drugs because breast cancer in males is rare. This has resulted in limited FDA-approved treatment options for males. Clinical management of male breast cancer is generally based on experience with and data from females with breast cancer, rather than on data from prospective, randomized clinical trials.

The draft guidance recommends sponsors discuss their breast cancer drug development plan early in development with CDER or CBER, as applicable. The draft guidance recommends that eligibility criteria for clinical trials of breast cancer drugs allow for inclusion of males. When males have not been included or when inclusion of males is very limited in clinical trials for breast cancer drugs, the guidance includes clinical development recommendations for when no difference in efficacy or safety is anticipated between males and females based on the drug's mechanism of action and for when there is a concern for differential efficacy or safety between males and females.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Male Breast Cancer: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under 0910–0338; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov.*

Dated: August 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18363 Filed 8–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Delta States Rural Development Network Grant Program; OMB No. 0915–0386—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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 ICR must be received no later than October 28, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Extension

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)), as Public Law 114–53. The Delta Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of Delta Program-supported projects 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 of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP) including the following: (a) Access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. These measures speak to FORHP's progress toward meeting the goals set.

Likely Respondents: Recipients of the Delta States Rural Development Network Program.

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
Delta States Rural Development Network Program Performance Improvement Measurement System	12	1	12	1.66	*20
Total	12		12		20

*Number is rounded to the nearest whole number.

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.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–18425 Filed 8–26–19; 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; Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx—NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, 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 September 26, 2019.

ADDRESSES: Submit your comments, including the ICR 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx—NEW.

Abstract: This ICR is for a new approval of measures for the Federal Office of Rural Health Policy's Office of Advancement of Telehealth programs. Specifically, grants administered in accordance with the following legislative statute (ii) Section 711(b) of the Social Security Act (42 U.S.C. 912(b)), as amended. The purpose of these programs are to provide grants that demonstrate how telehealth programs and networks can improve access to quality health care services in rural, frontier, and underserved communities. These grants will work to: (a) Expand access to, coordinate, and improve the quality of health care services; (b) improve and expand the training of health care providers; and (c) expand and improve the quality of health information available to health care providers and patients and their families for decision-making. In addition, these grants will help HRSA assess the effectiveness of evidence based practices with the use of telehealth for patients, providers, and payers.

A 60-day notice was published in the **Federal Register** on April 08, 2019, vol. 84, No. 67; pp. 13936. There were no public comments.

Need and Proposed Use of the Information: The measures will enable HRSA and HRSA to capture awardee-level and aggregate data that illustrate the impact and scope of federal funding along with assessing these efforts. The measures cover the principal topic areas of interest to HRSA including: (a) Population demographics; (b) access to health care; (c) cost savings and cost-effectiveness; and (d) clinical outcomes.

Likely Respondents: Award recipients of the Evidence Based Telehealth Network Program.

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
Evidence-Based Telehealth Network Program Report	50	12	600	14	8,400
Telehealth Performance Measurement Report	50	1	50	5	250