Supporting Statement – Part A

Value in Opioid Use Disorder Treatment Demonstration

(CMS-10728, OMB 0938-1388)

Background

Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act)[1], which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to "increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures." As required by statute, Value in Treatment will be implemented no later than January 1, 2021.

As required by statute, Value in Treatment will create two new payments for Participants in the Value in Treatment program:

1. **A per beneficiary per month care management fee (CMF)**, which the participant may use to "deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under [Title XVIII]"; and
2. **A performance-based incentive payment (PBIP)**, that would be payable based on the participant's performance with respect to criteria specified by CMS, which may include evidence-based medication-assisted treatment (MAT), as well as patient engagement and retention in treatment.

Payments made through Value in Treatment will be made in addition to the medication, counseling and behavioral therapies, treatment planning, and care coordination services that Medicare currently covers. OUD treatment services furnished through Value in Treatment are expected to result in improved outcomes and cost savings among beneficiaries who have health and social needs that go beyond the clinical services currently covered by Medicare.

Value in Treatment will test whether the CMF and PBIP will:

1. Reduce hospitalizations and emergency department (ED) visits;
2. Increase use of medication assisted treatment (MAT) for OUD;
3. Improve health outcomes for individuals with OUD, including reducing the incidence of infectious diseases such as Human Immunodeficiency Virus (HIV) and hepatitis C (HCV);
4. Reduce deaths from opioid overdose;
5. Reduce utilization of inpatient residential treatment; and
6. Reduce program expenditures to the extent possible

[1] 42 USC § 1395cc-6.

Data collection for this Value in Treatment program is both qualitative and quantitative. Table 1 below summarizes the purpose and the respondents, including participants and beneficiaries for each type of data collection.

As part of the Value in Treatment Demonstration, CMS implemented a Participation Agreement, which clearly outlines the implementation terms and requirements for participants selected to participate in the demonstration. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(h)(1), we believe the Participation Agreement to be exempt from the PRA. Therefore, we have not assigned burden to the instrument and will be submitting it as a supplementary document.

The statute defines participants as entities and individuals enrolled in Medicare, who are selected to participate in the Value in Treatment program. Applicable beneficiary includes an individual who: Is entitled to, or enrolled for, benefits under Medicare Part A and Part B; Is not enrolled in a Medicare Advantage plan under Part C and; Has a current diagnosis for an opioid use disorder and has agreed to receive services under Value in Treatment.

The Value in Treatment Demonstration will not be making any changes to the original package. There will not be any new reporting instruments or any change to existing tools. Therefore, there will not be any new requirements nor burden placed on the providers and/or beneficiaries.

CMS requests an extension of this collections (CMS-10728), which is due to expire on 12/31/2023. This extension intends to extend this collection with no changes to its requirements or instruments an additional year to complete the 4-year demonstration program.

A. Justification

1. Need and Legal Basis

Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary.

Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and PBIP under the Value in Treatment program, each participant shall report data necessary to: monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the PBIP. Additionally, 42 CFR 2.53 allows for patient identifying information, as defined in § 2.11, to be disclosed for the purpose of conducting a Medicare audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (e.g., Value in Treatment Participant).

2. Purpose and Use of the Information Collection

The data collection for the application will serve as the selection process for participation in the Value in Treatment demonstration as required by 1866F of Act.

Data collected from participant surveys will be used to monitor the Demonstration. Specifically, these data will provide information on the strategies implemented by participants, including information on care delivery settings and modalities, capacity building such as staffing, specific social support and recovery enabling services furnished, and referral patterns. In addition, these data seek to ascertain beneficiary make up, access, and engagement. These data will also be used to understand barriers and facilitators for accessing and remaining in OUD treatment.

The information collected from the Participant Compliance Audit and Participant Financial Report will be used to monitor the Value in Treatment program. Specifically, these data will be used to understand how payments made under the Demonstration were spent. This will allow CMS to monitor uses of CMF and PBIP funds. Data from the Participant Compliance Audit and Participant Financial Report will also ensure that implementation is occurring safely, and in accordance with the terms of the demonstration as set forth in the participation agreement; and to detect non-compliance with demonstration requirements; unintended consequences or inappropriate care for beneficiaries. Participant and OUD care team member Compliance Audits and Financial Report will track and report Value in Treatment payments and expenditures.

