NABP
National Association of Boards of Pharmacy

1600 Feehanville Dr
Mount Prospect, IL 60056

1.847.391.4406
help@nabp.pharmacy

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Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: *Docket No. HHS-OASH-2026-0496; Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances*

Dear Secretary Kennedy:

The National Association of Boards of Pharmacy ("NABP") is an independent, international, and impartial association that, since 1904, has worked with its member boards of pharmacy to protect public health. Its members are the boards of pharmacy in all 50 states, the District of Columbia, and the U.S. territories, along with pharmacy regulatory authorities in several Canadian provinces. NABP supports those boards through licensure, accreditation, inspection, and supply chain integrity programs.

These comments concern the Enforcement Discretion Policy published October 30, 2026. The policy sets ten conditions that certain compounders, including state-licensed pharmacies, must meet when using certain peptide bulk drug substances. State boards of pharmacy license, inspect, and discipline the pharmacies the policy covers, and they will carry much of the work of confirming those conditions are met. Several conditions reflect concerns NABP and its member boards have raised, including lot-level certificates of analysis, identification of the original manufacturer, and reporting of serious adverse events to the Food and Drug Administration (FDA) and the states. The recommendations below are intended to make those conditions verifiable and enforceable at the state level.

The policy marks a substantive and procedural departure from how access to prescription drugs has been regulated. Since 1938, the Federal Food, Drug, and Cosmetic Act (the Act) has relied on review before a drug reaches patients. For bulk drug substances used in 503A compounding, Congress set a deliberate path in which FDA consults the Pharmacy Compounding Advisory Committee and adds substances to the 503A bulks list through notice-and-comment rulemaking, and it left that path in place when it enacted the Drug Quality and Security Act in 2013. The speed of this policy, and the process by which it was issued, leave a number of significant questions unresolved. Those open questions make it harder for the state boards that will enforce the policy to protect the public health and safety.

NABP has encouraged its member boards to submit their own comments to this docket. The two-week comment period will be difficult for many boards to meet. NABP encourages the U.S. Department of Health and Human Services (HHS) to continue accepting feedback from state boards after the docket closes and to engage with them directly as the policy is implemented. Oversight of these drug substances will require closer collaboration and communication between federal and state regulators.

Bulk Drug Substance Sourcing and Certificate of Analysis Validation

The policy relies on FDA registration of the original manufacturer as a drug establishment and a certificate of analysis that names it. Registration and a named manufacturer allow a pharmacy or inspector to look up a company. They do not show whether anyone has qualified that manufacturer, whether it has been inspected, or whether the material in the container matches the document. Boards conducting investigations report pharmacies presenting certificates of analysis that cannot be read, are written in a foreign language, or appear to have been generated with AI tools and cannot be traced to the manufacturer they name. Boards have also encountered suppliers asserting that a registered facility may supply any substance, regardless of what it has listed with FDA.

Most compounders do not have staff qualified to assess manufacturers of bulk drug substances, and these compounders are not required to perform identity testing on ingredients prior to use. In practice, they depend on the repackagers and distributors that supply them. The policy recognizes this by permitting purchases through a registered repackager or reseller that has validated the manufacturer and its certificate of analysis. That condition is only as strong as the definition of validation. Additionally, resellers, such as wholesale distributors, do not open sealed containers. NABP recommends that HHS:

