

and iontophoresis devices intended for any other purposes as class III (premarket approval). The final rule was issued after consideration of three comments submitted in response to the 1979 proposed rule that disagreed with the proposal classifying into class III iontophoresis devices for uses other than diagnosing cystic fibrosis, application of fluoride in dentistry, or anesthetizing the tympanic membrane. Based on FDA's analysis of the available literature and input from the Physical Medicine; Ear, Nose and Throat; and Dental Device Classification Panels (see the preamble to the proposed rule 44 FR 50520), FDA disagreed with the comments and concluded that insufficient data exist to support uses of the device other than those specifically considered. In addition, the final rule removed the dental application of fluoride and local anesthesia of the intact tympanic membrane uses from the class II definition because it was determined that there were no marketed drugs with adequate instructions for use with an iontophoresis device for these uses. The effect of this change in the identification was to classify into class III iontophoresis devices for these two uses.

In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for iontophoresis devices intended for any other purposes (52 FR 17742, May 11, 1987).

On August 22, 2000, FDA published a proposed rule (65 FR 50949) to amend the iontophoresis device regulation to remove the class III (premarket approval) identification because FDA believed there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. The proposed rule stated that manufacturers of iontophoresis devices that had been cleared as class III 510(k)s could revise the labeling of their devices to meet the class II identification.

On November 4, 2004, FDA withdrew the proposed rule issued on August 22, 2000 (65 FR 50949), in response to comments received (69 FR 64266). FDA simultaneously issued a Notice of Intent to reclassify iontophoresis devices currently in class III into class II (special controls) and provided an opportunity for interested persons to submit any new information concerning the safety and effectiveness of iontophoresis devices (69 FR 64313). FDA did not take further regulatory action regarding iontophoresis devices prior to issuing the 2009 515(i) order on April 9, 2009

[Docket No. FDA-2009-M-0101], relating to their regulatory classification.

The discussion at the committee meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA), or reclassify to class I or class II (subject to 510(k)). The committee will further be asked to comment on whether general and/or special controls are adequate to reasonably ensure the safety and effectiveness of the device and whether, if reclassified to Class II, these devices should be exempt from premarket notification requirements.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 31, 2014. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. on February 21, 2014. 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 January 23, 2014. 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 January 24, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to

accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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: December 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-30580 Filed 12-23-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Administration for Children and Families

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS. Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) and the Administration for Children and Families (ACF) announce 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 and ACF seek comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn

Building, 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 or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Information System

OMB No. 0915-0357—Revision

Abstract: On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148), historic and transformative legislation designed to make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Through a provision authorizing the creation of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, the Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the federal, state, and community levels to improve health and development outcomes for at-risk children through voluntary evidence-based home visiting programs. The MIECHV Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V of the Social Security Act; (2) to improve coordination of services for at-risk communities; and (3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities.

The program is jointly administered by HRSA and ACF and includes grants to states, jurisdictions, and eligible non-profits (State MIECHV program) and grants to Tribes (including consortia of tribes), Tribal Organizations, and Urban Indian Organizations (Tribal MIECHV program).

The Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended by the Patient Protection and Affordable Care Act of 2010, requires that State and Tribal MIECHV grantees collect data to measure improvements for eligible families in six specified areas (referred to as “benchmark areas”) that

encompass the major goals for the program: (1) Improved maternal and newborn health; (2) prevention of child injuries, child abuse, neglect, or maltreatment, and reduction of emergency room visits; (3) improvement in school readiness and achievement; (4) reduction in crime or domestic violence; (5) improvements in family economic self-sufficiency; and (6) improvements in the coordination and referrals for other community resources and supports.

The Supplemental Information Request for the Submission of the Updated State Plan for a State Home Visiting Program, published on February 8, 2011, further listed a variety of constructs under each benchmark area for which State MIECHV grantees were to select and submit relevant performance measures. Per Section 511(d)(1)(B)(i) of the legislation, no later than 30 days after the end of the third year of the program, grantees are required to demonstrate improvement in at least four of the six benchmark areas. Funding opportunity announcements, notices of award, and program guidance documents for competitive, formula, and non-profit grants also require annual reporting on the constructs under each benchmark area, as well as on demographic, service utilization, budgetary, and other administrative data related to program implementation.

