fee amount of $10,000 (rounded to the nearest dollar). The reactivation fee is set at twice the initial/annual BPD amount at $20,000 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2027

The fee rates for FY 2027 are displayed in table 7.

TABLE 7—FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Initial BPD	$10,000
Annual BPD	10,000
Reactivation	20,000
Applications:	
Requiring Clinical Data	1,124,936
Not Requiring Clinical Data	562,468
Program Fee	195,887

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2027, *i.e.,* the period from October 1, 2026, through September 30, 2027. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in the BPD program for the product must pay all annual BPD fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

Initial BPD, reactivation, or application fee 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 or after completing the User Fee Cover Sheet and generating the user fee ID number.

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 or cover sheet 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 unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID 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, Acct. 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 section 744H(g) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2027 annual BPD and program fees under the new fee schedule in August 2026. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees will be due on October 1, 2026.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2026, FDA will issue invoices in December 2026 to sponsors subject to fees for FY 2027 that qualify for the annual BPD fee after the August 2026 billing. FDA will issue invoices in December 2027 for any products that qualify for the annual program fee after the August 2026 billing.

C. Waivers and Returns

To qualify for consideration for a small business waiver under section 744H(d) of the FD&C Act, or the return of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than 180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15346 Filed 7–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Health Center Program Forms—OMB No. 0915–0285—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 28, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Forms, OMB No. 0915–0285—Revision.

Abstract: The Health Center Program, administered by HRSA, is authorized under Section 330 of the Public Health Service Act (42 U.S.C. 254b). Health centers are patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients and adjust fees based on income and family size. Nearly 1,400 health centers operate more than 16,000 service delivery sites that provide primary health care to more than 32 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses forms for health centers to report progress and change their scope of project.

Need and Proposed Use of the Information: The information HRSA collects from health centers via the Health Center Program-specific forms is necessary for the agency's oversight of Health Center Program awards. HRSA uses the information for program monitoring and for evaluating award recipients' compliance with Health Center Program statutory and regulatory requirements. These forms were approved by OMB on May 31, 2026, following 60- and 30-day public comment periods. Eight forms that were previously approved are being updated and three forms are being added to facilitate monitoring, improve scope of project documentation and oversight, increase the efficiency of the change in scope process, and enhance the accuracy of change in scope requests.

HRSA will modify the following forms to update and clarify data currently being collected:

Forms proposed to be modified: number/name	Description of modifications
Form 5A: Services Provided	Update labels and categories of services.
Form 5B: Sites	Modify fields collecting site information.
Checklist for Form 5A Scope Adjustments	Revise checklist statements and questions.
Checklist for Form 5B Scope Adjustments	Revise checklist statements and questions.
Checklist for Deleting a Service Site from Scope *Previously: Checklist for Deleting* Existing Service Delivery Site.	Revise checklist statements and questions.
Checklist for Adding a Service Site to Scope *Previously: Checklist for Adding a New Service Delivery Site.*	Revise checklist statements and questions.
Checklist for Adding a Service to Scope *Previously Checklist for adding a new service.*	Revise checklist statements and questions.
Checklist for Deleting a Service from Scope *Previously: Checklist for deleting existing service.*	Revise checklist statements and questions.

HRSA will add the following forms necessary for data collection and change in scope requests to simplify the process:

- Checklist for Replacing a Service Site in Scope
- Quality Improvement Fund (QIF) Final Report
- Loan Guarantee Progress Report

Likely Respondents: Health Center Program award recipients (those funded under section 330 of the Public Health Service Act) and Health Center Program look-alikes.

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.

These updates will reduce the estimated annual burden by 1,483.50 hours compared with the burden approved in the ICR on May 31, 2026. This is due to the modification of existing forms that is expected to reduce burden. In the burden table below, new forms are indicated through bold text, and revised forms are indicated through italicized text. All other forms are unchanged.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Form 5A: Services Provided	1,400	1	1,400	0.25	350.00
Form 5B: Sites	1,400	1	1,400	0.25	350.00
Checklist for Form 5A Scope Adjustments	1,000	1	1,000	1.00	1,000.00
Checklist for Form 5B Scope Adjustments	2,000	1	2,000	1.00	2,000.00
Checklist for Deleting a Service Site from Scope. Previously: Checklist for Deleting Existing Service Delivery Site	500	1	500	1.00	500.00
Checklist for Adding a Service Site to Scope. Previously: Checklist for Adding a New Service Delivery Site	1,250	1	1,250	1.50	1,875.00
Checklist for Adding a Service to Scope. Previously: Checklist for adding a new service	450	1	450	1.00	450.00
Checklist for Deleting a Service from Scope. Previously: Checklist for deleting existing service	500	1	500	1.00	500.00
Checklist for Replacing a Service Site in Scope	250	1	250	0.75	187.50

