NABP
National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: October 28, 2026

RE: HHS Peptide Enforcement Discretion Policy and October 30 FDA Engagement

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The National Association of Boards of Pharmacy (NABP) is notifying the boards of pharmacy that on October 28, 2026, the US Department of Health and Human Services (HHS) released an Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances. The notice will be published in the *Federal Register* on October 30, 2026. Comments are due two weeks after publication on Docket No. HHS-OASH-2026-0496. However, it appears that this policy is immediately in effect.

What the Policy Covers

HHS does not intend to take enforcement action against state-licensed pharmacies, federal facilities, or licensed physicians compounding the following six peptide bulk drug substances, each limited to the form and routes of administration specified in the policy:

- **BPC-157 acetate:** subcutaneous, intramuscular, oral, and topical
- **TB-500 acetate:** subcutaneous and intramuscular injection
- **Epitalon acetate:** subcutaneous and intramuscular injection, dispensed in intermittent courses
- **MOTS-c acetate:** subcutaneous and intramuscular injection
- **KPV acetate:** topical and oral
- **Semax free base:** intranasal

The policy applies until each peptide is addressed in a final rule as being included or not included on the 503A bulks list. HHS may revisit it if a safety signal or product quality issue arises.

Conditions

Enforcement discretion applies only when all of the following conditions are met:

1. **503A Interim Access List -** The peptide bulk drug substance appears in Appendix A of the policy. (For now, only the six peptides listed directly above are in Appendix A and permitted.)
2. **Identity -** The peptide bulk drug substance has the identity and route of administration limits described in Appendix B, including amino acid sequence, chemical structure, molecular weight, and molecular formula of the policy.
3. **Characterization -** The bulk drug substance comes from a facility registered with the US Food and Drug Administration (FDA) and is accompanied by a valid certificate of analysis with test results meeting the testing standard in Appendix B.
4. **Original manufacturer -** The original manufacturer, not a subsequent packer, repacker, labeler, or distributor, is registered with FDA and compliant with current good manufacturing practice

and applicable Food Drug & Cosmetic Act (FDCA) requirements. The facility's physical location is listed on the certificate of analysis. If the substance is obtained through a registered repacker, relabeler, or reseller, that entity must have performed and documented vendor validation of the manufacturer and its certificate of analysis.

5. **Adverse Event and Product Quality Reporting -** Compounders report products compounded, serious adverse events, whether or not considered drug related, and product quality issues to FDA's MedWatch program and to the states where products are compounded and sent. Product reports include the active ingredient and strength, the original manufacturer and its facility identifier, and the dosage form and route of administration. Labeling provided to the patient must explain how to report adverse events and product problems.
6. **Labeling -** The product is labeled "This is a compounded drug product. Not for resale."
7. **Single active ingredient -** The compounded product contains only one active pharmaceutical ingredient listed in Appendix A.
8. **Oral bioavailability -** For oral dosage forms, the compounder maintains documentation that the formulation achieves adequate oral bioavailability in humans.
9. **Delivery device -** The only delivery device co-packaged with or containing the product is an FDA 510(k)-cleared syringe.
10. **Other requirements -** The product is compounded in compliance with all other applicable requirements of the FDCA, including the prohibition on insanitary conditions and the section 503A patient-specific prescription requirement.

What This Means

Federal enforcement discretion extends to certain peptides in Appendix A used in compounding by state-licensed pharmacies, federal facilities, and licensed physicians under the described circumstances. These peptides are not FDA-approved and have not been added to the 503A bulks list or the Category 1 interim list. FDA staff recommended against their inclusion at the July 2026 Pharmacy Compounding Advisory Committee meeting. A product that does not meet every condition may be subject to action by FDA or the states. Boards should evaluate whether state law permits compounding with these substances.

Several questions remain open:

- How will compounders submit product reports?
- How will compounder product reports reach boards?
- Will FDA share MedWatch reports with boards?
- How will FDA compile the safety information on these peptides?
- Who verifies that the conditions are met?
- How will states coordinate interstate investigations?
- Will FDA or HHS provide access to registered peptide manufacturers?
- Will FDA or HHS issue additional guidance on any of the conditions?
- How long before the drug supply chain contains peptide bulk drugs that meet the conditions of the enforcement discretion?

Next Steps

On October 30, 2026, NABP and a group of board volunteers will meet with leadership of FDA's Office of Compounding Quality and Compliance (OCQC) and we will be working to address some of the

questions mentioned above. Matt Lash of CDER's Office of Compliance is also scheduled to join the executive officer call that day. Boards are encouraged to bring their questions to that call.

As discussed at the Executive Officer Forum, now that the policy has been released, NABP will finalize communication tools that boards can use to educate the public and policymakers. These include FAQs for licensees, prescribers, patients, and policymakers. NABP will share these resources with the boards as they are finalized.

If you have any questions, please contact Josh Bolin, senior advisor, via email at jbolin@nabp.pharmacy.

cc: NABP Executive Committee