Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
AB 1990 (Gipson) – As Amended March 9, 2026

NOTE: This bill is double referred and if passed by this Committee will be re-referred to the Assembly Committee on Privacy and Consumer Protection.

SUBJECT: Pharmacy Law: compounded medications: consumer protection.

SUMMARY: Establishes additional requirements for the compounding of drugs containing glucagon-like-peptide-1 (GLP-1) receptor agonists or similar drug substances used for obesity or weight management and provides that it is unlawful for any person to advertise compounded medications unless the advertisement is truthful and not misleading, as specifically defined.

EXISTING LAW:

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

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

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

4) Authorizes the BOP to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 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 Food and Drug Administration (FDA) and licensed by the BOP. (BPC § 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. (BPC § 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. (BPC § 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. (BPC § 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. (BPC § 4123)

10) Requires every pharmacy to establish a quality assurance program that documents medication errors attributable to the pharmacy or its personnel. (BPC § 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 (USP), including relevant testing and quality assurance; authorizes the BOP to adopt regulations to impose additional standards for compounding drug preparations. (BPC § 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. (BPC § 4126.9)

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

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

15) Prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the BOP. (BPC § 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. (BPC § 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. (BPC § 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. (BPC § 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. (BPC § 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. (BPC § 4192)

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

THIS BILL:

1) Defines "bulk drug substance," also known 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; exempts intermediates used in the synthesis of the substance from this definition.

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 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 USP or National Formulary monograph, if a monograph exists, and the USP 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.

3) Provides that it is unlawful for any manufacturer or wholesaler to sell, transfer, or distribute a bulk drug substance for use in compounding 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.

4) 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.

5) 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.

6) 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.

7) 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.

8) 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.

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

10) 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.

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

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

COMMENTS:

Purpose. This bill is sponsored by the author. 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.

Background.

California State Board of Pharmacy. The BOP is the regulatory body within the Department of Consumer Affairs responsible for overseeing pharmacies and pharmacist practice in California. The BOP is currently estimated to regulate over 50,700 pharmacists, 1,300 advanced practice pharmacists, 4,400 intern pharmacists, and 65,700 pharmacy technicians across 32 licensing programs. In addition to regulating professionals, the BOP licenses and oversees pharmacies, clinics, wholesalers, third-party logistic providers, and automated drug delivery systems.

The BOP has its own enforcement staff, which includes field inspectors responsible for conducting investigations and inspections of pharmacies as well as sterile compounding and outsourcing facilities. The BOP's enforcement program is its largest budget expenditure, historically comprising about 64 percent of its total operating expenses. The BOP regularly engages in investigations that may result in disciplinary action. The BOP's Enforcement and Compounding Committee provides oversight of all drug distribution and dispensing activities, including drug compounding, and is responsible for ensuring compliance with state and federal pharmacy laws.

During the BOP's sunset review in 2020, the Committees considered whether the Pharmacy Law's requirements for the appointment of pharmacists representing specific practice settings were sufficient to provide the BOP with expert perspectives on matters relating to compounding. The sunset background paper recognized that the practice of compounding had recently drawn national attention for both its importance and complexity, and that the BOP had recently put forth a number of regulations regarding pharmacy compounding. At the time, there had not been a compounding pharmacist specifically represented on the BOP. In response, the BOP's sunset bill was amended in 2021 to include a member from a compounding pharmacy specializing in human drug preparations.

Requirements for Drug Compounding. According to the FDA, drug compounding is generally described as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Combining two or more drugs is a form of compounding, as is the reconstitution of a drug into another ingestible form. Compounded drugs are not approved by the FDA for safety or effectiveness. Federal law establishes the authority for specified individuals to compound human drug products under provisions specified in section 503A of the federal Food, Drug, and Cosmetic Act. Drug products compounded under these provisions are exempt from some of the requirements for drug manufacturing and the drug approval process.

The USP is a combination of two compendia published by two longstanding nonprofits: the United States Pharmacopeia, published by the United States Pharmacopeial Convention; and the National Formulary, published by the American Pharmaceutical Association. As the FDA's officially designated compendium, the USP sets numerous standards for drug ingredients and manufacturing processes, including testing and quality assurance. Generally speaking, drug products and ingredients sold in the United States must conform to the USP to be considered unadulterated and of minimum quality.

