

(4) Facilities that registered but do not have an active OTC monograph drug product listing associated in their registration profile are not manufacturing or processing such drug products.

Each establishment paying the facility fee is counted as one fee-paying unit. The total estimate of fee-paying units is further analyzed to determine the number of respective MDF and CMO fee-paying units.

Based on the data obtained from eDRLS, FDA estimates there will be 1,712 fee-paying units. The Agency estimates that 90 percent ( $1,712 \times .90 = 1,541$ , rounded) will incur the MDF fee and 10 percent ( $1,712 \times .10 = 171$ , rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (1,541) and a value of  $\frac{2}{3}$  to each CMO ( $171 \times \frac{2}{3} = 114$ ) for a full facility equivalent of 1,655 (rounded). The target fee revenue of \$23,269,000 is then divided by 1,655 for an MDF fee of \$14,060 and a CMO fee of \$9,373.

**V. Fee Schedule for FY 2021**

The fee rates for FY 2021 are displayed in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2021

Fee category	FY 2021 fee rates
OMOR:	
Tier 1 .....	\$500,000
Tier 2 .....	100,000
Facility Fees:	
MDF .....	14,060
CMO .....	9,373

**VI. Fee Payment Options and Procedures**

The new fee rates are effective October 1, 2020, through September 30, 2021. To pay the OMOR, MDF, and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: [https://userfees.fda.gov/OA\\_HTML/omufaCAcdLogin.jsp](https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp). A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under \$25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use

*Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> (Note: Only full payments are accepted. No partial payments can be made online). Once an invoice is located, “Pay Now” should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA’s tax identification number is 53–0196965.

Dated: December 22, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–xxxx—New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30 day comment period for this Notice has closed.

**DATES:** Comments on this ICR should be received no later than January 28, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–xxxx—New.

*Abstract:* The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), section 6083, amended the Social Security Act (subsections 1834(o)(3) and 1833(bb)), authorizing the Secretary to pay Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) the average cost of

training to obtain DATA 2000 waivers for their physicians and practitioners to furnish opioid use disorder treatment services. To receive payment, FQHCs and RHCs must submit a formal application.

In order to be eligible for payment, as well as to provide HRSA with information necessary for validation and issuance of accurate payments, the form requires that FQHCs and RHCs provide information identifying the submitting organization and the number of practitioners who have completed training and obtained a DATA 2000 waiver. The form requires the submitting FQHC or RHC to include information regarding each claimed practitioner's name, physician or 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 medical license number, length of training, date the training was completed, date of waiver attainment, and DATA 2000 waiver number. Additionally, the form requires 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 this 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) that the statements

herein are true, complete, and accurate to the best of the applicant's knowledge. FQHCs and RHCs will need a System for Award Management account and a HRSA Electronic Handbooks account in order to apply (visit <https://sam.gov/SAM/> and <https://grants.hrsa.gov/2010/WebEPSEExternal/Interface/UserRegistration/RegistrationHome.aspx?controlName=ContentTabs> for more information on how to create an account).

A 60-day notice published in the **Federal Register** on October 6, 2020, vol. 85, No. 194; pp. 63121–22. There were no public comments.

**Need and Proposed Use of the Information:** The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act requires FQHCs and 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 allows FQHCs and 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. HRSA intends to validate and pay \$3,000 per eligible provider submitted on the form by FQHCs and RHCs. The form also provides HRSA with the requisite data to validate qualifying DATA 2000 waiver possessions for the purpose of ensuring accurate payments to FQHCs and RHCs.

The following changes were made since the publication of the 60 Day

notice. The number of respondents, total respondents, and total burden hours were updated to reflect administrative costs in the agency's spend plan. The figures assume a \$3,000 payment for each DATA 2000 waiver and \$750,000 in administrative costs, thereby leaving \$7,250,000 in funds available for payment to FQHCs and RHCs. Language was added in the "Need and Proposed Use of the Information" section to signal to stakeholders that HRSA intends to validate and pay \$3,000 per eligible provider submitted on the form by FQHCs and RHCs. Additionally, language was added in the "Abstract" section notifying FQHCs and RHCs that they will need a System for Award Management account and a HRSA Electronic Handbooks account in order to apply.

**Likely Respondents:** Only FQHC and RHC 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 .....	2,416	1	2,416	0.5	1,208
Total .....	2,416	.....	2,416	.....	1,208

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.

**Amy P. McNulty,**  
*Deputy Director, Executive Secretariat.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS–0990–New]

**Agency Information Collection Request; 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.