before the committee. Written submissions may be made to the contact person on or before September 4, 2015. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. on September 24, 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 24, 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 August 28, 2015.

FDA is opening a docket for public comment on this document. The docket will close on October 24, 2015. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Comments received on or before August 31, 2015, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Ann Marie Williams, at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 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 17, 2015.*

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–17985 Filed 7–21–15; 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, Department of Health and Human Services.

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 August 21, 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) 594–4306.

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

Information Collection Request Title: Providing Primary Care and Preventive Medical Services in Ryan White-funded Medical Care Settings: OMB No. 0915–XXXX—New.

Abstract: Since Congress passed the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act in 1990, the Ryan White HIV/AIDS Program (Ryan White Program) has funded the provision of care eligible to persons living with HIV (PLWH). Many Ryan White-funded clinics have long promoted the medical home model, which involves the provision of comprehensive and coordinated care services, including prevention and other non-medical care services to promote access and adherence to HIV/AIDS treatment. As PLWH live longer and normal lives with effective antiretroviral treatment, this model has become more complex. In recent years, clinics providing care to PLWH are also seeing their patients develop other common chronic diseases such as diabetes, heart disease, and hypertension associated with normal and aging populations. Guidelines [1] on primary care for PLWH have recently been released to help providers navigate the integration of primary and preventative care into HIV care. With already limited budgets, staffing and other resources, Ryan White-funded clinics may struggle to provide primary and preventative care services in-house or have insufficient referral systems. However, under the Affordable Care Act (ACA), most PLWH can obtain more affordable health insurance which can alleviate some burden on clinics and improve accessibility to primary and preventative care services.

This study will examine how Ryan White-funded clinics are integrating the provision of primary and preventative care services to the overall HIV care model. Specifically, it will look at the protocols and strategies used by clinics to manage care for PLWH, specifically care coordination, referral systems, and patient-centered strategies to keep PLWH in care.

[1] JA Aberg, JE Gallant, KG Ghanem, P Emmanuel, BS Zingman and MA Horberg. *Primary Care Guidelines for the Management of Persons Infected with HIV: 2013 Update by the HIV Medicine Association of the Infectious Disease Society of America;* CID 201_58 (January 1, 2014).

New York State Department of Health AIDS Institute, Office of the Medical Director. *Primary Care Approach to the HIV-Infected Patient; http://www.hivguidelines.org/clinical-guidelines/adults/primary-care-approach-to-the-hiv-infected-patient/* (Updated November 2014).

Need and Proposed Use of the Information: The proposed study will provide HRSA HIV/AIDS Bureau (HAB) and policymakers with a better understanding of how the RWHAP currently provides primary and preventative care to PLWH. The first online survey will be targeted to clinic directors from a sample of about 160 Ryan White-funded clinics and will collect data on care models used; primary care services, including preventive services; and coordination of care. Data collected from this survey will provide a general overview of the various HIV care models used as well as insight to possible facilitators and barriers to providing primary and preventative care services. More in-depth data collection will be conducted with a smaller number of 30 clinics representing clinic type (publicly funded community health organization, other community-based organization, health department, and hospital or university-based) and size. There will be three data collection instruments used: (1) An online survey completed by three clinicians at each of the clinics (clinician survey); (2) a data extraction of select primary and preventative care services; and (3) a telephone interview with the medical director. The clinician survey will provide a more in-depth look at the clinic protocols and strategies and how they are being used and implemented by the clinicians. The data extraction will provide quantitative information on the provision of select primary and preventative care services within a certain time period. With these data, the study team can assess the accuracy of information provided in the online surveys on the provision of care as well as the frequency at which primary and preventative care screenings are provided. Lastly, the interviews with the medical director will allow the study team to follow-up on the results of the clinician survey and data extraction and collect qualitative data and more in-depth details on the provision of primary and preventative care services from a clinic wide perspective, specifically any facilitators and barriers.

These data will provide HAB the background to make informed policies and changes to the Ryan White Program in this new era when the well-being of PLWH demands a more complex and long-term HIV care model.

Likely Respondents: Clinics funded by the Ryan White HIV/AIDS 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 Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses	Total responses	Average burden per response	Total burden hours
Clinic Director	130	1	130	1	130
Clinician	30	1	30	1	30
Data Extraction	30	1	30	3	90
Medical Director	30	1	30	1	30
Total	220				280

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. 2015–17883 Filed 7–21–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 37639–37640 dated July 1, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (RV). Specifically, this notice: (1) Establishes the Office of HIV/AIDS Training and Capacity Development (RVT); (2) transfers the Division of HIV/AIDS Training and Capacity Development (RV7) function to the newly established Office of HIV/AIDS Training and Capacity Development (RVT); (3) abolishes the Division of HIV/AIDS Training and Capacity Development (RV7); (4) establishes the Division of Domestic Programs (RVT1), and; (5) establishes the Division of Global Programs (RVT2).

Chapter RV—HIV/AIDS Bureau

Section RV–10, Organization

Delete the organization for the HIV/AIDS Bureau (RV) in its entirety and replace with the following:

The HIVAIDS Bureau (RV) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The HIV/AIDS Bureau includes the following components:

(1) Office of the Associate Administrator (RV);

(2) Office of Operations and Management (RV2);

(3) Division of Policy and Data (RVA);

(4) Division of Metropolitan HIV/AIDS Programs (RV5);