

effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PENNSAID (diclofenac sodium) Topical Solution 2%, is the subject of NDA 204623, held by Horizon Therapeutics Ireland DAC, and initially approved on January 16, 2014. PENNSAID is a nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knees. PENNSAID (diclofenac sodium) Topical Solution 2%, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Encube Ethicals Private Limited submitted a citizen petition dated May 6, 2024 (Docket No. FDA-2024-P-2220), under 21 CFR 10.30, requesting that the Agency determine whether PENNSAID (diclofenac sodium) Topical Solution 2%, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PENNSAID (diclofenac sodium) Topical Solution 2%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PENNSAID (diclofenac sodium) Topical Solution 2%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PENNSAID (diclofenac sodium) Topical Solution 2%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PENNSAID (diclofenac sodium) Topical Solution 2%, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued

from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 15, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-18615 Filed 8-19-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Updates to the Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Request for public comment on updates to uniform standard for waiver of the Ryan White HIV/AIDS Program core medical services expenditure requirement.

**SUMMARY:** The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Service Act requires that RWHAP Parts A, B, and C recipients expend 75 percent of Parts A, B, and C grant funds on core medical services for individuals who are identified with HIV/AIDS and eligible for RWHAP services under the statute, after reserving statutorily permissible amounts for administrative and clinical quality management costs. The statute also grants the Secretary authority to waive this requirement if certain factors are met. HRSA is proposing to update Policy Notice 21-01, "Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement," pertaining to the associated data collection form to clarify applicants' proposed allocation of resources between core medical and support services.

**DATES:** Submit comments no later than September 19, 2024.

**ADDRESSES:** Written/and or electronic comments should be submitted to Division of Policy and Data, HRSA,

HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, or [RyanWhiteComments@hrsa.gov](mailto:RyanWhiteComments@hrsa.gov).

**FOR FURTHER INFORMATION CONTACT:** Kristina Barney, Senior Public Health Policy Analyst, Division of Policy and Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, email [RyanWhiteComments@hrsa.gov](mailto:RyanWhiteComments@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The RWHAP statute grants the Secretary authority to waive this requirement for RWHAP Parts A, B, or C recipients if certain factors are met and a waiver request is submitted to HRSA for approval. RWHAP Parts A, B, and C core medical services waiver requests, if approved, are effective for a 1-year budget period and apply to funds awarded under the Minority AIDS Initiative.

For a core medical services waiver request to be approved, core medical services must be available and accessible, regardless of the payment source, within 30 days to all RWHAP-eligible individuals identified in the recipient's service area. The recipient may use existing, non-RWHAP resources in the service area to ensure availability and access to core medical services. Additionally, there must be no AIDS Drug Assistance Program waiting lists in the recipient's service area. Finally, a public process must be used to obtain input from impacted communities on the availability of core medical services and the decision to request the waiver. Impacted communities include clients and RWHAP-funded core medical services providers. The same method used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes may be used to meet this requirement.

Policy Notice 21-01, "Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement," outlines the requirements and includes the one-page "HRSA RWHAP Core Medical Services Waiver Request Attestation Form" that must be submitted to request a waiver.

HRSA proposes to modify Policy Notice 21-01 to reflect a new policy requiring that the proposed percentages of HIV service dollars allocated to core medical and support services be included on the waiver request form. This information will inform HRSA as to whether recipients are able to meet the statutory requirements found in sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act and will

clarify what proposed portion of funds will be allocated to core medical and support services. In response to stakeholder feedback, minor changes will also be made to the policy notice. The current policy notice is accessible at the following link: <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/pn-21-01-core-medical-services-waivers.pdf> and the proposed revised policy notice is included in this announcement. This notice provides the opportunity for public comment before implementation. In a separate notice entitled, *Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0906-0065-Revision*, 89 FR 122, 53110-12 (June 25, 2024), HRSA seeks comment on the changes to the data collection form associated with this proposed policy notice change.

*Summary of Proposed Changes:* Sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act require recipients to spend not less than 75 percent of funds on core medical services after reserving statutorily permissible amounts for administrative and clinical quality management costs. HRSA intends to add a requirement to include the proposed percentages of HIV service dollars allocated to core medical and support services. This proposed change will be included as a requirement on the Ryan White HIV/AIDS Program Core Medical Services Waiver Form and will be used to clarify what portion of HIV service dollars will be allocated to core medical and support services. The section of this notice entitled "Requesting a Waiver" contains a description of the new information that must be included on the waiver request form. Language and editorial changes have been made throughout.