1. Require that the original manufacturer have an inspection on record by FDA or by a regulatory authority FDA recognizes that confirms compliance with current good manufacturing practice (CGMP) requirements.
2. Define validation by a repackager to include, at a minimum, documented qualification of the manufacturer and identity testing of each lot in the United States before distribution. The validation documentation should be provided to the purchasing pharmacy and/or compounder and kept available for inspection. Require resellers of bulk drug substances to pass along an unaltered copy of the original certificate of analysis from the manufacturer to the compounder.
3. State that material received repackaged and relabeled for resale without identity testing does not meet the validation condition.
4. Require that certificates of analysis be issued in English or accompanied by a certified English translation.
5. Confirm that material labeled or sold for “research use only,” “professional use,” or any similar purpose does not qualify, even if accompanied by a certificate that appears to meet Appendix B. Additionally, state that peptide bulk drug substances that are in the marketplace labeled for research use only or with a similar designation, or otherwise imported through gray market channels, cannot be tested to meet specifications and relabeled as CGMP compliant. The bulk drug substance must be manufactured originally under CGMP conditions and cannot be tested into compliance.
6. Provide transparency in identifying bulk drug substances that are compliant and can be legally imported. NABP also recommends that FDA give state inspectors real-time access to manufacturer drug establishment registration, listing of peptide bulk drug substances they manufacture, inspection reports in English, and import alert status. For GLP-1 active ingredients, FDA uses Import Alert 66-80 to detain foreign bulk drug substance from any manufacturer not on a green list of firms that FDA has found, through inspection or records review, to appear compliant with CGMP requirements. NABP recommends that FDA apply the same process to the peptides listed in Appendix A as a minimum condition. Unlike the GLP-1 green list, which redacts firm names, the peptide list should be public and should name each manufacturer, the peptides it has listed, the location where each is manufactured, and its inspection and CGMP compliance status, so compounders and regulators

can confirm that compliant bulk drug substance was used. NABP also recommends that FDA establish a means to trace a lot of a covered bulk drug substance back to a registered manufacturer.

Substance Identity and Testing

Appendix B defines each covered substance by a specific form, sequence, and molecular formula. Products sold under the same names often differ. No official name and no official compendial monograph exist for these substances. NABP recommends that FDA publish a reference table for each covered substance, with name, form, sequence, molecular formula, Chemical Abstracts Service (CAS) number, and other identifiers, and require that certificates of analysis, compounding records, and labels use those identifiers. NABP also recommends that FDA work with the United States Pharmacopeia (USP) toward reference standards so that identity testing can be measured against an independent benchmark.

Appendix B lists the analyses a certificate must report but does not address who may perform them. NABP recommends that HHS set qualification expectations for laboratories performing that testing, including accreditation and validated methods appropriate to peptides. Boards also report that peptide testing requires capabilities beyond those routinely available to them. NABP recommends that FDA make laboratory support available to state boards that suspect a substance did not come from an appropriately qualified manufacturer or was not validated by a repackager.

Traceability and Labeling

Compounded drugs and bulk drug substances are excluded from the product tracing, verification, and serialization requirements of the Drug Supply Chain Security Act. If a lot of a covered peptide is found to be contaminated or misidentified, regulators have no standard method to identify where it came from or which purchasers received the same lot.

Closing that gap for bulk drug substances would likely require legislative or regulatory action beyond the scope of this policy. NABP would welcome the opportunity to work with the Secretary to explore how bulk drug substance tracing could be implemented as regulations for these substances are developed. NABP operates Pulse by NABP, a directory of supply chain trading partners built on state and federal license and registration records. That directory could be extended to manufacturers, repackagers, and distributors of bulk drug substances and to compounders, giving FDA and state boards a common record of who is in the supply chain and how to reach them when a lot must be traced or a safety signal investigated.

NABP recommends that HHS require compounders to keep lot-level distribution records showing the quantity dispensed or shipped and the destination state, and to produce them to FDA or a state board upon request. NABP also recommends that the container label carry the lot number and the substance identifier from Appendix B, so a patient, prescriber, or other reporter can tie an adverse event to a specific lot.

Enforcement Against Noncompliant Supply

One stated purpose of the policy is to move patients away from unregulated suppliers. Without enforcement, the policy may have the opposite effect. Sellers operating outside its conditions can market the same named peptides as products HHS now permits, often at lower cost, and patients have no

reliable way to tell the difference. The conditions protect patients only if products that fail to meet them are removed from the market. NABP recommends that HHS and FDA commit to a proactive investigation and enforcement program, with dedicated federal resources, against entities that sell, distribute, or compound these peptides outside the policy. That program should reach products labeled for research use only or professional use, sellers operating without state licensure, and marketing that suggests HHS or FDA approval. NABP also recommends that FDA support state boards that act against these entities, and that FDA and the Federal Trade Commission act against advertising of research-grade peptides for human use.

