

respondent to prepare and submit a plan for packaging and advertising for a total of 2,550 hours. We estimate that about half of respondents will submit a supplement each year. FDA estimates it will take respondents half the time per response to prepare and submit a supplement to an approved plan. We estimate receiving 8 supplements per year at 75 hours per response for a total of 600 hours. FDA estimates that the total annual hours for submitting initial plans and supplements will be 3,150.

Based on a review of the information collection since our last request for OMB approval, our reporting burden estimate has reduced from 11,100 to 3,150 hours annually.

Section 1141.10(g)(4) establishes that each tobacco product manufacturer required to randomly and equally display and distribute warnings on cigarette packages or quarterly rotate warnings in cigarette advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and 21

CFR part 1141 must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection requires that the FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

21 CFR part 1141 and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Original Submission (Initial Plan) Records	51	1.5	77	3	231
Total					231

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

² Numbers are rounded to the nearest whole number.

FDA estimates that 51 recordkeepers will keep a total of about 76.5 (rounded to 77) records at 3 hours per record for a total of 231 hours. As stated previously, these estimates are based on FDA’s experience with information collections for other tobacco product plans (*i.e.*, smokeless and cigars, consolidated under OMB control number 0910–0671). Based on our estimates for the submission of one-time, initial plans and supplements (*i.e.*, that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a “collection of information” under the PRA (44 U.S.C. 3501–3520). Rather, these labeling statements are a “public disclosure” of information originally supplied by the federal government to the recipient for the purpose of “disclosure to the public” (5 CFR 1320.3(c)(2)).

FDA estimates that the total burden for this information collection is 3,981 hours annually (3,150 hours for reporting + 231 hours for recordkeeping). We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated reporting burden for the information collection reflects an overall decrease of 76 annual respondents and a corresponding decrease of 7,386 annual hours. We

attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23474 Filed 12–18–25; 8:45 am]

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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: Allocations Report Forms, OMB No. 0915–0318—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 February 17, 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: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program: Allocations Reports, OMB No. 0915–0318—Revision.

Abstract: HRSA administers the Ryan White HIV/AIDS Program (RWHAP) authorized under Title XXVI of the Public Health Service Act. The RWHAP Allocations Reports allow HRSA to monitor and track the use of grant funds for compliance with statutory, program and grants requirements. To avoid duplication and reduce recipient reporting burden, HRSA created an electronic grantee contract management system (GCMS) that includes data required for the Allocations Reports. Recipients can access GCMS year-round to upload or manually enter data on their service provider contractors or subrecipients, the RWHAP core medical and support services provided, and their funding amounts. Data required for Allocations Reports are automatically prepopulated from GCMS.

Background Regarding Allocations and Expenditures Reports: Recipients funded under RWHAP Parts A, B, C, and D are required to report financial data to HRSA at the beginning (Allocations Report) and at the end (Expenditures Report) of their grant budget period. The Allocations Reports request information recipients already collect, including the use of RWHAP grant funds for core medical and support services; and on various program components, such as administration, planning and evaluation, and clinical quality management. Additionally, RWHAP Parts A and B recipients funded under the Ending the HIV Epidemic in the U.S. (EHE) initiative are also required to report allocations of the grant budget period in the EHE Allocations and Expenditure Reports. This allows HRSA

to track and report progress toward meeting the EHE goals.
For this submission, HRSA proposes to extend the following report forms in their current status:

- *RWHAP Part A Allocations Report*
- *RWHAP Part B Allocations Report*
- *RWHAP Part B Supplemental Allocations Report*
- *RWHAP Part C Allocations Report*
- *RWHAP Part D Allocations Report*
- *Ending the HIV Epidemic (EHE) Initiative Allocations Report*

Need and Proposed Use of the Information: Accurate allocation records of recipients receiving RWHAP and EHE funding are necessary for HRSA to fulfill its monitoring and oversight responsibilities.

Likely Respondents: RWHAP Part A, Part B, Part C, and Part D 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 use 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. HRSA expects a small decline of 268 burden hours compared to the currently approved collection, due to RWHAP recipients' familiarity with the updated reporting requirements introduced in the currently approved collection.

TOTAL 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 Allocations Report	52	1	52	2	104
Part B Allocations Report	54	1	54	6	324
Part B Supplemental Allocations Report	33	1	33	2	66
Part C Allocations Report	346	1	346	3	1,038
Part D Allocations Report	116	1	116	5	580
EHE Allocations Report	47	1	47	4	188
Total	648	2,300

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. 2025-23432 Filed 12-18-25; 8:45 am]
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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; Topics in Drug Development, Resistance, and Therapeutics.

Date: February 3, 2026.

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

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities,

Room 3F40A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5035, robert.unfer@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)

Dated: December 16, 2025.

Rosalind M. Niamke,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-23324 Filed 12-18-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as