The proposed change is in addition to the underlying requirements necessary to obtain a waiver: ensuring that the

state AIDS Drug Assistance Program has no waiting lists, all core medical services are available and accessible within 30 days in the jurisdiction or service area, and that the recipient has used a public process to determine the need for a waiver. HRSA will consider public comment on these changes and intends for the policy to become effective on October 1, 2024.

#### **Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement**

*Policy Notice 21-01(Revised 10/01/24) Replaces Policy Notice 13-07*

##### **Scope of Coverage**

Health Resources and Services Administration (HRSA) HIV/AIDS Bureau Ryan White HIV/AIDS Program (RWHAP) Parts A, B, and C.

##### **Purpose of Policy Notice**

This Policy Notice provides the processes and requirements for RWHAP Parts A, B, and C recipients to request waivers of the statutory requirement regarding expenditure amounts for core medical services.

The revised policy notice describes a new requirement included on the RWHAP Core Medical Services Waiver Attestation Form. It also includes various editorial changes to respond to stakeholder feedback to make the form clearer. The revised policy is effective beginning on October 1, 2024.

##### **Background**

Recipients must spend at least 75 percent of grant funds on core medical services. See Title XXVI of the Public Health Service Act (the RWHAP legislation, Part A section 2604(c), Part B section 2612(b), and Part C section 2651(c)). Grant funds include Minority AIDS Initiative funding but exclude the amounts allowable by statute for

administrative and clinical quality management costs. The Secretary can waive this requirement for a recipient if: (1) there are no waiting lists for the AIDS Drug Assistance Program (ADAP), (2) core medical services are available and accessible to all HRSA RWHAP eligible individuals in the recipient's service area, and (3) a public process must be used to obtain input on the waiver request. Approved RWHAP Part A, Part B, and Part C core medical services waivers are effective for one budget period of a grant award, which is 1 year.

##### **Requirements**

A HRSA RWHAP Parts A, B, or C recipient must meet the following requirements:

(1) Core medical services must be available and accessible, regardless of the payment source, within 30 days to all HRSA RWHAP eligible individuals identified in the recipient's service area. The recipient may use existing non-RWHAP resources in the service area to ensure availability and access to core medical services.

(2) There must be no ADAP waiting lists in the recipient's service area.

(3) There must be a public process to obtain input on the waiver request. This public process must seek input from impacted communities on the availability of core medical services and the decision to request the waiver. Impacted communities include clients and RWHAP-funded core medical services providers. The same method to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes may be used.

### **Example of Applying the Requirement**

If an RWHAP-eligible individual needs outpatient ambulatory health services, which is a core medical service, an appointment to see a provider must be available within 30 days within the recipient's service area, regardless of how that service is funded. If all core medical services are not similarly accessible and available, or if there is an ADAP waiting list, you do not qualify for a waiver.

#### Requesting a Waiver

To request a waiver, the Chief Elected Official, Chief Executive Officer, or a designee of either must complete and submit the HRSA RWHAP Core Medical Services Waiver Request Attestation Form (attached below) to HRSA as specified by the deadlines and methods described below.

#### Update to the Waiver Request Form

The form must specify the percentages of HIV service dollars, including Minority AIDS Initiative funds, the recipient proposes to allocate to core medical and support services, if the waiver is approved. Signature indicates attestations for eligibility and the requirement of documentation upon request.

No other documentation is required to be submitted with the HRSA RWHAP Core Medical Services Waiver Request Attestation Form.

#### Submitting Waiver Requests

RWHAP Part A and RWHAP Part C waiver requests must be submitted as an

attachment with the grant application or the mandatory non-competing continuation (NCC) progress report. Waiver requests do not count towards grant application or NCC progress report page limits.

RWHAP Part B recipients may submit a waiver request prior to the submission of a grant application, with the grant application or NCC progress report as an attachment or up to 4 months after the start of the budget period for which the waiver is requested.

RWHAP Part B recipients may request a waiver for the RWHAP Part B States/Territories Formula and ADAP Formula and ADAP Supplemental Awards (X07) and/or the RWHAP Part B States/Territories Supplemental Grant Program (X08). Recipients must request each waiver separately.

#### Methods for Submitting Waiver Requests

Waiver requests submitted with grant applications must be submitted through [www.grants.gov](http://www.grants.gov). Waiver requests submitted with the mandatory NCC

progress report must be submitted through the Electronic Handbooks.

Part B recipients planning to request a waiver before or after the submission of a grant application or NCC progress report must notify their project officer who will send a Request for Information through the Electronic Handbooks.

#### Waiver Review and Notification Process

HRSA will review waiver requests and notify recipients of its approval or denial within 4 weeks of receipt of the request.

Approved core medical services waivers are only effective for one budget period. Approved waivers are not required to be implemented, should circumstances change. Recipients must submit a new request(s) each budget period.

