Supporting Statement – Part A
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
Section 1003 Demonstration Evaluation
CMS-10786, OMB 0938-TBD (New Collection)

A. Background

The extent of the opioid epidemic in the United States is well known, and effective treatments exist. Medication-assisted treatment (MAT), which incorporates medication with psychosocial treatment and/or supports, is the gold standard for treating opioid use disorder (OUD) and can be effective for treating alcohol use disorder.[1] Despite the presence of evidence-based treatment, however, significant capacity shortfalls in substance use disorder (SUD) treatment or recovery services are widespread across the United States, particularly in rural areas.[2,3]

Section 1003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act authorizes the Secretary of the Department of Health and Human Services (HHS), in consultation with the Agency for Healthcare Research and Quality (AHRQ) and the Substance Abuse and Mental Health Services Administration (SAMHSA), to conduct a 54-month demonstration project (the section 1003 demonstration) designed to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services.[4] The capacity and role of Medicaid are important because Medicaid covers a substantial percentage of adults with SUD in the United States. An estimated 40 percent of adults younger than age 65 years with OUD are covered by Medicaid.[5] Enrollment of qualified SUD providers in Medicaid is critical and includes specialty SUD providers, general practitioners, and non-SUD specialties such as obstetricians.

The section 1003 demonstration comprises two components: (1) a planning period, with planning grants originally awarded for an 18-month period to 15 states with funding of up to $50 million in aggregate, and (2) a 36-month post-planning period, with up to five states selected from among the 15 planning grant states. The Centers for Medicare & Medicaid Services (CMS) extended the timing of the demonstration to allow states to complete the planning grant activities given impediments from the novel coronavirus (COVID-19) pandemic and the accompanying public health emergency. A related emergency waiver extended the planning grants an additional 6 months and postponed the beginning of the post-planning period accordingly. CMS plans to begin the 36-month post-planning period on October 1, 2021, to last through October 1, 2024. The demonstration will build on the planning period and will include enhanced reimbursement for defined Medicaid services.

Planning Grants

The 18-month planning grants were the first stage of the demonstration. The planning period included the award of up to $50 million in aggregate to the 15 selected states and the provision of technical assistance for these states. CMS selected the planning period states based on criteria that included a review of the applicants' submissions for the following:

1. Proposed activities to support the development of an initial assessment of the mental health and SUD treatment needs of the state to determine the extent to which providers are needed to address the SUD treatment or recovery needs of Medicaid beneficiaries;
2. Proposed activities that, taking into account the results of the assessment, would support the development of state infrastructure, including to recruit prospective providers and provide training and technical assistance to providers who deliver SUD treatment or recovery services to Medicaid beneficiaries;
3. Proposed activities to improve reimbursement, training, and education to expand Medicaid provider capacity to deliver SUD treatment or recovery services; and
4. Proposed activities to develop projections regarding the extent to which the state would increase the number and capacity of Medicaid providers offering SUD treatment or recovery services, as well as the willingness of Medicaid providers to offer SUD treatment or recovery services, during the demonstration project.

Post-Planning Period

The 36-month post-planning period will be a demonstration with up to five states. The demonstration will build on the planning period and include enhanced reimbursement for defined Medicaid services.

Section 1003 of the SUPPORT Act also requires that there be an evaluation of the demonstration. The evaluation began on September 1, 2020, and will end on August 31, 2025. Primary data collection for the demonstration includes a survey and focus groups of providers, each conducted twice during the evaluation timeline. Table 1 summarizes the purpose and the respondents for each type of data collection. Individual provider types who are eligible for the survey include disciplines eligible to prescribe medication for OUD, such as primary care providers, obstetricians, and SUD specialty physicians; nurse practitioners; and physician assistants. Focus group participants can also include SUD counselors and peer recovery specialists.

Table 1: Purpose and Respondents for Data Collection Activities

Data Collection	Purpose	Respondents	Timing
MAT provider survey	– To understand how prescribing or dispensing of buprenorphine, methadone, or naltrexone changed from the planning to the post-planning period; – To understand the barriers and facilitators of being a Medicaid provider; and – To characterize the type and setting of providers.	Providers in planning grant states	Once in Year 2 (2021) and once in Year 4 (September 2023 to April 2024)
SUD treatment provider focus groups	– To explore the impact of key aspects of implementation, such as perceived burdens associated with Medicaid enrollment or MAT delivery, access to referral placements, value of state-provided technical assistance, and benefits and unanticipated outcomes experienced by providers during the demonstration.	Providers in post-planning states	Once in Year 2 (2021) and once in Year 4 (September 2023 to April 2024)

B. Justification

1. Need and Legal Basis

The statute (Public Law No. 115-271) authorizing the SUPPORT Act requires the section 1003 demonstration. It states that the Administrator of CMS shall, in consultation with the Director of AHRQ and the Assistant Secretary for Mental Health and Substance Use from SAMHSA, submit to Congress a final report evaluating the demonstration.

