Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
State and Population Health Group

Value in Opioid Use Disorder Treatment Demonstration Program

Request for Applications (RFA)

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EXECUTIVE SUMMARY

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) was enacted on October 24, 2018.[1] CMS is implementing a number of new initiatives under that law that aim to increase options for treating beneficiaries with opioid use disorder (OUD), ensure prescriber accountability and improved safety for patients across CMS programs, and illuminate Medicaid prescribing data. One such initiative includes Value in Opioid Use Disorder Treatment (Value in Treatment). Value in Treatment is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act),[2] which was added by section 6042 of the 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." Value in Treatment will be implemented by April 1, 2021.

As required by statute, Value in Treatment will create two new payments for OUD treatment services furnished to applicable beneficiaries participating in the demonstration program:

1. A per beneficiary per month care management fee (hereafter, 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 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 performance based incentive will: reduce hospitalizations and emergency department (ED) visits; increase use of medication assisted treatment (MAT) for OUD; improve health outcomes for individuals with OUD, including reducing the incidence of infectious diseases such as Human Immunodeficiency Virus (HIV) and hepatitis C (HCV); reduce deaths from opioid overdose; reduce utilization of inpatient residential treatment; and reduce program expenditures, to the extent possible.

[1] https://www.congress.gov/bill/115th-congress/house-bill/6 https://www.congress.gov/bill/115th-congress/house-bill/6

[2] 42 USC § 1395cc-6.

VALUE IN TREATMENT DEMONSTRATION OVERVIEW

Background

The United States is in the midst of a national opioid crisis that has substantial health, economic, and societal costs. In 2017, more than 47,000 Americans died from drug overdoses related to prescription and illegal opioids – an almost two-fold increase compared to opioid-related deaths a decade earlier (2007).[3] The epidemic is widespread, with nearly every state having experienced increases in opioid-related deaths since 2000.[4] ED visits for opioid overdoses rose 30% from July 2016 through September 2017.[5] Despite the staggering statistics about the opioid crisis, prevention and treatment efforts remain largely uncoordinated. Geographic availability of behavioral health and substance use treatment is highly variable, and is particularly limited in rural and other areas where OUD morbidity and mortality rates have risen most steeply.[6] Medicare has experienced the largest annual increase in the number of opioid-related hospital stays over the past two decades, and currently pays for one-third of opioid-related hospital stays.[7]

MAT is the standard of care for OUD. MAT is a comprehensive, evidence-based approach that includes medication, counseling and behavioral therapies. A robust body of literature demonstrates the effectiveness of MAT for treating OUD.[8, 9, 10, 11, 12] Despite its effectiveness, many beneficiaries encounter barriers to accessing evidence-based MAT for OUD and remaining in treatment. These barriers include a lack of coverage, OUD treatment and behavioral health care provider shortages, co-occurring physical and behavioral health conditions, and unmet health-related social needs (housing, transportation, criminal justice, etc.). Research suggests that highly coordinated and integrated care management and social support services provided in conjunction with MAT can improve treatment success, including treatment adherence and continuity. [13,14]

Currently, Medicare fee-for-service (FFS) covers some MAT services, and added a new benefit category for opioid use disorder treatment services furnished by OTPs beginning January 1, 2020 through implementation of section 2005 of the SUPPORT Act (sections 1861(s)(2), 1861(jjj), 1833(a)(1), 1834(w), and 1866(e) of the Act). CMS also created a bundled episode of care payment for care for management and counseling treatment for OUD not furnished by OTPs under the CY2020 Medicare Physician Fee Schedule (PFS) (CMS-1715-F).[15] The bundled includes payment for the overall management, care

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[3] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, (December, 2018)
[4] http://www.shadac.org/sites/default/files/publications/2016StateOpioidBrief
[5] https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html
[6] https://www.ncbi.nlm.nih.gov/pubmed/25583888
[7]https://www.hcup-us.ahrq.gov/reports/statbriefs/sb239-Opioid-Payer-Hospital-Stays-ED-Visits-by-State.pdf
[8] Gibson, A., Degenhardt, L., Mattick, R. P., Ali, R., White, J., & O'Brien, S. (2008). Exposure to opioid maintenance treatment reduces long-term mortality. Addiction, 103(3), 462–468.
[9] Schwartz, R. P., Gryczynski, J., O'Grady, K. E., Sharfstein, J. M., Warren, G., Olsen, Y., Jaffe, J. H. (2013). Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995–2009. American Journal of Public Health, 103(5), 917–922.
[10] https://www.ajpb.com/journals/ajpb/2018/ajpb_januaryfebruary2018/clinical-and-cost-outcomes-of-buprenorphine-treatment-in-a-commercial-benefit-plan-population
[11] https://www.ncbi.nlm.nih.gov/pubmed/21761950
[12] https://www.ncbi.nlm.nih.gov/pubmed/20627427
[13] https://www.ncbi.nlm.nih.gov/books/NBK402343/
[14] https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction
[15] https://www.federalregister.gov/documents/2019/08/14/2019-16041/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other

coordination, individual and group psychotherapy and counseling for office-based OUD treatment. But even with these additions, current Medicare rules do not sufficiently provide for the full range of OUD treatment services that many beneficiaries need to achieve a successful outcome. Additionally, value based payments are not applied widely in behavioral health and substance use treatment settings. Value based payment for OUD treatment can facilitate improved outcomes and reduced costs by incentivizing high quality care and tying payment to value. This demonstration program presents a unique opportunity to drive OUD treatment providers toward value based payments and build an evidence base for implementing such payments in substance use treatment settings.

Timeline

Value in Treatment is a four-year demonstration, that will begin April 1, 2021. Table 1 below summarizes the anticipated timelines for application, selection, implementation, and performance periods. Actual timelines may vary.