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
QIF Final Report	25	1	25	3.00	75.00
Loan Guarantee Progress Report	22	4	88	1.00	88.00
Capital Semi-Annual Progress Report	500	2	1,000	1.00	1,000.00
Equipment List	130	1	130	0.50	65.00
Federal Object Class Categories Form	500	1	500	0.25	125.00
Loan Guarantee Program Financial Performance Indicators	5	1	5	1.00	5.00
Form 1A: General Information Worksheet	1,370	1	1,370	0.75	1,027.50
Form 1B: Funding Request Summary	900	1	900	0.75	675.00
Form 1C: Documents on File	1,460	1	1,460	0.50	730.00
Form 2: Staffing Profile	1,370	1	1,370	1.00	1,370.00
Form 3: Income Analysis	1,370	1	1,370	1.00	1,370.00
Form 5C: Other Activities/Locations	550	1	550	0.25	137.50
Form 6A: Current Board Member Characteristics	1,370	1	1,370	1.00	1,370.00
Form 6B: Request for Waiver of Board Member Requirements	1,370	1	1,370	1.00	1,370.00
Form 8: Health Center Agreements	1,370	1	1,370	1.00	1,370.00
Form 12: Organization Contacts	970	1	970	0.50	485.00
Funding Sources	130	1	130	0.50	65.00
FY 2022 Accelerating Cancer Screening Progress Report	29	1	29	1.50	43.50
Grant Number Form	400	1	400	0.25	100.00
HCCN Progress Report	50	1	50	0.50	25.00
Health Center Program Progress Report	130	1	130	1.00	130.00
HRSA Loan Guarantee Program Application	5	1	5	1.00	5.00
Impact Form	400	1	400	1.00	400.00
NHHCIA NCC Clinical Performance Measures	5	1	5	1.50	7.50
NHHCIA NCC Financial Performance Measures	5	1	5	0.50	2.50
NHHCIA NCC Income Analysis Form	5	1	5	0.15	0.75
NHHCIA Sample Project Work Plan	2	1	2	0.15	0.30
NH–NCC Project Work Plan Update	5	1	5	1.00	5.00
Operational Plan	350	1	350	2.00	700.00
Other Requirements for Sites	130	1	130	0.50	65.00
Participating Health Centers List	90	1	90	1.00	90.00
Project Cover Page	130	1	130	1.00	130.00
Project Narrative Update	1,325	1	1,325	4.00	5,300.00
Project Overview Form	500	1	500	1.00	500.00
Project Qualification Criteria	130	1	130	0.50	65.00
Project Work Plan	508	1	508	4.00	2,032.00
Proposal Cover Page	130	1	130	1.00	130.00
QIF Evaluative Measures Report	25	2	50	1.50	75.00
QIF Progress Report	25	12	300	1.50	450.00
QIF TJI Evaluative Measures Report	54	10	540	1.50	810.00
QIF TJI Progress Report	54	10	540	1.50	810.00
QIF Project Plan Form	100	1	100	1.00	100.00
Summary Page (New Access Point)	500	1	500	1.00	500.00
Summary Page (Service Area Competition)	360	1	360	0.50	180.00
LAL Cover page	110	1	110	0.50	55.00
Checklist for Adding a Transitional Care in a Carceral Setting Site to Scope	50	1	50	1.00	50.00
Totals	27,769.00	.....	29,607.00	.....	31,302.05

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.

[FR Doc. 2026–15419 Filed 7–29–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Interagency Autism Coordinating Committee, July 31, 2026, 09:00 a.m. to 05:00 p.m. ET., National Institutes of Mental Health (NIMH), Neuroscience Center (NSC), 6001 Executive Boulevard, Rockville, MD 20852 which was published in the