The purpose of this evaluation is to meet the statutory goals and examine the extent to which the states participating in the section 1003 demonstration achieved the goals they established to increase SUD treatment or recovery provider capacity under the Medicaid program. This includes both the planning period and the post-planning period of the demonstration. To collect the information required by statute, the evaluation of the demonstration will include a survey of MAT prescribers and focus groups with Medicaid SUD treatment or recovery providers, as described in more detail below.

MAT Provider Surveys

The provider surveys will inform the required Final Report to Congress and will gather information on provider experiences related to Medicaid provider enrollment, SUD service delivery, and changes in OUD medication treatment, including barriers and enablers of prescribing and dispensing. The evaluation team proposed to implement 10-minute cross-sectional surveys of OUD medication prescribers in all planning grant states in the second and fourth years of the evaluation contract. The surveys will capture data from providers eligible to prescribe or dispense medication for OUD treatment across all 15 planning grant states at the beginning and near the end of the post-planning period. The objective of having two surveys is to compare the incremental effect on medication treatment for OUD of the post-planning period activities, relative to those states that participated only in the planning period.

Provider Focus Groups

In the second and fourth year of the evaluation, the evaluation team will conduct virtual focus groups with providers in post-planning states, two groups per state. We anticipate between six to eight participants for each 90-minute focus group, which will be conducted via password-secured Zoom or another virtual conferencing platform. The evaluation team will recruit a range of Medicaid-enrolled SUD providers (e.g., primary care and SUD specialty physicians, nurse practitioners, physician assistants, peer providers, and obstetricians) who are the primary targets of the respective states participating in the post-planning period of the section 1003 demonstration. In discussion with the Contracting Officer's Representative and the states, we will choose provider types that reflect the goals of each state, with particular attention given to areas that the state aimed to support and develop.

The focus groups will explore the impact of key aspects of implementation, such as perceived challenges associated with Medicaid enrollment or delivery of SUD treatment or recovery services, access to referral placements, the value of state-provided technical assistance, and benefits and unanticipated outcomes experienced by providers. Focus groups allow for

interaction across participants and may elicit comments and insights that would not surface in one-on-one discussions.

2. Information Users

The information collected from the provider surveys and focus groups will be used by the evaluation team, CMS, and its federal partners to inform the mandated Final Report to Congress regarding the SUPPORT Act section 1003 demonstration. All data will be reported at the aggregate level.

The information collected from the provider surveys will be used to understand how MAT prescribing has changed during the demonstration, identify challenges to prescribing, and compare the incremental effect of the post-planning period, relative to those states who participated only in the planning period, on increased capacity for SUD treatment or recovery service delivery. The focus groups will provide strategic information on the impact of key aspects of implementation, such as perceived challenges associated with Medicaid enrollment or MAT delivery, access to referral placements, the value of state-provided technical assistance, and benefits and unanticipated outcomes experienced by providers during the demonstration. The data collected will allow for an understanding of challenges and facilitators to state demonstration implementation plans, as well as unintended consequences, both positive and negative, with respect to service delivery and demonstration outcomes.

3. Use of Information Technology

All information (100 percent) will be collected electronically via web-based platforms. The provider surveys will be conducted via a web-based platform, and the focus groups will be conducted virtually via the Zoom platform. Electronic data collection poses a lesser burden than completing manual data collection (e.g., a paper-based survey) and is also less costly. Neither the surveys nor the focus groups require any signatures from the respondents. Additionally, all participation is voluntary. The surveys will be implemented on a platform that ensures the highest protection as per Health Information Technology for Economic and Clinical Health Act requirements, including the Federal Information Security Modernization Act of 2002, and meets or exceeds the minimum requirements as outlined in Federal Information Processing Standards Publication 200.

4. Duplication of Efforts

This information collection does not duplicate any other efforts, and the information cannot be obtained from any other source. There are no other data sources that contain the specific information on demonstration implementation and outcomes related to increasing Medicaid SUD treatment or recovery provider capacity required to suitably evaluate the demonstration and meet statutory requirements.

5. Small Businesses

Data collection from providers required for the evaluation may involve small businesses (e.g., provider practices). To reduce the burden on small businesses, the survey will collect only the most critical information necessary for the evaluation and that which cannot be collected through other sources. The survey will take no more than 15 minutes to complete, and the focus group will last no more than 90 minutes. All participation is voluntary.

