

for states, it is not updated for this 2024 iteration as states have access to the metrics in the submission portal. The data specifications document is updated to reflect the changes made in this 2024 iteration of the Eligibility Processing Data Report.

States submit the application processing data in the Eligibility Processing Data Report until states complete working on pending applications received before unwinding began and report to CMS that zero applications remain pending. When the Eligibility Processing Data Report was first launched, states previously submitted a one-time baseline report prior to submitting the monthly reports and could make corrections to this report as needed. The baseline report form has remained available in the submission portal. CMS is not extending the use of the baseline report in this 2024 iteration since it was intended to be a one-time submission. The baseline report form will also be removed from the submission portal in late summer/early fall 2024.

Additionally, states submitted to CMS a one-time State Report on Plans for Prioritizing and Distributing Renewals Following the End of the Medicaid Continuous Enrollment Provisions (“State Renewals Report”) that was used to assess state’s plans for processing renewals and mitigating against inappropriate beneficiary coverage losses when states begin restoring routine Medicaid and CHIP operations after the public health emergency. CMS is not extending the use of this report in this 2024 iteration.

*Form Number:* CMS–10434 #66 (OMB control number: 0938–1188); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,344; *Total Annual Hours:* 18,816. (For policy questions regarding this collection contact: Shannon Lovejoy at (410) 786–1718.)

**William N. Parham III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–D–2682]

**Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment.”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 to help sponsors in the clinical development of drugs to treat pediatric patients with inflammatory bowel disease. 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.

**DATES:** Submit either electronic or written comments on the draft guidance by September 17, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2024–D–2682 for “Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: [https://](https://www.regulations.gov)

[www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf](http://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.*

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**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](mailto: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](mailto: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