Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 15, 2015, from 8:30 a.m. to 2:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

For those unable to attend in person, the meeting will also be webcast and will be available at the following link *https://collaboration.fda.gov/cbervrbpac0915/.*

Contact Person: Sujata Vijh or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, 240–402–7107 or 240–402–8158, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 15, 2015, from 8:30 a.m. to 2:30 p.m., the committee will meet in open session to discuss and make recommendations on the safety and immunogenicity of Seasonal Trivalent Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59 (FLUAD) manufactured by Novartis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 8, 2015. Oral presentations from the public will be scheduled between approximately 12:15 p.m. to 1:15 p.m. on September 15, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 31, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 1, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sujata Vijh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17559 Filed 7–16–15; 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

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 September 15, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, 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: Bureau of Health Workforce (BHW) Uniform Data System (UDS).

OMB No. 0915–XXXX—NEW.

Abstract: The UDS is the Bureau of Primary Health Care's (BPHC's) annual reporting system for HRSA-supported health centers. The UDS is a program performance reporting system that tracks a variety of information, including patient demographics, services provided, staffing, clinical indicators, utilization rates, costs, and revenues. BHW proposes that HRSA Nurse Managed Health Clinic (NMHC) grantees and Interprofessional Collaborative Practice (IPCP) program cooperative agreement awardees also submit data into the UDS.

This request is to expand the UDS data reporting resource to the BHW NMHC grantees and IPCP program cooperative agreement awardees. Calendar year data would be submitted annually to enable BHW to track clinical practice and patient outcome data. The data collection is limited to NMHC and IPCP grantees and cooperative agreement awardees because of the similarities these care models share with health centers; therefore, the use of the pre-existing infrastructure will enable HRSA to populate the data set with additional sources, making the resource more robust.

Need and Proposed Use of the Information: HRSA collects UDS data which are used to ensure compliance with legislative and regulatory requirements, improve grantee and cooperative agreement awardee performance and operations, and report overall program accomplishments. BHW proposes to collect core data elements that include patient demographics, healthcare services, clinical indicators and outcomes, provider utilization, and costs. BHW will use the patient and provider-level data to determine the impact of healthcare services on patient outcomes. The data will also enable BHW to establish or expand targeted programs and identify effective services and interventions to improve the health of underserved communities and vulnerable populations. In addition, the UDS data are useful to BHW grantees and cooperative agreement awardees for performance and operations improvement, patient forecasts, identification of trends/patterns, implication of access barriers, and cost analysis to support long-term sustainability.

Likely Respondents: The respondents will be HRSA BHW Nurse Managed Health Clinic (NMHC) grantees and Interprofessional Collaborative Practice (IPCP) program cooperative agreement awardees.

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 hours: Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Universal Report	81	1	81	170	13,770
Grant Report	81	1	81	22	1,782
Total	162				15,552

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,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–17552 Filed 7–16–15; 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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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 August 17, 2015.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Access to Emergency Devices Grant Program OMB No. 0915–xxxx—NEW.

Abstract: This program is authorized by the Public Health Improvement Act Title IV—Cardiac Arrest Survival Act of 2000, Subtitle B—Rural Access to Emergency Devices, Section 413, (42 U.S.C. 254c (Note) and the Consolidated and Further Continuing Appropriations Act (Pub. L. 113–235). The purpose of this grant program is to: (1) Purchase automated external defibrillators (AEDs) that have been approved, or cleared for marketing, by the Food and Drug Administration; (2) provide defibrillator and basic life support training in AED usage through the American Heart Association, the American Red Cross, or other nationally recognized training courses; and (3) place the AEDs in rural communities with local organizations.

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 (GPRA) of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) The number of counties served by the program; (b) the number of AEDs purchased and placed and the