November 13, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Washington, DC 20201

Re: Comments on Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances (Docket No. HHS-OASH-2026-0496 | FR Doc. 2026-22192 | RIN 0910-ZD94)

Dear Secretary Kennedy:

The Alliance for Pharmacy Compounding and the National Community Pharmacists Association appreciate the opportunity to comment on the Department of Health and Human Services' Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances, announced October 30, 2026.

APC is the national professional association representing state-licensed compounding pharmacies and FDA-registered outsourcing facilities – and the pharmacists, technicians, and other professionals who work in them. Our pharmacy members prepare individualized medications pursuant to prescriptions from authorized healthcare practitioners under state and federal law and applicable United States Pharmacopeia standards.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 235,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

We support the Department's decision to establish a pathway for 503A compounding of the six specified peptides under defined conditions. Patients and prescribers are already seeking these substances, including from sellers outside the regulated healthcare system. A properly safeguarded pathway through state-licensed pharmacies can provide greater accountability for prescriptions, preparation, ingredient quality, and reporting.

As the Department moves forward, we see opportunities to clarify and strengthen specific provisions so the policy can operate effectively. Our recommendations focus on a workable, verifiable supply chain for these particular peptides; a clear explanation of reporting obligations; and practical guidance for pharmacies and state regulators.

Three issues merit particular attention: (1) a temporary sourcing safeguard while manufacturers of the covered peptide active pharmaceutical ingredients establish and demonstrate compliance with the policy's testing and quality requirements; (2) a clear distinction between adverse-event reporting and any intended routine utilization reporting, with meaningful independent analysis if the latter is required; and (3) timely communication of the policy's conditions to state boards of pharmacy. Specific comments follow.

I. Establish a temporary, verifiable sourcing pathway for the covered peptide APIs (Conditions 3 and 4; Appendix B)

The peptide-specific specifications in Appendix B are substantial — so much so that we question the ability of many manufacturers to be immediately compliant. While manufacturers and suppliers adapt their processes to meet and document those standards, pharmacies need a reliable basis for determining that the API they receive meets them. FDA establishment registration is not itself proof that a particular API lot complies with the policy or that the information on its certificate of analysis (COA) is accurate. Especially in a newly authorized market, unsupported or inaccurate claims of compliance could permit noncompliant material to enter the regulated pharmacy supply chain — frankly, as we have seen in abundance prior to the announcement of this interim policy on October 30.

This is a concern about the emerging supply chain for the six covered peptide substances, not a generalized criticism of API manufacturers. Nor is it a recommendation that HHS permanently restrict peptide API purchases to a particular type of supplier. Manufacturers may need time to refine their processes, complete the required testing, and establish reliable documentation demonstrating compliance with the policy's standards. During that transition, additional safeguards should be considered to prevent noncompliant API from entering the legitimate pharmacy supply chain.

APC and NCPA therefore recommend that, for an initial, defined transition period, 503A pharmacies be required to obtain the covered APIs through FDA-registered U.S. repackagers or relabelers. During this period, the registered repackager or relabeler would be responsible for qualifying the original manufacturer, reviewing the manufacturer's documentation, and verifying that each API lot meets the applicable requirements before release for pharmacy use. That verification should occur in the United States and include independent testing by a qualified U.S. laboratory where manufacturer documentation alone does not adequately establish compliance. We suggest a limited exception for pharmacies that independently demonstrate equivalent manufacturer qualification and certificate of analysis verification capabilities. A pharmacy may satisfy these criteria by using an FDA-registered analytical testing laboratory to perform needed testing, provided the laboratory's results and the pharmacy's oversight are documented.

APC recommends an initial period of one year, subject to review, during which HHS and FDA would assess whether manufacturers have demonstrated consistent compliance with the policy's standards.

Once those standards have been demonstrated, HHS could permit direct manufacturer-to-pharmacy sourcing more broadly for entities that can demonstrate their ability to appropriately qualify manufacturers and verify COA compliance. This phased approach would protect patients and the integrity of the pharmacy supply chain during a period of rapid market development without imposing an indefinite restriction on legitimate sourcing arrangements. Nor should it delay implementation of the policy where compliant API is already available through appropriately qualified and verified intermediaries.

We request three specific clarifications:

- If the original manufacturer's COA does not have a required specification, may the registered intermediary or purchasing pharmacy arrange for testing by a qualified U.S.-based independent laboratory and document conformity with the applicable specification(s) before the API is used in compounding?
- What does HHS intend by the immunogenicity-related testing referenced for these synthetic peptide APIs? Please identify what is scientifically appropriate and feasible for these substances and whether the requirement is lot-specific.
- May manufacturer identity and underlying qualification records be retained by the registered intermediary and made available to FDA for inspection, without requiring routine public disclosure of confidential commercial manufacturer relationships? The pharmacy should receive sufficient documentation to verify that its purchased lot meets the applicable requirements.

