

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Notifications to trading partners of an illegitimate product	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total					42,416

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN ¹

Consultation with FDA and termination of notification	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	800	1	800	1	800
Wholesale Distributors	160	1	160	1	160
Dispensers	40	1	40	1	40
Total					1,000

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

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Notifications to trading partners of an illegitimate product termination	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total					42,416

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

Dated: September 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review

of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 15, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request 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 the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 594-4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program Fiscal Year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Progress Report for Formula Grant OMB No. 0915-0355—Extension.

A 30-day notice was previously published on July 8, 2015, for this information collection request but it contained incorrect burden figures.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. All fifty states, the District of Columbia, and five territories and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions eligible for formula awards and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection

is needed for eligible entities to report progress under the Home Visiting Program annually. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA), Section 2951 of the ACA amending Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Home Visiting Program (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf, pages 216–225). A portion of funding under this program is awarded to participating states and eligible jurisdictions by formula. The purpose of formula funding is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices.

The information collected will be used to review grantee progress on proposed project plans sufficient to permit project officers to assess whether the project is performing adequately to achieve the goals and objectives that were previously approved. This report will also provide implementation plans for the upcoming year, which project officers can assess to determine whether the plan is consistent with the grant as approved, and will result in

implementation of a high-quality project that will complement the home visiting program as a whole. Progress Reports are submitted to project officers through the Electronic HandBooks (EHB). Failure to collect this information would result in the inability of the project officers to exercise due diligence in monitoring and overseeing the use of grant funds in keeping with legislative, policy, and programmatic requirements. Grantees are required to provide a performance narrative with the following sections: Project identifier information, accomplishments and barriers, home visiting program goals and objectives, update on the home visiting program promising approach, implementation of the home visiting program in targeted at-risk communities, progress toward meeting legislatively-mandated reporting on benchmark areas, home visiting quality improvement efforts, and updates on the administration of the home visiting program.

In the event a new Funding Opportunity Announcement is issued annually for the formula grant program, the application for new grant funds may take the place of completion of a non-competing continuation progress report.

Likely Respondents: Grantees with Home Visiting Formula Awards Awarded in Federal FYs 2013–2017.

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 ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours: The burden estimates presented in the table below are based on consultations with a few states on the guidance. Grantees receive a new formula grant annually and are expected to report on progress annually, so the expectation is that grantees would submit non-competing continuation progress reports four times between Federal Fiscal Years 2015 and 2018. Only seven grantees are currently implementing a promising approach and require an annual update on the promising approach.

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
Formula Grant Award	56	1	56	42	2,352
Total	56	1	56	42	2,352

Jackie Painter,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Planning Grants

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

ACTION: Notice of class deviation from competition requirement for one-time extension for the State Planning Grants for Improving Services for Children and Youth with Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD) Grant Program.

SUMMARY: HRSA announces the award of a one-time extension in the amount of \$54,244 each to four State Planning Grants for Improving Services for Children and Youth with Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD) grants. The purpose of the program is to support states in the planning and development of activities that are designed to improve state systems of care for children and youth with ASD and related DDs and increase access to comprehensive coordinated health care. Grantees develop comprehensive, measurable state plans in collaboration with a diverse group of stakeholders that outline an approach to improve access to comprehensive, coordinated health care and related services for children and youth with ASD and other DDs. The purpose of this notice is to award a one-time, 12-month extension to ensure the completion of activities

and an orderly phase out of HRSA support.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Awards: University of Arkansas System, University of Massachusetts, New Hampshire Department of Health and Human Services, and the University of Texas Health Science Center at Houston.

Amount of Each Non-Competitive Award: \$54,244.

Period of Low-Cost Extension Funding: 9/1/2015–8/31/2016.

CFDA Number: 93.110.

Authority: Public Health Service Act, § 399BB (42 U.S.C. 280i–1) and the Combating Autism Act of 2006 (Pub. L. 109–416), as amended by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112–32) and the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2014 (H.R. 4631; Pub. L. 113–157).