orphan@fda.hhs.gov; or by mailing the required information to the OOPD at the address found on our website. New users of the CDER NextGen Portal must register for an account. For designation requests submitted by email, the Agency recommends using automated read receipt to verify receipt of the email.

Sponsors and others who plan to email information to FDA that is private, sensitive, proprietary, or commercial confidential are strongly encouraged to send it from an FDA-secured email address so the transmission is encrypted. The Agency will assume the addresses of emails received or email addresses provided as a point of contact are secure when responding to those email addresses. Sponsors and others can establish a secure email address link to FDA by sending a request to *SecureEmail@fda.hhs.gov.* There may be a fee to a commercial enterprise for establishing a digital certificate before encrypted emails can be sent to FDA.

Respondents to the information collection are sponsors who develop investigational drugs and biologicals for commercial use and who seek orphan drug designation, and upon approval or licensure, orphan drug exclusivity.

In the **Federal Register** of June 13, 2023 (88 FR 38513), we published a 60-day notice soliciting comment on the proposed collection of information. Although we received one comment, it was not responsive to the information collection topics solicited and therefore is not addressed in this notice.

We estimate the burden of this collection of information as follows based on data from 2022:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part or section; activity	Number of respondents	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Part 316 associated records	780	1.25	975	135	131,625
§§ 316.20, 316.21, 316.26 (Form FDA 4035)	780	1.25	975	32	31,200
§ 316.22; Notifications of changes in agents	300	1	300	0.5	150
§ 316.24(a); Deficiency letters and granting orphan-drug designation	20	1	20	2	40
§ 316.27; Submissions to change ownership of orphan-drug designation	90	1	90	3	270
§ 316.30; Annual reports	2,039	1	2,039	3	6,117
§ 316.36; Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug	1	3	3	15	45
Guidance Recommendations: Meeting requests to OOPD and related submission packages	807	1.5	1,211	4	4,842
Total			5,613		174,289

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our burden estimate includes those activities related to: (1) requesting orphan drug designation; (2) responding to deficiencies letters with submissions of amendments; (3) keeping files current with contact information for agents and transfer of ownership, when applicable; (4) submitting annual reports while products have designation status; and (5) requesting and preparing for both informal and formal meetings. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government, we account for these activities cumulatively in table 1 above. Upon a recent evaluation of the information collection, we adjusted our burden estimate to reflect an overall increase of 50,616 hours and an increase of 766 records annually. We attribute this adjustment to an increase in the number of submissions, amendments, and annual reports.

Dated: November 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26544 Filed 12–1–23; 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: DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–0061

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 February 2, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N39, 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 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: DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–0061—Revision.

Abstract: The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271), section 6083, amended the Social Security Act (subsections 1834(o)(3) and 1833(bb)),

authorizing the HHS Secretary to pay Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) for the average cost of training for purposes of receiving a DATA 2000 waiver for their physicians and practitioners to furnish opioid use disorder treatment services. The SUPPORT Act made $6 million available to FQHCs and $2 million available to RHCs under the DATA 2000 Waiver Training Payment Program. To receive payment, FQHCs and RHCs must submit an application in the manner specified by the Secretary. Authority to administer the DATA 2000 program has been delegated to HRSA. Further information about the program can be found in the link below which provides guidance on the requirements of the DATA 2000 program and how qualified FQHCs and RHCs can apply to the program: *https://help.hrsa.gov/display/public/EHBSKBFG/DATA+2000+Waiver+Training+Payment+Program+FAQs.*

This purpose of this revision is to update the burden estimate for the RHC application process because the funding appropriated for FQHC DATA 2000 payments has been fully expended. Therefore, no new applications for FQHC DATA 2000 payments can be accepted or approved. Only Medicare participating RHCs can apply for payments through the DATA 2000 program, and pursuant to the authorizing statute and subsequent legislation eliminating the DATA 2000 waiver requirement, such RHCs may only receive payments with respect to providers who first received their DATA 2000 Waiver between January 1, 2019, and December 29, 2022.

Applicant entities must provide information identifying the submitting organization and the number of practitioners who have completed training and obtained a DATA 2000 waiver. The form will also require the entity to include information regarding each claimed practitioner's name, practitioner type (*e.g.,* physician, physician assistant, nurse practitioner, certified nurse midwife, clinical nurse specialist, certified registered nurse, or anesthetist), National Provider Identifier number, Drug Enforcement Administration number, state license number, length of training, date the training was completed, date of waiver attainment, and DATA 2000 waiver number. Additionally, the form will require signature of an attestation statement certifying that: (1) each practitioner for which the entity is seeking payment under the application is employed by or working under contract for the applicant health facility; (2) it is the first time the entity is seeking payment on behalf of the listed practitioner(s); (3) the entity is eligible to seek payment under 42 U.S.C. 1395m(o)(3) or 42 U.S.C. 1395l(bb); (4) each practitioner is furnishing opioid use disorder treatment services; and (5) the statements herein are true, complete, and accurate to the best of the applicant's knowledge.

Need and Proposed Use of the Information: The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act requires RHCs to submit to the Secretary an application for payment at such time, in such manner, and containing such information as specified by the Secretary in order to receive a payment under section 6083. This form will allow RHCs to apply for such payments based on the average cost of training to obtain DATA 2000 waivers, as determined by the Secretary, for their physicians and practitioners to furnish opioid use disorder treatment services. The form will also provide HRSA with the requisite data to validate qualifying DATA 2000 waiver possessions for the purpose of ensuring accurate payments to RHCs.

Likely Respondents: Only Medicare participating RHCs are eligible to apply.

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
DATA 2000 Waiver Training Payment Program Application for Payment	300	1	300	0.5	150.0
Total	300	1	300		150.0

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. 2023–26554 Filed 12–1–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Urban Indian Behavioral Health Awareness

Announcement Type: New.

Funding Announcement Number: HHS–2024–IHS–NUIBH–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.