Tribal MIECHV grantees must also report annually on demographic, service utilization, budgetary, and other administrative data related to program implementation. In addition, Tribal MIECHV grantees must propose a plan for meeting the benchmark requirements specified in the legislation and must report on improvement on constructs under each benchmark area at the end of Year 4 and Year 5 of their 5-year grants.

Need and Proposed Use of the Information: The data collected from the proposed Home Visiting (HV) forms will be used to track State and Tribal MIECHV grantees’ progress in demonstrating improvement under each benchmark area and provide an overall picture of the population being served. The proposed data collection forms are as follows:

Home Visiting Form 1—Demographic and Service Utilization Data for Enrollees and Children—This form requests data to determine the unduplicated number of participants and of participant groups by primary insurance coverage. This form also requests data on the demographic characteristics of program participants such as race, ethnicity, and income. The

form is used by both State and Tribal MIECHV grantees. As this form has current approval from OMB and is in use, no changes are proposed.

Home Visiting Form 2—State Grantee Performance Measures: Grantees have already selected relevant performance measures for the legislatively identified benchmark areas. This form provides a template for grantees to report aggregate data on their selected performance measures. This form is used by State MIECHV grantees only. As this form has current approval from OMB and is in use, no changes are proposed.

Home Visiting Form 3—Tribal Grantee Performance Measures: To show quantifiable, measurable improvement in benchmark areas, each Tribal MIECHV grantee must submit data demonstrating improvement on constructs in each of the six benchmark areas. The purpose of the proposed collection on Home Visiting Form 3 will be to track Tribal MIECHV grantees’ progress in demonstrating improvement under each benchmark area. This form is used by Tribal MIECHV grantees only. As this form was not included in the previous submission to OMB, this form is new to the information system.

Likely Respondents: Home Visiting Form 1 is used by all MIECHV Program grantees. Home Visiting Form 2 is used by the states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, American Samoa, and non-profit organizations providing services within states through the State MIECHV Program. Home Visiting Form 3 will be used by Tribal MIECHV grantees.

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 Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours: (Note: We will need to confirm the total number of respondents (grantees) for this table.)

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HV Form 1: Demographic and Service Utilization Data for Enrollees and Children.	81 ¹ (All MIECHV grantees including Tribal grantees).	1	81 (All MIECHV grantees including Tribal grantees).	731	59, 211
HV Form 2: Grantee Performance Measures.	56 ² (State MIECHV grantees)	1	56 (State MIECHV grantees)	313	17, 528
HV Form 3: Tribal-Grantee Performance Measures.	25 ³ (Tribal MIECHV grantees).	1	25 (Tribal MIECHV grantees)	475	11,875
Total	81	81	88, 614

¹ In addition to 56 jurisdictions and non-profit organizations, it is estimated that 25 Tribal MIECHV program grantees will utilize Form 1 to report on demographic and service utilization data for all participant families.

² This number does not include Tribal MIECHV program grantees.

³ This number reflects the number of Tribal MIECHV grantees.

HRSA and ACF specifically request 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.

Dated: December 17, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination, Health Resources and Services Administration.

Linda K. Smith,

Deputy Assistant Secretary and Inter-Departmental Liaison for Early Childhood Development, Administration for Children and Families.

[FR Doc. 2013-30613 Filed 12-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Mental Health Council.

Date: January 23, 2014.

Closed: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate the NIMH Division of Intramural Research Programs.

Place: National Institutes of Health (NIH), Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Open: 9:30 a.m. to 2:30 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health (NIH), Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Closed: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Contact Person: Jane A. Steinberg, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-5047.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed

and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: December 18, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-30599 Filed 12-23-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA