Based on updated data, we have revised our estimate for sections 905(b), 905(c), 905(d), 905(h), or 905(i) of the FD&C Act. ''Tobacco Product Establishment Initial Registration and Listing''; Form FDA 3741: ''Registration and Product Listing for Owners and Operators of Domestic Establishments''; Form FDA 3741a: ''Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments'' (Electronic and Paper submissions) reflects a reduction from 200 to 75 respondents and ''Tobacco Product Establishment Renewal Registration and Listing''; Form FDA 3741: ''Registration and Product Listing for Owners and Operators of Domestic Establishments''; Form FDA 3741a: ''Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments'' (Electronic and Paper submissions) reflects a reduction from 2,572 to 1,003 respondents.

Under sections 905(b), 905(c), 905(d), 905(h), or 905(i) of the FD&C Act, FDA estimates up to 75 new establishments will submit one initial establishment registration and product listing report each year. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. The Agency estimates that up to 75 tobacco establishments will each submit 1 initial establishment registration and product listing report each year using the new Form FDA 3741, ''Registration and Product Listing of Tobacco Product Manufacturing Establishments'', which is expected to take 1.5 hours, for a total 113 burden hours.

FDA estimates up to 75 establishments will submit one initial listing of tobacco products report each year. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. The Agency estimates that up to 75 tobacco establishments will each submit 1 initial product list and material file information spreadsheet each year using the new Form FDA 3741b, which is expected to take 2 hours, for a total 150 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 20 minutes annually per confirmation or update per establishment. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 1,003 establishments will each submit one confirmation or updated report each year, using the new Form FDA 3741, which is expected to take 0.33 hour (20 minutes) for a total 331 burden hours.

FDA estimates that the confirmation or updating of listing of tobacco products will take 30 minutes annually per confirmation or update per establishment. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 1,003 establishments will each submit one confirmation or updated report each year, using the new Form FDA 3741b, which is expected to take 0.5 hour (30 minutes) for a total 502 burden hours.

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Ingredients may be submitted electronically through the CTP portal or if unable to submit ingredients electronically then by mail using Form FDA 3742. FDA estimates that 16 establishments will initially submit one report annually at 2 hours per report, for a total of 32 hours.

Based on FDA's experience and the number of new products authorized to be introduced or delivered for introduction into interstate commerce submitted over the past 3 years, FDA estimates that 37 establishments will each submit 10 reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) for a total 148 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

Our estimated burden for the information collection reflects an overall increase of 655 hours and a decrease of 616 responses. We attribute this adjustment to the proposed revisions to this information collection to add the updated and comprehensive Form FDA 3741, ''Registration and Product Listing of Tobacco Product Manufacturing Establishments'' and add Form FDA 3741b, ''Product List and Material File Information Spreadsheet''.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01217 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal and Child Health Jurisdictional Survey Instrument for the Title V MCH Block Grant Program

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than February 18, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at

paperwork@hrsa.gov or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal and Child Health Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906–0042—Revision.

Abstract: The purpose of the Title V Maternal and Child Health (MCH) Services Block Grant is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating Federal/State partnerships that provide each State/jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring State flexibility. Using a three-tiered national performance measure framework, which includes National Outcome Measures, National Performance Measures, and Evidence-Based and -Informed Strategy Measures, State MCH Block Grant programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the State and Federal program offices to assess the progress achieved in key MCH priority areas and to document MCH Block Grant program accomplishments.

By legislation (section 505(a) and 506(a) of title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH health agency. In establishing State reporting requirements, HRSA considers the availability of national data from Federal agencies. Data for the National Performance and Outcome Measures are pre-populated for States in the Title V Information System. Such national data sources often do not include data from the title V jurisdiction grantees, with the exception of the District of Columbia. As a result, the eight remaining jurisdictions (*i.e.,* American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, Puerto Rico, the Republic of the Marshall Islands, the Federated States of Micronesia, and U.S. Virgin Islands) have limited access to significant data and MCH indicators, with limited resources for collecting these data.

Sponsored by HRSA, the MCH Jurisdictional Survey is designed to produce data on the physical and emotional health of mothers and children under 18 years of age in the following eight jurisdictions: American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, Puerto Rico, the Republic of the Marshall Islands, the Federated States of Micronesia, and U.S. Virgin Islands. More specifically, the MCH Jurisdictional Survey collects information on factors related to the well-being of children, including health status, visits to health care providers, health care costs, and health insurance coverage. In addition, the MCH Jurisdictional Survey collects information on factors related to the well-being of mothers, including health risk behaviors, health conditions, and preventive health practices. Collecting these data will enable the jurisdictions to meet Federal performance reporting requirements and demonstrate the impact of MCH Block Grant funding on MCH outcomes.

The MCH Jurisdictional Survey was designed based on information-gathering activities with title V leadership and program staff in the jurisdictions, Federal experts, and organizations with relevant data collection experience. Survey items are based on the National Survey of Children's Health, the Behavioral Risk Factor Surveillance System, the Youth Behavior Surveillance System, and selected other Federal studies. The Survey is designed as a core questionnaire to be administered across all jurisdictions with a supplemental set of survey questions customized to the needs of each jurisdiction.