To ensure 503A compounding pharmacies have access to appropriately tested API, we recommend that HHS collaborate with API manufacturers, resellers, repackagers, and other interested parties to establish a formal process for continuously submitting alternative characterization and testing approaches. Because analytical science and testing technologies continually advance, this process would allow HHS's requirements to keep pace with modern methods that may characterize API as well as, or better than, the currently specified approaches. We recommend that HHS establish an expedited review process, with an initial response to scientifically justified alternative methods within 15 days of submission and a timely determination of their acceptability. HHS should also maintain a publicly available list of accepted alternative methods so that manufacturers, suppliers, and pharmacies can rely on consistent testing standards.

The critical principle is straightforward: A manufacturer's unsupported assertion of compliance should not be the only checkpoint before peptide API covered by the HHS enforcement discretion policy enters a pharmacy. The end state should be demonstrable compliance, not a permanent requirement to purchase through any particular channel.

II. Clarify what Condition 5 requires before establishing a utilization-reporting mechanism

We appreciate HHS's clear intent to establish MedWatch reporting as the mechanism for serious adverse events and product quality issues under this enforcement discretion policy. However, we

believe the opening language of Condition 5 could benefit from clarification to prevent misunderstanding among compounders.

The phrase "Report products compounded, serious adverse events, and product quality issues" could be read by some as requiring routine dispensing or utilization reports for all compounded covered peptide medications. We recognize this is likely not HHS's intent, particularly since MedWatch—a system designed specifically for adverse event and product problem reporting—is the designated reporting mechanism. Routine dispensing data would not fit naturally within that system.

To avoid confusion and ensure consistent implementation across pharmacies and states, we recommend HHS explicitly state that Condition 5 requires:

- Reporting of serious adverse events to MedWatch
- Reporting of product quality issues to MedWatch
- Reporting of serious adverse events and product quality issues to the appropriate state authorities

This clarification will help pharmacies understand their obligations with certainty and support HHS's goal of meaningful safety surveillance without creating unnecessary compliance ambiguity. If HHS intends only serious adverse-event and product quality reporting, it should say so and remove language that could be read to require separate routine product reporting. APC and NCPA support a clear serious adverse-event reporting obligation, not the creation of an unspecified reporting system by implication.

III. If routine utilization data are required, pair collection with independent research and analysis

If HHS intends routine utilization reporting, gathering records is not enough. A repository can receive and safeguard data; it cannot, by that fact alone, determine whether apparent trends reflect actual use, reporting gaps, changing participation, or differences among dosage forms and routes. Nor can simple counts of reported adverse events be treated as incidence rates without appropriate denominators, assessment of reporting bias, and an explanation of the data's limitations. *Public figures without such context may be misunderstood or used to draw conclusions they do not support, which can undermine the intent of the HHS policy.*

Emory University's Rollins School of Public Health offers a particularly useful model for an independent academic approach. Researchers including Drs. Hui Shao and Donghai Liang have been developing a standardized compounding dispensing-data framework designed to produce credible aggregated findings. A limited dataset can capture drug, strength, dosage form, patient sex, and month of dispensing, with any additional fields for this policy chosen for their demonstrated analytical value. Research methods, data quality assessment, interpretation, and publication of findings would be the responsibility of the academic researchers — independent of APC and participating pharmacies.

We urge HHS to engage Emory's research team as an independent partner in designing and analyzing any routine utilization reporting required under this policy. Such a partnership could provide a clear analytical plan, consistent data definitions, evaluation of completeness and

representativeness, confidentiality safeguards, and reports explaining both the findings and their limits.

If routine reporting is required, we recommend periodic aggregate submissions — semiannually or annually, as warranted — rather than unnecessary patient-by-patient submissions. HHS should specify a single, secure method of submitting the required dataset and explain how that method would interact with state reporting obligations. Analysis should remain separate from serious adverse-event investigations, and no conclusion about safety or causation should be inferred from utilization totals alone.

IV. Specify adverse-event and state reporting obligations without duplicative submissions (Condition 5)

APC and NCPA support reporting of serious adverse events and product quality issues. HHS should specify when the reporting clock begins, the deadline to submit a report, the required content, and whether the submitting pharmacy or another party bears responsibility when multiple parties become aware of an event.

The policy should also identify how reporting to "appropriate states" is intended to operate. MedWatch reports do not necessarily substitute for reports required by state law, and state boards currently use different channels, including forms, email, and other notification processes. HHS should clarify whether a pharmacy must separately report to its licensing state, the patient's state, or both in interstate situations. Where legally and operationally possible, we favor a single submission or information-sharing arrangement over redundant federal and state reports containing the same facts. At minimum, HHS should state that its policy does not itself create an unspecified new state reporting portal or displace existing state reporting requirements.

