entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles'' (October 4, 2002).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''The Least Burdensome Provisions: Concept and Principles.'' 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1332 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations, guidance, form, and statutory provision have been approved by OMB as listed in the following table:

21 CFR part or section; guidance; FDA form; or statute	Topic	OMB control No.
820	Quality System Regulation	0910–0073
812	Investigational Device Exemption	0910–0078
807, subpart E	Premarket Notification	0910–0120
860.123	Reclassification Petition	0910–0138
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
806	Medical Devices; Reports of Corrections and Removals	0910–0359
803	Medical Device Reporting	0910–0437
822	Postmarket Surveillance	0910–0449
Form FDA 3670	Adverse Event Reports/MedSun Program	0910–0471
801 and 809	Labeling	0910–0485
''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Waiver	0910–0598
807, subparts A through D	Registration and Listing	0910–0625
807, 812, and 814	Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices.	0910–0741
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
42 U.S.C. 241	Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices.	0910–0769
830	Unique Device Identification System	0910–0720
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01022 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–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; Information Collection Request Title: Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Revision

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

ACTION: Notice.

SUMMARY: In compliance with 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 March 7, 2019.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

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

Information Collection Request Title: Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361, Revision

Abstract: To ensure the best use of public funds and to meet the Government Performance Review Act requirements, the Office for the Advancement of Telehealth (OAT) in collaboration with the Telehealth Resource Centers (TRCs) created a set of performance measures that grantees can use to evaluate the technical assistance services provided by the TRCs. Grantee goals are to provide customized telehealth technical assistance across the country. The TRCs provide technical assistance to health care organizations, health care networks, and health care providers in the implementation of cost-effective telehealth programs to serve rural and medically underserved areas and populations.

Need and Proposed Use of the Information: In order to evaluate existing programs, data are submitted to OAT through HRSA's Performance Improvement Management System (PIMS). The data are used to measure the effectiveness of the technical assistance. There are two data reporting periods each year; during these biannual reporting periods data are reported for the previous six months of activity. Programs have approximately six weeks to enter their data into the PIMS system during each biannual reporting period.

The instrument was developed with the following four goals in mind:

1. Improving access to needed services;
2. Reducing rural practitioner isolation;
3. Improving health system productivity and efficiency; and
4. Improving patient outcomes.

The TRCs currently report on existing performance data elements using PIMS. The performance measures are designed to assess how the TRC program is meeting its goals to:

1. Expand the availability of telehealth services in underserved communities;
2. Improve the quality, efficiency, and effectiveness of telehealth services;
3. Promote knowledge exchange and dissemination about efficient and effective telehealth practices and technology; and
4. Establish sustainable technical assistance (TA) centers providing quality, unbiased TA for the development and expansion of effective and efficient telehealth services in underserved communities.

Additionally, the PIMS tool allows OAT to:

1. Determine the value added from the TRC Cooperative Agreement;
2. Justify budget requests;
3. Collect uniform, consistent data which enables OAT to monitor programs;
4. Provide guidance to grantees on important indicators to track over time for their own internal program management;
5. Measure performance relative to the mission of OAT/HRSA as well as individual goals and objectives of the program;
6. Identify topics of interest for future special studies; and
7. Identify changes in healthcare needs within rural communities, allowing programs to shift focus in order to meet those needs.

This renewal request proposes changes to existing measures. After compiling data from the previous tool over the last three years, OAT conducted an analysis of the data and compared the findings with the program needs. Based on the findings, the measures are being revised to better capture information necessary to measure the effectiveness of the program. The measure changes include: additional demographic details from organizations requesting technical assistance, streamlined methods of inquiry; additional topics of technical assistance inquiries aligning with the current telehealth landscape; streamlined types of services provided by the grantees; deletion of client satisfaction survey results; and deletion of telehealth sites developed as a result of grantee technical assistance. A 60-day **Federal Register** Notice was published in the **Federal Register** on April 9, 2018, vol. 83, No. 68; pp. 15164–65. There were no public comments.

Likely Respondents: The likely respondents will be telehealth associations, telehealth providers, rural health providers, clinicians that deliver services via telehealth, technical assistance providers, research organizations, and academic medical centers.

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
Telehealth Resource Center Performance Data Collection	14	42	588	0.07	41
Total	14		588		41

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–01107 Filed 2–4–19; 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; Information Collection Request Title: Medicare Rural Hospital Flexibility Program Performance, OMB No. 0915–0363—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 should be received no later than April 8, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail to Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, Room 14N136B, 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 Lisa Wright-Solomon, 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: Medicare Rural Hospital Flexibility Program Performance Measures, OMB No. 0915–0363—Extension

Abstract: This information collection comment request is for continued approval of the Medicare Rural Hospital Flexibility Program Performance Measures. HRSA is proposing to continue this data collection with no changes. The current performance measures are collected electronically in the Performance Improvement and Measurement System, which awardees access securely through the HRSA Electronic Handbooks.

The Medicare Rural Hospital Flexibility Program (Flex Program) is authorized by Section 1820 of the Social Security Act (42 U.S.C. 1395i–4), as amended. The purpose of the Flex Program is to enable state designated entities to support critical access hospitals in quality improvement, quality reporting, performance improvement, and benchmarking; to assist facilities seeking designation as critical access hospitals; and to create a program to establish or expand the provision of rural emergency medical services.

Need and Proposed Use of the Information: For this program, performance measures were developed to provide data useful to the Flex program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Modernization Act of 2010 (GPRA). These measures cover principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) Quality reporting, (b) quality improvement interventions, (c) financial and operational improvement initiatives, (d) population health management, and (e) innovative care models. In addition to informing the Office's progress toward meeting the goals set in GPRA, the information is important in identifying and understanding programmatic improvement across program areas, as well as guiding future iterations of the Flex Program and prioritizing areas of need and support.

Likely Respondents: Respondents are the Flex Program coordinators for the states participating in the Flex Program. There are currently 45 states participating in the Flex 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
Medicare Rural Hospital Flexibility Program	45	1	45	70	3,150
Total	45		45		3,150