

Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2014-23206 Filed 9-29-14; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-0345]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 30, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the

OMB control number 0910-0695. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Data To Support Drug Product Communications as Used by the Food and Drug Administration—(OMB Control Number 0910-0695)—Extension**

Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews. The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have two major purposes:

- (1) To obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns; and
- (2) To assess the potential effectiveness of messages and materials

in reaching and successfully communicating with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education.

Annually, FDA projects about 45 communication studies using the variety of test methods listed in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of April 7, 2014 (79 FR 19096), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, this comment did not address the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys .....	19,822	1	19,822	0.24 (14 minutes)	4,757

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 24, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-23236 Filed 9-29-14; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities; Proposed Collection: Public Comment Request**

**AGENCY:** Health Resources and Services Administration, 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) 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 Information Collection Request must be received no later than December 1, 2014.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto: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](mailto: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 (MIECHV) Program Competitive Grant Final Report OMB No. 0915–xxxx—New

*Abstract:* On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (the Act), Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant and Early Childhood Home Visiting Program (MIECHV) ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h3590enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf), pages 216–225). The legislative authority of this Act was extended by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93). 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.

Under this program, competitive funding has been awarded since June 2011 for Competitive Development Grants and Competitive Expansion

Grants. Competitive Development Grants were intended to support the efforts of states and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek a Competitive Expansion Grant in the future. Competitive Expansion Grants were intended to support the efforts of states and jurisdictions that had already made significant progress towards a high quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system.

Since federal fiscal year 2011, 19 states have been awarded Competitive Development Grants, and 26 states have been awarded Competitive Expansion Grants. These competitive grants are for 2 years (Development Grants) and 4 years (Expansion Grants), respectively. Grantees of the competitive grant program will need to complete final reports in order to comply with HRSA reporting requirements. Grantees that were awarded Competitive Development Grants during federal fiscal year 2011 were eligible for Competitive Expansion Grants in federal fiscal year 2013. For this reason, some grantees have been awarded up to two Competitive Grants to date. Ten grantees have both a Competitive Development Grant and a Competitive Expansion Grant. Additional funds are being made available for Competitive Grants in federal fiscal year 2015. Up to 35 grants are anticipated to be awarded on March 1, 2015, with a project period equal to 2 years and 7 months. Grantees are expected to use 2015 competitive grant funds to provide ongoing support to high-quality evidence-based home visiting programs and for the development and expansion of evidence-based home visiting programs funded, in whole or in part, by the MIECHV program through increased enrollment and retention of families served. After Competitive Grant issuance in 2015, some MIECHV grantees may have up to three competitive grants for which final reports need to be submitted.

HRSA is collecting information from MIECHV grantees that have received competitive grant funds as part of the

agency’s final reporting requirements. The final report will be completed by grantees funded under the Competitive Grant Program and submitted to HRSA within 90 days of the project period end date.

The burden estimates presented in the table below are based on consultations with a few states on the final reporting requirements described in the competitive grant guidance documents.

*Need and Proposed Use of the Information:* Submission of a final report is a reporting requirement under the grant award. The final report will enable assessment of program effectiveness and impact on the health and development of service recipients. Each final report will be assessed to measure and quantify the degree to which each grantee was successful in implementing the grant and ensuring yearly program improvement. Data will be extracted from final reports and aggregated, using suitable analytic approaches, to compare, contrast, and identify successes, areas for improvement, and promising practices across the program. These findings will be used to identify the accomplishments of the MIECHV program, support program or grantee improvement, and craft or inform dissemination strategies.

*Likely Respondents:* MIECHV grantees that have received a competitive (D89) grant award.

*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:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
MIECHV Competitive Grant Final Report—Fiscal Year 2011 and 2012 Development Grantees .....	19	1	19	25	475

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
MIECHV Competitive Grant Final Report—Fiscal Year 2011, 2012, 2013, and 2014 Expansion Grantees .....	31	1	31	25	775
MIECHV Competitive Grant Final Report—Fiscal Year 2015 Expansion Grantees .....	35	1	35	25	875
Total .....					2125

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.

Dated: September 24, 2014.

**Jackie Painter,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**

**AGENCY:** Health Resources and Services Administration, 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) 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 Information Collection Request must be received no later than December 1, 2014.

**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: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy). OMB No. 0915-0047—Extension.

*Abstract:* The statutory authorities for the Health Professions Student Loan (HPSL) Program, as authorized by Public Health Service (PHS) Act sections 721-722 and 725-735, and the Nursing Student Loan (NSL) Program, as authorized by PHS Act sections 835-842, contain a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable regulations for these programs under 42 CFR Part 57 details the various requirements (see chart below).

*Need and Proposed Use of the Information:* The requirements are essential for assuring that borrowers are aware of their rights and responsibilities, academic institutions have accurate records of the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that academic institutions maintain adequate records for audit and assessment purposes to help the U.S. Department of Health and Human Services safeguard federal funds made through the Federal Capital Contribution (FCC). Academic institutions are free to use improved information technology to manage the information required by the regulations.

*Likely Respondents:* Financial Aid Directors working at institutions participating in the HPSL and NSL Programs.

*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:

**RECORDKEEPING REQUIREMENTS**

Regulatory/section requirements	Number of recordkeepers	Hours per year	Total burden hours
HPSL Program:			
57.206(b)(2), Documentation of Cost of Attendance .....	435	1.17	509
57.208(a), Promissory Note .....	435	1.25	544
57.210(b)(1)(i), Documentation of Entrance Interview .....	435	1.25	544
57.210(b)(1)(ii), Documentation of Exit Interview .....	*477	0.33	157
57.215(a) & (d), Program Records .....	*477	10	4,770