Eligible applicants will apply to participate in Value in Treatment through this Request for Applications (RFA). Application questions, including eligibility, deadlines, and contact information, can be found in the Application section of this RFA. Applicants must submit all application materials by emailing a pdf and/or word document to ValueinTreatment@cms.hhs.gov by the deadline. It is the responsibility of the applicant to ensure that they include all required information in their application.

Selected applicants will be required to execute a participation agreement with CMS prior to the start of the first performance year in order to participate in the demonstration program.

CMS may consider adding additional participants through a second solicitation after the first performance year, if available funding allows (see Monitoring Costs Related to CMFs and Performance-Based Incentives). In the event that CMS does issue a second solicitation, we expect that the same eligibility and selection criteria as outlined in this document would apply.

Table 1. Value in Treatment Timeline

Milestone	Timeline
RFA Released	Fall 2020
RFA Application Submission Period	Fall/Winter 2020 (application will be open for 45 days)
Participants Selected	Winter 2020/2021
Performance Year 1	April 1,2021 – December 31, 2021
Performance Year 2	January 1, 2022 – December 31, 2022
Performance Year 3	January 1, 2023 – December 31, 2023
Performance Year 4	January 1 2024 – December 31, 2024

Authority

This demonstration program will be implemented under the authority of section 1866F of the Act, added by section 6042 of the SUPPORT Act.

DEMONSTRATION DESIGN

Demonstration Overview

Value in Treatment will test whether a performance-based payment for OUD treatment services can improve access to treatment, improve outcomes, and reduce expenditures for Medicare beneficiaries

with OUD. Value in Treatment has been designed to address barriers to high quality OUD treatment services that have been identified by stakeholders. Specifically, Value in Treatment will provide participants with the resources and flexibility needed to:

- Furnish OUD treatment services, as appropriate, including services not otherwise eligible for payment under Medicare;
- Hire or contract with multi-disciplinary OUD care team members to address health related social needs; and
- Provide these OUD treatment services in ways that would not be covered or paid, or would be difficult to provide, under current Medicare rules (e.g., counseling and care management services provided via mobile outreach; therapy or counseling services furnished by clinical professional counselors and clinical alcohol and drug counselors who are permitted to furnish such services by state law within their applicable scope of practice; broadened scope of care management, care coordination, and social support services provided by auxiliary personnel who furnish services incident to the professional services of a physician or non-physician practitioner, including community health workers, care managers, and peer specialists).

Participant and OUD Care Team Eligibility

The statute defines participants as entities and individuals enrolled in Medicare who are selected to participate in the demonstration program under an application and selection process established by the Secretary, who establish an OUD care team, and who are one of the following types of individuals or entities:

- Physician;
- Group practice comprised of at least one physician;
- Hospital outpatient department;
- Federally qualified health center (FQHC);
- Rural health clinic (RHC);
- Community mental health center;
- Clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014;
- Any other individual or entity specified by the Secretary

Under the discretion afforded by the statute, CMS will also permit the following types of individuals and entities to participate in Value in Treatment:

- Group practice comprised of at least one Nurse Practitioner;
- Opioid treatment program; and
- Critical Access Hospital

Under the discretion afforded by the statute, CMS is also specifying that each Value in Treatment participant must be identified by a single taxpayer identification number (TIN) and be a separate and unique legal entity that is recognized and authorized to conduct business under applicable federal, state, or tribal law. Moreover, each participant must be capable of repaying demonstration payments to CMS, if applicable, establishing reporting mechanisms, including but not limited to mechanisms for reporting on quality measures, and ensuring compliance with demonstration requirements.

As required by statute, in order to participate in Value in Treatment, participants must also establish an OUD care team by employing or contracting with the following heath care practitioners, at minimum:

- At least one physician furnishing primary care services or addiction treatment services to an applicable beneficiary, and
- At least one eligible practitioner (defined in the statute as a physician or other health care practitioner that is enrolled in Medicare and authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment).

Under the statute, participants may also choose to include on their OUD care team one or more practitioners licensed under state law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries. These additional OUD care team members may include auxiliary personnel who furnish services incident to the services of a physician or non-physician practitioner, including professional counselors, clinical alcohol and drug counselors, marriage and family therapist, peer specialists, community health workers, or care managers who are licensed and permitted to furnish such services by state law within their applicable scope of practice. The CMF and performance based incentive paid through this demonstration program may be used to support hiring or contracting with such OUD care team members.

Under the discretion afforded by the statute, CMS is specifying that the OUD care team members must have a collaborative, integrated relationship with the participant, and must be available to provide services on a face-to-face basis, though certain services may be provided on a non-face-to-face basis or using telecommunications technology (e.g. consultation with an OUD treatment center of excellence or "hub"; assistance with transportation; legal assistance; psychotherapy; crisis intervention; naloxone training; contingency management; care management activities that do not include direct beneficiary interaction). CMS does not anticipate creating additional requirements or expectations about who is on the OUD care team beyond what is outlined in statute and in this RFA, nor does CMS anticipate creating requirements about the nature of the relationship between the participant and OUD care team. The flexibility for participants to determine the nature of their relationship with the OUD care team is important given the diversity in how OUD treatment providers operate depending on their geography, populations served, workforce capacity, local laws and regulations, etc.

Projected Participation

The statute stipulates that not more than 20,000 applicable beneficiaries may participate in the demonstration program at any one time. Additionally, the statute makes available $10,000,000 from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Act for each of fiscal years 2021 through 2024 for the purposes of making CMF and incentive payments.

Based on available funding, projected CMF and performance-based incentive payment rates, and projected costs of the beneficiary cost-sharing waiver, CMS anticipates a maximum of 5,847 unique beneficiaries receiving services under the demonstration program at any time during the performance year. Given the limits on beneficiary participation, CMS may limit the number of qualified applicants that may participate in the Value in Treatment demonstration program, based on the selection criteria outlined in Application Scoring.