The 'Participation Agreement' outlines participation terms and requirements and establishes a formal agreement between CMS and the selected participants to implement the Value in Treatment Demonstration. The 'Participants' in the Participation Agreement include: an entity or individual that is enrolled in Medicare and that is a physician, a group practice comprising at least one physician; a nurse practitioner; a hospital outpatient department; a federally qualified health center (FQHC); a rural health clinic; community mental health center; clinic certified as a certified community behavioral health clinic; an opioid treatment program (OTP); and, a critical access hospital. The Participation Agreement establishes the terms of agreement that binds CMS and the participant, to include such terms as: effective date of the agreement; and performance period of the Demonstration.

Surveys with participants will provide information on their experiences under the Value in Treatment, including but not limited to MAT treatment and retention, counseling and social support services. The information will also be used to monitor who is on the OUD care team and to enable vetting of participants and OUD care team members. Finally, these data will be used to ensure that implementation of Value in Treatment is occurring safely and in accordance with the terms of the Value in Treatment as set forth in the participation agreement, to detect non-compliance with Value in Treatment requirements, unintended consequences or inappropriate care for beneficiaries, and potential program integrity issues.

Data collection using the Health Survey will provide information on functional and mental health status prior to and during the Value in Treatment, as required by 1866F(b)(C).

Beneficiary Notification will be used to collect information from participants on which applicable beneficiaries have opted-in to data sharing. This will allow CMS to provide data that will include individually identifiable demographic and Medicare eligibility status information and various summary reports with data relevant to performance under Value in Treatment (such as data related to quality,

utilization, expenditures, etc.), and detailed claims data files that will include individually identifiable claim and claim line data for services furnished by Medicare-enrolled providers and suppliers to applicable beneficiaries.

All of the data collection tools are provided in Appendix A.

Institutional Review Board (IRB) Approval and Informed Consent

IRB exemption will be sought for the research project, which is conducted pursuant to the specific federal statutory authority.

Table 1: Purpose and Respondents for Data Collection Activities

Data collection	Purpose	Respondents	Timing
Application			
Request for Application	To evaluate eligibility and suitability of applicants' selection into the Value in Treatment demonstration.	Applicants	Once during the demonstration period
Beneficiary Engagement			
Beneficiary notification	To comply with statutory requirement under 1866F of the SSA that an applicable beneficiary must agree to receive services under the Value in Treatment demonstration in order to receive them. To obtain beneficiary consent to share data.	Participants	Prior to receiving services under Value in Treatment from a Participant
Monitoring and Evaluation			
Health Survey (SF-36)	• To determine physical, mental, and functional status	Participating Beneficiaries	Annual
Participant Survey	• To monitor: the types of interventions participants implemented, their use of CMF and PBIP, and any	Participants	At least once and no more than twice per year

Data collection	Purpose	Respondents	Timing
	challenges and successes. • To monitor participants' use of CMF and PBIP to build capacity, e.g. hire staff		
Participant Compliance Audit	• To ensure that implementation of Value in Treatment is occurring safely, and in accordance with the terms of the Demonstration as set forth in the participation agreement. • To detect non-compliance with Value in Treatment requirements, unintended consequences or inappropriate care for beneficiaries, and potential program integrity issues • To monitor use of CMF and PBIP funds	Participants	Annual, if selected at random among 10% of all Participants
Participant Financial Report	• To monitor use of CMF and PBIP funds • Participant and OUD care team member vetting	Participants	Annually

3. Use of Information Technology and Burden Reduction

Data collection under the Demonstration may be administered electronically as budget permits, as it would pose a lesser burden than completing manually. The current options for data collection include a CMS Enterprise solution for uploading of documents, a dedicated mailbox managed by CMS, and electronic submission via an on-line survey software that ensures the highest protection as per HITECH requirements, including the FISMA Act of 2002, and meets or exceeds the minimum requirements as outlined in FIPS Publication 200.

4. Duplication of Efforts

This information collection does not duplicate any other effort.