Pharmacy professionals who engage in the practice of drug compounding in California are required to obtain a license from the BOP. However, prior to 2020, there were no state laws that outlined specific requirements for the compounding of prescription medication. Partially in response to a significant multistate outbreak of fungal meningitis for which the unsafe compounding of a preservative-free steroid injection resulted in numerous deaths, the BOP sponsored legislation in 2019 to require that compounding in California must be performed consistent with standards established in the pharmacy compounding chapters of the current version of the USP. The USP develops and publishes standards for drug substances, drug products, excipients, and dietary supplements. These standards are recognized in the federal Food, Drug, and Cosmetic Act.

The BOP recently completed rulemaking to clarify requirements for drug compounding by licensees in response to changes enacted to the USP. These efforts began when changes to the USP were initially proposed in 2019, at which time the BOP held a series of public meetings to discuss proposed language with stakeholders; however, these discussions were paused following delays in the USP's process. Following the finalization of the USP Chapters, the BOP resumed efforts to revise its compounding regulations and held another series of meetings to receive further comments from stakeholders. The changes proposed by the BOP included restructuring its regulations to align with the USP Chapters, eliminating and clarifying requirements, and adding new requirements.

The BOP approved proposed regulation text in April 2023 to amend the BOP's regulations regarding compounded drug preparations to implement, clarify, or make more specific requirements related to the USP-National Formulary for nonsterile compounding, sterile compounding, the handling of hazardous drugs, and the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals. The new USP Chapters became effective on November 1, 2023; because the BOP's proposed regulations were not yet effective, the BOP released an updated Policy Statement in September 2023 providing stakeholders with additional guidance.

On April 19, 2024, the BOP formally distributed its proposed regulation text to interested parties for a 45-day comment period, which ended on June 3, 2024. An additional regulation hearing was held on June 18, 2024. Through this process and throughout these public meetings, stakeholders submitted numerous comments to the BOP expressing concerns about the proposed regulations. Representatives of compounding pharmacies specifically raised concern that the provisions relating to sterile compounding exceeded the requirements of the USP and national standards and would result in fewer pharmacies providing compounding services in California. Stakeholders further criticized the BOP for what was characterized as excessive enforcement activity against licensees for minor infractions.

In the months following the conclusion of the formal comment period, the BOP approved multiple sets of changes to its proposed text in response to the concerns it had received. During its November 2024 meeting, the BOP voted to approve a modified regulation text for a 30-day comment period, which ended on December 9, 2024. An additional 15-day comment period was then initiated following further modifications by the BOP during its January 2025 meeting, and yet another 15-day comment period was initiated following changes made during the BOP's February 2025 meeting. The BOP's final updated regulations governing nonsterile compounding, sterile compounding, hazardous drugs, and radiopharmaceuticals took effect on October 1, 2025.

Throughout the rulemaking process, organizations opposed to the BOP's proposed regulations organized a robust public campaign, specifically citing concerns that the regulations would limit patient access to compounded products such as glutathione, methylcobalamin, and NAD+ infusions. Representatives of the veterinary medical profession also raised additional issues specific to animal patients. In its sunset report to the Committees, the BOP argued that it had provided a fair and transparent rulemaking process, providing numerous opportunities for interested stakeholders to participate. The BOP believed there had been significant misinformation in the public domain misrepresenting the requirements of federal law.

Additional issues relating to compounding were raised during the BOP's sunset review in 2025. As reported by the BOP, in recent years, the FDA has released warnings about instances of drug products being compounded under insanitary conditions. Many of these warnings stem from compounding occurring in sites that are not regulated by the BOP or other regulatory agencies, including medical spas and IV hydration clinics. Following an incident in California where a patient was hospitalized and treated for suspected septic shock with multi-organ failure after receiving an IV vitamin infusion in her home, the FDA reported that it was aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by hydration clinics where it is unknown and undocumented if the drug products are prepared, packed, or held under insanitary conditions. Additionally, it is unknown whether a licensed practitioner is on-site to evaluate patients and write prescriptions for the drug products being administered.