Care Delivery Intervention

Value in Treatment will enable the provision of enhanced MAT and comprehensive care coordination by allowing participants and their OUD care teams to provide services that address physical, behavioral, and health-related social needs for applicable beneficiaries – including, as allowed by statute, "services not otherwise eligible for payment under [Title XVIII]." As outlined in statute, this includes use of: "[MAT];

treatment planning; psychiatric, psychological, or counseling services (or any combination of such services), as appropriate; social support services, as appropriate; and care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team."

Services furnished under Value in Treatment must be based on an applicable beneficiary's individualized OUD treatment plan, aligned with OUD treatment services defined in statute, and have a reasonable expectation of improving or maintaining the health or overall function of applicable beneficiaries. Under Value in Treatment, participants may use the CMF payments received from CMS for demonstration-related activities and services, and other activities allowed by Statute. Participants may use the demonstration payments to support the staff time needed to build internal practice capacity to furnish these services (or arrange to have such services furnished) to applicable beneficiaries, for example by consulting with an addiction specialist and/or hub.

The following list includes examples, which are not exhaustive, of how participants may use the CMF and performance based incentive payments made through this demonstration:

- Expand care delivery settings or modalities (e.g., beneficiary's home; using telecommunications technology; mobile outreach);
- Hire or contract for additional staffing in a manner that complies with applicable fraud and abuse laws (e.g., licensed professional counselors, licensed clinical alcohol and drug counselors, certified peer specialists, community health workers, or care managers who are permitted to furnish such services by state law within their applicable scope of practice; additional staff to provide after-hours care; staff time to engage with a hub; training to build staffing capacity and skills);
- Provide recovery support services[16] on a limited or extended duration, in a manner that complies with applicable fraud and abuse laws and as determined by the participant to be necessary to improve or maintain the health or overall function of applicable beneficiaries. Recovery support services may be provided in-house (if appropriate) or in coordination with state/local agencies and community-based organizations. Proposed recovery support services may include provision of social services that enable recovery (e.g., transportation [17, 18], supportive/recovery housing[19,20], job training, nutrition support, needle exchange[21, 22, 23] ; beneficiary incentives or contingency management[24]).

[16] https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(17)30195-2/fulltext
[17] https://www.sciencedirect.com/science/article/pii/S0740547201001854?via%3Dihub
[18] https://www.commonwealthfund.org/sites/default/files/2019-06/ROI-Calculator-Evidence-Guide%20-%20FINAL.pdf
[19] https://aspe.hhs.gov/basic-report/housing-options-recovery-individuals-opioid-use-disorder-literature-review
[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2916946/
[21] https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html
[22] https://www.who.int/hiv/pub/prev_care/effectivenessssterileneedle.pdf
[23] https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0178-6
[24] Contingency management provides incentives to substance use disorder (SUD) patients contingent upon treatment attendance and/or verified drug abstinence in order to increase the likelihood of these behaviors. Contingency management is an adjunct to a psychosocial treatment such as SUD counseling or cognitive-behavioral therapy and can be used with or without appropriate SUD medications.

Participants may also use payments made through Value in Treatment to support improved transitions from inpatient hospitals and EDs to ongoing community-based OUD treatment services for individuals who have received treatment for an opioid overdose, for example to staff certified peer specialists in ED settings. Overdose represents a key opportunity to intervene, and research has demonstrated improved outcomes when MAT is initiated in the ED and individuals are linked with ongoing treatment.[25,26] There is growing evidence that suggests that peer support specialists, in particular, effectively connect individuals with OUD to ongoing treatment and recovery services.[27, 28] Additionally, to the extent permitted under applicable state law, participants will be required to query the prescription drug monitoring program (PDMP) for each new beneficiary prior to initiating treatment, if a PDMP exists in the state in which the participant is furnishing OUD treatment services, and at least quarterly thereafter through the course of each individual's treatment. If the new beneficiary is a resident of a border area or neighboring state(s), a participant may also elect to query the adjoining state's PDMP, to the extent permitted under applicable state law. At all times, participants will be expected to ensure that their handling of protected health information and personally identifiable health records complies with applicable state and Federal laws, including, but not limited to laws and regulations governing the security and confidentiality of such records.

The examples noted above regarding how participants may invest payments made through Value in Treatment are drawn from peer reviewed literature, which shows that the use of certain social support services, such as peer recovery support[29,30], warm handoffs from ED to ongoing OUD treatment[31,32], mobile treatment[33,34], waiver of copayments, and housing assistance,[35,36], when combined with evidence-based MAT, positively correlate with effective treatment and reductions in cost and utilization. Additionally, addressing common barriers to treatment, including a lack of childcare services, transportation, involvement with the criminal justice system, unstable housing or risk of homelessness, can facilitate treatment initiation and retention.[37],[38] See Appendix A for a summary of such literature.

Payment Methodology

As required by statute, Value in Treatment will create two new payments for OUD treatment services furnished to applicable beneficiaries: a per applicable beneficiary per month care management fee (CMF) and a performance based incentive.

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[25] https://jamanetwork.com/journals/jama/fullarticle/2279713
[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442013/
[27] https://www.thenationalcouncil.org/wp-content/uploads/2018/12/Peer-Support-Workers-in-EDs-Issue-Brief.pdf
[28] https://www.sciencedirect.com/science/article/pii/S0740547216000167?via%3Dihub
[29] https://www.thenationalcouncil.org/wp-content/uploads/2018/12/Peer-Support-Workers-in-EDs-Issue-Brief.pdf
[30] https://www.sciencedirect.com/science/article/pii/S0740547216000167?via%3Dihub
[31] https://jamanetwork.com/journals/jama/fullarticle/2279713
[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442013/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442013/
[33] https://www.sciencedirect.com/science/article/pii/0376871696012732?via%3Dihubhttps://www.sciencedirect.com/science/article/pii/0376871696012732?via%3Dihub
[34] https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(18)30446-X/fulltext
[35] https://aspe.hhs.gov/basic-report/housing-options-recovery-individuals-opioid-use-disorder-literature-review
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2916946/
[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1986793/pdf/nihms-29642.pdf
[38] https://aspe.hhs.gov/report/best-practices-and-barriers-engaging-people-substance-use-disorders-treatment/synthesis-findings-and-study-implications

Care Management Fee

CMS will implement the care management fee required by statute as a $125 per applicable beneficiary per month payment. The CMF will be paid to participants on a quarterly basis through the appropriate Medicare Administrative Contractor (MAC), based on billed claims for the CMF for applicable beneficiaries. A given participant may bill Medicare no more than one time in a calendar quarter period per applicable beneficiary. CMS will create demonstration-specific G-code(s) to identify claims submitted by participants for the CMF for applicable beneficiaries.

