ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on FDA's Web site of the Agency's final implementation plan published as part of Booz Allen Hamilton's independent assessment of the process for the review of medical device submissions. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years (FYs) 2013–2017. The assessment is described in section V, Independent Assessment of Review Process Management, of the commitment letter dated April 18, 2012, and entitled ''MDUFA Performance Goals and Procedures'' (MDUFA III Commitment Letter). The assessment is being conducted in two phases. The final implementation plan is FDA's response to Booz Allen Hamilton's comprehensive findings and recommendations and the final deliverable resulting from the first phase of the assessment.

FOR FURTHER INFORMATION CONTACT: Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3372, Silver Spring, MD 20993–0002, 301–796–9384, *Amber.Sligar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).[1] Title II of FDASIA is the Medical Device User Fee Amendments of 2012 (MDUFA III), which gives FDA the authority to collect device user fees from industry for FYs 2013–2017. MDUFA III took effect on October 1, 2012, and will continue through September 30, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the Agency, whenever they submit an application or a notification to market a new medical device in the United States, and for certain other types of submissions. Under MDUFA III, FDA is authorized to collect user fees that will total approximately $595 million (plus adjustments for inflation) over 5 years. With this additional funding, FDA will be able to hire more than 200 full-time-equivalent workers over the course of MDUFA III. In exchange, FDA has committed to meet certain performance goals outlined in the MDUFA III Commitment Letter.[2]

II. Assessment of FDA's Process for the Review of Device Submissions

Section V of the MDUFA III Commitment Letter states that FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment will be conducted in two phases by a private, independent consulting firm, under contract with FDA, that is capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment as described in the MDUFA III Commitment Letter.

FDA will incorporate findings and recommendations from the assessment, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and assure its effectiveness. FDA also will incorporate the results of the assessment into a Good Review Management Practices (GRMP) guidance document for medical devices. FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff, and periodic audits of compliance with the guidance.

FDA awarded the contract for the independent assessment in June 2013 to the consulting firm Booz Allen Hamilton. Findings on high-priority recommendations (*i.e.,* those likely to have a significant impact on review times) were published December 11, 2013.[3] Final comprehensive findings and recommendations were published June 11, 2014.[4] FDA agreed to publish an implementation plan within 6 months of receipt of each set of recommendations. The first of these implementation plans was published June 11, 2014.[5] The second and final implementation plan is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.* For Phase 2 of the independent assessment, the contractor will evaluate the implementation of recommendations and publish a written assessment no later than February 1, 2016.

FDA's implementation plan based on the contractor's final findings and recommendations (issued June 11, 2014) is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.*

Dated: December 16, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29800 Filed 12–19–14; 8:45 am]

BILLING CODE 4164–01–P

[1] *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.*

[2] *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[3] *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf.*

[4] *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM400676.pdf.*

[5] *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM400674.pdf.*

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 February 20, 2015.

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: Rural Health Care Services Outreach Program Measures OMB No. 0915-XXXX—New.

Abstract: The Rural Health Care Services Outreach (Outreach) Program is authorized by Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), as amended, to ''promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.'' The goals for the Outreach Program are the following: (1) Expand the delivery of health care services to include new and enhanced services exclusively in rural communities; (2) deliver health care services through a strong consortium in which every consortium member organization is actively involved and engaged in the planning and delivery of services; (3) utilize and/or adapt an evidence-based or promising practice model(s) in the delivery of health care services; and (4) improve population health, demonstrate health outcomes and sustainability.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data 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. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. Several measures will be used for the Outreach Program. All measures will speak to ORHP's progress toward meeting the goals set.

Likely Respondents: The respondents would be recipients of the Rural Health Care Services Outreach grant funding.

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
Rural Health Care Services Outreach Grant Program Measures	50	1	50	3	150
Total	50	1	50	3	150

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.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–29837 Filed 12–19–14; 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 no later than February 20, 2015.

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: Rural Health Network Development Program OMB No. 0915–XXXX—New

Abstract: This program is authorized under Section 330A(f) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254c(f). This authority directs the Office of Rural Health Policy (ORHP) to support grants for eligible entities to promote, through planning and implementation, the development of integrated health care networks that have combined the functions of the entities participating in the networks in order to: (i) Achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole.

The Rural Health Network Development Program is designed to assist rural health care providers to acclimate to the evolving health care environment by addressing relevant