In light of the patient safety concerns associated with compounding taking place in unregulated clinics, the BOP submitted a proposal to require hydration clinics to obtain a license from the BOP prior to compounding or administering sterile injectable products, subject to inspection by the Board. Clinics would also be required to designate a licensed prescriber as the professional director responsible for the safe, orderly, and lawful provisions of compounding and administration of the sterile injectable products. Ultimately, however, this proposal was not included in the BOP's sunset bill.

GLP-1 Medications. GLP-1 medications are a class of prescription drugs originally developed to treat type-2 diabetes and are now widely used for chronic weight management. These medications mimic the action of a naturally occurring gut hormone, GLP-1, which helps regulate blood sugar, appetite, and digestion. GLP-1 drugs work by stimulating insulin release in response to food, suppressing glucagon (a hormone that raises blood sugar), slowing gastric emptying to prolong fullness, and acting on brain appetite centers to reduce hunger and food cravings. Well-known examples include semaglutide (marketed as Ozempic or Wegovy) and liraglutide (Saxenda), while related or newer agents such as tirzepatide (Zepbound) act on similar incretin pathways and are often grouped with GLP-1–based therapies. These drugs are part of a broader class of "incretin mimetics," and ongoing research has produced additional variants that expand on the same biological mechanisms. Most FDA-approved GLP-1 medications are delivered via injection pens or, more recently, oral tablets.[1]

Section 503A of the federal Food, Drug, and Cosmetic Act allows for GLP-1 medication to be compounded under specific, limited circumstances. Compounding pharmacies operating under sections 503A (traditional pharmacies) and 503B (outsourcing facilities) are allowed to prepare customized versions of drugs only when there is a legitimate medical need that cannot be met by an FDA-approved product. For example, if a patient requires a different dosage form, strength, or ingredient due to an allergy, a patient-specific version of the medication may be compounded. Additionally, an FDA-approved drug may be compounded when the FDA has officially declared a shortage of that drug. GLP-1 medications, such as semaglutide, were previously included on the FDA drug shortage list due to high demand following an increase in public awareness of the potential to use the drug for weight loss; however, as of February 2025, they are no longer on the official shortage list, and cannot be compounded under that exception.

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 NextMed to cease its misconduct and pay $150,000, which is expected to be used to provide refunds to consumers.[2]

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."[3] The warning letters included specific alleged violations, including unlawful claims to consumers that compounded drugs are the same as FDA-approved products.

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[1] Drucker, Daniel J. "Mechanisms of Action and Therapeutic Application of Glucagon-like Peptide-1." *Cell Metabolism*, vol. 27, no. 4, 2018.
[2] "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.
[3] U.S. Food and Drug Administration. "*FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s*." *FDA*, March 2026.

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.

This bill would similarly establish additional requirements and restrictions on compounding pharmacies that produce GLP-1 medications. The bill would require all bulk substances used in compounded drugs containing GLP-1 drug substances to be pharmaceutical-grade, comply with USP and FDA standards and requirements, undergo quality control testing, be accompanied by a valid certificate of analysis, and sourced from FDA-registered and recently inspected facilities. The bill would require records of those bulk drug substances to be maintained and made available for inspection by the BOP.

Additionally, this bill specifically makes it unlawful for any person to advertise or otherwise promote compounded medications unless the advertisement is truthful and not misleading. The bill provides that an advertisement is not truthful and is misleading if it includes any unsubstantiated claim with respect to the product, or if it fails to include specified disclosures. These provisions are within the jurisdiction of the Assembly Committee on Privacy and Consumer Protection, which has also been referred this bill.

Current Related Legislation. AB 2141 (Patterson) would authorize the BOP to resolve a potential cause for discipline by a licensee through a stipulated settlement agreement prior to the filing of a formal accusation. *This bill is pending in the Assembly Committee on Judiciary.*

Prior Related Legislation. AB 1503 (Berman), Chapter 196, Statutes of 2025 extended the sunset date for the BOP and made additional changes to the Pharmacy Law.