The CMF payment rate has been informed by peer reviewed and gray literature related to interventions similar to the types of items or services that would be allowable under Value in Treatment that have demonstrated positive or promising outcomes (e.g., reductions in utilization/cost).

The CMF will be paid to participants in addition to payments made for medication, counseling, and behavioral therapies, treatment planning, and care coordination services for which Medicare payment is currently made. This includes services described by existing care management codes in the PFS, with the exception of FQHCs and RHCs, which will not be permitted to bill HCPCS codes G0511 (general care management) or G0512 (psychiatric collaborative care model) within a calendar quarter period of billing the Value in Treatment demonstration G-code(s) for the same beneficiary.

The CMF will be paid to participants in addition to CMFs paid under certain Innovation Center models (see Program Overlaps and Synergies for more detail), the OUD bundled payments finalized in the CY 2020 Medicare PFS final rule, and the new OTP benefit created under Section 2005 of the SUPPORT Act and published as a rider in the CY2020 Medicare PFS final rule. Value in Treatment has been designed to be complementary to existing Medicare covered services, such that CMF payments for demonstration services as described in this document would not constitute a duplication of payment. In addition, CMS will conduct participant monitoring, including chart audits, to understand how participants are using CMF and performance based incentive payments and to ensure there is no duplication of payment.

The quarterly CMF payments are intended to give participants the resources to invest in the infrastructure, staff, and resources needed to meet a beneficiary's individual needs and preferences, while at the same time recognizing that an individual beneficiary's stage in recovery and level of care required may change as they move through initial engagement and progress toward longer-term recovery. This flexibility is important given the variation in clinical strategies across treatment settings, as well as the variation in individual beneficiary needs. CMS also makes quarterly payments to participants in other Innovation Center models focused on primary care transformation, including Primary Care First (PCF) and Comprehensive Primary Care Plus (CPC+).

The CMF payment rate will not be adjusted based on patient demographics (age, gender) or acuity due to budget limitations. However, as is noted in the Performance-Based Incentive subsection below, such adjustments may be considered for incentive payment purposes.

CMS will pursue debt collection in accordance to regulation and may collect any CMF Payments improperly paid to a Participant by reducing payments that would otherwise be made to the Participant, including ongoing Medicare FFS payments. Any debt collection and payment to CMS processes will be outlined by CMS in the Participation Agreement.

Under the statute, in order to participate in the demonstration program, an applicable beneficiary shall agree to receive OUD treatment services from a participant. Prior to submitting a claim for a new

applicable beneficiary under the demonstration, participants will be required to notify beneficiaries via written notice of the participant's participation in Value in Treatment, along with a summary of the beneficiary's rights under section 1866F of the Act to terminate participation in the demonstration at any time, and to continue to see any Medicare provider and receive medically necessary covered services (no restrictions to or changes in Medicare FFS benefits apply).

Performance-Based Incentive

To motivate participants to achieve improved quality and reduced cost, a portion of participant CMF payments will be subject to a quality withhold, such that a certain percentage (0% in performance year 1; 5% in performance year2; and 10% in each performance years 3-4 thereafter) of the CMF will be withheld for each quarterly payment. Participants who meet quality criteria, to be specified in the participation agreement, during a given performance year will be eligible to earn back withheld monies. Participant performance will be assessed on an annual basis in the second quarter following the performance year, after a claims run out during the first quarter following the performance year, and the performance-based incentive will be paid to eligible participants in the third quarter following the performance year. CMS is considering the following claims-based measures for inclusion in the Value in Treatment performance-based incentive:

- Retention in treatment
- ED utilization
- Use of Pharmacotherapy for Opioid Use Disorder
- Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence
- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Participants must meet minimum criteria, including a minimum number of beneficiaries participating in Value in Treatment and a threshold for quality relative to a nationwide benchmark, to be eligible to earn back withheld monies. These measures may be risk-adjusted to account for demographics, regional variation, or other factors. CMS will pool participants who do not meet minimum patient volume criteria. CMS may also consider compliance with data collection requirements (as outlined in Participant Monitoring) when determining participant eligibility for the performance-based incentive. Measure specifications and risk adjustment methodology will be outlined in the participation agreement.

The performance measures list for performance year 2 will be communicated to participants in advance of that performance year. The list of measures tied to the performance-based incentive may be updated by CMS on an annual basis thereafter.

Beneficiary Cost Sharing

A key aim of this demonstration is to increase access to OUD treatment services, and beneficiary cost-sharing and deductibles are often a barrier to successful treatment outcomes. Moreover, because it is expected that beneficiaries will receive OUD treatment services through the demonstration in addition to other OUD treatment services covered by Medicare, CMS will use its waiver authority under section 1866F(i) of the Act to waive the requirements of section 1833(a) and 1833(b) of the Act for Medicare Part B payment systems, such that Medicare will pay 100 percent of the cost of services furnished to applicable beneficiaries by OTPs and for services furnished through the OUD bundled payments finalized in the CY 2020 Medicare PFS final rule. This waiver would apply on a uniform basis without regard to

patient-specific factors and be applied to claims submitted by participants for applicable beneficiaries for HCPCS codes G2067-G2080, G2086-G2088, and any other HCPCS codes specified by CMS for use by OTPs.