6. Less Frequent Collection

The evaluation team will need to collect, at a minimum, the items listed in Table 1 to fulfill the statutory mandates of the demonstration evaluation.

7. Special Circumstances

There are no special circumstances for this data collection effort.

8. Federal Register/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register on September 24, 2021 (86 FR 53060). Comments were received and are attached to this package along with our response and Crosswalks. While some changes were made, none of the changes impact our burden estimates.

The 30-day notice published in the Federal Register on February 22, 2022 (87 FR 9625). Comments are due on/by March 24, 2022.

Consultation

The evaluation team discussed all proposed data collection activities and developed the data collection instruments in consultation with the CMS Contracting Officer's Representative and other CMS representatives involved in the SUPPORT Act section 1003 demonstration project.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

The data collected under the demonstration evaluation will be maintained as required by the Privacy Act of 1974 (5 U.S. Code 552a). There is no protected health information or personally identifiable information collected in the data collection instruments. Respondents will be informed that the information supplied is voluntary in nature, and data will be deidentified and reported in aggregate only.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

For the survey and focus groups, the burden hours are calculated by multiplying the number of responses estimated for each year by the hours per response. Table 2 reflects the annual burden estimate for the evaluation year when it would be realized and Table 3 reflects the estimated annual and overall costs. The burden hour estimates for the survey are based on the length of time each respondent is likely to need to read the survey invitation and instructions (5 minutes) and complete the survey questions (10 minutes). Estimates of the annual respondent costs were based on median hourly family physician wages, regardless of specialty, according to the U.S. Department of Labor, Bureau of Labor Statistics.[6] We recognize that physician assistants and nurse practitioners may also prescribe medication for OUD and likely serve Medicaid patients; however, because we do not know the distribution of each discipline in the target population, we chose a "middle ground" of family physicians to account for the range of possible wages. We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage (which doubles the base wage) to account for fringe benefits and overhead.[7]

The survey will include all current prescribers or dispensers of buprenorphine or methadone, for the states participating in the planning period. This "census" approach ensures that we recruit all types of providers who are qualified to provide those two types of medication and are the targets of each state's demonstration. We will use data from SAMHSA's provider locator database, supplemented by data from the State Opioid Treatment Authorities, to obtain provider contact information.

Table 2: Estimated Annual Respondent Overall Burden in Each Round of Data Collection

Type of Collection	Annual Estimated No. of Total Responses (1)	No. of Responses per Respondent per Year (2)	Average Burden per Response (hours) (3)	Estimated Total Annual Burden (hours) (1)*(2)*(3)
Focus group round 1	70	1	1.50	105
Focus group round 2	70	1	1.50	105
Surveys round 1	14,335	1	0.25	3,584
Surveys round 2	14,335	1	0.25	3,584
Round 1 total	14,405	**1**	(average)	3,689 (total)
Round 2 total	14,405	**1**	(average)	3,689 (total)
Annualized average	14,405	**1**	**Annualized average**	3,689
Overall total	**28,810**	**1**	**Overall total**	**7,378**

Notes: Focus groups responses are calculated as 7 persons*2 groups per state*5 states. Survey responses are estimated from data on buprenorphine prescribers in the 15 planning grant states from SAMHSA's treatment locator supplemented with data from State Opioid Treatment Authorities.

Table 3: Estimated Annual Respondent Burden, Cost and Overall

Type of Respondent	Average Hourly Wage Rate (including benefits) per respondent ($)	Average Burden per Response (hours)	Average Cost per Response ($)	Estimated Total Annual Burden (hours)	Estimated Total Annual Burden Cost ($)
Column	*1*	*2*	*(3)=(1)*(2)*	*4*	*(3)*(4)*
Focus group round 1	199.40	1.50	299.10	105	31,405.50
Focus group round 2	199.40	1.50	299.10	105	31,405.50
Surveys round 1	199.40	0.25	49.85	3,584	178,649.94
Surveys round 2	199.40	0.25	49.85	3,584	178,649.94
Round 1 total	199.40 (average)	0.29 (average)	56.94 (average)	3,689	210,055.44
Round 2 total	199.40 (average)	0.29 (average)	56.94 (average)	3,689	210,055.44
Overall annualized average	**199.40 (average)**	**0.29 (average)**	**56.94 (average)**	**3,689**	**210,055.44**

13. Capital Costs

There are no capital costs to respondents other than their time to participate in the survey or focus group.

