electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tiffany Kelley, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–348–1970, *Tiffany.Kelley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** on March 29, 2019, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''Review and Update of Device Establishment Inspection Processes and Standards.''

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop thoughtful and detailed input.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until June 27, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. 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. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information.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 21 CFR part 803 have been approved under OMB control number 0910–0437. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet at either *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry'' may send an email request to *ORAPolicyStaffs@fda.hhs.gov* to receive an electronic copy of the document.

Dated: May 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11012 Filed 5–24–19; 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; 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 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 June 27, 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: 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.

A 60-day **Federal Register** Notice was published in the **Federal Register** on February 5, 2019, vol. 84, No. 24; pp. 1751–1752. There were no public comments.

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. Several measures will be used for this program and will inform the Office's progress toward meeting the goals set in GPRA. Furthermore, obtained 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 coordinator 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.

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 Estimated Annualized Burden—Hours	45		45		3,150

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–11050 Filed 5–24–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Radiation Therapeutics and Biology.

Date: June 14, 2019.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Syed M. Quadri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301–435–1211, *quadris@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Accelerating the Pace of Drug Abuse Research Using Existing Data.

Date: June 19, 2019.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Karen Nieves Lugo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, *karen.nieveslugo@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biochemistry and Biophysics of Biological Macromolecules Fellowship Applications.

Date: June 20–21, 2019.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1504, *sudha.veeraraghavan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: June 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.

Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 437–8135, *huzhuang@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Disease Prevention and Management, Risk Reduction and Health Behavior Change.

Date: June 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Michael J. McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301–480–1276, *mike.mcquestion@nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: June 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Crowne Plaza Seattle, 1113 6th Avenue, Seattle, WA 98101.

Contact Person: Angela Y. Ng, Ph.D., MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301–435–1715, *ngan@mail.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: June 24–25, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71, East Wacker Dr., Chicago, IL 60601.

Contact Person: Katherine Colona Morasch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, *moraschkc@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: June 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel; Academic-Industrial Partnerships for Translation of Medical Technologies.