Medicare coverage upon FDA market authorization. Participation in the RAPID coverage pathway does not change the review standards for FDA market authorization of a device, which are separate and distinct from the standards governing a CMS NCD.

4. AHRQ

Currently, AHRQ reviews all CED NCDs established under section 1862(a)(1)(E) of the Act. Consistent with section 1142 of the Act, AHRQ collaborates with CMS to define standards for clinical research studies to address the CED questions and meet the general standards for CED studies (*https://www.cms.gov/medicare/coverage/evidence*). Since we anticipate that a subset of NCDs conducted under the RAPID coverage pathway could result in CED decisions, AHRQ will continue to review all CED NCDs consistent with current practice.

F. RAPID Coverage Pathway and Parallel Review

While the RAPID coverage pathway will be limited to Breakthrough Devices, other potential expedited coverage mechanisms, such as Parallel Review, remain available. Eligibility for the Parallel Review program is broader than for the RAPID pathway and could facilitate expedited CMS review of non-Breakthrough Devices. To achieve greater efficiency and to simplify the coverage process generally, CMS intends to work with FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

G. RAPID Coverage Pathway and TCET

The TCET pathway will be paused for new candidates upon publication of this notice with comment period as CMS focuses on the successful implementation of the RAPID coverage pathway. Upon the announcement of the RAPID coverage pathway on April 23, 2026, FDA and CMS began engaging with manufacturers of devices potentially eligible for the RAPID coverage pathway so these manufacturers can be positioned to benefit from the efficiencies that RAPID is intended to provide. For manufacturers who are past the point of initiating their IDE study and believe there is sufficient evidence to support national coverage of their device, we recommend that they contact CMS to discuss available coverage mechanisms, including a potential NCD request submission as outlined in 78 FR 48164. CMS will apply lessons learned across coverage pathways to strengthen and improve Medicare coverage processes over time.

H. RAPID Coverage Pathway Prioritization

Due to CMS' commitment to issue proposed NCDs for devices in the RAPID coverage pathway on the same day as FDA market authorization, CMS proposes to prioritize the opening of RAPID NCDs over non-RAPID NCDs from the NCD Wait List if we are unable to address the total volume of NCDs within our available resources at any given time.

When we consider opening or reconsidering non-RAPID NCDs, we will continue to apply the circumstances described in the August 2013 notice as we prioritize topics. The circumstances described in the August 2013 notice are relevant to how we prioritize internally generated and externally requested NCDs. We consider when, practitioners, patients, or other members of the public have raised significant questions about the health outcomes attributable to the use of the items or services for the Medicare beneficiary population; new evidence or reasonable reinterpretation of previously available evidence indicates that a national coverage review may be warranted; local coverage policies on a particular item or service may vary in language or implementation; the health technology represents a substantial clinical advance and is likely to result in a significant improvement in patient health outcomes or positive impact on the Medicare program; rapid diffusion of an item or service is anticipated, if the evidence may inadequately address questions regarding impact on the Medicare population, target subgroup populations, practitioner or facility qualifications, etc., or on beneficiary health outcomes; or any combination thereto.

Also, given that we currently have topics on the NCD Wait List, we reiterate from the August 2013 notice that ''[i]n the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.''

I. RAPID Coverage Pathway Transparency

We believe it is important to provide maximum transparency regarding the devices accepted into the RAPID coverage pathway. CMS proposes to make the identity of specific manufacturers and devices in the RAPID coverage pathway publicly available. Examples of where this information could be made publicly available include the respective device's listing on the CMS Approved IDE Studies web page and the NCD Dashboard.[24]

III. Collection of Information Requirements

This notice with comment period refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Applicable collections of information include: (1) Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies (OMB 0938–1250); (2) Medicare Program Revised Procedures for Making National Coverage Determinations (OMB 0938–0776); (3) Medicare Coverage of Items and Services for Coverage with Evidence Development (CMS–OMB 0938–1387); and (4) Q-Submissions and Early Payor Feedback Request Programs and Medical Device Development Tools (FDA–OMB 0910–0756).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 7, 2026.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–16368 Filed 8–7–26; 4:15 pm]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0873]