Adverse Event and Product Quality Reporting

The policy requires compounders to report products compounded, serious adverse events, and product quality problems to FDA and to the states involved. Compounders are to report serious adverse events and product quality issues to FDA's MedWatch system. The value of these reports depends on details the policy does not yet specify. NABP recommends that HHS:

1. Define serious adverse events and reportable product quality problems consistent with the definitions that apply to 503B outsourcing facilities, so data are comparable across both pathways.
2. Set a reporting timeframe consistent with the timeframe that applies to outsourcing facilities.
3. Define the states involved to include, at a minimum, the state where the pharmacy is located and the state where the patient received the drug.
4. Specify minimum data elements. Boards have identified the peptide drug and form, lot, original manufacturer and supplier, route, pharmacy (or other compounder), prescriber, severity, outcome, quantity distributed from the affected lot and the states it reached, prior reports involving the pharmacy or product, and a named facility contact.
5. Define the compounded product reporting obligation as periodic reporting of each covered peptide, dosage form, and volume compounded, and the states to which product is shipped.
6. Specify where the compounded product reports are to be submitted and the frequency for submission.
7. Permit a single submission to a designated clearinghouse that routes reports to FDA and the affected states, so a compounder satisfies both obligations without reporting twice.
8. Share MedWatch reports and compounded product reports involving covered peptide drugs with state boards through 21 CFR 20.88 arrangements.

Many states do not have a mechanism to receive these reports, and some lack authority to share them with other states. NABP is developing a national adverse event reporting clearinghouse for 503A compounded drugs and has convened state boards on its design. NABP would welcome the opportunity to align that work with the reporting conditions above so reports reach regulators in a usable form and in a timely manner.

Federal-State Coordination and Enforceability

Under the Act, a bulk drug substance without a monograph or an approved product reaches 503A compounding through inclusion on the 503A bulks list, after advisory committee review and notice-and-comment rulemaking. Under this policy, oversight begins after the product is in patients' hands, and most of that oversight falls to the states. NABP recommends that HHS set a timeline for addressing these

substances through the 503A bulks list process, so the conditions in this policy rest on a durable regulatory basis.

Enforcement discretion is not binding, and state boards typically anchor their regulations and inspections to federal standards. Without a clear federal statement, each state must decide on its own how to treat the conditions listed, which leads to inconsistent approaches that create openings for activity to move to states with less developed oversight or limited resources. NABP recommends that HHS:

1. State explicitly that compounding of peptide drugs listed under Appendix A that does not meet all ten conditions falls outside the policy.
2. State that the conditions describe federal expectations for these substances only, and that states may adopt, reference, or enforce them under state law.
3. State that peptides compounded under the policy must be compounded in compliance with all requirements of section 503A, including USP chapters <795> and <797>.
4. Confirm that the conditions, including reporting, apply equally to licensed physicians who compound under the policy. Physician compounding falls outside the jurisdiction of most boards of pharmacy, so HHS should also address how state medical boards will be informed and engaged.
5. Notify state boards promptly when HHS revisits the policy for a drug substance, when a new safety signal or product quality issue arises, and when FDA takes action against a compounder or supplier of a peptide listed in Appendix A, including through warning letters and import alerts.

Conclusion

State boards of pharmacy will carry much of the day-to-day oversight of compounding under this policy. They license and inspect the pharmacies, receive complaints, investigate patient harm, and take action when the conditions described in the enforcement discretion notice are not met. The conditions will work only if the boards responsible for confirming them help shape how they are applied and have the details necessary to apply these conditions consistently. NABP urges HHS to treat state feedback as an ongoing part of implementing this policy, and to establish a standing channel with state boards for implementation questions, safety signals, and future revisions. NABP is prepared to convene state boards for that purpose.

NABP and its member boards are also prepared to work with HHS and FDA on bulk drug substance sourcing and certificate of analysis validation, on reporting mechanisms, and on inspection resources for state boards. The changes recommended above would give state boards the detailed information and footing they need to confirm the conditions are met and to act quickly when they are not.

Respectfully submitted,

Lemrey “Al” Carter, PharmD, MS, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy