Supporting Statement A

DATA 2000 Waiver Training Payment Program Application for Payment

OMB Control No. 0906-XXXX

New Request

Terms of Clearance: None

A. Justification

1. <u>Circumstances Making the Collection of Information Necessary</u>

The Substance Use - Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L.115-271), section 6083, authorizes the HHS Secretary to pay Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) the average cost of training to obtain DATA 2000 waivers for their physicians and practitioners to furnish opioid use disorder treatment services. Section 6083 further stipulates that, in order to receive a payment, FQHCs and RHCs must submit an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. Consequently, this information collection is necessary to provide up to \$6,000,000 in payments to FQHCs and \$2,000,000 in payments to RHCs, furthering the Administration's efforts to address the opioid public health emergency through expanded access to opioid use disorder treatment services.

2. Purpose and Use of Information Collection

This form allows FQHCs and RHCs to apply for payments based on the average cost of training to obtain DATA 2000 waivers for their physicians and practitioners to furnish opioid use disorder treatment services. 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.

3. Use of Improved Information Technology and Burden Reduction

This information collection activity is web-based; the form and any relevant instructions or guidance will be posted on the HRSA website: https://www.hrsa.gov/. The web portal for submission will be minimally burdensome and automated, such that applicants will not be responsible for submission of any supplemental information or paper records for validation or any other purposes.

4. Efforts to Identify Duplication and Use of Similar Information

The information collected is specific to the applicant and unique to this program. No other single source of this information is known to exist for completion of the form.

5. Impact on Small Businesses or Other Small Entities

The information collection will not have a significant impact on small entities.

6. <u>Consequences of Collecting the Information Less Frequently</u>

Section 6083 of the SUPPORT for Patients and Communities Act stipulates that, in order to receive a payment under the section, FQHCs and RHCs must submit an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. If this information is not collected, HRSA will be unable to provide up to \$6,000,000 in payments to FQHCs and \$2,000,000 in payments to RHCs, hindering the Administration's efforts to address the opioid public health emergency through expanded access to opioid use disorder treatment services.

HRSA is also unable to reduce the frequency of reporting any further. By law, FQHCs and RHCs may not request payment for the same physician or practitioner's waiver possession more than once. As such, the frequency of collection is contingent on the frequency of staff changes at submitting FQHCs and RHCs, their willingness to submit subsequent applications for any additional waiver possessions, as well as the availability of funds to keep the application portal open. HRSA does not anticipate receiving more than one application per FQHC or RHC over the lifespan of available funds.

7. <u>Special Circumstances Relating to the Guidelines of 5 CFR 1320.5</u>

The request fully complies with the regulation.

8. <u>Comments in Response to the Federal Register Notice/Outside Consultation</u> The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on October 6, 2020, vol. 85, No. 194; pp. 63121-22. There were no public comments.

Additionally, this program consulted with Centers for Medicare and Medicaid Services (CMS), Substance Abuse and Mental Health Services Administration (SAMHSA) and HHS Office of General Counsel to obtain constructive feedback to improve the application, improve efficiency, and minimize the collection burden. The comments on clarity of the application and forms were positive.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payment/gifts.

10. Assurance of Confidentiality Provided to Respondents

This project does not require an Institutional Review Board review/approval.

Data will be collected through a secure web portal and retained through the lifespan of the program.

11. Justification for Sensitive Questions

HRSA requires individual physician and practitioner Drug Enforcement Administration (DEA) numbers and DATA 2000 waiver numbers, or other proof of waiver approval, to ensure payments are being issued in accordance with statutory requirements. Specifically, HRSA must validate that each submitted physician or practitioner attained their DATA 2000 waiver on or after January 1, 2019 in order to process a payment for the applying FQHC or RHC. HRSA will cross-reference submitted data with extant CMS and SAMHSA datasets to confirm the accuracy of submissions.

12. Estimates of Annualized Hour and Cost Burden

	Number of	Number of Responses per	Total	Average Burden per Response	Total Burden
Form Name	Respondents	Respondent	Responses	(in hours)	Hours
DATA 2000 Waiver Training Payment Program Application for Payment	2,416	1	2,416	0.5	1,208
Total	2,416	1	2,416		1,208

Estimated Annualized Burden Hours

Basis for estimates:

The number of FQHC practitioners possessing DATA 2000 waivers was projected for 2019-2021 based on linear best-fit trend using 2016-2018 Uniform Data System (UDS) data. The average number of DATA 2000 waivers per FQHC was then calculated by dividing the total number of waivers in a given year by the 2018 FQHC population which provided data (1,362). The total hypothetical demand for waiver payments was then calculated by dividing the target payment rate per waiver (\$1,500) by the number of total number of waivers in a given year. The hypothetical demand for waiver payments per FQHC was then calculated by multiplying the number of waivers in a given year by the estimated average number of waivers per FQHC for that year. With these figures, the number of FQHCs paid until all funds are expended was calculated by dividing available funds (\$6 million) by the demand for waiver payments per FQHC, resulting in 1,993, rounded. Given that the \$6 million in possible payments was projected to be significantly less than the estimated total demand for waiver payments in 2019 alone (\$9.5 million), HRSA used 1,993 as the basis for the number of respondents. HRSA will not accept applications after available funds have been expended.

HRSA based the estimated number of RHC respondents on FQHC data because HRSA does not oversee RHCs and does not possess data to make an estimate unique to RHCs; this estimate assumes the aforementioned FQHC data and assumptions are representative of the RHC population. Therefore, similar to FQHCs, HRSA calculated an estimated 423 RHC respondents by dividing available funds for RHCs (\$2 million) by the demand for waiver payments per respondent.

These calculations further assume that the HRSA FQHC grantee population is representative of the broader FQHC population.

Average burden per response derived from dry run form completions, assuming that respondents have the capability to automatically query administrative systems for relevant data.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Information and Record Clerks, All Other	1,208	\$19.89	\$24,027
Total	1,208		\$24,027

13. <u>Estimates of other Total Annual Cost Burden to Respondents or</u> <u>Recordkeepers/Capital Costs</u>

Other than time, there is no cost to respondents.

14. Annualized Cost to Federal Government

Instrument	Base Pay	Project Time	Number of	Total
	Rate	per FTE	FTEs	Annual Cost
DATA 2000 Waiver Training Payment Program Application for Payment	\$102,662 GS-13, Step 1	1.0	1.0	\$102,662

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation, Publication, and Project Time Schedule

The data submitted as part of this information collection will not be published, tabulated, or manipulated (i.e., summarized, segmented, or altered).

17. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>

The OMB number and expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.