Reauthorization of the Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

[24] The NCD Dashboard can be found here: *https://www.cms.gov/files/document/ncddashboard.pdf.*

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a public meeting to discuss proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years (FYs) 2028 to 2032. GDUFA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to assess and collect fees to support human generic drug activities. The current legislative authority for GDUFA expires at the end of September 2027. At that time, new legislation will be required for FDA to continue to assess and collect generic drug user fees for future fiscal years. The FD&C Act directs FDA, following negotiations with the regulated industry and periodic consultations with other stakeholders, to present recommendations for reauthorization of the GDUFA program to the relevant Congressional committees, publish the recommendations in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The hybrid public meeting will be held on September 17, 2026, from 9:00 a.m. to 2:00 p.m. Either electronic or written comments on this public meeting must be submitted by October 17, 2026.

ADDRESSES: The public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern on October 17, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–0873 for ''Reauthorization of the Generic Drug User Fee Amendments; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Anastazjia Ray, Food and Drug Administration, *GDUFAReauthorization@fda.hhs.gov,* 301–796–0541.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a hybrid public meeting to discuss proposed recommendations for the reauthorization of GDUFA, which authorizes FDA to assess and collect user fees to support human generic drug activities, which are defined under the FD&C Act [1] to include the activities necessary for the review (also called ''assessment'') of generic human drug applications and Type II active pharmaceutical ingredient (API) drug master files (DMFs),[2] and for conducting

[1] See sec. 744A(9) (21 U.S.C. 379j–41(9)).

[2] Type II active pharmaceutical ingredient drug master file means a submission of information to the Secretary by a person that intends to authorize the FDA to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the

Continued

inspections related to generic drugs, and to engage in other related activities. The current authorization of the program (GDUFA III) expires at the end of September 2027. Without new legislation, FDA will no longer be able to assess and collect user fees to help fund human generic drug activities for future fiscal years.

Section 744C(f)(5) of the FD&C Act (21 U.S.C. 379j–43(f)(5)) requires that after FDA negotiates with the regulated industry,[3] we do the following:

(1) Present recommendations to the relevant Congressional committees, (2) publish such recommendations in the **Federal Register**, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) after consideration of such public views and comments, revise such recommendations as necessary.

This notice, the 30-day comment period, and the public meeting described in this notice will satisfy certain of these statutory requirements. After the public meeting, we will revise the recommendations as necessary and present the proposed recommendations to the appropriate Congressional committees.

The purpose of the public meeting announced in this **Federal Register** notice is to obtain the public's views on the proposed recommendations for the reauthorized program (GDUFA IV). The following information is provided to help potential meeting participants better understand the history and evolution of the GDUFA program and the proposed GDUFA IV recommendations.

II. What is GDUFA and what does it do?

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, which included GDUFA (Pub. L. 112–144, Title III), was signed into law by the President. The GDUFA program was reauthorized two times since then, most recently in the Generic Drug User Fee Amendments of 2022 (GDUFA III), which authorizes FDA to collect fees with respect to certain generic human drug applications, drug master files, and drug manufacturing facilities for fiscal years 2023 through 2027. GDUFA fees support the Agency's human generic drug activities and facilitate timely access to safe and effective generic drugs for the public. As described in the GDUFA III Commitment Letter, FDA committed to achieve certain performance goals and measurable generic drug program enhancements designed to maximize the efficiency and utility of each assessment cycle, with the intent to reduce the number of assessment cycles for abbreviated new drug applications, and to foster the development, assessment, and approval of complex generic products.

