www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kelly Richards, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5378, Silver Spring, MD 20993–0002, 240–402–4276.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment.'' The draft guidance was prepared by the Division of Gastroenterology in the Center for Drug Evaluation and Research at FDA.

The purpose of the draft guidance is to help sponsors in the clinical development of drugs to treat pediatric patients with inflammatory bowel disease. Specifically, the draft guidance provides FDA's recommendations about the necessary attributes of clinical studies for drugs being developed for the treatment of pediatric ulcerative colitis or pediatric Crohn's disease, including study population, study design, efficacy considerations, and safety assessments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314.50(d)(5) have been approved under OMB control number 0910–0001. The collections in 21 CFR 601.2 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 pertaining to the content and format of labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 pertaining to the protection of human subjects in clinical trials and institutional review board considerations have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15942 Filed 7–18–24; 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: HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities, OMB No. 0915–XXX New

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 should be received no later than September 17, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

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

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities, OMB No. 0906–xxxx—New.

Abstract: The Ryan White HIV/AIDS Program's (RWHAP) AIDS Education and Training Center (AETC) Program, authorized under Title XXVI of the Public Health Service Act, supports a network of regional centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating people with HIV. The RWHAP Regional AETC Program's purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage people with HIV. The RWHAP Regional AETC Program recipients are required to report data on the training activities and trainees to HRSA once a year. HRSA is requesting the approval of new AETC data collection forms to accurately capture data relating to Regional AETC activities, participants, and site information for both Practice Transformation (PT) and Interprofessional Education (IPE) sites as well as involvement in the HIV care and treatment workforce (1-year post-participation), knowledge gained through participating in an activity, and

satisfaction with the activity. The RWHAP Regional AETC Program recipients will gather data on the training activities they conduct using six data collection instruments. The Individual Participant Record is completed at least once every reporting period by participants actively engaging in Regional AETC activities. This form includes Regional AETC participant demographic, workplace, and client-served data for the participant's respective provider sites. The Training Activity Record is a form completed at the end of each Regional AETC activity that takes place during the reporting period and is completed by the regional recipients. This form describes the activity in hours, modality, and topic(s). The PT Site Characteristics/Outcomes form collects site characteristics information for PT recipient sites only, like clinic activities and procedures, and aggregate counts of clients. PT sites provide clinical services and differ from IPE sites that support students, thus necessitating a different form. The IPE Site Characteristics/Outcomes form collects site characteristics information for IPE recipient sites only. The Participant Post-Activity Immediate Survey collects information from participants immediately after an activity, specifically, their satisfaction and potential increased knowledge due to participating in said activity. The IPE Long-Term form collects 1-year post-participation information from participant students who engaged in an IPE program to gauge involvement in the field of HIV care and treatment.

Need and Proposed Use of the Information: HRSA uses the data collected when conducting RWHAP AETC programmatic assessments to determine future program needs. These data allow HRSA to identify where gaps exist in training HIV professionals as well as to measure whether training activities are meeting the goals of the National HIV/AIDS Strategy and the RWHAP statute.

Likely Respondents: RWHAP Regional AETC participants complete the Individual Participant Record at least once a reporting period. Regional AETC recipients complete a Training Activity Record for each training activity they conduct during the reporting period. All Regional AETC participants will take the Participant Post-Activity Survey immediately after any attended activity. The IPE Long-Term form will only be completed by participants who engaged in an IPE program, 1-year post-participation in the IPE program. Finally, PT recipients will complete the PT Site Characteristics/Outcomes form at least once per reporting period, and IPE recipients will complete the IPE Site Characteristics/Outcomes form at least once per reporting period.

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
Individual Participant Record	59,576	1	59,576	0.27	16,085.52
Training Activity Record	12,226	1	12,226	0.21	2,567.46
PT, Site Characteristics and Outcomes	128	1	128	0.31	39.68
IPE, Site Characteristics and Outcomes	86	1	86	0.09	7.74
Participant Post-Activity Immediate Survey	59,576	3	178,728	0.06	10,723.68
IPE, Long-Term	4,403	1	4,403	0.07	308.21
Combined Data Set	8	1	8	64	512.00
Total	136,003	.....	255,155	.....	30,244.29

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–15957 Filed 7–18–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will convene the 82nd full council meeting on Wednesday, August 28–Thursday, August 29, 2024. The meeting will include panels on the U.S. government's global HIV response; the science and impact of ''Undetectable = Untransmittable'', or U = U; Affordable Care Act risk adjustment model to expand access and uptake of PrEP. It will be open to the public and there will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Wednesday, August 21, 2024. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Thursday, September 5, 2024. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://*