**BILLING CODE 4165-15-P**

OMB Number: 0906-0065

## HRSA Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Request Attestation Form

*This form is to be completed by the Chief Elected Official, Chief Executive Officer, or a designee of either. Please initial to attest to meeting each requirement after reading and understanding the corresponding explanation. Include the proposed percentages of HIV service dollars allocated to core medical and support services in the Proposed Ratio for RWHAP Core Medical and Support Services section.*

Name of recipient \_\_\_\_\_

☐

RWHAP Part A recipient

☐

RWHAP Part B recipient

☐

RWHAP Part C recipient

☐

Initial request

☐

Renewal request

Year of request \_\_\_\_\_

REQUIREMENT	EXPLANATION
<b>No ADAP waiting lists</b>	By initialing here and signing this document, you attest there are no AIDS Drug Assistance Program (ADAP) waiting lists in the service area. <input type="checkbox"/>
<b>Availability of, and accessibility to core medical services to all eligible individuals</b>	By initialing here and signing this document, you attest to the availability of and access within 30 days to core medical services for all HRSA RWHAP eligible individuals in the service area. Such access is without regard to funding source, and without the need to spend at least 75 percent of funds remaining from your RWHAP award (after reserving statutory permissible amounts for administrative and clinical quality management costs). You also agree to provide HRSA HAB supportive evidence of meeting this requirement upon request. <input type="checkbox"/>
<b>Evidence of a public process</b>	By initialing here and signing this document, you attest to having had a public process during which input related to the availability of core medical services and the decision to request this waiver was sought from impacted communities, including clients and RWHAP funded core medical services providers. You also agree to provide supportive evidence of such process to HRSA HAB upon request. <input type="checkbox"/>
<b>PROPOSED RATIO FOR RWHAP CORE MEDICAL AND SUPPORT SERVICES</b>	
<b>RWHAP core medical services</b>	<b>RWHAP support services</b>
<b>%</b>	<b>%</b>

**SIGNATURE OF CHIEF ELECTED OFFICIAL OR CHIEF EXECUTIVE OFFICER (OR DESIGNEE)**\_\_\_\_\_  
PRINT NAME\_\_\_\_\_  
TITLE\_\_\_\_\_  
DATE

**Public Burden Statement:** HRSA uses the documentation submitted in core medical services waiver requests to determine if the applicant/grant recipient meets the statutory requirements for waiver eligibility including: (1) No waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) evidence of core medical services availability within the grant recipient's jurisdiction, state, or service area to all people with HIV identified and eligible under Title XXVI of the Public Health Services Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0906-0065 and it is valid until 08/31/2027. This information collection is required to obtain or retain a benefit (Ryan White HIV/AIDS Treatment Extension Act of 2009, Part A section 2604©, Part B section 2612(b), and Part C section 2651(c)). Data will be kept private to the extent required by law. Public reporting burden for this collection of information is estimated to average 0.49 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov). Please see <https://www.hrsa.gov/about/508-resources> for the HRSA digital accessibility statement.

### Expiration Date 08/31/2027

Carole Johnson,  
Administrator.

[FR Doc. 2024-18649 Filed 8-19-24; 8:45 am]

BILLING CODE 4165-15-C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD or Committee) will hold one additional public meeting in the 2024 calendar year. Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings>. This notice is consistent with information about ACTPCMD's 2024 meetings published in the **Federal Register** on May 15, 2024, titled "Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry." **DATES:** The ACTPCMD meeting will be held on:

- November 15, 2024, 10:00 a.m. to 5:00 p.m. Eastern Time.

**ADDRESSES:** This meeting will be held by teleconference and/or a video conference platform. For updates on how the meeting will be held, visit the ACTPCMD website 20 days before the date of the meeting, where instructions for joining the meeting will be posted. For meeting information updates, go to

the ACTPCMD website meeting page at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings>.

#### FOR FURTHER INFORMATION CONTACT:

Shane Rogers, Designated Federal Officer, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-5260; or [SRogers@hrsa.gov](mailto:SRogers@hrsa.gov).

#### SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under section 747 of title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary of Health and Human Services as well as the Chair and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. ACTPCMD also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under title VII, part C of the PHS Act, and recommends appropriation levels for programs under this Part.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For the November 15, 2024, meeting, agenda items may include, but are not limited to, discussion of recommendations for the Committee's 23rd report, as well as exploratory topic discussions for the Committee's 24th

report. Refer to the ACTPCMD website listed above for all current and updated information concerning the November ACTPCMD meeting, including the agenda and meeting materials that will be posted 20 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date.

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the November 15, 2024, meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024-18553 Filed 8-19-24; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Advisory Council.

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