

treatment of opportunistic infections and health care coverage assistance. As health care coverage environments, treatment options, and program financing mechanisms continue to evolve, ADAPs face increasing operational complexity related to eligibility determination; client enrollment and retention; health care coverage navigation; pharmacy management; rebate administration; and data infrastructure. HRSA currently lacks comprehensive, national-level information about how ADAPs manage these operational functions and address emerging challenges.

To address these information gaps, HRSA developed the ADAP Transformation: Optimization and Best Practices in the Evolving Health Care Landscape study. Through this effort, HRSA will collect program-level information from ADAPs nationwide through a web-based survey, qualitative interviews with a purposeful sample of ADAP staff, and virtual listening sessions with the broader ADAP community. The study will identify operational best practices, barriers, and opportunities for technical assistance to strengthen ADAP capacity and support

access to HIV care and treatment services. No client-level information, personally identifiable information, or protected health information will be collected.

Need and Proposed Use of the Information: The proposed information collection will provide HRSA with systematic information on operational and administrative practices across ADAPs nationwide. Survey, interview, and listening session data will help HRSA identify effective strategies for managing eligibility processes; client enrollment and recertification; health care coverage continuity; pharmacy operations; rebate management; cost-containment efforts; and data systems modernization.

Findings will support the development of tailored technical assistance, tools, guidance, and dissemination activities designed to strengthen ADAP operations. Results will also inform HRSA program planning and future data collection efforts. Study findings will be reported only in aggregate or de-identified form and will not be used for compliance monitoring or funding decisions.

Likely Respondents: Respondents will consist of staff from state and territorial

ADAPs, including program administrators, eligibility and enrollment staff, pharmacy and benefits coordinators, financial and rebate management staff, data systems personnel, and other staff responsible for ADAP operations. HRSA will also invite ADAP staff to participate in virtual listening sessions focused on validating and contextualizing study findings.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Quantitative Survey	54	1	54	0.5	27
Qualitative Interview	54	1	54	1.5	81
Listening Sessions	177	1	177	1.5	265.5
Total	285		285		373.5

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS-OASH-2026-0496]

RIN 0910-ZD94

Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of availability.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) is announcing the availability of an "Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances." This document describes the Secretary of HHS's enforcement policy regarding the use of

certain peptide bulk drug substances in compounding pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking.

DATES: This announcement is published in the **Federal Register** as of October 30, 2026.

ADDRESSES: Written comments can be submitted until 2 weeks after date of publication in the **Federal Register** via [regulations.gov](https://www.regulations.gov) on Docket No. HHS-OASH-2026-0496

FOR FURTHER INFORMATION CONTACT: Victoria Marshall, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Washington, DC, 202-690-7694, OASH-RFI@hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of a draft “Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.” This document describes the HHS Secretary’s enforcement policy regarding the use of certain peptide bulk drug substances in compounding pursuant to section 503A of the FD&C Act while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking (21 U.S.C. 353a).

Compounding is generally 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. Compounded drugs are not FDA-approved, which means FDA does not review their safety, effectiveness, or quality before they are marketed. Although compounded drugs can serve an important medical need for certain patients, they also may pose risks to patients. However, based on the Pharmacy Compounding Advisory Committee meetings and data regarding utilization of peptides, HHS believes that there is significant interest in the use of these peptides in compounding given the lack of availability of approved products. Therefore, to expand and improve patient access, HHS does not intend to take enforcement action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a peptide bulk drug substance found in Appendix A. FDA’s future rulemakings may propose adding some or all of these peptides to the 503A bulks list based on the available evidence.

HHS may revisit application of this interim policy (in whole or in part) if, among other things, a safety signal or product quality issue arises with a compounded drug product within the scope of this policy. The draft Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances does not establish any rights for any person and is not binding on HHS or the public.

II. Paperwork Reduction Act of 1995

This policy contains no collection of information. Therefore, clearance by the Office of Management and Budget under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.hhs.gov/sites/default/files/hhs-503a-peptide-enforcement-discretion-policy-appendix-b.pdf>, or <https://www.regulations.gov>. Use the HHS website listed in the previous sentence to find the most current version of the policy.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–22192 Filed 10–28–26; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: National Advisory Board on Medical Rehabilitation Research
Date: December 6–7, 2027.

Time: December 06, 2027, 10:00 a.m. to 3:00 p.m.

Agenda: NICHD Director’s Report, NCMRR Director’s report; Election of a new Board Chair-Elect; Scientific Talk on Rehabilitation Research topic.

Address: Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20817.

Meeting Format: In Person and Virtual Meeting.

Time: December 07, 2027, 10:00 a.m. to 2:00 p.m.

Agenda: Update on NIH policy issues; Discussion of Research support and Training; Scientific Talk; Planning for Next NABMRR Meeting.

Address: Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health,

6710 B Rockledge Drive, Bethesda, MD 20817.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Joseph Bonner, Ph.D., National Center for Medical Rehabilitation Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20817, (301) 827–8303, joe.bonner@nih.gov.

Registration is not required to attend this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

Information is also available on the Institute’s/Center’s home page: <https://www.nichd.nih.gov/about/advisory/nabmrr>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)