

- Regulations for postmarket surveillance studies,
- Challenges and opportunities for collaborative efforts,
- Innovative methodologies and scientific infrastructure to promote innovation,
- Role of networks, registries and observational studies,

4. *Where can I find out more about this public workshop?*

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/cdrh/meetings.html>.

**Comments:** Regardless of attendance at the public workshop, interested persons may submit electronic comments, or written comments by April 6, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comment to the Division of Dockets Management (HFA-305), Food and Drug Administration 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics listed in paragraph 3 of the "Agenda for the Public Workshop" section of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Any written request for a transcript is to be sent to the Division of Freedom of Information. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated February 10, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. 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 the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program Information System (OMB No. 0915-xxxx)—[New]

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 evidence-based home visiting programs. The MIECHV Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V; (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 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 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. The Supplemental Information Request for the Submission of the Updated State Plan for a State Home Visiting Program (SIR), published on February 8, 2011, further listed a variety of constructs under each benchmark area for which 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. The SIR and subsequent MIECHV guidance documents for both competitive and formula grants also require that grantees report annually on the constructs under each benchmark area, as well as on demographic, service utilization, budgetary and other administrative data related to program implementation.

The proposed data collection and reporting forms were developed by an internal MIECHV workgroup in consultation with Home Visiting Model Developers and selected grantees. The data collected from the proposed forms will be used to track the grantees' progress in demonstrating improvement under each benchmark area and to provide an overall picture of the population being served. The proposed data collection forms are as follows:

**Form 1—Demographic and Service Utilization Data for Enrollees and Children:** This form will request data to determine the unduplicated number of participants and of participant groups by primary insurance coverage. This form will also request data on the demographic characteristics of program participants. For example, data will be

collected on the race/ethnicity of program participants and household demographics including income data.  
Form 2—State Performance Measures Template: 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 State-selected performance measures.

While there will be variation in the data collection and reporting burden to the grantees based on the number of families served and state data system capacity, the estimated average annual burden is as follows:

Reporting document	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Form 1: Demographic and Service Utilization Data for Enrollees and Children .....	56	1	56	731	40,936
Form 2: State Performance Measures Template .....	56	1	56	313	17,528
Total .....	56	.....	56	.....	58,464

Email comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 10, 2012.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Extension of an Existing Information Collection Request; Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review: Form N–25, Request for Verification of Naturalization.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice, OMB Control Number 1615–0049, is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until April 16, 2012.

During this 60-day period USCIS will be evaluating whether to revise the Form N–25. Should USCIS decide to revise this form it will advise the public when it publishes the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The

public will then have 30-days to comment on any revisions to this form.

Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Clearance Office, 20 Massachusetts Avenue NW., Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–0997, or via email at [uscisfrcomment@dhs.gov](mailto:uscisfrcomment@dhs.gov). When submitting comments by email, please add the OMB Control Number 1615–0049 in the subject box.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Request for Verification of Naturalization.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–25. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Not for Profit Institutions. This form will allow U.S. Citizenship and Immigration Services (USCIS) to obtain verification from the courts that a person claiming to be a naturalized citizen has, in fact, been naturalized.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,000 responses at 15 minutes (.25) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 250 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit: <http://www.regulations.gov/search/index.jsp>.

We may also be contacted at: USCIS, Regulatory Management Division, 20 Massachusetts Avenue NW., Washington, DC 20529, telephone number 202–272–8377.

Dated: February 10, 2012.

**William Bacon,**

*Deputy Chief, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

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