

weaknesses in program services and processes. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting a generic approval from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance

provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees, to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve services and processes. Focus groups may also be used to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys,

and telephone surveys are expected to be the preferred data collection methods.

A generic approval will permit HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If generic approval is granted, information on each individual partner survey will not be published in the **Federal Register**.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
In-Class Evaluations .....	40,000	1	40,000	.05	2,000
Mail/Telephone Surveys .....	12,000	1	12,000	.25	3,000
Focus Groups .....	250	1	250	1.5	375
Total .....	52,250	.....	.....	.....	5,375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: May 30, 2012.

**Reva Harris,**  
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: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program FY 2012 Competitive Funding Opportunity Announcement (OMB No. 0915-xxxx)—[New]**

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 ([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 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 \$91 million was made available to eligible States and territories by formula in FY 2010, and in FY 2011, \$125 million was made available by formula. Additionally, a competitive funding opportunity announcement (FOA) was issued in June 2011 to allow interested States to apply for one of two possible grant types: Development Grants and Expansion Grants. Development Grants are intended to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts. Expansion Grants are intended to recognize States and jurisdictions that have already made significant progress towards a high-quality home visiting program or towards embedding their

home visiting program into a comprehensive, high-quality early childhood system. Of State applicants to the competitive grant program, 13 States were awarded Development Grants, and nine States were awarded Expansion Grants. Currently, the 54 States and jurisdictions participating in the formula-funded program have begun implementing their State Home Visiting Plans.

Because the FY 2011 formula grants were for 2 years, no additional FOA will be issued this year for such grants, but the State grantees will be completing non-competing progress reports in order to secure the release of their FY 2012 allocations. The 22 States that received competitive grant funding have also begun to carry out these proposed programs, integrating them with their formula-based programming. These competitive grants are for 2 years (Development Grants) and 4 years (Expansion Grants) respectively, and those grantees will also be completing non-competitive progress reports for FY 2012.

An additional \$83.9 million is available in FY 2012 for the 2-year Development and Expansion Grants. Ten Expansion Grants, totaling \$71.9 million, have been awarded by rank order from among high-ranking applicants under the FY 2011 announcement. An FY 2012 competitive FOA will announce approximately \$12 million for new Development Grants. The intent of these Development Grants, as announced in FY 2011, is to support 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 to sustain

successful home visiting programs. It is anticipated that between four and eight Development Grants will be awarded. The total grant award may range between \$1 million to \$3 million

annually. Applicants may apply for a ceiling amount of up to \$3 million per year. The project period is 2 years. The annual estimate of burden associated with the FY2012 competitive

Development Grant Funding Opportunity Announcement is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Introduction .....	20	1	20	10	200
Needs Assessment .....	20	1	20	14	280
Methodology .....	20	1	20	31	620
Work Plan .....	20	1	20	31	620
Resolution of Challenges .....	20	1	20	14	280
Evaluation and Technical Support Capacity .....	20	1	20	48	960
Organizational Information .....	20	1	20	10	200
Additional Attachments .....	20	1	20	13	260
<b>Total .....</b>	<b>160</b>	<b>.....</b>	<b>160</b>	<b>171</b>	<b>3,420</b>

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: May 29, 2012.

**Reva Harris,**

*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: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915-0327)—[Revision]**

Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) of the PHS Act to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

**Enrollment/Registration**

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA requires entities to submit administrative information (e.g. shipping and billing arrangements, Medicaid participation, etc.), certifying information and signatures from appropriate grantee level or entity level authorizing officials and State/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Drug Pricing Program. This information is entered into the 340B database by entities and verified by OPA staff according to 340B Drug Pricing Program requirements. Accurate records are critical to implementation of the 340B Drug Pricing Program legislation, especially to prevent diversion and duplicate discounts. To maintain accurate records, OPA also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is low for recertification and minimal for submitting change requests.

**Contract Pharmacy Self-Certification**

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and certifications that signed agreements are in place with those contract pharmacies.

The estimates of annualized burden are as follows: