

before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before July 10, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 8, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 9, 2020.

For press inquiries, please contact the Office of Media Affairs at [fdama@fda.hhs.gov](mailto:fdama@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Yu (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 2, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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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: The Maternal, Infant, and Early Childhood Home Visiting Program Pay for Outcomes Supplemental Information Request, 0906-XXXX, NEW

**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 a Supplemental Information Request (SIR), described below, to the Office of Management and Budget (OMB). Prior to submitting the SIR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the SIR.

**DATES:** Comments on this SIR should be received no later than September 8, 2020.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, 14N136B, 5600 Fishers Lane, Rockville, MD 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](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** *Information Collection Request Title:* The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) Pay for Outcomes Supplemental Information Request, OMB No. 0906-XXXX, New.

*Abstract:* HRSA is requesting approval to collect information in response to a SIR, which will include eligible entities' plans for implementation and evaluation of Pay for Outcomes (PFO) initiatives to be applied for through the MIECHV Program. The Bipartisan Budget Act of 2018 (Pub. L. 115-123) added subsection (c)(3) to Section 511 of the Social Security Act, 42 U.S.C. 711. The new provision authorizes MIECHV Program funding recipients to use up to

25 percent of the funds awarded under subsection 511(c)(1) "to enable eligible entities to deliver services under early childhood home visitation programs" for "outcomes or success payments related to a pay for outcomes initiative that will not result in a reduction of funding for services delivered by the entity under a childhood home visitation program under this section while the eligible entity develops or operates such an initiative." Subsection 511(j)(3)(B) further requires that "funds made available to an eligible entity under this section for a fiscal year (or portion of a fiscal year) for a pay for outcomes initiative shall remain available for expenditure by the eligible entity for not more than 10 years after the funds are so made available."

Eligible entities may propose to use MIECHV funds for outcomes or success payments related to a PFO initiative in response to the upcoming fiscal year 2021 MIECHV Notice of Funding Opportunity and in succeeding fiscal years pending availability of future funds, and will submit their plans (henceforth referred to as a PFO SIR Response) in response to the forthcoming SIR.

*Need and Proposed Use of the Information:* Congress, through enactment of the Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended, established the MIECHV Program. The MIECHV Program is designed to: (1) Strengthen and improve the programs and activities carried out under Title V of the Social Security Act; (2) improve coordination of services for at risk communities; and (3) identify and provide comprehensive services to improve outcomes for families who reside in at risk communities. The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA, in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, territories, tribal entities, and in certain circumstances, nonprofit organizations are eligible to receive funding through MIECHV and have the flexibility, within the parameters of the authorizing statute, to tailor the program to serve the specific needs of their communities.

Section 50603 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) amended section 511 of the Social Security Act, and provides new authority for MIECHV awardees to use up to 25 percent of MIECHV grant funds awarded under section 511(c) for outcomes or success payments related to

a PFO initiative. HRSA considers PFO initiatives to be an innovative approach to funding home visiting service delivery, which may result in social benefit, as well as cost savings or cost avoidance to the public sector.

In response to the forthcoming SIR, MIECHV awardees planning to use MIECHV grant funds for outcomes or success payments related to a PFO initiative will be required to submit a PFO SIR Response outlining how their plans will meet all of the applicable statutory requirements and identifying what specific MIECHV funds (e.g., fiscal year 2021 formula funding) they propose to use to (1) develop and implement their PFO initiative; and (2) make PFO outcomes or success payments based on the planned PFO initiative.

Regarding a PFO initiative, the MIECHV authorizing statute requires the following:

(1) A PFO initiative may not result in a reduction of funding for services delivered by the entity under a childhood home visitation program under this section while the eligible entity develops or operates such an initiative (section 711(c)(3)); and

(2) The PFO initiative for which outcome or success payments may be made must include:

(a) A feasibility study that describes how the proposed intervention is based on evidence of effectiveness;

(b) A rigorous, third-party evaluation that uses experimental or quasi-experimental design or other research methodologies that allow for the strongest possible causal inferences to determine whether the initiative has met its proposed outcomes as a result of implementation;

(c) An annual, publicly available report on the progress of the initiative; and

(d) A requirement that payments are made to the recipient of the grant, contract, or cooperative agreement only when agreed upon outcomes are achieved, excluding payments made to a third party conducting the evaluation. See 42 U.S.C. 711(k)(4).

The forthcoming SIR will provide further instructions to awardees in proposing a PFO initiative and submitting the required information to HRSA. Awardees are not required to propose or implement a PFO initiative, but if they wish to do so, they must submit a PFO SIR Response describing how their PFO initiative will meet all of

the applicable statutory requirements. HRSA will use the information collected through the PFO SIR Response to ensure that MIECHV awardees proposals to use grant funds for PFO initiatives meet statutory requirements and to provide technical assistance to awardees. The implementation of a PFO initiative is not intended to disrupt current services or negatively impact communities that have benefited from home visiting programs and must not result in a reduction of funding for home visiting services.

*Likely Respondents:* MIECHV Program awardees that are states, territories, and, where applicable, nonprofit organizations providing home visiting services within states.

*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 and supporting materials; to collect and analyze data and information to develop the PFO SIR Response; engage with stakeholders and coordinate with state level partners; and to draft and submit the PFO SIR Response. The table below summarizes the total annual burden hours estimated for this SIR.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Instrument	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
MIECHV PAY FOR OUTCOMES SIR .....	15	1	15	92	1,380
Total .....	15	.....	15	.....	1,380

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. 2020-14658 Filed 7-7-20; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier OS-0990-0379]

**Agency Information Collection Request: 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before August 7, 2020.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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