

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved 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). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: October 24, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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: Maternal and Child Health Jurisdictional Survey Instrument for the Title V Maternal and Child Health Block Grant Program

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 December 30, 2024.

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 Joella Roland, 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: Maternal and Child Health (MCH) Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906–0042—Revision

Abstract: The purpose of the Title V 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. Utilizing 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.

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 (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) 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 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 ² |
|--|----------------|-----------------------|------------------------------------|-----------------|--|-----------------------|---------------------------------|
| 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—Common-wealth 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 | 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.

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.

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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,” 89 FR 22182–22190

(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/>.

² For the purposes of this table, numbers are rounded to the nearest hundredth decimal place.