Multi-payer Alignment

The statute requires that the Secretary "encourage other payers to provide similar payments and to use similar criteria" as applied in Value in Treatment. CMS will continue to engage with commercial payers and state Medicaid agencies to understand what alignment with Value in Treatment might look like. CMS may provide additional information on this topic in the future. CMS will also plan to publish the payment methodology for Value in Treatment so other payers can align their methodology for payments related to OUD treatment services as outlined in Value in Treatment.

Beneficiary Eligibility

Applicable Beneficiaries

As defined in statute, an applicable beneficiary includes an individual who:

- Is entitled to, or enrolled for, benefits under Part A and enrolled for benefits under Part B;
- Is not enrolled in a Medicare Advantage plan under Part C;
- Has a current diagnosis for an opioid use disorder;[39] and
- Meets such other criteria as the Secretary determines appropriate.

CMS is not establishing any additional criteria for applicable beneficiaries.

Applicable beneficiaries include those who are dually eligible for Medicare and Medicaid, if the criteria listed above are also met. Under the statute, in order to participate in the demonstration program, an applicable beneficiary shall agree to receive OUD treatment services from a participant.

ADVANCED APM AND MIPS STATUS

Advanced Alternative Payment Model (APM) Status

Advanced APMs are APMs that meet these 3 criteria:

Requires participants to use certified EHR technology;

Provides payment for covered professional services based on quality measures comparable to those used in the Merit based Incentive Payment System (MIPS) quality performance category; and

Either: (1) is a Medical Home Model expanded under CMS Innovation Center authority OR (2) requires participants to bear a significant financial risk.

Because this demonstration does not require use of certified EHR technology, is not a medical home, and does not require participants to bear a significant financial risk, we anticipate that Value in Treatment will not be an Advanced APM.

[39] "Current diagnosis for an opioid use disorder" shall be determined based on the diagnosis and procedure codes included in the CCW flag for OUD, as outlined here: https://www2.ccwdata.org/documents/10280/19140001/oth-cond-algo-oud.pdf

MIPS APM Status

MIPS APMs are those in which: (1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; (2) the APM is designed such that APM Entities participating in the APM include at least one MIPS eligible clinician on a Participation List; (3) the APM bases payment on cost/utilization and quality measures; and (4) the APM is not a new APM (an APM for which the first performance year begins after the first day of the applicable MIPS performance period) or an APM in final year of operation for which the APM scoring standard is impracticable.

Value in Treatment requires participants to sign a participation agreement with CMS; keeps lists of clinicians who are members of the OUD care team that will include at least one MIPS eligible clinician; and bases payment on cost or utilization, and quality measures. The demonstration will not be considered a "new APM", given that the first performance year would begin before or on the first day of the applicable MIPS performance period. Value in Treatment will satisfy all of the MIPS APM criteria and therefore is a MIPS APM as of January 2021 (PY1).

PROGRAM OVERLAPS AND SYNERGIES

An entity may concurrently participate in Value in Treatment and certain other CMS initiatives, including shared savings, total cost of care, and medical home initiatives. Practices participating in CPC+, PCF, or the Maryland Primary Care Program (MDPCP) will not be eligible to participate in Value in Treatment due to potential redundancy in payments for services. For entities that simultaneously participate in Value in Treatment and any other CMS initiative, CMS reserves the right to potentially include additional requirements, revise initiative parameters, or ultimately prohibit simultaneous participation in multiple initiatives, based on a number of factors, including CMS's capacity to avoid counting savings twice in interacting initiatives and to conduct a robust evaluation of each such initiative.

Participation in other CMS Quality Initiatives

Participants and OUD care team members must continue to participate in all applicable CMS quality reporting initiatives for the duration of Value in Treatment.

Beneficiaries dually eligible for Medicare and Medicaid

As defined in statute, applicable beneficiaries generally include those who are dually eligible for Medicare and Medicaid, if other criteria are also met. However, some state Medicaid agencies currently include as a covered service some items that are also allowable under Value in Treatment (e.g., peer recovery support specialists, transportation for non-emergency medical needs, transportation for non-medical needs), which creates a potential for duplication. Participants will not be permitted to use demonstration program payments to enhance or supplant something Medicaid is already paying for. Participants will be required to document in the medical record how demonstration program funds are used to furnish services to dually eligible beneficiaries, so that CMS can monitor the overlap with existing Medicaid services in that state.

PARTICIPATION AGREEMENT

The performance period of Value in Treatment is anticipated to begin on April 1, 2021 for participants selected to participate based on this RFA and conclude on December 31, 2024.

Selected Value in Treatment participants must comply with requirements set forth in the Participation Agreement, including a requirement to comply with all applicable fraud and abuse laws and provisions related to monitoring and reporting, data sharing, and termination.

Fraud and Abuse Waivers

The authority for this demonstration program is section 1866F of the Social Security Act (the Act), which specifies that the Secretary may waive any provision of title XVIII of the Act as may be necessary to carry out the demonstration program. No fraud and abuse waivers are being issued in this RFA, and section 1866F of the Act does not authorize any waivers of title XI fraud and abuse authorities, including the Anti-Kickback Statute and the beneficiary inducement prohibition. Accordingly, any arrangement under this demonstration program that implicates those laws must be structured to comply with those laws, including as it relates to the provision of social support services to applicable beneficiaries.

