

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR part FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.41(a) ³ Identification of initial importers defined in 21 CFR 807.3(g) by foreign establishments (FDA 3673)	2,955	1	2,955	0.5	1,478
807.41(b) ³ Identification of other importers (defined in 21 CFR 807.3(x) and (y) that facilitate import by foreign establishments (FDA 3673)	3,234	1	3,234	0.5	1,617
Total	56,546

¹ Totals are rounded to the nearest whole number.

² One Time Burden—Firm only provides initially.

³ Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d) ² List of Officers, Directors & Partners	22,338	1	22,338	.25	5,585
807.26 ² Labeling & Advertisements Available for Review	17,032	4	68,128	.5	34,064
Total	39,649

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Recurring burden—Firm is required to keep records.

Our estimated burden for the information collection reflects an overall decrease of 17,637 hours and a corresponding decrease of 34,526 responses. Burden estimates are based on recent registration and listing information collected from establishments registering for the first time (initial registration) and establishments re-registering. We attribute this adjustment to a decrease in the number of submissions we received over the last approval period.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16630 Filed 8-28-25; 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: Ryan White HIV/AIDS Program (RWHAP) Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906-0047—Extension

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 October 28, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 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: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906-0047—Extension.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states and territories, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people diagnosed with HIV. Nearly two-thirds of RWHAP clients (patients) live at or below 100 percent of the federal poverty level (FPL). Since 1990, RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people with diagnosed HIV—more than 50 percent of all people with diagnosed HIV in the United States.

Grant recipients funded under RWHAP Parts A, B, C, and D (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of each grant budget period (Expenditures Report) using the designated HRSA grant submission software which is approved by OMB under the 0915-0318 control number. HRSA collects unobligated balances (UOB) of federal funds and rebate addendum information by subprogram from their grant recipients. A UOB is the cumulative amount that is available for obligation in an unexpired account. HRSA uses the UOB and rebate addendum financial information to determine formula funding as directed by the RWHAP

statute. HRSA is not planning to make changes to this information collection as part of this extension request.

Federal award expenditure data were previously collected when grant recipients submitted their annual Federal Financial Report (FFR SF-425), which HRSA then combined with the UOB and rebate addendum tables submitted by recipients using the designated HRSA grant submission software. HRSA created the currently approved instrument, which has been in use for several years now, to streamline the process for grant recipients by collecting financial information in the same location and at the same time as

the FFR SF-425. Whereas grant recipients previously completed the FFR SF-425 in the HRSA EHBs, they now complete it in the Payment Management System. Additionally, grant recipients complete the UOB and rebate addendum data tables as part of their FFR SF-425 submission in the Payment Management System.

Need and Proposed Use of the Information: Before implementing the current process described above, RWHAP Part A and Part B recipients completed the UOB and rebate addendum tables in a non-electronic form and uploaded them as attachments to their FFR SF-425 submission.

Renewal of the current process will continue to increase transparency and improve the quality of data submitted to HRSA. These UOB and rebate addendum tables are essential for allowing HRSA to ensure that RWHAP recipients are meeting the goal of accountability to Congress, clients, advocacy groups, and the general public. Information provided in the UOB and rebate addendum tables is critical for HRSA, cities, states and territories, local clinics, and individual providers to evaluate the effectiveness of these programs.

CURRENTLY APPROVED RWHAP PART A TABLE

Unobligated balance (UOB) of federal funds by subprogram				
Category	Federal funds authorized	Unexpended carryover	Prior year (FY20XX)	Current year (FY 20XX)
<i>Part A Formula.</i>				
<i>Part A Supplemental.</i>				
<i>Part A MAI.</i>				

CURRENTLY APPROVED RWHAP PART B TABLE

Unobligated balance (UOB) of federal funds by subprogram				
Category	Federal funds authorized	Unexpended carryover	Prior year (FY20XX)	Current year (FY 20XX)
<i>Part B Base.</i>				
<i>Part B ADAP.</i>				
<i>Part B Emerging Communities.</i>				
<i>Part B MAI.</i>				
<i>Part B ADAP Supplemental.</i>				
<i>Part A Transfer.</i>				

CURRENTLY APPROVED RWHAP PART B REBATE TABLE

Ryan White rebate funding				
Total Rebates Available				
Expended Rebate Amount				
Unexpended Rebate				
Expended Rebate Amount to be Used to Reduce UOB				

Likely Respondents: HRSA RWHAP Parts A and B Grant Recipients.

