

limited; therefore, FDA may limit the number of in person participants from each organization. If you need special accommodation due to a disability, please contact GDUFAReauthorization@fda.hhs.gov no later than September 3, 2026.

Opportunity for Public Comment: If you wish to speak during the public comment session, complete the request form on <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032> and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by September 3, 2026, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. FDA we will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by September 10, 2026. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: When available, the virtual link to the hybrid public meeting will be posted on FDA's public web page at <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032>. FDA will also distribute the link via email to registered attendees.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-16353 Filed 8-10-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Health Center Program Scope of Project Policy Manual Guidance

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

ACTION: Notice.

SUMMARY: The Health Center Program Scope of Project Policy Manual (Scope Manual) is program guidance to assist health centers in understanding what constitutes the Health Center Program scope of project under section 330 of the Public Health Service (PHS) Act.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, contact HRSA through the HRSA Bureau of Primary Health Care Contact Form: <https://hrsa.my.site.com/support/s/> and select "Scope Manual General Inquiry" under "Health Center Program Policy and Information" or call Lauren Spears, Bureau of Primary Health Care, HRSA, at 301-594-4300.

SUPPLEMENTARY INFORMATION: This final Scope Manual update provides program guidance for all health centers that apply for and receive a federal award under the Health Center Program, as authorized by section 330 of the PHS Act, as well as section 330 subrecipient organizations, and health centers designated as Health Center Program look-alikes.

HRSA released a Notice of Availability for the draft Scope Manual (89 FR 97629) on December 9, 2024, for a 60-day public comment period. The Notice of Availability of Draft Health Center Program Scope Manual Guidance is available online at <https://www.federalregister.gov/documents/2024/12/09/2024-28748/notice-of-availability-of-draft-health-center-program-scope-policy-manual-guidance>. HRSA's "Summary of Comments and HRSA Responses" is also available online at: <https://bphc.hrsa.gov/sites/default/files/bphc/compliance/scopemanual-comments.pdf>. HRSA received a total of 2,767 comments from 135 organizations and individuals on the draft Scope Manual. After thorough review and consideration of all comments received, HRSA made a substantial number of updates to the Scope Manual to incorporate suggestions and requests for further clarification. The final Scope Manual takes effect upon release and is available online at: <https://bphc.hrsa.gov/sites/>

[default/files/bphc/compliance/scopemanual.pdf](https://bphc.hrsa.gov/sites/default/files/bphc/compliance/scopemanual.pdf).

HRSA provides grants to eligible applicants authorized under section 330 of the PHS Act (42 U.S.C. 254b), to support the delivery of preventive and primary care services to the nation's medically underserved individuals and families. HRSA also designates eligible entities as look-alikes under the Health Center Program under sections 1861(aa)(4)(B) and 1905(l)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B) and 42 U.S.C. 1396d(l)(2)(B)(iii)) respectively. Look-alikes do not receive Health Center Program funding but must meet the Health Center Program requirements. Health centers are local organizations that provide comprehensive, high-quality preventive and primary health care services tailored to their communities regardless of their ability to pay. HRSA's Health Center Program is a cornerstone of our country's health care system, especially for individuals and families who are uninsured; enrolled in Medicaid; or living in rural, remote, or medically underserved areas. Nearly 1,400 HRSA-funded health centers and more than 150 HRSA-designated look-alikes operate more than 16,200 service delivery sites that provide care to more than 33.9 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of this document, the term "health center" refers to entities that are authorized to receive a federal award under section 330 of the PHS Act, as well as subrecipients and organizations designated as look-alikes, unless otherwise stated.

Organizations receiving Health Center Program federal awards, including subrecipients, and organizations designated as Health Center Program look-alikes, continue to be subject to all requirements stated in Notices of Funding Opportunity, Notices of Award, Look-Alike Initial Designation and Redesignation Instructions, Notices of Look-Alike Designation, as well as other applicable laws, regulations, and policies. Organizations are also subject to the distinct statutory, regulatory, and program requirements of other federal programs in which they participate.

Margaret M. Bush,

Deputy Administrator.

[FR Doc. 2026-16348 Filed 8-10-26; 8:45 am]

BILLING CODE 4165-15-P