

generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information.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 314 relating to the submission of drug master files, new drug applications, and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 relating to the submissions of biologics licensed applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 514 relating to the submission of veterinary drug master files have been approved under OMB control number 0910–0032. The collections of information in 21 CFR part 511 relating to the submission of new animal drugs for investigational use have been approved under OMB control number 0910–0117. The collections of information in 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) relating to the submission of an Abbreviated New Animal Drug Application have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 820 relating to device master files have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 relating to IDE submissions are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, relating to 510(k) submissions are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, relating to premarket approval, are approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 860, subpart D, relating to De Novo requests are approved under OMB control number 0910–0844.

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Persons with access to the internet may obtain the draft guidance at 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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents), or <https://www.regulations.gov>.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Revision

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 January 26, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 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 Samantha Miller, 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: Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Revision.

Abstract: The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program (CBDPP) under Part F of the Ryan White

HIV/AIDS Program (RWHAP) offer funding to accredited dental education programs to support the education and training of oral health providers in HIV oral health care and reimbursement for the provision of oral health services for people eligible for the RWHAP. Institutions eligible for the RWHAP DRP and CBDPP are accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency. The RWHAP DRP Application for the Notice of Funding Opportunity includes the Dental Services Report (DSR) that applicants use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV and to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff–111(b)). The DSR is also used by CBDPP recipients to report on services rendered, patients served, and partnerships as an annual requirement. The DSR collects data on program information, client demographics, oral health services, funding, and training. It also requests applicants/recipients to provide a narrative description of the services offered, the types of facilities available, and their linkage and collaboration with community-based oral health service providers.

Beginning with the 2022 DSR submission, the DSR website provided RWHAP DRP applicants and RWHAP CBDPP recipients an easily accessible and secure location to enter and submit their aggregate DSR data annually. All RWHAP DRP applicants and RWHAP CBDPP recipients will be authorized users of a web-based platform that allows users to easily navigate the site and enter their data. Users can see their report submission status and no longer need to email their dataset to HRSA. The implementation of the DSR website contributed to the overall decrease in burden hours. HRSA proposes minor modifications to the DSR data reporting tool:

- Remove the question regarding gender to align with Administration priorities.
- Add an “Unknown” response option for the “Sex at Birth” variable.
- Remove “People and Communities Disproportionately Impacted by HIV” from section 4.

Need and Proposed Use of the Information: The primary purpose of

collecting this information annually is to verify applicant eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of CBDDP grant recipients. This information allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating persons with HIV, (2) the number and characteristics of clients who receive RWHAP supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to persons with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, community groups, and the public, information collected in

the DSR is critical for HRSA and recipients to assess the status of existing HIV-related health service delivery systems. The information will provide the measurement data for the HRSA budget justifications on the following indicators: number of persons for whom a portion/percentage of their unreimbursed oral health costs were reimbursed and the number of providers trained through the RWHAP Part F Dental Reimbursement and Community-Based Partnership Programs.

Likely Respondents: Accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in

general dentistry, or a general dental practice residency.

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 use 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	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Dental Services Report	DRP Applicants	56	1	56	32.0	1,792
	CBDPP Recipients	12	1	12	1.5	18
Total	68	68	1,810

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Catastrophic Health Emergency Fund (CHEF) Threshold

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the Catastrophic Health Emergency Fund

(CHEF) threshold established at \$19,095 for Fiscal Year 2025 CHEF requests.

SUPPLEMENTARY INFORMATION: The Indian Health Service (IHS) administers the CHEF pursuant to section 202 of the Indian Health Care Improvement Act (IHCA). The purpose of the CHEF is to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses who are within the responsibility of the Service. The CHEF was established by section 202 of the IHCA, Public Law 94-437 (25 U.S.C. 1621a). The Patient Protection and Affordable Care Act, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (collectively, the Affordable Care Act or "the ACA"), reauthorized the IHCA and amended the CHEF, directing the Secretary to promulgate regulations governing the administration of the CHEF. The final CHEF regulation (2024-19421 (89 FR 70527)) was published on August 30, 2024, in the **Federal Register**, establishing the threshold cost of \$19,000 for Fiscal Year (FY) 2024. See 42 CFR 136.503(a). The threshold amount in subsequent years is calculated from the threshold amount of the previous year, and increased by the

percentage increase in the medical care expenditure category of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with December of the previous year. See 42 CFR 136.503(b). The Consumer Price Index is released monthly. For FY 2025, "December of the previous year" is December 2023, because December 2024 is part of FY 2025. The "12-month period ending with December of the previous year" is therefore December 2022 to December 2023. The medical care expenditure category for this 12-month period was 0.5%, thereby increasing the threshold to \$19,095 for FY 2025 CHEF requests.

Dated: October 30, 2025.

P. Benjamin Smith,
Acting Director, Indian Health Service.

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