

of risk projected and different approaches taken by manufacturers seeking to meet those requirements. FDA would like to convene sessions of experts and hold focused meetings over the next 3 years to discuss REMS implementation to date, and explore practical policy approaches relevant to restricted distribution processes and quality care counseling.

#### C. Eligibility Information

This supplement is available only to the existing grant recipient, Brookings.

#### D. Requirements of the Supplemental Application

1. The application clearly demonstrates an understanding of the purpose and objectives of the program expansion as described in section B of this document.

2. The application clearly describes the steps involved in a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the program expansion.

3. The application establishes Brookings ability to perform the responsibilities under the program expansion including the availability of appropriate staff and sufficient funding.

4. The application describes Brookings ability to act as a neutral, independent third party to convene a wide group of diverse stakeholders with relevant expertise related to selected topics.

5. The application specifies the manner in which interaction with FDA will be maintained throughout the lifetime of the project.

6. The application specifies how Brookings will monitor progress of the work under the program expansion and how progress will be reported to FDA.

7. The application shall include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, and supplies and (2) the sources of funds to meet those needs, if other than FDA.

## II. Award Information/Funds Available

#### A. Award Amount

FDA anticipates supplementing this program expansion by providing approximate total cost of \$501,534 (direct costs only) in each budget period beginning in 2010, and the remaining budget periods (years: 2011, 2012, and 2013).

#### B. Length of Support

The initial supplemental award will be awarded to correspond with the 2010

budget period, and the remaining budget periods (2011, 2012, and 2013) will be dependant on the grantee's successful performance, and financial management.

### III. Paper Application and Submission Information

To submit a paper application in response to this supplemental notice, applicants should download the PHS-398 form at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

For all paper application submissions, the following steps are required:

Submit paper via Express mail to (*see the For Further Information and Additional Requirements Contact section of this document*).

Dated: November 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

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: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements (OMB No. 0915-0307)—Extension

HRSA utilizes standards for granting waivers of the core medical services requirement for the Ryan White HIV/AIDS Program. These standards meet the intent of the Ryan White HIV/AIDS Program to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS who are identified and eligible under Title XXVI of the Public Health Service (PHS) Act. The core medical services waiver uniform standard and waiver request process will apply to Ryan White HIV/AIDS Program Grant awards under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services waivers will be effective for a 1-year period that is consistent with the grant award period.

Title XXVI, Section 2671 of the PHS Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111-87, (Ryan White HIV/AIDS Program), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS who are identified and eligible under the legislation. In order for grantees under Parts A, B, and C to be exempt from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA.

Grantees must submit the waiver request with the annual grant application that includes the certifications and documentation which will be utilized by HRSA in making determinations regarding waiver requests. Grantees must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all individuals with HIV/AIDS who are identified and eligible under Title XXVI of the PHS Act in the service area within 30 days.

The annual estimate of burden is as follows:

Application	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Waiver Request .....	10	1	10	6.5	65
Total .....	10	1	10	6.5	65

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 30 days of this notice.

Dated: November 23, 2010.

**Robert Hendricks,**

*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: 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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443–1129.

*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:* Healthy Weight Collaborative (OMB No. 0915–NEW)—[NEW].

*Background:* The mission of the Healthy Weight Collaborative (HWC) is to discover, identify, develop, and disseminate both evidence-based and promising clinical and community-based interventions to prevent and treat obesity. The HWC was funded by the Health Resources and Services Administration under Title V, Section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)) and Section 4002 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

The goal of the HWC is to value and leverage each community team's strengths, networks, grantees, and expertise towards the common goal of promoting healthy weight for all populations, especially those at high risk for overweight and obesity.

The HWC is modeled after the Institute for Healthcare Improvement Collaborative Model for achieving breakthrough improvement. Also known as the Breakthrough Series, this model was developed in 1996 to help healthcare organizations make breakthrough improvements in quality

while reducing costs. This model is designed to close the gap between science and practice by creating a structure in which organizations can easily learn from each other and from recognized experts in topic areas in which they want to make quality improvements.

Approximately 50 community teams will be recruited to participate in the HWC. The intended beneficiaries of this program are children and their families, and teams in the HWC can include health departments, community-based organizations, HRSA and the Department of Health and Human Services (HHS) grantees; especially safety net providers and other stakeholders in the HRSA and HHS program network. Teams will be asked to report on non-personally identifiable aggregate information from clinical and public health or community interventions related to four domains, including clinical and public health:

- Body Mass Index (BMI), collected from an electronic health record.
- Nutrition, which includes measures related to change in knowledge, attitudes, behavior, and consumption.
- Physical Activity, which includes measures related to change in knowledge, attitudes, behavior, and levels of activity.

- Partnerships and Process Improvement, which includes measures related to linkages made between clinical and community-based or public health programs, increased efficiencies related to these linkages, and the number of people served by these linkages.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
BMI .....	50	30	1,500	.10	150
Nutrition .....	50	30	1,500	.20	300
Physical Activity .....	50	30	1,500	.20	300
Partnerships and Process Improvement .....	50	50	2,500	.20	500
Total .....	50	.....	7,000	.....	1,250

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10–33,

Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments

should be received within 60 days of this notice.