5. Small Businesses

Data collection from participants required for the implementation, monitoring, and evaluation of Value in Treatment may involve small businesses. To reduce the burden on small businesses, the survey will be conducted with the use of a written survey protocol that will be provided to each respondent in advance. The use of the written survey protocol will ensure data collection is limited to only the information necessary for the implementation, monitoring, and evaluation of Value in Treatment. The survey for the participant may require approximately 20 minutes, compliance audit may take 40 minutes, and the financial report will take 30 minutes of the respondent's time. The health survey for the beneficiary will require about 5 minutes.

6. Less Frequent Collection

Less frequent data collection than indicated in Table 1 will result in not being able to fulfill the statutory mandates of the four-year demonstration project.

7. Special Circumstances

There are no special circumstances for this data collection effort.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on 03/10/2023 (88 FR 15035).

No comments received

The 30-day notice published in the Federal Register on 05/29/2023 (88 FR 34502).

Outside Consultation

There will be no outside consultation in this evaluation effort.

9. Payments/Gifts to Respondents

No payments or gifts will be offered to respondents. The expectations for data collection as a requisite for participation in the demonstration will be clearly defined in the Participation Agreement. The goal of the demonstration as written above, is to "increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures." Participation in the demonstration will assist the respondents in meeting these goals.

10. Confidentiality

The data collected under the Demonstration will be maintained as required by the Privacy Act of 1974 (5 U.S.C. 552a). In addition, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule defines the standards for protecting individuals' sensitive and private health information and covers all settings, personnel, and procedures that have access, handle, or share individuals' health care information.

The system of records for this Demonstration is: 09-70-0591 Master Demonstration, Evaluation, and Research Studies for the Office of Research Development and Information (DERS)SORN history: 72 FR 19705 (4/19/07), 83 FR 6591 (2/14/18).

Health Survey (SF-36)

Survey may solicit information that is subject to protection under the HIPAA Privacy Rule, which, in §164.502(d), permits a covered entity or its business associate to create information that is not individually identifiable by following the de-identification standard and implementation specifications in §164.514(a)-(b). CMS is a covered entity under the Act, and the CMS contractors administering the survey are covered as business associates of the covered entity.

Health respondents will be de-identified through the use of randomly-assigned respondent ID numbers, which will also be their usernames if on-line version of the survey will be implemented. No one outside the program team will have access to the individual survey responses, nor will anyone outside the team be able to identify an individual respondent by their responses. All covered information will be maintained in password-secured location (i.e., only members of the program team will have access to the files).

Completed surveys will have the option to be mailed to a dedicated mailbox managed by CMS or submitted electronically, via an on-line survey software that ensures the highest protection as per HITECH requirements, including the FISMA Act of 2002, and meets or exceeds the minimum requirements as outlined in FIPS Publication 200.

Upon completion of the survey field work and appropriate data cleaning steps, the identifiers that link a survey respondent with the respondent's name and contact information will be destroyed. All assigned team members will acknowledge and sign the required Code of Business Conduct and Ethics form, which (among other things) enforces to maintain the integrity, confidentiality, and accuracy of all data and information obtained during the course of this data collection effort.

11. Sensitive Questions

There will be no sensitive questions.

12. Burden Estimates (Hours & Wages)

The burden estimates for survey data collection are as follows:

For all data collection activities, the burden hours are calculated by multiplying the number of responses estimated for each year by the hours per response. These activities are expected to be initiated and completed within one calendar year; therefore, Table 2 can be considered an "annual" burden estimate for the one calendar year in which burden would be realized. Unlike other data in Table 2, the application would only need to be completed once upon entry.

Health Survey (SF-36)

The burden hour estimates for the survey are based on the length of time each type of respondent is likely to need to both read the survey invitation (5 minutes) and complete the survey questions (5 minutes). We

also assume that 100 percent of beneficiaries who receive the survey will complete it. The survey respondents are eligible for Medicare, and thus are likely to be over 65 years-old and more likely than the general population to be retired. For those who are currently in the workforce or who were once in the workforce, they might have had any number of occupations. The wages used for survey respondents reflect the median hourly wage for all occupations in the US, $22.00 (BLS, 2021a). The median hourly wage for all occupations in the United States is used to capture the variety of occupations they might currently hold or once have held. We then calculated a loaded hourly wage, with benefits and overhead accounting for c100 percent of the total hourly wage. This results in a loaded hourly wage of $44.00

