Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2442 (Patterson) – As Amended March 19, 2026

SUBJECT: Peptides.

SUMMARY: Creates the California Investigational Peptide and Novel Compound Research and Therapeutic Access Program authorizing specified entities to establish and administer peptide and novel compound research and investigational therapeutic access programs. Requires participating entities to submit annual safety and utilization reports to the State Department of Public Health (DPH), and requires DPH to submit a statewide program evaluation report to the Legislature on or before January 1, 2032, as specified. Sunsets this bill on January 1, 2037. Specifically, **this bill**:

1) Creates the California Investigational Peptide and Novel Compound Research and Therapeutic Access Program authorizing specified entities to establish and administer peptide and novel compound research and investigational therapeutic access programs.

2) States that the following entities are authorized, but not required, to establish and administer peptide and novel compound research and investigational therapeutic access programs*:*

    a) The University of California (UC);

    b) Any accredited California medical school;

    c) Any teaching hospital affiliated with an accredited California medical school;

    d) Any licensed general acute care hospital; and,

    e) Any licensed physician group practice employing five or more physicians.

3) Authorizes participating entities to do any of the following:

    a) Contract for manufacturing;

    b) Conduct independent batch testing;

    c) Certify batches meeting institutional standards;

    d) Maintain internal compound and batch registries;

    e) Operate research dispensing or investigational therapeutic access programs; and,

    f) Collect and report safety and usage data to DPH.

4) States that nothing in this bill authorizes general retail sale to the public without licensed health care supervision.

5) Requires participating entities to ensure that all manufacturing conducted under this bill complies with current Good Manufacturing Practice (cGMP) and federal compounding regulations.

6) Requires all sterile manufacturing or compounding activities conducted under this bill to comply with applicable United States Pharmacopeia (USP) standards, including, but not limited to, all of the following:

   a) USP General Chapter <797> (Pharmaceutical Compounding – Sterile Preparations).

   b) USP General Chapter <800> (Hazardous Drugs – Handling in Health care Settings), where applicable.

   c) International Organization for Standardization (ISO) 14644 cleanroom classification standards appropriate to the level of sterile production performed.

7) Requires all analytical testing of compounds under this chapter to be performed exclusively by laboratories holding valid certification under the Clinical Laboratory Improvement Amendments of 1988. Requires each laboratory to maintain documented standard operating procedures for every assay performed, including validated methods for identity, purity, potency, sterility, and endotoxin testing, where applicable.

8) Requires all bulk active pharmaceutical ingredients and source compounds to be obtained exclusively from licensed wholesale distributors in full compliance with the federal Drug Supply Chain Security Act (Public Law 113-54), and all applicable federal Food and Drug Administration (FDA) importation, tracing, and distribution requirements.

9) Requires at minimum, each batch produced or dispensed under this chapter to undergo all of the following:

   a) Identity confirmation using mass spectrometry or equivalent validated methodology;

   b) Purity analysis using high-performance liquid chromatography or equivalent validated methodology;

   c) Potency verification, where applicable;

   d) Sterility testing for injectable or sterile products; and,

   e) Endotoxin testing for injectable products.

10) Requires participating entities to maintain comprehensive chain-of-custody documentation for all compounds, including, at a minimum, all of the following:

   a) Manufacturing origin;

   b) Distributor verification;

   c) Batch numbers and certificates of analysis;

   d) Storage conditions and tracking; and,

e) Full traceability from source material to final dispensation.

11) Prohibits this bill from being interpreted to permit manufacturing practices below the standards required under federal law for comparable activities.

12) Requires each participating entity to maintain a peptide and novel compound oversight committee.

13) Requires the committee to include, at minimum, all of the following:

a) A biomedical researcher;

b) A licensed physician;

c) A pharmacologist;

d) A toxicologist; and,

e) A patient or community representative.

14) Requires the committee to oversee all of the following:

a) Safety review;

b) Adverse event review;

c) Protocol review; and,

d) Annual update of institutional standards.

15) Authorizes a licensed health care practitioner acting within their scope of practice to prescribe or dispense investigational therapeutic compounds that meet all of the following:

a) Meet institutional certification standards;

b) Are dispensed through authorized institutional programs; and,

c) Are accompanied by written informed consent.

16) Prohibits a licensed health care practitioner's participation under this bill, by itself, from constituting unprofessional conduct.

17) Prohibits an entity, health care practitioner, pharmacist, manufacturer, or researcher acting in good faith and in compliance with this chapter from being subject to civil liability solely for recommending, prescribing, dispensing, administering, manufacturing, or studying a compound authorized under this bill. Specifies that this prohibition does not apply to the following:

a) Gross negligence;

b) Reckless misconduct;

c) Intentional wrongdoing;

d) Fraud or misrepresentation; and,

e) Failure to obtain informed consent.

18) States that this bill does not create a private right of action.

19) Requires participating entities to submit annual safety and utilization reports to DPH.