14. Cost to Federal Government

The cost to the government for this data collection consists mainly of the salaries of the five CMS staff who oversee the section 1003 evaluation project to monitor and oversee demonstration activities (see Table 4). The staff activity includes contractor meetings, review of data collection instruments, oversight of the scope of work conducted under the evaluation, and review of evaluation design reports and interim and final demonstration reports. It is estimated that needed staff time for the CMS staff to cover the items mentioned above is 0.1 full-time equivalents at the GS-13 Level (step 1), per agency level, for a total of $51,841 annually. Wage rates are for staff in the Washington, DC, area, based on the Office of Personnel Management's 2021 General Schedule Salary & Wages.[8]

Table 4: Estimated Annual Government Staff Costs

Federal Program Staff Level	Total Annual Burden Hours	Hourly Wage Rate	Total Staff	Total Annual Government Staff Cost
GS-013	1,044	$49.68	5	$51,841.08

Notes: Burden hours reflect a calculation of five staff at 0.1 full-time equivalents*2,087 annual hours.

15. Changes to Burden

There are no changes as this is a new information collection.

16. Publication/Tabulation Dates

These data will be aggregated or reported out by state or provider type; this will not indicate the results of individual participants.

Plans for tabulation. The analysis of the survey data will involve producing univariate (descriptive) (e.g., means, medians, frequency distributions, and cross-tabulations) and bivariate statistics (t-tests and chi-square tests) to describe and compare among types of providers. Closed-ended responses from the survey data will be reported in tables to facilitate an understanding of results and comparisons across subgroups (e.g., types of providers, states). Specific planned comparisons include:

- Survey outcomes (e.g., changes in MAT prescribing) across types of providers
- Characteristics of provider types across states

We will analyze the focus group data to describe and characterize implementation experience, including activities, challenges, and drivers of success. We will categorize these factors and produce summary tables to help contextualize quantitative findings and to elucidate the provider and organizational factors that may contribute to the demonstration implementation experience.

We will also use publicly available data to understand the socio-demographic characteristics and SUD treatment and prevalence rates of communities with demonstration providers. We will link these data to survey data by ZIP Code or county geographic identifiers to create visual maps to show the geographic distribution of demonstration providers and the characteristics of their communities.

Reports. The survey and focus group data will be used to inform the Final Report to Congress on the section 1003 demonstration. The Final Report to Congress will include evaluation findings, discussion of the results, and implications of the results. The findings will include survey and focus group results in tables. The Final Report to Congress will be published in 2025. Table 5 provides the target timeline for the data collection activities during the evaluation.

Table 5: Information Collection Activity Timeline

Activity	Target Date (first round)	Target Date (second round)
Draft data collection instruments	November 2020	Not applicable
Provide primary data collection instruments to CMS	November 2020	Not applicable
Begin institutional review board process and Office of Management and Budget clearance	May 2021	Not applicable
Begin focus group recruitment	October 2021	July to August 2023
Begin provider survey recruitment	October 2021	July to August 2023
Begin focus group and provider survey data collection	November 2021 to January 2022	September to October 2023

17. Expiration Date

The surveys and focus group guides will display the approved expiration date, CMS Number, Office of Management and Budget Control Number, and Disclosure Statement.

18. Certification Statement

No exceptions are requested.

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[1] Substance Abuse and Mental Health Services Administration. *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose.* HHS Publication No. SMA-18-5093. 2018. https://store.samhsa.gov/product/Medicaid-Coverage-of-Medication-Assisted-Treatment-for-Alcohol-and-Opioid-Use-Disorders-and-of-Medication-for-the-Reversal-of-Opioid-Overdose/SMA18-5093

[2] Huskamp HA, Busch AB, Souza J, et al. How is telemedicine being used in opioid and other substance use disorder treatment?. *Health Affairs (Millwood)*. 2018;37(12):1940-1947.

[3] Browne T, Priester MA, Clone S, Iachini A, DeHart D, Hock R. Barriers and facilitators to substance use treatment in the rural South: a qualitative study. *Journal of Rural Health*. 2016;32(1):92-101.

[4] SUPPORT Act, Section 1003(aa)(1),(2).

[5] Henry J. Kaiser Family Foundation. *Medicaid's Role in Addressing the Opioid Epidemic.* Published June 3, 2019. https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/

[6] Please see the following: Bureau of Labor Statistics. Occupational employment and wage statistics. May 2020. https://www.bls.gov/oes/current/oes_nat.htm

[7] For more information, see p. 29–30 of the following: Office of the Assistant Secretary for Planning and Evaluation. *Guidelines for Regulatory Impact Analysis*. 2016. https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.

[8] Please see the following: Office of Personnel Management. Salary Table 2021-DCB: Annual Rates by Grade and Step. https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf and

Office of Personnel Management. Salary Table 2021-DCB: Hourly Basic (B) Rates by Grade and Step Hourly Title 5 Overtime (O) Rates for FLSA-Exempt Employees by Grade and Step. https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB_h.pdf