

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mark Ascione, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1150, Silver Spring, MD 20993-0002, 301-796-7652, FAX: 301-847-8443.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112-114), authorizes FDA to assess and collect fees for biosimilar biological products from October 2012 through

September 2017. FDA uses these fees to expedite the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

As part of BsUFA, FDA is required to contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications. This notice solicits comments on the final report. The final report is described in section 744I(d) of the FD&C Act (21 U.S.C. 379j-53(d)) (<http://uscode.house.gov/view.xhtml?req=granuleid:U.S.C.-prelim-title21-section379j-53&num=0&edition=prelim>), as amended by the Food and Drug Administration Safety and Innovation Act enacted in 2012 (<http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>). (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

##### II. Electronic Access

The final report can be accessed at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm459682.htm>.

Dated: March 9, 2016.

**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 April 14, 2016.

**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](mailto: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](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Maternal and Child Health Bureau Performance Measures for Discretionary Grants

*OMB No.:* 0915-0298—Revision  
*Abstract:* The Maternal and Child Health Bureau's (MCHB) Discretionary Grant Information System (DGIS) electronically captures performance measure, program, financial, and abstract data, and products and publications about these discretionary grants from the grantees. The data collected are used by MCHB project officers to monitor and assess grantee performance as well as assist in monitoring and evaluating MCHB's programs.

*Need and Proposed Use of the Information:* The Health Resources and Services Administration (HRSA) proposes to continue using reporting requirements for grant programs administered by MCHB, including national performance measures as previously approved by OMB, and in accordance with the "Government Performance and Results Act (GPRA) of 1993" (Pub. L. 103-62). This Act requires the establishment of measurable goals for Federal Programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of performance measures for these grants. The revised performance measures are categorized by population domains (Adolescent Health, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health) consistent with Title V,

with the addition of a Capacity Building domain, specific to DGIS. There are also program-specific measures included for a subset of discretionary grant programs including the Healthy Start program, Emergency Medical Services for Children program, and programs within the Division of MCH Workforce Development. Grant programs will be assigned measures in the domains that are appropriate for their activities. Comments were received related to structure, content, and volume of performance measures during the 60-day public comment period and those comments were taken into consideration in the final revision of the DGIS performance measures and overall DGIS data collection.

MCHB's purpose in revising the performance measures is to better measure progress toward program goals. These program goals include alignment with and support of the Title V Block

Grant, specifically population domains and National Performance Measures, where reasonable. Further, the revised measures will more accurately capture the scope of services provided through this grant funding. The overall number of performance measures has been reduced from prior DGIS data collection, and the average number of performance measures each grantee will be required to report is reduced as well. Further, the structure of the data collection has been revised to better measure the various models of programs and the services each funded program provides. This revision will allow a more accurate and detailed picture of the full scope of services provided through grant programs administered by MCHB. The data collected are also used by MCHB project officers to monitor and assess grantee performance as well as assist in monitoring and evaluating MCHB's programs.

*Likely Respondents:* Discretionary grant programs administered by the Maternal and Child Health Bureau.

*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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grant Report .....	600	1	600	36	21,600
Total .....	600	1	600	36	21,600

**Jackie Painter,**  
 Director, Division of the Executive Secretariat.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

[Document Identifier: HHS-OS-0945-0004 60D]

**Agency Information Collection Activities; Proposed Collection; Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.  
**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the

Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0945-0004, which expires on May 31, 2016. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before May 16, 2016.

**ADDRESSES:** Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-60D for reference.

*Information Collection Request Title:* Health Insurance Reform Security Standards—Final Rule.

The final rule was published in the **Federal Register** (68 FR 8334) as CMS-0049-F published on February 20, 2003. On May 22, 2013, CMS 0938-0949 was transferred to OCR 0945-0004.

*Abstract:* Office of Civil Rights, OCR requests approval to extend this collection without change while OMB reviews our request to incorporate the burdens of compliance with the Security Rule into another existing ICR (OMB #0945-0003, for the HIPAA Privacy Rule and Supporting Regulations), which is being revised to better reflect our experience in administering and enforcing the HIPAA Rules. This ICR extends the existing approved information collection for applicable compliance activities associated with the HIPAA Security Rule. When the revised ICR with OMB #0945-0003 is approved, we will request that this ICR (OMB# 0945-0004) be discontinued.

*Likely Respondents:* HIPAA covered entities and their business associates.