

report on the existence of a system to collect all information needed to determine and redetermine eligibility for Medicaid and CHIP. The State Medicaid/CHIP agency will attest to using the PARIS system in determining eligibility in Medicaid or CHIP benefit programs. *Form Number:* CMS–R–74 (OMB control number: 0938–0467); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 55; *Total Annual Responses:* 3,241; *Total Annual Hours:* 1,082. (For policy questions regarding this collection contact: Abby Kahn at 410–786–4321.)

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

Administration for Children and Families
 [OMB #: 0970–0145]

Submission for Office of Management and Budget Review; Temporary Assistance for Needy Families (TANF) Program State Plan Guidance

AGENCY: Office of Family Assistance, Administration for Children and

Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Program State Plan Guidance (TANF Program State Plan; Office of Management and Budget #0970–0145, expiration October 31, 2025). There are no changes requested to this information collection.

DATES: *Comments due December 26, 2025.*

ADDRESSES: The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0970-008. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: The TANF Program State Plan is a mandatory statement submitted to the Secretary of the U.S. Department of Health and Human Services by the state. 42 U.S.C. 602. It consists of an outline specifying how the state’s TANF program will be administered and operated and contains certain required certifications by the state’s Chief Executive Officer. 42 U.S.C.

602(a). It is used to provide the public with information about the program. 42 U.S.C. 602(c). Authority to require states to submit a State TANF Plan is contained in section 402 of the Social Security Act (42 U.S.C. 602), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, 110 Stat. 2105. States are required to submit new plans within a 27-month period. 42 U.S.C. 602(a).

Respondents: The 50 states of the U.S., the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.

Annual Burden Estimates

The state TANF plan requirements for the 54 states (which includes three territories and the District of Columbia) will create a triennial burden with an average of 18 states responding annually. We estimate the annual burden to be an average of 30 hours per response. We also estimate that the triennial burden of plan amendments for the 54 states, with an average of 18 respondents annually spending approximately 3 hours per response.

Instrument	Total number of respondents per year	Total number of annual responses per respondent	Average burden hours per response	Annual burden hours
Title Amendments	18	1	3	54
State TANF plan	18	1	30	540
Estimated Total Annual Burden Hours				594

Authority: 42 U.S.C. 602.

Mary C. Jones,
 ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA–2025–D–5715]

Cross-Center Master Files: Where To Submit; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “Cross-Center Master Files: Where to Submit.” The draft guidance provides recommendations to industry, specifically master file holders, regarding where (*i.e.*, to which FDA center) to submit a master file that is referenced in and intended to support more than one regulatory submission for which the lead center for those submissions may vary or where the information in the master file may need to be accessed and reviewed by more than one center to support review of the referencing submission(s). The

recommendations apply to master files submitted to the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and certain types of master files submitted to the Center for Veterinary Medicine (CVM).

DATES: Submit either electronic or written comments on the draft guidance by February 24, 2026 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-2025-D-5715 for "Cross-Center Master Files: Where to Submit." 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://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 the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, 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: Stephanie Shapley, Office of Combination Products/Office of the Chief Medical Officer, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301-796-4836, stephanie.shapley@fda.hhs.gov or combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Cross-Center Master Files: Where to Submit." The draft guidance provides recommendations to master file holders

regarding where (*i.e.*, to which center) to submit a master file: (1) that is referenced in and intended to support more than one regulatory submission for which the lead center for those submissions may vary, or (2) where the information in the master file may need to be accessed and reviewed by more than one center to support review of the referencing submission(s). When a master file would be accessed by more than one center, it is referred to as a cross-center master file. The recommendations in this draft guidance apply to master files submitted to CBER, CDER, CDRH, and to master files submitted to CVM other than CVM veterinary master file types VI, VII, and VIII and their Public Master Files. The recommendations, once finalized, are for new master file submissions going forward.

Master files are voluntary submissions to FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more FDA-regulated biological products, drugs, devices, or combination products. Master files can contain other types of information as well (*e.g.*, nonclinical evaluations such as toxicology information, shared system risk evaluation and mitigation strategy).

The draft guidance provides background on master files, including examples of scenarios in which staff from more than one center might access and review the master file; recommendations for determining the hosting center for a master file for combination products and for non-combination products; and hypothetical examples to illustrate the recommendations for determining the hosting center. These recommendations are intended to help master file holders to determine which center to submit their master file. In turn, this may help master file holders identify any center-specific master file submission recommendations applicable to their situation.

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 "Cross-Center Master Files: Where to Submit." 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may

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