

A. Priority Review Voucher Notification of Intent Requirement

All three priority review vouchers have a notification requirement. To comply with this requirement, the sponsor must notify FDA not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the estimated submission date. See sections 524(b)(4), 529(b)(4)(B)(i), and 565A(b)(3)(A) of the FD&C Act.

B. Priority Review Voucher User Fee Due Date

Under sections 524(c)(4)(A) (tropical disease priority review user fee), 529(c)(4)(A) (rare pediatric disease priority review user fee), and 565A(c)(4)(A) (material threat MCM priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.*, the obligation to pay the fee is incurred) upon submission of a human drug application for which the priority review voucher is used.⁸

V. Fee Payment Options and Procedures

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, “Pay Now” should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card

is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the invoice number to ensure that the payment is applied to the correct fee(s). Without the invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA’s tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

VI. Reference

The following reference is on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at <https://www.regulations.gov> as this reference is copyright protected. FDA has verified the website address as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, “Developing Drugs for Developing Countries,” *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006, available at: <https://www.healthaffairs.org/doi/full/10.1377>

hlthaff.25.2.313.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18464 Filed 9–9–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Notice of Supplemental Funding, Medicare Rural Hospital Flexibility Program**

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is providing additional fiscal year 2026 funding under the Medicare Rural Hospital Flexibility (Flex) Program using the program’s established funding methodology, including a baseline increase for all recipients and an additional adjustment for states with newly designated Critical Access Hospitals (CAHs). This funding will support state efforts to strengthen CAHs, improve quality and performance, and sustain access to essential rural health care services.

FOR FURTHER INFORMATION CONTACT:

Sheena Johnson, Deputy Division Director, Hospital State Division, Federal Office of Rural Health Policy, HRSA, at sjohnson@hrsa.gov and (872) 271–6370.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Award: 2 Flex Program Recipients.

Amount of Non-competitive awards: 2 awards totaling \$620,742.

Project Period: September 1, 2026, to August 31, 2027.

Assistance Listing Number: 93.241.

Award Instrument: Cooperative Agreements.

E3. Authority:

42 U.S.C. 1395i–4(g)(1)–(2) (https://www.ssa.gov/OP_Home/ssact/title18/1820.htm).

TABLE 1—RECIPIENTS WITH FUNDING INCREASES EXCEEDING 25 PERCENT

Grant number	Award recipient name	State	Award amount
U2WRH33293	Alabama Department of Public Health	AL	\$146,403

⁸ In the case of a “rolling review” application (as discussed in FDA’s May 2014 guidance entitled *Expedited Programs for Serious Conditions—Drugs and Biologics*, available at: [https://www.fda.gov/files/drugs/published/Expedited-Programs-for-](https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf)

Serious-Conditions-Drugs-and-Biologics.pdf) for which a tropical disease priority review voucher, rare pediatric disease priority review voucher, or material threat MCM priority review voucher is redeemed, FDA considers the application to be

submitted on the date FDA receives the final portion of the application that the applicant identifies as complete. Also see section 506(d) of the FD&C Act, relating to review of incomplete applications for approval of a fast track product.

TABLE 1—RECIPIENTS WITH FUNDING INCREASES EXCEEDING 25 PERCENT—Continued

Grant number	Award recipient name	State	Award amount
U2WRH33313	Texas Department of Agriculture	TX	474,339

Justification: HRSA received increased funding in the Consolidated Appropriations Act, 2026, (<https://www.govinfo.gov/content/pkg/PLAW-119publ75/pdf/PLAW-119publ75.pdf>), H.R. 7148, for the Medicare Rural Hospital Flexibility Program. The Flex Program supports states in strengthening CAHs, improving quality and performance, supporting financial and operational improvement activities, and sustaining access to essential rural health care services. For fiscal year 2026, HRSA will apply a 2.5 percent funding increase to all 45 Flex Program recipients and an additional increase of 5 percent for each newly designated CAH in a state. This approach provides all Flex recipients with a baseline increase while directing additional resources to states with expanded program responsibilities due to CAH growth.

As a result of this increase, the two recipients listed in Table 1 will receive additional funding due to the number of newly designated CAHs in their states. The additional funds will provide additional support to strengthen CAHs, improve quality and performance, support financial and operational improvement activities, and sustain access to essential health care services in rural communities.

Thomas J. Engels,
Administrator.

[FR Doc. 2026–18425 Filed 9–9–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Cancer Biomarker Development, Assay Validation, and Translational Technologies.

Date: October 13, 2026.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Hasan Siddiqui, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 451–0395, hasan.siddiqui@nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Drug and Biologic Therapeutic Delivery Study Section.

Date: October 13–14, 2026.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Janice Duy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3139, janice.duy@nih.gov.

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Interspecies Microbial Interactions and Infections Study Section.

Date: October 13–14, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irene Ramos Lopez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4891, irene.ramoslopez@nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: October 13–14, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer Chien Villa, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–5436, jennifer.villa@nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Basic Mechanisms of Cancer Health Disparities Study Section.

Date: October 13, 2026.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Wing-Hang Tong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (302) 402–0360, tongw@mail.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Immunology and Infection Study Section.

Date: October 14–15, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rupali Das, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0023, rupali.das@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Center Support Grant.

Date: October 14–15, 2026.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mukesh Kumar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 809 C, Bethesda, MD 20892, (301) 451–0359, mukesh.kumar3@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)