

Committee would be held on December 16–17, 2014. The **ADDRESSES** portion of the document is to read as follows:

ADDRESSES: FDA is opening a docket for public comment on this meeting. The docket will open for public comment on November 13, 2014. The docket will close on January 15, 2014. Interested persons may submit either electronic comments regarding this meeting to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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>. All comments received will be posted without changes, including any personal information provided. Comments received on or before December 1, 2014, will be provided to the committee before the meeting.

On page 49091, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will discuss how risk assessments should account for the susceptibility to the effects of a particular chemical exposure because of factors such as genetics, age, sex, and health status and the circumstances under which FDA would decide to conduct a separate risk assessment for these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: November 7, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-26823 Filed 11-12-14; 8:45 am]

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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 January 12, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C-03, 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: Evaluation and Initial Assessment of the HRSA Teaching Health Centers Graduate Medical Education Program.

OMB No.: 0906-xxxx—New.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to provide funding support for new and the expansion of existing primary care residency training programs in community-based settings. The primary goals of this program is to increase the production of primary care providers who are better prepared to practice in community settings, particularly with underserved populations, and improve the geographic distribution of primary care providers.

Statute requires the Secretary to determine an appropriate THCGME program payment for indirect medical expenses (IME) as well as to update, as deemed appropriate, the per resident

amount used to determine the Program's payment for direct medical expenses (DME). To inform these determinations and to increase understanding of this model of residency training, the George Washington University (GW) is conducting an evaluation of the costs associated with training residents in the Teaching Health Center (THC) model. GW has developed a standardized costing instrument to gather data from all THCGME programs. The information gathered in the standardized costing instrument includes, but is not limited to, resident and faculty full-time equivalents, salaries and benefits, residency administration costs, educational costs, residency clinical operations and administrative costs, and patient visits and clinical revenue generated by medical residents.

Need and Proposed Use of the Information: HRSA is collecting costing information related to both DME and IME in an effort to establish a THC's total cost of running a residency program, to assist the Secretary in determining an appropriate update to the per resident amount used to calculate the payment for DME and an appropriate IME payment. The described data collection activities will serve to inform these statutory requirements for the Secretary in a uniform and consistent manner.

Likely Respondents: THCGME grantees.

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.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center Costing Instrument	60	1	60	10	600
Total	60	1	60	10	600

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: October 31, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014-26854 Filed 11-12-14; 8:45 am]

BILLING CODE 4165-15-P

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 December 15, 2014.

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) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915-0172—Revision.

Abstract: The Health Resources and Services Administration (HRSA) is revising the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*. The Guidance is used annually by the 50 states and nine jurisdictions in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. In partnership with the leadership in State Title V Maternal and Child Health (MCH) programs as well as with other national MCH leaders and stakeholders, HRSA's Maternal and Child Health Bureau (MCHB) has been working over the past year to develop and refine a vision for transforming the MCH Block Grant to States program to better meet current and future challenges facing our nation's mothers and children, including children with special health care needs (CSHCN) and their families. The proposed revisions to the Application and Annual Reporting requirements and to the data forms that are contained in the revised guidance reflect this transformative vision.

Relative to the state's submission of a yearly Application, Annual Report and 5-year Needs Assessment, the aims of the MCH Block Grant to States program transformation are threefold: (1) Reduce burden to states, (2) maintain state flexibility, and (3) improve accountability. Revisions to this edition are intended to enable the state to tell a more cohesive and comprehensive Title V story and to better reflect on the program's leadership role and its contributions to the state's public health system in building improved and expanded systems of care for the MCH population. It is recognized that the full extent of the anticipated burden reduction will be realized over time as states become more familiar with the

new instructions and reporting requirements. The burden estimates presented in the table below are based on previous burden estimates, consultations with a few states on the proposed changes, and comments received during the 60-day public comment period.

Specific changes to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) Narrative reporting will be organized by six population health domains (i.e., Women's/Maternal Health; Perinatal/Infant's Health; Child Health; CSHCN; Adolescent Health and Cross-cutting or Life Course); (2) Revised National Performance Measure (NPM) framework will be implemented with states selecting 8 of 15 NPMs for their programmatic focus; (3) state-level program data, such as breakdowns of MCH populations by race/ethnicity, health indicator data, and national performance and outcome measure data will be provided by MCHB, as available, from national data sources, thus, reducing the annual reporting burden for states; (4) Given that most MCH issues are multifactorial, the state will establish evidence based or evidence informed strategies to address each of the selected NPMs and will report on one or more of the Evidence-based or informed Strategy Measures (ESMs) developed for each NPM; (5) Revised instructions and the inclusion of a logic model for the State Title V MCH Block Grant Application/Annual Report process will provide greater emphasis on the need for the state priority needs and national MCH priority areas to drive the state's reporting on the 5-year (and ongoing) Needs Assessment findings, the selection of eight (8) NPMs which target the state-identified priority needs, the development of evidence based or informed strategies and related ESMs for addressing each of the selected NPMs, and the establishment of between three (3) and five (5) State Performance Measures (SPMs) which respond to the state's identified unique needs; (6) State Application/Annual Report will include a 5-year Action Plan for addressing the identified MCH priority areas; (7) An