Table 2: Estimated Respondent Overall Burden

Type of Respondent	Estimated Number of Total Responses	Estimated Number of Responses per Respondent	Average Burden per Response (in hours)	Estimated Total Annual Burden Hours
Request for Application				
Applicants	100	1	2.00	200
Beneficiary Notification				
Participants	47	1	0.08	3.8
Survey				
Beneficiaries – SF-36	100	1	0.08	8
Participants	47	1	0.33	15.5
Compliance Audit				
Participants	47	1	0.66	31
Participant Financial Report				
Participant	47	1	0.50	23.5
Grand Total (Overall Average)	**388**	**1**	**3.65**	**282**

Note: Totals may not sum and calculations may produce different results due to rounding and truncated inputs.

The total annual burden cost is calculated by multiplying the estimated annual burden hours by the loaded hourly wage rate to derive the total cost for all respondents (Table 3).

Table 3: Estimated Respondent Annual Burden Cost and Overall

Type of Respondent	Hourly Wage Rate (including Benefits)	Average Burden per Response (in hours)	Average Cost per Response	Estimated Total Burden Cost
column	*(1)*	*(2)*	*(3)=(1)*(2)*	*(4)*
Request for Application (RFA)				
Participants**	$121.31	2.0	$246.62	$24,262
Beneficiary Notification				
Beneficiaries	$24.48	0.08	$1.96	$11,460.00
Survey				
Beneficiaries (SF-36)	$24.48	0.08	$1.96	$15,988.03
Participants	$121.31	0.33	$40.03	$1881.52
Participant Compliance Audit				
Participants*	$44.00	0.66	$29.04	$1364.88
Participant Financial Report				
Participants*	$44.00	0.50	$22.00	$1034.00
Grand Total	**$379.58**	**3.65**	**$325.71**	**$538774.40**

Note: Totals may not sum and calculations may produce different results due to rounding and truncated inputs **Assumes that request for applications, participant surveys will be completed by a Physician.
* Assumes office staff or Care Coordinators will be completing the Financial Report and Compliance Audit

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The cost of this data collection effort annually for the Value in Treatment and overall cost to the Federal government is provided in Table 4.

The government activity involves efforts of program staff in designing and reviewing of data collection instruments, including the request for application (RFA), participant survey tool, compliance audit guide, participant financial report guide, and the beneficiary notification document.

The implementation and monitoring contractor (IMC) activities will include participant survey, compliance audit, data collection, analysis, and reporting.

Table 4: Cost to the Federal Government

	Year (Annual)	Total (2021-2024)
Government Activity		
Design and review data collections instruments (RFA, survey, audit & financial report guides, & beneficiary notification). Reviewing and providing guidance on instruments, OMB clearance, and data collection approach	**$38,515.00[β]**	**$154,060.00**
Contractor Activity¥		
Survey		
Data collection	$19,323.00	$77,292.00
Data analysis/Report	$19,323.00	$77,292.00
Subtotal	**$38,646.00**	**$154,584.00**
Total Costs		
Total Costs	**$38,646.00**	**$154,584.00**

Notes:

β =Assuming Half-FTE (0.5) at GS-11 Step-1 salary of $72,030 based on OPM General Schedule Salary & Wages https://www.opm.gov/policy-data oversight/pay-leave/salaries-wages/

¥= IMC to be determined, and assuming an estimated quarter-FTE (0.25) of Contractor's effort using annualized BLS current average loaded wages of $37.16.

15. Changes to Burden

This document considers the 2021 wage rate calculations, which is updated from the original having used the 2018 wage rate numbers. These changes in the wage rate calculations have resulted in a slight change to the overall calculated financial burden. Additionally, this statement now reflects actual, rather than anticipated, provider numbers. This new approach shows a decrease (from 100 to 47) in actual participation, and therefore there is a slight decrease in burden measured hourly and financially.

16. Publication/Tabulation Dates

This information collection will not be published.

17. Expiration Date

The data collection instruments/instructions will display the approved expiration date, CMS Number, OMB Control Number, and Disclosure Statement.

18. Certification Statement

No exceptions are requested