documenting which adverse events are anticipated in the population under study and would not likely be reported as a single occurrence, but instead would be evaluated by assessing whether there are differences in the rate of occurrence of such events between those receiving the intervention and the concurrent or historical control.

This public workshop is being held in response to public comments received to Docket No. FDA–2015–D–4562 for the draft guidance entitled ''Safety Assessment for IND Safety Reporting'' issued in December 2015 requesting a public meeting to discuss the draft guidance recommendations and their implications, including the new recommendations regarding the formation of a safety assessment committee and the submission of a portion of the safety surveillance plan to the IND before initiating phase 2 or 3 studies. The public workshop is intended to engage external stakeholders in discussions related to finalizing the draft guidance entitled ''Safety Assessment for IND Safety Reporting.''

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will address a range of issues related to the draft guidance ''Safety Assessment for IND Safety Reporting'', issued in December 2015. Items for discussion will include topics raised in public comments submitted to the draft guidance docket, including but not limited to: The entity that conducts aggregate analysis of safety data for IND safety reporting, concerns with unblinding of data and trial integrity, methods for determining the threshold for reporting, and developing and documenting a plan for safety surveillance. Furthermore, input will be sought on other factors that drive over-reporting of safety events that do not meet the definition of a suspected unexpected serious adverse reaction.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: *https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting* and register online by January 8, 2018, midnight Eastern Time. There will be no onsite registration. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by January 8, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Duke-Margolis will post on its Web site if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy, 202–791–9561, *sarah.supsiri@duke.edu,* no later than January 4, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast; archived video footage will be available at the Duke-Margolis Web site (*https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting*) following the workshop. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, we recommend that you review these technical system requirements in advance.

Transcripts: Please be advised that transcripts will not be available.

FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and publicly available at the Duke-Margolis Web site: *https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting.*

Dated: November 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25454 Filed 11–24–17; 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: Rural Health Care Services Outreach Program Performance Improvement and Measurement Systems (PIMS) Measures, OMB No. 0906–0009—Revision

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 January 26, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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: Rural Health Care Services Outreach Program Performance Improvement and Measurement Systems (PIMS) Measures OMB No. 0906–0009 Revision.

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 as follows: (1) Expand the delivery of

health care services 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: The PIMS measures for the Outreach Program enable HRSA and the Federal Office of Rural Health Policy to capture awardee-level and aggregate data that illustrate the impact and scope of federal funding. The collection of this information helps further inform and substantiate the focus and objectives of the grant program. The measures encompass the following topics: (a) Access to care; (b) population demographics; (c) consortium/network; (d) sustainability; and (f) project specific domains.

There are proposed revisions to the currently approved Outreach Program PIMS measures. The proposed Outreach PIMS measures reflect a reduced number of measures including the following: 16 process measures applicable to all awardees (previously 22), consolidation of the project-specific measures (currently 7, previously 8), and 8 clinical measures (previously 9). In addition, the proposed measures include the addition of two Centers for Disease Control and Prevention (CDC) calculators: The CDC Heart Age calculator and the CDC BMI Percentile Calculator for Child and Teen. Data for both calculators will be collected on an aggregate level and only from awardees with applicable projects; the CDC Heart Age calculator is specific to awardees participating in the Health Improvement Special Project while the CDC BMI calculator is for projects focusing on childhood obesity.

Likely Respondents: The respondents are award recipients of the Rural Health Care Services Outreach 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
Name of instrument	25	1	25	3.0	75.0
Total	25		25		75.0

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–25508 Filed 11–24–17; 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: Rural Health Network Development Program, OMB No. 0906–0010—Revision

AGENCY: Health Resources and Services Administration (HRSA), Derpartment 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 Information Collection Request must be received no later than January 26, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Rural Health Network Development Program OMB No. 0906–0010—Revision.

Abstract: The purpose of the Rural Health Network Development (RHND) program is to support mature, integrated rural health care networks that have combined the functions of the entities participating in the network in order to address the health care needs of the targeted rural community. Awarded programs combine the functions of the entities participating in the network to create innovative solutions to local healthcare needs while addressing the following statutory charges: (i) Achieve efficiencies; (ii) expand access, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole.