that are based on FDA-approved products to include safety disclosures derived from the approved drug's labeling. This presents several fundamental problems:
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> - **Scientific mismatch**: Compounded drugs are not identical to FDA-approved products and have not been evaluated in the same clinical trials. Applying the branded drug's risk disclosures to a compounded preparation is not scientifically accurate and risks misleading patients.
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> - **Legal inconsistency**: Federal law does not permit compounders to rely on or incorporate branded drug labeling in this way. In fact, doing so may create the false impression that the compounded drug has been reviewed or endorsed by FDA.

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[22] National Consumers League September 2025 letter to Andrew Ferguson, Chairman, Federal Trade Commission, https://nclnet.org/wp-content/uploads/2025/09/NCL-Petition-to-the-FTC-on-Deceptive-FTC-Adverising-of-Compounded-GLP-1-Drugs-09.22.2025.pdf.
[23] "NYSE: Hims. Hims & Hers Health, Inc.," *The Rosen Law Firm,* https://rosenlegal.com/case/hims-hers-health-inc/#:~:text=Details%20of%20the%20case:,Wegovy%20alongside%20compounded%20semaglutide%20products..
[24] "FTC Approves Final Order against Telehealth Provider NextMed."
[25] Jessica M. Scully, "New Study Finds Online Advertising for Compounding Diabetes and Weight-Loss Drugs May Mislead Consumers," *Yale School of Medicine,* (Feb. 19, 2025), https://medicine.yale.edu/news-article/new-study-finds-online-advertising-for-compounded-diabetes-and-weight-loss-drugs-may-mislead-consumers/.

- **Intellectual property and data concerns**: The clinical trial data underlying FDA-approved labeling belongs to the drug sponsor and is not available for reuse by compounders.

While compounded drug manufacturers are required to state that they are not FDA-approved, accurate disclosures of information (including potential side effects linked with any active ingredients found in FDA-approved medications) are also required. Therefore, clear disclosures outlining that the compounded drug is not identical to the FDA-approved product would prevent concerns of scientific mismatch whilst also abiding by current federal law. Proposed amendments outlined below intend to address the opposition's concerns regarding intellectual property and data.

7) **Amendments.** In order to ensure that disclosure requirements do not infringe upon the intellectual property of data collected during FDA-approved clinical trials, the author has agreed to the following amendment:

> 4157.4 (c)(1) A disclosure of the potential side effects, adverse reactions, contraindications, precautions, and warnings associated with active ingredients in the medication, including ***the potential side effects, adverse reactions, contraindications, precautions, and warnings in the labeling of any FDA-approved drug containing the active ingredients named in the compounding drug, unless the advertiser can demonstrate that a particular disclosure is not relevant to the compounded drug.*** ~~any noted from clinical trials, research, and other appropriate information sources.~~

ARGUMENTS IN SUPPORT: The California Life Sciences Association writes in support:

> Over the past several years, the market for compounded weight loss medications has grown at an unprecedented pace. Unlike FDA-approved drugs, which undergo years of rigorous research, clinical trials, and ongoing safety monitoring, compounded drugs are not subject to FDA premarket review for safety, quality, or efficacy. This regulatory gap has created an opening for bad actors to introduce illicit, inauthentic, or substandard materials into the supply chain – many sourced from facilities in China that have never been inspected by the FDA. The consequences for patients are serious, impurities, contaminants, and inconsistent dosages have led to measurable patient harm, and widespread deceptive advertising has left consumers misinformed about the products they are using.
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> AB 1990 addresses these risks directly by mandating that compounders verify all bulk drug substances originate from FDA-registered and FDA-inspected facilities. By requiring documented proof of sourcing and compliance with federal manufacturing standards, the bill prevents substandard or contaminated materials from reaching California patients. The legislation also empowers the California State Board of Pharmacy to inspect compounders and their ingredient suppliers and to obtain records providing regulators with the tools they need to identify and act against bad actors before patient harm occurs.
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> […]
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> The bill also addresses the proliferation of misleading advertising for compounded weight loss medications, which has too often exploited patients' health goals while omitting critical safety information. AB 1990 requires all advertisements for compounded medications to be truthful, to disclose potential side effects and contraindications, and to include a clear,

conspicuous statement that the product has not been approved by the FDA and has not been evaluated for safety or efficacy.

It is important to note what AB 1990 does not do. The bill does not restrict access to legitimately compounded medications for patients who need them. It does not apply to compounded drugs made from FDA-approved drugs commonly used in hospital and clinical settings, does not apply to outsourcing facilities, and preserves the ability of prescribers to determine when a compounded drug is clinically necessary. What it does is ensure that when patients in California receive a compounded medication, it is made from ingredients that are authentic, properly tested, sourced from inspected facilities, and that the advertising they encounter is honest.

By enacting AB 1990, California has the opportunity to establish a national model for compounding oversight that protects patients, upholds supply chain integrity, and promotes honest communication between providers, compounders, and consumers.

ARGUMENTS IN OPPOSITION: In opposition to the bill, California Pharmacists Association argues:

California already requires pharmacies to comply with United States Pharmacopeia (USP) standards, including USP <795>, <797>, and <800>, which provide a comprehensive, risk-based framework for safe compounding. Compounding pharmacies adhere to these standards and operate with a strong commitment to patient safety. Licensed pharmacies operate under these standards alongside oversight from the California State Board of Pharmacy.

AB 1990 departs from this framework by imposing requirements that more closely resemble those applied to pharmaceutical manufacturers. These include mandatory impurity profiling of bulk drug substances, batch and expiration testing of finished compounded products, and extensive supply chain verification obligations. These requirements exceed USP standards and are not reflective of pharmacy practice. This could effectively force many compliant compounding pharmacies out of the market, reducing patient access to necessary medications.

Additionally, the bill imposes severe penalties, including fines of $1,000 per dose and potential license revocation, for violations, even in cases where pharmacists are acting in good faith. This punitive framework creates significant liability risk and uncertainty, discouraging pharmacists from providing compounded therapies, even when clinically appropriate and necessary for patients. As a result, the bill risks reducing access to compounded medications that are essential for patients with unique clinical needs.

The bill's restrictions are particularly concerning, given the important role compounding pharmacists play in addressing drug shortages and meeting individualized patient needs when commercially available products are not suitable. Limiting pharmacists' ability to compound medications, especially in high-demand therapeutic areas, may drive patients toward unregulated or unsafe alternatives, undermining the very consumer protections the bill seeks to advance.

[…]

If the Legislature seeks to address unsafe compounding practices, a more targeted approach focused on enforcement against noncompliant or unlicensed entities would be more effective than imposing broad requirements on already regulated pharmacies.

The Association of Compounding Pharmacists write in opposition:

Risk of Increased Consumer Confusion

Ironically, the advertising provisions in AB 1990 may undermine, rather than enhance, consumer protection:

- Patients could reasonably interpret the inclusion of FDA-derived safety language as an indication that the compounded drug has been evaluated by FDA.
- Conflicting or inapplicable disclosures may obscure, rather than clarify, important information about how a compounded medication differs from an FDA-approved product.
- Pharmacies attempting to comply with both federal and state requirements may be forced into inconsistent or overly complex messaging that is difficult for patients to understand.

REGISTERED SUPPORT / OPPOSITION:

Support

American Diabetes Association
Biocom California
California Life Sciences Association
National Hispanic Health Foundation
Partnership for Safe Medicines

Opposition

Alliance for Pharmacy Compounding
California Pharmacists Association
Chamber of Progress

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