ASSEMBLY THIRD READING
AB 1990 (Gipson)
As Amended April 23, 2026
Majority vote

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.

Major Provisions

1) Define "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) Make 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 generic equivalent approved by the federal Food and Drug Administration (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 Pharmacopeia (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) Provide 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) Subject 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) Authorize the California State Board of Pharmacy (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.

6) Provide 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.

7) Expressly provide 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 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.

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.

COMMENTS

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. Through the public rulemaking process, stakeholders submitted comments to the BOP expressing concerns 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 its sunset report to the Committees, the BOP argued that it believed there had been significant misinformation in the public domain misrepresenting the requirements of federal law. The BOP's final updated regulations governing nonsterile compounding, sterile compounding, hazardous drugs, and radiopharmaceuticals took effect on October 1, 2025.

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.

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.

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.

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

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 disclosures would include information about 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.

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."

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."

Arguments in Opposition
The *Alliance for Pharmacy Compounding* 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."

FISCAL COMMENTS

According to the Assembly Committee on Appropriations, costs of an unknown but potentially significant amount to the BOP, which 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 BOP 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. Additional one-time costs of $800 to the DCA.

VOTES

ASM BUSINESS AND PROFESSIONS: 17-1-1
YES: Berman, Johnson, Addis, Ahrens, Bains, Bauer-Kahan, Caloza, Chen, Elhawary, Haney, Hart, Irwin, Jackson, Lowenthal, Macedo, Nguyen, Pellerin
NO: Hadwick
ABS, ABST OR NV: Alanis

ASM PRIVACY AND CONSUMER PROTECTION: 15-0-0
YES: Bauer-Kahan, Macedo, Bryan, DeMaio, Hoover, Irwin, Lowenthal, McKinnor, Ortega, Patterson, Pellerin, Petrie-Norris, Ward, Wicks, Wilson

ASM APPROPRIATIONS: 13-0-2
YES: Wicks, Hoover, Aguiar-Curry, Calderon, Caloza, Fong, Mark González, Krell, Pacheco, Pellerin, Sharp-Collins, Solache, Tangipa
ABS, ABST OR NV: Dixon, Ta

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