Monitoring and reporting

Participant Monitoring

The purpose of participant monitoring is 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. CMS will monitor participants to detect non-compliance with demonstration requirements, unintended consequences or inappropriate care for beneficiaries, and potential program integrity issues. In addition, participant monitoring will enable CMS to be aware of strategies implemented by participants. Negative findings from such monitoring may result in heightened monitoring, imposition of a Corrective Action Plan (CAP), or termination from Value in Treatment, depending on the severity of the findings. CMS will employ a range of methods to monitor and assess compliance by participants, which may include, but is not limited to:

- Claims analyses to identify fraudulent behavior or program integrity risks such as inappropriate reductions in care, overutilization, and cost-shifting to other payers or populations;
- Interviews with individual participants or OUD care team members participating in demonstration activities;
- Interviews with beneficiaries served as part of the demonstration;
- Audits of charts, medical records, and other data from participants and participating OUD care teams;
- Screening of participants and their OUD care teams on the basis of program integrity issues;
- Monitoring for appropriate use of demonstration program funds (i.e., that services furnished under Value in Treatment are based on an applicable beneficiary's individualized OUD treatment plan, aligned with OUD treatment services defined in statute, and have a reasonable expectation of improving or maintaining the health or overall function of applicable beneficiaries);
- Conducting a participant survey to obtain qualitative information on functional, physical, mental, and overall health status of the beneficiaries enrolled and non-enrolled in the demonstration program, the interventions implemented, and implementation experience. This may be done through a secure online survey;
- Participant reporting on Value in Treatment revenue and expenditures, including the approximate clinical labor, non-clinical labor, and non-labor expenses paid with CMFs and performance-based incentives.

CMS is committed to taking corrective action against participants that violate the terms of the participation agreement or engage in non-compliance, fraud, or abuse. The Innovation Center will screen and monitor participants in Value in Treatment to prevent, identify, and respond to fraud and abuse related to Value in Treatment, including monitoring for overutilization of services associated with the demonstration. Participants that do not meet the demonstration requirements outlined in their

participation agreement will be considered for corrective action, such as funding restriction, and/or termination from the demonstration. CMS and its contractors will work with CMS' Center for Program Integrity and the HHS Office of Inspector General to report and refer any suspected non-compliance, fraud, or abuse for further investigative or administrative action as appropriate under existing law. These actions may include overpayment recovery, exclusion from Federal health care programs, imposition of civil monetary penalties, and/or referral to law enforcement.

Monitoring Costs Related to CMFs and Performance-Based Incentives

For the purposes of making payments under the demonstration, the statute makes available $10,000,000 from the Federal Supplementary Medical Insurance Trust Fund under section 1841 for each of fiscal years 2021 through 2024. In order to ensure spending does not exceed the amount allowed by statute, CMS will take the following steps:

- **Per Participant Beneficiary Cap:** CMS will stipulate a cap on and notify the Participant of the number of beneficiaries each participant is permitted to treat under Value in Treatment in any given quarter. Cap calculations will be based on a participant's historical claims and a projection of beneficiary cost sharing costs. Beneficiary caps will be unique to each participant, as participant capacity may vary. CMS may adjust caps quarterly, if needed (e.g., if a participant is continuously under-spending, their cap may be reduced and another participant's cap increased to ensure Value in Treatment is serving the maximum number of beneficiaries possible). Beneficiary caps are specific to Value in Treatment, and in no way will restrict beneficiary freedom of choice or ability to access non-demonstration services from a participant.
- **Cost and Quality Monitoring:** CMS will conduct programmatic monitoring to ensure the demonstration does not exceed the annual $10,000,000 budget. This includes 1) monitoring participant billing and 2) monitoring quality measure performance to assess participant performance. In an effort to be transparent, CMS will update participants on their performance, if requested.

Data Sharing

The statute requires all Value in Treatment participants to report certain data needed for CMS' or CMS' contractors' auditing and evaluation work. This includes data and other information to support auditing, quality measurement, and monitoring to track beneficiary experience and ensure that the demonstration program meets its goal of improving outcomes and reducing costs for applicable beneficiaries. Data reporting may include submission on a quarterly basis of beneficiary-specific encounter information, information on OUD care team members, data from quality measures that cannot be calculated from claims and/or the beneficiary-specific encounter information, and other information needed to monitor participants and assess performance as it pertains to the Performance-based Incentive. CMS reserves the right to require the production of any other data required by law, and to request such data as may be permitted by applicable law that is needed to operate the program.

As described in Monitoring and reporting, participants may also be asked to participate in a survey to obtain qualitative information on interventions implemented and implementation experience. This may be done through a secure online survey.

Participant reporting and data sharing requirements will be outlined in the participation agreement. Failure to meet reporting requirements may result in corrective action and/or termination.

As noted above, CMS may also share performance information with participants, including historical and/or monthly claims data. All information will be provided consistent with all applicable laws and regulations, including HIPAA and the Part 2 regulations governing the disclosure and use of certain substance use disorder patient records. Because we assume all beneficiaries receiving services under Value in Treatment will be protected by Part 2 regulations, CMS will only share patient-identifiable information for beneficiaries who have opted in to data sharing.

Specifically, under appropriate agreements (e.g., the participation agreement) and upon a participant's request, CMS may make available several types of Medicare data for the sole purposes of developing and implementing activities related to coordinating care and improving the quality and efficiency of care for applicable beneficiaries who have opted in to data sharing.

Upon request from the participant, CMS may provide (1) data on applicable beneficiaries who have opted in to data sharing 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 (2) 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. Historical data files for applicable beneficiaries will be limited to three years of historical data, consistent with the approach under the CPC+ Model and shared savings initiatives.

Claims data provided to participants will not include individually identifiable data for applicable beneficiaries who have not opted in to data sharing. Participants will be required to notify new beneficiaries at the start of their OUD treatment with a Value in Treatment participant, in compliance with applicable laws and regulations, regarding the participant's intent to request their claims data from CMS, including beneficiary-level data regarding the utilization of substance use disorder treatment services. Such notification must include information or forms regarding the beneficiary's opportunity to opt in to or decline data sharing, the mechanism by which the beneficiary can make this election, and contact information for answers to any questions about data sharing of data regarding substance use disorder services. CMS will provide participants with a Data Sharing Opt-In Form.

Termination

CMS reserves the right to terminate a participation agreement, or to require a participant to terminate its agreement with an OUD care team member, for reasons including but not limited to:

- If the participant consistently does not meet quality performance thresholds or benchmarks required under the demonstration program participation agreement.
- If the participant fails to meet reporting requirements specified in the participation agreement, including failure to report data on monitoring and quality measures.
- If the participant is subject to action by the Department of Health and Human Services (HHS) or the Department of Justice involving violations of applicable laws, statutes, and regulations, including but not limited to: federal criminal laws, the federal False Claims Act, antitrust laws, the federal anti-kickback statute, the federal civil monetary penalties law, the federal physician self-referral law or any other applicable Medicare laws, rules or regulations that are relevant to this demonstration program.
- If the participant, or OUD care team that the participant has engaged, has failed to comply with any requirement of the participation agreement, which includes but is not limited to a prohibition against restricting access to medically necessary care.

- If the participant fails to pay back money owed to the Medicare program as specified in the demonstration program participation agreement or any audit issued pursuant thereto.
- If the participant unreasonably interferes with or impedes CMS's and its designees' monitoring and evaluation activities.
- If the participant is unable to implement the demonstration program due to state or local laws or scope of practice barriers.
- If the participant has failed to comply with any of the Federal requirements for participation as a Medicare provider or supplier, including the Conditions of Participation, Conditions for Coverage, or Requirements of Participation.

The participation agreement may detail additional grounds for termination.

EVALUATION

CMS, under contract with an independent evaluator, will conduct an evaluation of the demonstration mandated by the statute. As outlined in 1866F(c) of the Act, all demonstration participants are required to cooperate with efforts to conduct the independent evaluation of the demonstration program. This may include but would not be limited to participation in surveys, interviews, site visits, focus groups, and other activities that CMS determines necessary to conduct a comprehensive evaluation. CMS anticipates all data collected from participants will be reported at an aggregate-level data so as to avoid the disclosure of private and sensitive data of specific participants and beneficiaries.

The evaluation will assess the extent that the demonstration program:

a) Reduced hospitalizations and emergency department visits;
b) Increased use of medication-assisted treatment for opioid use disorders;
c) Improved health outcomes of individuals with OUD, including reducing the incidence of Hepatitis C and HIV;
d) Did not increase the total Medicare spending on items and services;
e) Reduced deaths from opioid overdose; and
f) Reduced the utilization of inpatient residential treatment.

In addition, the evaluation findings will include the extent to which the performance-based incentive under the demonstration program:

i. Increased retention in treatment;
ii. Increased the use of pharmacotherapy for Opioid Use Disorder;
iii. Increased follow-ups after an emergency department visit for alcohol and other drug abuse or dependence; and
iv. Initiated as well as increased engagement in alcohol and other drug dependence treatment.

APPLICATION

The statute requires that participants in Value in Treatment must be selected pursuant to an application and selection process established by the Secretary. Such process is outlined in this section and the remaining sections of the RFA.

Application Submission Guidance

Individuals and entities interested in participating in Value in Treatment must submit to CMS all application materials via email no later than January 3rd, 2021, at 11:59pm ET ValueinTreatment@cms.hhs.gov.

What should I submit as part of the application?

- Appendix A and B (combined in a single document)- the completed request for application (RFA) and signed RFA checklist
- Attachment 1- the completed OUD Care Team Roster

Where can I find the application package?

- Application materials will be available at https://innovation.cms.gov/innovation-models/value-in-treatment-demonstration . These materials will be posted along with the RFA.

When should I submit the application package?

- Value in Treatment applications will be accepted from November 18th, 2020 to January 3rd, 2021. All applications must be submitted no later than 11:59pm ET on January 3rd, 2021.

How and where should I submit the application package?

To submit an application, applicants must submit via encrypted email all application materials to ValueinTreatment@cms.hhs.gov using the following format and naming conventions.

- Appendix A and B (in combined document)
    - Format
        - Same font format as Appendix A and B (Calibri Light, 11)
        - Same page size as Appendix A and B (8.5" x 11" letter-size, with 1" margins)
        - Where narrative is requested, it must be single-spaced and no longer than the noted word count (figures are not counted towards word count)
        - A PDF or word document
    - Naming Convention
        - <'DemoID'>_ViTRFA)_AppendixA-B_<'MMDDYYYY'>
            - 'DemoID'> = ShortName-ID (Example: CMMI-1234), where ShortName is a 7 character name with no space (abbreviation, initials, acronyms, other short name identified by applicant), and ID is the last four digits of the 9-digit Tax ID Number (TIN).
            - 'MMDDYYYY is the date of application submission
- Attachment 1 (OUD Care Team Roster)
    - Format
        - Same font format as the "2. OUD Care Team" tab (Calibri, 11)
        - Refer to "1. Data Dictionary" tab for data element definitions and requirements
    - Naming Convention
        - <'DemoID'>_ViTOUDCareTeam_Attachment1.xlsx
            - 'DemoID'> = ShortName-ID (Example: CMMI-1234), where ShortName is a 7 character name with no space (abbreviation, initials, acronyms, other short name identified by applicant), and ID is the last four digits of the 9-digit Tax ID Number (TIN).

What if I don't meet the eligibility criteria at the time of application?

CMS will promptly reject applications submitted by individuals or entities that do not meet eligibility criteria at the time of application, unless the applicant submits an exception request and anticipates satisfying all eligibility requirements by the later of April 1, 2021 or the Effective Date of the Participation Agreement(e.g., an OTP that has applied to participate in Medicare but not yet completed the enrollment process).

Exception requests may be submitted within Appendix A (RFA question 9). The exception request must describe the specific eligibility criteria for which an exception is sought, why the exception is needed under the applicant's specific circumstances, and indicate whether the eligibility criteria is expected to be satisfied by the beginning of the first performance year.