AB 3063 (McKinnor) of 2024 would have exempted the addition of flavoring agents to a drug from the state's requirement that such actions comply with pharmacy compounding standards set under the USP. *This bill was vetoed by the Governor.*

AB 782 (McKinnor) of 2023 was substantially similar to AB 3063. *This bill was vetoed by the Governor.*

AB 973 (Irwin), Chapter 184, Statutes of 2020, requires compounding to comply with the USP.

ARGUMENTS IN SUPPORT:

The *California Life Sciences Association* supports this bill, writing:

> 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.
>
> 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.

ARGUMENTS IN OPPOSITION:

The *Alliance for Pharmacy Compounding* (APC) opposes this bill, writing:

> Compounding plays a critical role not only when commercially available products are not clinically appropriate, but also during FDA-recognized drug shortages, when patients may have no access to the FDA-approved drug at all. GLP-1s have experienced ongoing supply challenges and are often needed in customized dosages or formulations for patients with obesity or diabetes. This bill would apply even in shortage scenarios, potentially cutting off access at the very moment patients need alternatives most.

APC further argues that the bill would impose overly restrictive API sourcing requirements; duplicative testing, documentation, and verification mandates; excessive penalties and enforcement provisions; and advertising and labeling requirements that are not aligned with compounding practice.

POLICY ISSUE(S) FOR CONSIDERATION:

Potentially Overbroad Application. This bill's requirements would apply to compounded medicines containing drug substances that are glucose-dependent insulinotropic polypeptide receptor or GLP-1 receptor agonists used for obesity or weight management, or a drug substance that is a component of a similar drug approved by the FDA for obesity or weight management. The term "similar drug" may inadvertently capture more medications than intended by the bill. Additionally, language in the bill placing new requirements on bulk drug substances used in compounding and prohibiting certain advertisements do not specifically refer back to GLP-1 drug substances, implying broader applicability. The author may wish to substitute the term "generic equivalent" for "similar drug" and insert additional clarifying language regarding the scope of this bill.

Unclear Enforcement Jurisdiction. This bill would establish specific enforcement mechanisms for violations of its requirements and prohibitions. The BOP would be authorized to engage in inspections to confirm compliance and to adopt regulations to implement the bill. However, not all licensed professionals who would potentially be covered by the bill are within the BOP's jurisdiction. For example, concerns have been raised that physicians and surgeons, who are licensed and overseen by either the Medical Board of California or the Osteopathic Medical Board of California, could be inadvertently subject to enforcement by the BOP under this bill, despite not being the intended target of the legislation. The author may wish to add language exempting physicians and surgeons from the bill, while ensuring that existing requirements for those licensees remain in place.

AMENDMENTS:

1) To confirm that the scope of the bill applies only to GLP-1 medications or other drugs intended to be captured:

   - Add the following subdivision to the proposed Section 4157:

     This article applies solely to compounded drugs that are glucose-dependent insulinotropic polypeptide receptor or glucagon-like peptide-1 receptor agonists or other amino acid polymers intended to be used by humans for obesity or weight management. This article does not relieve, exempt, or otherwise limit the applicability of any state or federal law to compounded drugs that do not fall within the scope of this article.

   - Amend subdivision (a) of the proposed Section 4157.1 to replace the term "similar drug" with "generic equivalent."

   - Insert additional cross-references to subdivision (a) of the proposed Section 4157.1 to confirm what types of compounded medications are subject to requirements and prohibitions in the bill.

2) To clarify that the bill's requirements and prohibitions do not apply to licensed physicians and surgeons or subject those licensees to enforcement by the BOP, add the following subdivision to the proposed Section 4157.5:

   This article does not apply to physicians and surgeons licensed pursuant to Chapter 5 (commencing with Section 2000). This subdivision does not alter the obligation of a physician and surgeon to comply with any other applicable law.

REGISTERED SUPPORT:

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

REGISTERED OPPOSITION:

Alliance for Pharmacy Compounding
California Pharmacists Association
Chamber of Progress

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