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 last total annual burden hours estimated are summarized in the table below.

TOTAL OF PREVIOUSLY ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Part A UOB Table	52	1	52	0.5	26.0
Part B UOB Table	59	1	59	0.5	29.5
Total	111	111	55.5

Note: This is the previously estimated annualized burden hours. A current assessment of recipient burden hours is under way. The newly captured estimates will be included in the 30-day FRN.

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. 2025-16667 Filed 8-28-25; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding; Autism Longitudinal Data Project and Linking the Boston Birth Cohort and Pregnancy to Health Databases: A Longitudinal Cohort of Mother-Child Dyads

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is announcing supplemental award funds through the Patient-Centered Outcomes Research Trust Fund to the current HRSA award recipient to build further data capacity under the Autism Longitudinal Data Project. The funding will support this multi-agency data linkage project

linking existing datasets to create a comprehensive longitudinal dataset. Supplemental funding was previously awarded in fiscal year 2024 for the initial phase of the project, which started in July 2024, and this award will continue that work.

FOR FURTHER INFORMATION CONTACT:

Evva Assing-Murray, Senior Health Scientist, Division of Research, Office of Epidemiology and Research, Maternal and Child Health Bureau, HRSA, at *EAAssing-Murray@hrsa.gov* or 301-594-4113.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Johns Hopkins University.

Amount of Non-Competitive Award: One award for \$533,887.

Project Period: September 1, 2022, to August 31, 2027.

Assistance Listing Number: 93.877.

Award Instrument: Non-competitive single-source supplement.

Authority: 26 U.S.C. 9511(d)(2)(C).

TABLE 1—RECIPIENT(S) AND AWARD AMOUNT(S)

Grant No.	Award recipient name	City, state	Award amount
UT7MC45949 ...	Johns Hopkins University	Baltimore, MD	\$533,887

Justification: There is a lack of longitudinal data from birth cohorts in the United States to assess maternal and infant health and inter-generational health from a life course perspective. Through this supplement, the data linkage will generate a rich dataset with a broad array of data on biological, socio-economic, home and neighborhood environment, behavioral risk and protective factors, health services, and expenses across the developmental and life stages. Johns Hopkins University is uniquely qualified to conduct this work because it has:

- A long-standing record of successfully completing government-funded projects. Johns Hopkins University is currently in the 4th year of its second 5-year award from HRSA and has consistently met its goals and objectives.

- Led and managed the Boston Birth Cohort since its inception in 1998. As such, Johns Hopkins University is experienced in the:
 - Complexities of data sharing across institutions, and
 - Technical aspects of linking data.
 - Access to these restricted datasets. The Boston Birth Cohort is a restricted use data resource that contains personally identifiable, confidential data, the disclosure of which is protected by law. Johns Hopkins University and its clinical site, Boston Medical Center, maintain these data and are the only entities that currently have access to the datasets required for this activity.

This data linkage project will run from July 2024 to July 2027. This is a continuation of an ongoing activity that was funded in fiscal year 2024 to the same intended recipient. The Patient-

Centered Outcomes Research Trust Fund, administered by the Office of the Assistant Secretary for Planning and Evaluation, funds this supplement.

Thomas J. Engels,

Administrator.

[FR Doc. 2025-16649 Filed 8-28-25; 8:45 am]

BILLING CODE 4165-15-P