The MCH Jurisdictional Survey has been conducted annually since 2019, with several modifications to address emerging issues and challenges related to survey questions and methods. The 2022 extension (ICR 202203–0906–002) enhanced the detail in collecting demographic data through race and ethnicity survey questions in response to jurisdictional feedback. Since the 2022 extension, two non-substantive change requests (ICRs: 202211–0906–001, and 202404–0906–002) allowed for adjustments, such as refining hurricane-related questions, to make them more general and increasing sample sizes.

A 60-day notice published in the **Federal Register** on October 31, 2024, 89 FR 86822 and 86823. There were no public comments.

Need and Proposed Use of the Information: There is an ongoing need for future data collections, as data from the MCH Jurisdictional Survey is used to measure progress on national performance and outcome measures under the Title V MCH Services Block Grant Program. This survey instrument is critical to collect information on factors related to the well-being of all mothers, children, and their families in the jurisdiction MCH Block Grant programs, which address their unique MCH needs.

This revision enables continued data collection for Federal reporting and to show the impact of MCH Block Grant funding on jurisdiction MCH priorities. The current request proposes further updates to survey questions to align with new Federal data standards, including updated guidance from OMB on collecting information on race and ethnicity.[1] Updates also reflect program oversight and administration needs.

To continue improving the precision of the data in all jurisdictions, HRSA also seeks to increase the sample size. Given the varying populations of children in each jurisdiction, the increased sample size varies for each jurisdiction. While the target number of interviews for each jurisdiction may be limited by funding, the maximum number of completed interviews possible for each jurisdiction is as follows: American Samoa, 450; Guam, 450; Commonwealth of the Northern Mariana Islands, 500; Republic of Palau, 250; Puerto Rico, 1,250; Republic of the Marshall Islands, 300; Federated States of Micronesia, 450; and U.S. Virgin Islands, 350.

Likely Respondents: The respondent universe is women age 18 or older who live in one of the eight targeted jurisdictions and who are mothers or guardians of at least one child aged 0–17 years living in the same household.

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

[1] Office of Management and Budget, ''Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity,'' **Federal Register**, 89 FR 22182 through 22190 (March 29, 2024), *https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and/.*

hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Burden hours per form	Total burden hours
Adults—Puerto Rico	Screener	5,205	1	5,205	0.03	156.15	1,093.65
	Core	1,250	1	1,250	0.75	937.50	
Adults—U.S. Virgin Islands	Screener	1,457	1	1,457	0.03	43.71	288.71
	Core	350	1	350	0.70	245	
Adults—Guam	Screener	1,334	1	1,334	0.03	40.02	337.02
	Core	450	1	450	0.66	297	
Adults—American Samoa	Screener	564	1	564	0.03	16.92	345.42
	Core	450	1	450	0.73	328.50	
Adults—Federated States of Micronesia.	Screener	625	1	625	0.03	18.75	324.75
	Core	450	1	450	0.68	306.00	
Adults—Republic of the Marshall Islands.	Screener	360	1	360	0.03	10.80	205.80
	Core	300	1	300	0.65	195.00	
Adults—Commonwealth of the Northern Mariana Islands.	Screener	670	1	670	0.03	20.10	395.10
	Core	500	1	500	0.75	375	
Adults—Republic of Palau	Screener	285	1	285	0.03	8.55	183.55
	Core	250	1	250	0.70	175	
Total	Screener	10,500	1	10,500	0.03	315.00	[2] 3,155
	Core	4,000	1	4,000	0.71	2,840.00	

The table above shows a total annual burden of 3,155 hours, a decrease from the previously estimated 3,480.52 hours in ICR 202404–0906–002. Although the total number of interviews has increased, the burden hours have declined due to two factors: (1) survey timings have been adjusted to reflect actual survey times from the three completed rounds of data collection, rather than prior estimates and (2) eligibility assumptions and response rates have been updated based on actual results from the same three rounds of data collection experience.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–01150 Filed 1–16–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Environmental Information and Documentation (EID), OMB No. 0915–0324, Extension

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than February 18, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA Environmental Information and Documentation, OMB No. 0915–0324—Extension.

Abstract: HRSA proposes an extension of the Paperwork Reduction Act approval for the Environmental Information and Documentation (EID) checklist, which consists of information that the agency is required to obtain to comply with the National Environmental Policy Act (NEPA) of 1969 as amended by the Fiscal Responsibility Act of 2023. NEPA establishes the federal government's national policy for protection of the environment. The EID checklist must be completed and submitted by applicants for HRSA funds that plan to engage in construction or other projects that will potentially impact the environment. HRSA uses the checklist to ensure that decision-making processes are consistent with NEPA and other related environmental and historic preservation laws. The extension will support HRSA's implementation of programs with capital improvements that have the potential to significantly affect the human environment, such as construction/expansion and alteration/renovation activities, as defined in the associated HRSA program guidance, or installation of fixed equipment.

A 60-day notice published in the **Federal Register** on October 24, 2024, 89 FR 84898, No. 2024–24732; pp. 84898 and 84899. There were no public comments.

Need and Proposed Use of the Information: Applicants for HRSA funds must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed during the Pre-Award stage (and/or prior to the implementation of the project). The information is reviewed in the Post Award stage for project changes and the information is reviewed before the implementation of the project changes.

[2] For the purposes of this table, we have rounded to the nearest hundredth decimal place, which may result in slight discrepancies in the total burden hours.