Federal Peptide Compounding Policy in 2026: Implications for Sexual Medicine and Andrology

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Background

Peptide drugs range from FDA-approved GLP-1 receptor agonists to unapproved compounds such as BPC-157, which are sold online and through telehealth clinics.

In 2026, federal regulators moved in two directions: easing restrictions on several unapproved peptides while moving to end large-scale compounding of GLP-1 drugs. Compounded PT-141 and enclomiphene, both used in sexual medicine, sit in the same channels.

Objective

To summarize 2026 federal and state peptide compounding actions and their relevance to sexual medicine.

Methods

We reviewed FDA notices, advisory committee records, the Federal Register, and legal and trade press, current as of October 6, 2026.

Implications for Urology

- Enforcement aimed at gray-market peptides may reach legitimate telehealth prescribing of PT-141 and enclomiphene.
- Without affordable GLP-1s, some men with obesity-related hypogonadism may return to testosterone therapy.
- States are filling the gap unevenly. CT, AL, NY, CA, MA, and LA have restricted peptide compounding; TX, FL, NV, and AZ have not.

Findings

Table 1. Federal actions on compounded peptides, 2023–2026.

Date	Action	Effect
Sep 2023	FDA places 19 peptides, including BPC-157 and TB-500, in Category 2 (safety concerns)	Compounding effectively halted
Dec 2024–Feb 2025	Tirzepatide and semaglutide shortages declared resolved	Ends basis for copy compounding
Feb 2026	HHS Secretary says on a podcast that about 14 of the 19 should return to compounding	No formal action
Apr 2026	FDA removes 12 peptides from Category 2	Neither prohibited nor listed
Apr 30, 2026	FDA proposes excluding semaglutide, tirzepatide, and liraglutide from the 503B bulks list	Comments closed Jun 29; final decision pending
Jul 23–24, 2026	Advisory committee recommends 6 of 7 peptides for the 503A list, including BPC-157 (8–6)	Advisory only; FDA staff opposed

Table 2. Status of compounds relevant to sexual medicine, October 2026.

Compound	Regulatory status	Use in andrology
BPC-157	Off Category 2; recommended by advisory committee; not on 503A list	None established
Bremelanotide (PT-141)	Approved (Vyleesi) for premenopausal women only	Compounded off-label for men
Enclomiphene	Not FDA-approved; 2022 advisory review did not support listing	Secondary hypogonadism
Compounded GLP-1s	503B exclusion proposed	Obesity-related hypogonadism

Policy Recommendations

1. Tie 503A listing of unapproved peptides to defined safety data and adverse-event reporting.
2. Distinguish evidence-based andrology prescribing from gray-market peptides in enforcement.
3. Require a documented diagnosis and baseline labs before telehealth prescribing of hormone-modulating drugs.
4. Develop an AUA and SMSNA position on andrology-relevant compounding.

Open Questions

- Will FDA adopt the advisory committee's recommendations?
- Will PT-141 and enclomiphene be affected by the BPC-157 precedent?
- If 503B GLP-1 compounding ends, will demand move to the gray market?

References

1. FDA. Proposal to exclude semaglutide, tirzepatide, and liraglutide from the 503B bulks list. Fed Regist. May 1, 2026.
2. FDA Pharmacy Compounding Advisory Committee meeting, Jul 23–24, 2026.
3. FDA. Bulk drug substances under section 503A: category updates, Apr 2026.
4. Atta H. Peptide regulation debate intensifies after FDA advisory panel's controversial vote. AJMC. Sep 25, 2026.