20) Requires DPH to submit a statewide program evaluation report to the Legislature on or before January 1, 2032. Requires the report to include, at a minimum, all of the following:

a) Safety outcomes;

b) Research output;

c) Therapeutic outcomes;

d) Economic impact; and,

e) Recommendations.

21) Sunsets the provisions of this bill on January 1, 2037.

22) Defines the following for purposes of this bill:

a) "Investigational therapeutic compound" to mean a peptide or novel compound that meets all of the following:

i) Is not currently approved for marketing by the United States (US) FDA with active patent or regulatory exclusivity protections;

ii) Is manufactured and tested under institutional standards established pursuant to this bill; and,

iii) Is dispensed only under supervision of a licensed health care practitioner within a bona fide practitioner-patient relationship.

b) "Peptide" to mean a compound consisting of two or more amino acids linked by peptide bonds and includes synthetic peptides, recombinant peptides, modified peptides, conjugated peptides, and peptide analogs intended for research or investigational therapeutic use.

c) "Novel compound" to mean a synthetically produced small-molecule compound that meets all of the following:

i) Is not scheduled under state or federal controlled substances law;

ii) Is not approved for marketing by the FDA under 2) of existing federal law below, unless patent and regulatory exclusivity protections have expired and a generic version is lawfully marketed in the US; and,

iii) Is not currently in Phase II or Phase III clinical trials for which a manufacturer or sponsor continues to actively pursue full FDA approval.

23) Makes several findings and declarations to the effect that:

i) Many promising peptide-based and novel small-molecule therapeutic compounds demonstrate potential benefit in early research settings but do not progress through traditional drug development pathways due to economic, patent, or market limitations; and,

ii) Expanded research and investigational therapeutic access programs may accelerate scientific discovery while maintaining appropriate patient safety protections.

24) States the intent of the Legislature to do both of the following:

a) Support voluntary state-authorized research programs, investigational therapeutic access under medical supervision, institution-level safety oversight, and high-quality manufacturing and testing standards; and,

b) Establish a state-authorized research and investigational therapeutic framework that complements existing federal regulatory structures while expanding opportunities for scientific research and medically supervised investigational therapeutic access.

25) States legislative intent that participation in this chapter is voluntary. Prohibits this bill from being construed to require participation by any public or private institution, health care practitioner, or research entity.

EXISTING LAW:

State Law

1) Establishes the State Board of Pharmacy (Board) to administer and regulate the Pharmacy Law. [Business and Professions Code (BPC) § 4001]

2) Provides that protection of the public is to be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. [BPC § 4001.1]

3) Authorizes the Board to adopt rules and regulations as may be necessary for the protection of the public. [BPC § 4005]

4) Defines “pharmacist” as a natural person to whom a license has been issued by the Board which is required for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription. [BPC § 4036; BPC § 4051]

5) Authorizes a pharmacy to furnish dangerous drugs only to certain individuals and entities. [BPC § 4126.5]

6) Establishes the Sherman Law, which provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements, under the administration and enforcement of DPH. [Health & Safety Code (HSC) § 109875, *et seq*.]

Federal Law

1) Establishes the federal Food, Drug and Cosmetic Act (FDCA) which provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements, enforced by the FDA. [21 United States Code (USC) § 301, *et seq*.]

2) Prohibits a person from introducing or delivering for introduction into interstate commerce any new drug, unless an approval of a new drug application or abbreviated new drug is effective with respect to such drug. [21 USC § 355]

3) Establishes the Current Good Manufacturing Practice (cGMP) for manufacturing, packaging, labeling, and holding operations for dietary supplements. [21 Code of Federal Regulations (CFR), Part 111].

4) Prohibits a person from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary of Health and Human Services applicable to the category of examinations or procedures which includes such examination or procedure. Establishes requirements for the issuance and renewal of certificates. [42 USC § 263a]

5) Establishes the Clinical Laboratory Improvement Amendments of 1988 regulations which apply to all US facilities or sites that test human specimens for health or disease assessment. [42 CFR § 493.1, *et seq*.]

6) Establishes requirements for the compounding of drugs. [21 USC § 353a]

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill puts California at the forefront of medical innovation by creating a safe and organized program for studying and using new peptides. The author states that currently, access to these amazing health advancements are those with the means to afford them or those taking a risk in the unregulated "grey market." The author continues that this bill counters this by expanding safe and legal access for patients under the care of a medical provider. The author concludes that by creating a structured approach, this bill promotes patient access, innovation, and a responsible scientific study of peptides in California.

