Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new control number); *Title of Information Collection:* The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS); *Use:* The HIPAA Act of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The Transactions and Code Sets final rule (65 FR 50312) published in the **Federal Register** on August 17, 2000 adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2 for diagnosis codes and ICD–9–CM Volume 3 for inpatient hospital services procedures as standard code sets for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard).

The ICD–10–PCS code set has been maintained, enhanced and expanded as a direct result of recommendations for updates (*e.g.,* adding new codes, deleting codes, and editing descriptive material related to existing codes) received from interested stakeholders from both the public and private sectors. Thus, information collected in the application is significant to code set maintenance. The ICD–10–PCS code set maintenance is an ongoing process, as changes are implemented and updated; therefore, the process requires continual collection of information from applicants on a bi-annual basis. As new technology evolves and new complex medical procedures are developed, requests are submitted to CMS requesting modifications to the ICD–10–PCS code set. Requests have been received prior to HIPAA implementation and must continue to be collected to facilitate quality decision-making.

The Committee provides two meetings each year as a public forum to discuss proposed changes to ICD–10. Suggestions to CMS for ICD–10–PCS procedure code modifications come from both the public and private sectors. ICD–10–PCS modification requests can be proposals for new or revised procedure codes or requests for technical coding updates including but not limited to, enhancements to existing procedure code concepts, such as adding a new body part value or a new approach value. Requestors are asked to include a description of the procedure code or change being requested, and rationale for why the procedure code or change is needed. Supporting references and literature may also be submitted. Interested parties submit these ICD–10–PCS modification requests three months prior to a scheduled Spring or Fall C&M meeting via email to the following email address: *ICDProcedureCodeRequest@cms.hhs.gov. Form Number:* CMS–10744 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions and Private Sector; *Number of Respondents:* 80; *Total Annual Responses:* 80; *Total Annual Hours:* 800. (For policy questions regarding this collection contact Marilu Hue at 410–786–4510.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System; *Use:* Section 201(b) of the BBRA 1999 amended section 1833(t) of the Act by adding new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for certain drugs, radiopharmaceuticals, biological agents, medical devices and brachytherapy devices. Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(i) provides that the additional payment for drugs and biologicals be the amount by which the amount determined under section 1842(o) of the Act exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that the Secretary determines to be associated with the drug or biological.

Interested parties such as hospitals, pharmaceutical companies, and physicians will apply for transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals used with services covered under the hospital OPPS. After we receive all requested information, we will evaluate the information to determine if the criteria for making a transitional pass-through payment are met and if an interim healthcare common procedure coding system (HCPCS) code for a new drug, biological, or radiopharmaceutical is necessary. We will advise the applicant of our decision, and update the hospital OPPS during its next scheduled quarterly update to reflect any newly approved drug, biological, or radiopharmaceutical. We list below the information that we will require from all applicants. *Form Number:* CMS–10008 (OMB control number: 0938–0802); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 480. (For policy questions regarding this collection contact Raymond A. Bulls at 410–786-7267.)

Dated: May 5, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–09908 Filed 5–10–21; 8:45 am]

BILLING CODE 4120–01–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; The Maternal, Infant, and Early Childhood Home Visiting Program Pay for Outcomes Supplemental Information Request, OMB NO. 0906–XXXX NEW

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted a Supplemental Information Request (SIR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this SIR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this SIR should be received no later than June 10, 2021.

ADDRESSES: Submit your comments, including the SIR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request title for reference.

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program 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 Maternal, Infant, and Early Childhood Home Visiting (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 fiscal year 2021 MIECHV Notice of Funding Opportunity and in succeeding fiscal years pending availability of future funds, the recipient must submit a detailed application that responds to the forthcoming SIR (henceforth this application is referred to as a PFO SIR Response).

A 60-day notice was published in the **Federal Register** on July 8, 2020. HRSA received four comments. Comments sought clarification on guidance related to third-party evaluation, selection of outcome measures, partnership agreements, budgeting PFO funds, annual reports, and maintenance of service delivery. Other comments highlighted topics that would benefit from specific technical assistance, indicated support for various aspects of the guidance, or offered suggestions that were outside the intended scope of the guidance. After taking the public comments into consideration, HRSA is proposing final revisions to the PFO SIR Guidance by making the following changes:

- Revising the SIR to further describe expectations and best practices associated with conducting feasibility studies and ensuring independence and accountability in the process. HRSA will not specify credentials or level of experience of evaluators or researchers, allowing recipients to have flexibility to determine what will work best for their context.
- Revising the SIR to further clarify that applicants are to select outcome measure(s) that will have meaningful impacts for the children and families served.
- Editing the SIR to broaden the requirements around obtaining signed partnership agreements so that a draft agreement or letter of intent, as well as a signed partnership agreement, would be acceptable.
- Revising the SIR to clarify that recipients can set aside funds awarded in multiple years as part of its PFO initiative. Recipients must propose a PFO project extending over the project period of the entire initiative, and must work closely with HRSA to ensure appropriate monitoring of use of funds for this purpose over the 10-year period of availability.
- Revising the SIR to clarify that the required annual reports must be made available to the public and removing language that may suggest that the annual reports will include outcomes that have been achieved and/or payments made.
- Revising the SIR to clarify the expectation that recipients must continue to meet program and model fidelity requirements with no reduction of funding for services. HRSA will further develop and apply criteria as part of the review and approval process of any proposed PFO initiatives to ensure PFO initiatives have no negative impact on high-quality service delivery.

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 50605 of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123) added new Section 511(c)(3), which authorizes MIECHV recipients the option to use up to 25 percent of MIECHV funding for ''outcomes or success payments related to a PFO initiative that will not result in reduction of funding for home visiting services. The new authority establishes new requirements, including that the PFO initiative ''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.'' Under Section 511(j)(3)(A), funds used by recipients for a PFO initiative remain available for expenditure by the eligible entity for not more than 10 years after the funds are made available.

In response to the forthcoming SIR, MIECHV recipients 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 recipients in proposing a PFO initiative and submitting the required information to HRSA. Recipients 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 recipients' proposals to use grant funds for PFO initiatives meet statutory requirements and to provide technical assistance to recipients. 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 recipients 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. 2021–09910 Filed 5–10–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: May 17, 2021.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fisher Lane, Room 3G45, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Vanitha Sundaresa Raman, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G45, Rockville, MD 20852, 301–761–7949, *vanitha.raman@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 5, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–09913 Filed 5–10–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) 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; PAR–20–131: Mammalian Models for Translational Research.

Date: June 7, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, (301) 272–4596, *smileyja@csr.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Basic