

#### IV. Attendance and Registration

The FDA Conference Center at the White Oak Campus is a Federal facility with security screening and limited seating. Individuals who wish to attend the public workshop must register on or before February 24, 2014, by visiting <https://www.surveymonkey.com/s/MW5WZDW> and contacting Ping Zhao (see **FOR FURTHER INFORMATION CONTACT**). Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the workshop will be based on space availability.

During the workshop, time will be designated for questions and answers throughout the day and for general comments and questions from the audience following the panel discussions.

In this **Federal Register** document, FDA has included specific issues that will be addressed by the panel. If you wish to address one or more of these issues in your presentation, please indicate this at the time you register so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 2 weeks before the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm> (select this workshop meeting from the events list).

If you need special accommodations because of a disability, please contact Ping Zhao (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

A live webcast of this workshop will be viewable at <https://collaboration.fda.gov/bpik/> on the day of the workshop. A video record of the workshop will be available at the same web address for 1 year.

#### V. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### VI. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (see **ADDRESSES**) and at <http://www.regulations.gov> approximately 30 days after the workshop. A transcript will also be made available in either hard copy or on CD-ROM upon submission of a Freedom of Information request. Send requests to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 5, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-02883 Filed 2-10-14; 8:45 am]

**BILLING CODE 4160-01-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 within 60 days of this notice.

**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:* Children's Hospitals Graduate Medical Education Payment Program. OMB No. 0915-0247 Revision.

*Abstract:* The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106-129 and reauthorized by Public Law 109-307 to provide federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs, and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the **Federal Register** regarding Sections 5503, 5504, 5505, and 5506 of the Affordable Care Act of 2010, Public Law 111-148 on Wednesday, November 24, 2010. This final rule included policy changes on counting resident time in non-provider settings, counting resident time for didactic training, and the redistribution of resident caps. It required modification of the data collection forms within the CHGME Payment Program application. The necessary modifications were made and received OMB clearance on June 30, 2012.

On September 30, 2013, CMS published revised forms on their Web site, requiring additional modifications of the data collection forms in the CHGME Payment Program application. The CHGME Payment Program application forms have been adjusted to accommodate the most recent CMS policy changes. These changes require OMB approval.

*Need and Proposed Use of the Information:* Data are collected on the number of full-time equivalent residents in applicant children's hospitals' training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that

requires the reporting of discharges, beds, and case mix index information from participating children's hospitals.

Hospitals will also be requested to submit data on the number of full-time equivalent (FTE) residents trained during the federal fiscal year to participate in the reconciliation payment process. Auditors will be requested to submit data on the number of FTE residents trained by the hospitals in an FTE resident assessment summary. An assessment of the hospital data ensures that appropriate CMS regulations and CHGME program guidelines are followed in determining

which residents are eligible to be claimed for funding. The audit results impact final payments made by the CHGME Payment Program to all eligible children's hospitals.

*Likely Respondents:* Hospitals applying for and receiving CHGME funds and fiscal intermediaries auditing data submitted by the hospitals receiving CHGME funds.

*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
Application Cover Letter (Initial) .....	60	1	60	0.33	19.8
Application Cover Letter (Reconciliation) .....	60	1	60	0.33	19.8
HRSA 99 (Initial) .....	60	1	60	0.33	19.8
HRSA 99 (Reconciliation) .....	60	1	60	0.33	19.8
HRSA 99-1 (Initial) .....	60	1	60	26.50	1,590.0
HRSA 99-1 (Reconciliation) .....	60	1	60	6.50	390.0
HRSA 99-1 (Supplemental) (FTE Resident Assessment) ..	30	1	30	3.67	110.1
HRSA 99-2 (Initial) .....	60	1	60	11.33	679.8
HRSA 99-2 (Reconciliation) .....	60	1	60	3.67	220.2
HRSA 99-4 (Reconciliation) .....	60	1	60	12.50	750.0
HRSA 99-5 (Initial) .....	60	1	60	0.33	19.8
HRSA 99-5 (Reconciliation) .....	60	1	60	0.33	19.8
CFO Form Letter (Initial) .....	60	1	60	0.33	19.8
CFO Form Letter (Reconciliation) .....	60	1	60	0.33	19.8
FTE Resident Assessment Cover Letter (FTE Resident Assessment) .....	30	1	30	0.33	9.9
Conversation Record (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit C (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit F (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit N (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit O(1) (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit O(2) (FTE Resident Assessment) .....	30	1	30	26.5	795.0
Exhibit P (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit P(2) (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit S (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit T (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit T(1) (FTE Resident Assessment) .....	30	1	30	3.67	110.1
Exhibit 1 (FTE Resident Assessment) .....	30	1	30	0.33	9.9
Exhibit 2 (Initial, Reconciliation and FTE Resident Assessment) .....	90	1	90	0.33	29.7
Exhibit 3 (Initial, Reconciliation and FTE Resident Assessment) .....	90	1	90	0.33	29.7
Exhibit 4 (Initial, Reconciliation and FTE Resident Assessment) .....	90	1	90	0.33	29.7
Total .....	90	.....	90	.....	5,962.8

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: February 4, 2014.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-02897 Filed 2-10-14; 8:45 am]

**BILLING CODE 4165-15-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 within 60 days of this notice.

**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: Delta States Rural Development Network Grant Program (Delta States Grant Program)**

*OMB No. 0915-xxxx—New.*

*Abstract:* The Delta States Rural Development Network Grant Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of programs are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

**Need and Proposed Use of the Information**

For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy (OPRHP), including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to ORHP's progress toward meeting the goals set.

*Likely Respondents:* Delta States Rural Development Network Grant Program award recipients.

*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
Delta States Rural Development Network Grant Program Performance Improvement Measurement System measures .....	12	1	12	6	72
<b>Total .....</b>	<b>12</b>	<b>1</b>	<b>12</b>	<b>6</b>	<b>72</b>

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: January 31, 2014.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-02908 Filed 2-10-14; 8:45 am]

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