2) **BACKGROUND.** Peptides are chains of amino acids in the body that serve many different functions, prompting cells to perform actions like decreasing inflammation or increasing collagen production. Peptides comprise a vast category of compounds. Some, like insulin, have long been used as treatments, but many others have received little study and much remains unknown about their benefits or harms.

a) **FDA approval for drugs.** The FDA regulates the approval, manufacturing, and distribution of drugs. According to the FDA's website, the FDA's Center for Drug Evaluation and Research evaluates new drugs before they can be sold, ensuring that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks. The FDA approval process requires multiple phases of clinical trials to establish safety and efficacy before a drug can be marketed.

b) **Compounding.** The FDA allows for compounding, which is a practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. This practice is intended to help patients who cannot be treated with an FDA-approved medication, such as a patient who has an allergy to a certain dye and needs a medication to be made without it, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form. Practitioners in hospitals, clinics, and other health care facilities sometimes provide compounded drugs to patients when an FDA-approved drug is not medically appropriate to treat them. In these situations, compounding can serve an important patient need. Compounded drugs are not FDA-approved, meaning FDA does not verify the safety, effectiveness or quality of compounded drugs before they are marketed. The FDA states that unnecessary use of compounded drugs may expose patients to potentially serious health risks. For example, poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much or too little active ingredient. This can lead to serious patient injury and death.

   State-licensed physicians and pharmacists that compound under 6) of existing federal law above, which is section 503A of the FDCA are only authorized compound drug products using bulk drug substances that:

   i) Comply with an applicable USP or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;

   ii) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or

   iii) Appear on FDA's list of bulk drug substances that can be used in compounding (the 503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

   A 2026 article published by *The New York Times* titled, "Heeding Kennedy's Wishes, FDA Is Expected to Lift Restriction on Peptides," notes that in 2023, 14 peptides were removed from a list of products that the FDA allows compounding pharmacies to produce. The pharmacies tailor products for individual patients' needs. The peptides had not been approved by the FDA as safe or effective and, in recent years, the agency had noted that they were increasingly being marketed with unproved claims that they had cosmetic, anti-aging and disease-fighting benefits.

   Since the agency removed the 14 peptides from the compounding pharmacies' list, they have been primarily sold online in a "gray" market, as compounds for research, which are

not subject to regulation. The FDA can warn companies against products they deem illicit, seize them or ban them from entering the country.

The federal Health and Human Services Health Secretary has said in recent podcast appearances that he is pushing for the FDA to reverse the prohibition on the peptides, which include some that act as growth-hormone stimulators.

This bill creates a state authorized program allowing participating entities, including the UC, hospitals, and physician groups to dispense nonapproved peptides with physician supervision. This bill exempts physicians who dispense these peptides from civil liability except in the case of gross negligence; reckless misconduct; intentional wrongdoing; fraud or misrepresentation; and, failure to obtain informed consent.

3) PREVIOUS LEGISLATION.

a) AB 3063 (McKinnor) of 2024 would have specified that the addition of a flavoring agent to a conventionally manufactured product is not considered compounding if certain conditions are met, including that the flavoring agent does not alter a medication's concentration beyond the level of variance accepted by the United States Pharmacopeia. Would have required the addition of the flavoring agent to be documented in the prescription record, as specified. AB 3063 was vetoed by the Governor, who stated in part:

AB 3063 creates an exception to national standards for compounding which poses a risk to consumer health and safety. This bill would undermine AB 973, which I signed in 2019, that required both sterile and non-sterile compounding in California to be consistent with the United States Pharmacopeia-National Formulary's guidelines. AB 973 was passed and enacted to ensure the state adheres to the federally required minimum standards of consumer protection.

b) AB 782 (McKinnor) of 2023 would have specified that compounding does not include reconstitution of a drug pursuant to a manufacturer's directions, the sole act of tablet splitting or crushing, capsule opening, or the addition of a flavoring agent to enhance palatability. Would have required a pharmacy to retain documentation that a flavoring agent was added to a prescription and to make that documentation available to the board or its agent upon request. AB 782 was vetoed by the Governor who stated in part:

AB 782 would create standards for California that do not meet the United States Pharmacopeia-National Formulary's guidelines regarding compounding that have been put in place to minimize patients' risk of harm. AB 782 also contradicts AB 973, which I signed in 2019, which required both sterile and non-sterile compounding in California to be consistent with the United States Pharmacopeia guidelines, which ensured clear compounding standards and provided greater consumer safety. AB 782 would make exceptions to federal guidelines, which would pose a risk to consumers.

c) AB 973 (Irwin), Chapter 184, Statutes of 2020 requires the compounding of drug preparations by a pharmacy for furnishing, distribution, or use to 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.

4) **POLICY COMMENT.** Investigational compounds and novel compounds may lack robust clinical evidence regarding safety, efficacy, dosing, and long-term effects. This bill includes little oversight to protect against potential harm to patients, except for annual safety and utilization reports to be submitted to DPH.

5) **AMENDMENTS.** The committee may wish to significantly amend this bill as follows:

   a) Delete the findings and declarations and the authorization of specified entities to establish and administer peptide and novel compound research and investigational therapeutic access programs and make conforming changes.

   b) Require DPH to convene a working group to study and make recommendations regarding the creation of a state-authorized research and investigational therapeutic framework that complements existing federal regulatory structures while expanding opportunities for scientific research and medically supervised investigational therapeutic access.

   c) Require DPH to submit a report on its findings and recommendations to the legislature by 2029.

6) **DOUBLE REFERRAL.** This bill is double referred, upon passage in this Committee, it will be referred to the Assembly Committee on Judiciary.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file

Opposition

None on file

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