Additional information concerning GDUFA, including the text of the law, the GDUFA III Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa.*

III. Proposed GDUFA IV Recommendations

In preparing the proposed recommendations to Congress for GDUFA reauthorization for GDUFA IV, FDA conducted discussions with the regulated industry and consulted with patient and consumer advocacy groups, as required by the law, among other stakeholders. FDA began the GDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on the reauthorization and announcing a public meeting, which was held on July 11, 2025 (90 FR 21313, May 19, 2025). The meeting included presentations by FDA and different stakeholder groups, including patient and consumer advocacy groups, health professionals, and academic researchers. The materials from the meeting, including the agenda, presentations, and transcript can be found at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-07112025.*

Following the July 2025 public meeting, FDA conducted negotiations with the regulated industry and held monthly consultations with other stakeholders from October 2025 through March 2026. As directed by Congress, FDA posted minutes of these meetings on its website ''GDUFA IV: Fiscal Years 2028–2032'', available at *https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032.* The proposed enhancements for GDUFA IV address many of the top priorities identified by FDA, the regulated industry, and other stakeholders.

These include proposed program enhancements to stabilize fee revenue, advance approvals in fewer review cycles, improve program efficiency, enhance processes around complex data issues, and provide mechanisms to facilitate onshoring of generic drug manufacturing. The full descriptions of these proposed recommendations can be found in the proposed GDUFA IV Commitment Letter (Proposed Commitment Letter), which will be posted prior to the public meeting on FDA's website ''GDUFA IV: Fiscal Years 2028–2032, available at *https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032.*

Each significant new or modified enhancement is described briefly below with references to the relevant section of the Proposed Commitment Letter where more detailed information can be found.

A. Controlled Correspondence

FDA proposes that Abbreviated New Drug Application (ANDA) applicants will use a pre-assigned ANDA number or ANDA number when submitting controlled correspondences to allow linkages between ANDA applications and these communications. FDA also proposes a new 90-day timeline for controlled correspondences for specific topics. Details can be found in the Proposed Commitment Letter, section I.E.

B. ANDA Assessment Transparency and Communications Enhancements

FDA proposes updates to review timelines and other efficiency enhancements for some steps of the ANDA assessment process and increased communications throughout the process, including inclusion of a new goal date extension option for applicants to select at the time of application submission. FDA proposes a new 120-day goal extension for a Potential Official Action Indicated (pOAI) alert, in certain circumstances, to allow time for FDA to finalize the inspection classification and take appropriate action within the same review cycle. Details can be found in the Proposed Commitment Letter, section II.A and B.

FDA proposes a new post pre-approval inspection meeting, when needed, to discuss inspection findings that may impact application approval and corrective actions that may address issues identified. Details can be found in the Proposed Commitment Letter, Section II.B. and section VI.D.

Lastly, FDA proposes improved management of applications with complex data issues, to help ensure efficient use of review resources. FDA proposes that if FDA identifies a complex data issue which cannot be fully assessed and resolved for

generic drug submission applicant. Section 744A(13) of the FD&C Act (21 U.S.C. 379j–41(13)).

[3] Section 744C(f)(3) of the FD&C Act requires periodic consultation with representatives of patient and consumer advocacy groups during negotiations with the generic drug industry.

appropriate action by the goal date, FDA will assign a new goal date of 6 months after the original goal date. FDA proposes that if the new goal date is not met, FDA will contact the applicant and the relevant site or facility for which a complex data issue has been identified and offer an opportunity for a meeting with the agency. Details can be found in the Proposed Commitment Letter, sections II and IX. FDA proposes similar enhancements for original applications for which the goal date will be missed by more than 60 days due to a complex regulatory issue or other reason. For these applications FDA proposes assigning a new goal date of 6 months after the original goal date, and proposes that if the new goal date is not met, FDA will contact the applicant and offer an opportunity for a meeting with the agency. Details can be found in the Proposed Commitment Letter, section II.B.9.

C. Application-Related Meetings

FDA proposes a new more streamlined and efficient meeting structure for application-related meetings, specifies the types of questions to be addressed and outlines processes for each of the updated meeting types. These proposed enhancements will also support complex generic development by facilitating new or faster meeting opportunities for companies developing complex generics. Details can be found in the Proposed Commitment Letter, section III.C.

