FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour (52 × 900), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09769 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of Medical Products and Tobacco; Center for Drug Evaluation and Research; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 15, 2016, and effective on April 17, 2016.

FOR FURTHER INFORMATION CONTACT: Melanie Keller, Office of Management, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–3291.

I. Summary

This organization will expand current activities in the Office of Medical Policy and foster efficient oversight of clinical trials conducted through policy initiatives that build quality upfront and science-based inspectional approaches. This will provide an oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to improve science and efficiency trials.

The Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has been restructured as follows:

DKKNF. ORGANIZATION. The Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following organizational units:

Office of Medical Policy
Office of Prescription Drug Promotion
Division of Advertising and Promotion Review I
Division of Advertising and Promotion Review II

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guides (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: April 19, 2016.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2016–09761 Filed 4–26–16; 8:45 am]

BILLING CODE 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 June 27, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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: Building Futures: Supporting Youth Living with HIV OMB No. 0915–xxxx New.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), administered by the HRSA HIV/AIDS Bureau (HRSA/HAB), provides HIV-related services in the United States for people living with HIV (PLWH) who do not have sufficient health care coverage or financial resources to pay for HIV-related services. Fourteen percent of the approximately 512,000 RWHAP clients in 2014 were young adults between the ages of 13 and 30.[1] HRSA/HAB has awarded a contract, *Building Futures: Supporting Youth Living with HIV,* to identify and document best-practices and challenges associated with providing HIV care to youth living with HIV. Information learned from high performing and low performing sites serving young people living with HIV (aged 13–24 years) will help identify effective strategies and barriers for helping this population reach viral suppression. The high performing and low performing sites will be chosen from RWHAP-funded providers based on health outcome data from the 2014 Ryan White HIV/AIDS Services Report. Information gathered at these visits will help inform technical assistance (TA) conducted at low performing sites, as well as additional TA products to be made available to other RWHAP providers to improve health outcomes for young people living with HIV.

Need and Proposed Use of the Information: Youth (defined for the purposes of this project as age 13 through 24) in the United States are disproportionately impacted by HIV. In 2014, 9,731 (22 percent) of the 44,073 new HIV diagnoses in the U.S. were among youth between the ages of 13 and 24, with a large majority (81 percent) of these youth diagnoses among older youth aged 20–24.[2] Young people living with HIV also experience disparities in outcomes along the HIV care continuum.[3] Among RWHAP clients in 2014, older youth aged 20–24 had the lowest rates of retention in care and both 15–19 year olds and 20–24 year olds had notably lower rates of viral load suppression as compared to other age groups. Additionally, certain subpopulations such as young men who have sex with men (MSM) of color, lesbian, gay, bisexual, transgender and questioning youth (LGBTQ), and young women of color bear a disproportionate share of the disease burden and have poorer outcomes in the areas of retention in care and viral suppression.[4][5]

The *Building Futures: Supporting Youth Living with HIV* project aims to strengthen RWHAP engagement with young people aged 13–24 living with HIV to improve their health outcomes. Through this project, HRSA/HAB will systematically document strategies used by providers funded by the RWHAP to achieve high rates of youth retention in care and viral suppression. HRSA/HAB will also learn about gaps and challenges from providers that have demonstrated poorer outcomes in these areas.

Specialized Site Visits will be conducted with 10 high performing providers to identify, understand, and document replicable evidence-based best practices and models of care. Interviews will be conducted with program support and clinical staff, in addition to HIV-positive youth patients. HIV-positive youth leaders will be engaged as consultants to the site visit team to pretest instruments, review site visit conclusions with the project team, and offer a perspective of young people living with HIV on the data gathered from the high-performing sites and implementation of changes to improve performance of lower performing sites.

Performance Improvement Site Visits will be conducted with 16 lower performing providers to better understand the gaps and challenges to providing RWHAP care to youth, share best practices and lessons learned from high performing providers, and provide action-oriented TA to overcome barriers and optimize health outcomes. Youth consultants will co-lead a panel/advisory board of young people living with HIV and a planning session to better understand technical assistance implementation issues.

Sampled providers will be selected based on viral load and retention in care rates and the diversity of client populations, as identified in 2014 Ryan White HIV/AIDS Services Report data.

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 per respondent	Total responses	Average burden per response (hours)	Total burden hours
Online Questionnaire	26	1	26	0.5	13
Onsite Observational Tool	26	1	26	0.5	13
Program Manager and Clinical Director Interview Guide (High) *	20	1	20	1.5	30
Program Manager and Clinical Director Interview Guide (Low) **	32	1	32	1.5	48

[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2014. *http://hab.hrsa.gov/data/servicesdelivered/2014RWHAPDataReport.pdf.* Published December 2015. Accessed 1/29/2016.

[2] Centers for Disease Control and Prevention, "Diagnoses of HIV Infection in the United States and Dependent Areas, 2014," HIV Surveillance Supplemental Report; Vol 26, November 2015, *http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf.*

[3] "HIV/AIDS Care Continuum," accessed January 26, 2016, *https://www.aids.gov/federal-resources/policies/care-continuum/.*

[4] Centers for Disease Control and Prevention, "HIV Among Youth," *HIV Among Youth,* June 30, 2015, *http://www.cdc.gov/hiv/group/age/youth/index.html.*

[5] "Youth and Young Adults in the Ryan White HIV/AIDS Program," September 2015, *http://hab.hrsa.gov/data/reports/youthdatareport2015.pdf.*

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Program and Administrative Staff Interview Guide (High) *	50	1	50	1	50
Program and Administrative Staff Interview Guide (Low) **	80	1	80	1	80
Youth Focus Group	156	1	156	1	156
Youth Interview	26	1	26	0.5	13
Panel/advisory board of young people living with HIV (Low) **	80	1	80	1.5	120
Total	496	....	496	....	523

* High indicates high performing sites.
** Low indicates low performing sites.

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 Executive Secretariat.
[FR Doc. 2016–09772 Filed 4–26–16; 8:45 a.m.]
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 must be received no later than May 27, 2016.

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: HRSA AIDS Education and Training Centers Evaluation Activities

(OMB No. 0915–0281)—Revision

Abstract: The AIDS Education and Training Centers (AETC) Program, under the Title XXVI of the Public Health Service Act, as amended, supports a network of regional and national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

Need and Proposed Use of the Information: As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects information on AETC training events, and is required to report aggregate data on their activities to HRSA. The data provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by AETC trainees, and the increase in capacity achieved through training events. Collection of this information allows HRSA to provide information on training activities and types of education and training provided to Ryan White HIV/AIDS Program recipients, resource allocation, and capacity expansion.

Likely Respondents: Trainees are asked to complete the Participant Information Form once a year and trainers are asked to complete an Event Record for each training event they conduct during the year. In addition, each regional AETC (8 total) will compile these data into a data set and submit to HRSA once a year.

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.