V. Clarify oral bioavailability documentation (Condition 8)

Condition 8 requires documentation of an "adequate level of oral bioavailability in humans," without defining the evidentiary standard or whether one entity's study may be relied upon by multiple pharmacies using the same sufficiently comparable formulation. This leaves pharmacies uncertain about what establishes "adequate" compliance.

Please confirm whether a pharmacy may rely on qualified published or unpublished data generated by a manufacturer, research institution, or other entity rather than being required to commission a separate human study for each pharmacy.

For oral preparations intended to act locally in the gastrointestinal tract, including potential BPC-157 and KPV formulations, APC and NCPA recommend that HHS not require systemic oral bioavailability as a condition of this interim policy.

Finally, please clarify whether the condition applies to buccal and sublingual preparations. FDA distinguishes those routes from oral administration, and the policy should use route terminology consistently.

VI. Clarify ordinary containers, dosing aids, and permitted routes (Condition 9)

Condition 9's reference to an FDA 510(k)-cleared syringe could be read to restrict packaging and administration for dosage forms the policy otherwise permits. We seek clarification limited to the meaning of this condition for these peptides.

- Please confirm that conventional single-dose and multi-dose sterile vials are drug containers, and are permissible for storing and transporting injectable preparations. Syringes generally are not intended as long-term storage containers.
- For intranasal Semax, please confirm that the policy does not require intranasal administration by a 510(k)-cleared syringe and explain whether conventional nasal spray pumps, droppers, or atomizers may be used.
- For permitted topical and oral liquids, please clarify whether ordinary dispensers, oral dosing syringes, or dosing cups may be supplied as appropriate to the dosage form.

VII. Clarify the precise peptide forms, routes, and single-API limitation (Conditions 2 and 7; Appendices A and B)

APC and NCPA support the interim policy's single-active-ingredient limitation. To help pharmacies apply it, HHS should list in Appendix A, or in a consolidated cross-reference, the specific covered form or forms of each peptide and the routes permitted for each form. The policy should make clear that formulations outside the stated forms and routes are not covered by its enforcement discretion.

For Semax, we ask HHS to clarify the scientific basis for limiting the policy to the free base and whether a future evidence-based supplement could consider Semax acetate. Commercial availability alone would not justify adding a different form; any expansion should be supported by comparable quality and safety information.

The Department should also confirm that "single active pharmaceutical ingredient" prohibits a second API, including a non-peptide active ingredient.

VIII. Define "intermittent courses" for epitalon (Appendix B)

Appendix B refers to epitalon acetate use in "intermittent courses" without defining the term. HHS should either provide the applicable evidence-based maximum duration and minimum interval or clarify that those decisions rest with the prescribing practitioner's clinical judgment. Pharmacies need a definite standard, or a definite allocation of responsibility, to apply the condition consistently.

IX. Confirm the policy's present status and how changes will be communicated

The Federal Register notice describes the policy as a draft, while the document uses language indicating that HHS does not intend to pursue enforcement when its conditions are met. We ask HHS to state plainly whether the enforcement discretion is already operative, its effective date, and whether any additional Department action is required before pharmacies may rely on it.

Please also identify how pharmacies and state boards will be notified of revisions, suspension, or withdrawal. If HHS materially changes sourcing or other conditions, a clearly stated transition approach would help pharmacies manage existing inventory and patient prescriptions in good faith.

APC and NCPA are not requesting an estimated date for final rulemaking, which necessarily depends on the rulemaking process.

X. Communicate directly with state pharmacy regulators

HHS enforcement discretion does not bind state boards of pharmacy, and we do not ask the Department to override their independent authority. Still, the policy's success will depend in part on whether boards understand the federal conditions and how they are intended to operate. Several state boards are already discussing their response to the federal announcement.

APC and NCPA ask HHS and FDA to communicate the policy, its rationale, its sourcing and reporting safeguards, and subsequent clarifications directly to state boards and relevant national organizations.

Timely and accurate communication may reduce avoidable differences in interpretation, even where states ultimately exercise their own authority differently. A coherent explanation of the federal approach is more useful than implying that HHS can require the states to adopt it.

Conclusion

We support the Department's decision to offer an accountable pathway for 503A compounding of these specified peptides. Our recommendations are intended to make that pathway clear and practicable while protecting patients: a temporary, independently verifiable sourcing mechanism until manufacturers can demonstrate consistent compliance; precise reporting instructions; qualified independent analysis if routine utilization reporting is required; and direct communication with state regulators.

We also urge HHS and FDA to publish a publicly accessible FAQ addressing the policy's effective date, API sourcing and testing requirements, acceptable documentation, reporting obligations, permissible dosage forms and delivery devices, and the relationship between federal enforcement discretion and state pharmacy laws.

We appreciate the opportunity to comment and would welcome further discussion with HHS and FDA on these specific recommendations.

Sincerely,



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