D. Additional Program Enhancements

FDA proposes continuing to update the Inactive Ingredient Database (IID) on an ongoing basis and posting quarterly notices of such updates made. Proposed new updates include adding inactive ingredients newly and accurately identified in labeling approved by FDA on or after October 1, 2027, or adding upon request ingredients accurately identified in labeling approved by FDA before October 1, 2027. FDA also proposes to continue the transition in the IID from providing maximum potency to maximum daily exposure (MDE) information. Details can be found in the Proposed Commitment Letter, section IV.A.

FDA proposes to establish a public Maximum Daily Dose (MDD) database populated with at least 500 MDD values for reference listed drugs (RLDs) by the end of FY 2028 and to continue to populate that database with MDD values. FDA also proposes seeking public input on the utility of the MDD database. Details can be found in the Proposed Commitment Letter, section IV.B.

FDA proposes providing or updating standard tables and format information for applicants to use when submitting certain data in ANDAs and providing external training on best practices. Once updated, industry would aspire to provide data in the updated formats. Details can be found in the Proposed Commitment Letter, section IV.C.

E. DMF Assessment Program

FDA proposes expanding the eligibility criteria for DMF prior assessments to include complex API and prior approval supplements seeking to add a new API source located in the U.S., and to expand eligibility for DMF prior assessment requests related to ANDAs submitted within a certain timeframe of the date all patents and exclusivities for the RLD will expire. FDA also proposes enhancing submission procedures for these DMF assessment requests to add a cover letter template signed by the ANDA applicant and Form FDA 3938. Details can be found in the Proposed Commitment Letter, section V.E.

F. Supporting Domestic Manufacturing

FDA is committed to encouraging domestic manufacturing to reduce supply chain risk. FDA proposes statutory changes to increase the foreign fee differential from $15,000 to $25,000 starting in FY 2028 for all foreign Active Pharmaceutical Ingredient (API), Finished Dosage Form (FDF) and Contract Manufacturing Organization (CMO) facilities. FDA also proposes statutory amendments for a one-time application fee waiver for an original ANDA submission fee if a domestic applicant satisfies the proposed requirements of having the application identify only facilities located in the U.S. as both the FDF manufacturer(s) and the API supplier(s). In addition to these statutory changes, FDA proposes an opportunity for existing U.S. generic API and FDF facilities without recent inspection history the opportunity to request an inspection in advance of a planned DMF or ANDA submission that will include the facility. Details can be found in the Proposed Commitment Letter, section VI.E.

G. User Fee Resource Management

FDA is committed to ensuring the sustainability of GDUFA program resources and to enhancing the operational agility of the generic drugs program. FDA will continue activities to promote transparency of the use of GDUFA financial resources in support of the generic drugs program through publication of a GDUFA 5-year financial plan (along with annual updates). FDA proposes to update the topics included in the financial plan, as well as in the annual GDUFA Financial Report submitted to Congress. FDA will also offer one technical staff meeting per year with industry focused on program finances, and FDA will publish minutes from these meetings on its public website. FDA also proposes to make cover sheets for annual fees available on August 15th or the following business day of each year and to add language to the GDUFA website explaining payment timelines. Details can be found in the Proposed Commitment Letter, section VII.C.

In addition, FDA proposes to amend the statute to modify the date used to establish liability for annual fees for the upcoming fiscal year, to improve predictability. FDA also proposes statutory language for GDUFA IV to change the percentage of total fee revenues to be derived from ANDA submission fees to 26% (from 33%) and shift allocation of the difference to the percentage derived from program fees. FDA also proposes allocating a portion of fees for restaffing the generic drugs program.

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The meeting will include presentations by FDA and a series of panels with FDA and regulated industry representatives to present and discuss the agreed-upon proposed enhancements. The meeting will also include verbal comments on the proposed enhancements from other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, and the general public. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032.*

B. Participating in the Public Meeting

Registration: Information about how to register for the public meeting is available on FDA's web page for this public meeting: *https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032.* Registration is free for both in person and virtual attendance. In person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is

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.*

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.

Margeret M. Bush,

Deputy Administrator.

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

BILLING CODE 4165–15–P