If an applicant with an approved exception request is selected to participate in the demonstration but does not qualify by the beginning of the first performance year, the applicant will be deemed ineligible for the demonstration program.

Other Information Requests and Inquiries

In addition to questions included in this RFA, CMS reserves the right to request additional information from applicants to assess their applications (e.g., through interviews, site visits, or additional written information related to application responses).

CMS will accept Value in Treatment applications from individuals or entities that meet preliminary eligibility requirements, as outlined in Participant and OUD Care Team Eligibility. The application must be certified as true, accurate, and complete by an individual authorized to bind the individual or entity applicant (i.e., the legal entity submitting the application).

Questions about the Value in Treatment application should be directed to ValueinTreatment@cms.hhs.gov. CMS may publicly share questions or responses or compile them into a Frequently Asked Questions compendium to ensure that all interested applicants have access to information regarding Value in Treatment. CMS will safeguard individually identifiable information in accordance with applicable law, including, where applicable the Privacy Act of 1974, as amended (5 U.S.C. § 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/AboutWebsite/02_Privacy-Policy.asp.

Participant Screening

Participants will apply and be accepted into Value in Treatment based on the content of their application and the results of a program integrity screening. CMS will conduct an initial eligibility assessment and comprehensive review of applications, and conduct a program integrity screening. Program integrity screenings may not be completed by the time applicants are notified of the Value in Treatment selection decision. These decisions will be contingent, pending completion of program integrity screening. Program integrity screenings of all members of the OUD care team may be conducted on an ongoing basis throughout the Value in Treatment performance period.

Initial Eligibility Assessment

Upon application submission, CMS staff will conduct an initial eligibility assessment to determine if applicants are eligible to participate in Value in Treatment (based on the *Applicant Eligibility* questions of the application). If the initial assessment deems an application ineligible, CMS will not proceed with the program integrity screening and comprehensive application review.

Comprehensive Application Review

A comprehensive application review will be conducted for applicants determined eligible for Value in Treatment. During application review, CMS will assess and score applications in accordance to the scoring and selection criteria noted in the application. CMS reserves the right to contact applicants to clarify

responses, if responses provided are considered incomplete or unresponsive. Applicants with the highest scores will be given preferential selection.

Program Integrity Screening

All applicants will be subject to program integrity screening, which includes, if applicable, an assessment of the applicant's current status in the Medicare program by CMS' Center for Program Integrity (CPI). Additionally, applicants must disclose any sanctions, investigations, probations, actions or corrective action plans to which its practitioners, owners or managers, and/or other participating organizations, entities, or individuals are currently subject or have been subject at any point during the last five years. Further, applicants must not be in arrears in the payment of any obligations due and owing to the State or the federal government, including the payment of taxes and employee benefits. Participants must similarly not become in arrears during the term of their participation agreement.

CMS may deny an application on the basis of information found during a program integrity screening regarding the applicant, any OUD care team members, or any other relevant individuals or entities. Applicants must disclose present or past sanctions or other actions of an accrediting organization or a federal, state, or local governmental agency within the past 5 years; investigations including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, or being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action; the imposition of remedial action or termination in regard to participation in a CMS demonstration or a CMS Innovation Center model authorized under 1115A of the Act; or any other administrative enforcement actions; each related to the applicant, its affiliates or any other relevant persons and entities. Applicants must also disclose all debts currently due and owing to CMS by the applicant, its affiliates, or any other relevant persons or entities. If selected, each participant will continue to be subject to periodic screening throughout the demonstration program performance period, at CMS's discretion.

The participant will also be required to identify to CMS all OUD care team members throughout the demonstration program performance period to allow CMS to screen each such provider or supplier before approving the OUD care team member to furnish services through the demonstration program. Proposed OUD care team members who are not enrolled in Medicare will be required to provide more information than Medicare-enrolled counterparts as part of the screening process.

Selection Notification

We anticipate applicants will be notified of the selection decision in early February via email from ValueinTreatment@cms.hhs.gov. The point of contact listed in the application will be emailed the selection decision letter and forwarded the next steps to complete the Value in Treatment participation agreement.

Application Scoring

Each applicant may receive up to 100 points in its application. As is indicated in Table 2, a maximum number of points may be earned in each section based on applicant responses based on the noted selection criteria.

Table 2: Application Scoring and Selection Criteria

Section	Score (n=100 pts.)	Selection Criteria
Applicant Eligibility	0	• Applicant must meet eligibility requirements.

Section	Score (n=100 pts.)	Selection Criteria
Applicant Information and Government Structure	10	• All requested contact and billing information is provided. • Has an organizational structure that promotes the goals of Value in Treatment. • Has a history of compliance. • Does not exceed maximum page limits, where instructed.
OUD Care Team	20	• Identifies all OUD care team members, including the required physician furnishing primary care services and/or addiction treatment services. • Completes and submits Attachment 1, as instructed. • Confirms formal relationship with OUD care team members.
Proposed Demonstration Region	20	• Lists each state and county where OUD treatment services will be furnished under the demonstration. • Prevalence and utilization rates exceed the national average in specified county(s) and state(s).
Applicant Medicare Patient Volume	15	• Provides requested data figures to assess OUD treatment capacity. • Furnishes OUD treatment services to a high number of applicable beneficiaries.
Proposed OUD Treatment Services	35	• Clearly identifies OUD treatment challenges and how proposed OUD treatment services under the demonstration intend to address those challenges. • Ability to ensure care access outside of normal business hours and office-based visits. • Partners with emergency department or hospital as part of patient follow-up protocol. • Partners with emergency department or hospital and other community partners to coordinate care for OUD patients. • Uses Health Information Exchange (HIE) or other mode(s) of data sharing for enhanced patient care communication and coordination. • Confirms patient safety and communication plans, including involvement of family and caregivers. • Does not exceed maximum page limits, where instructed.
Program Duplication Assessment	0	• Confirms participation in other Medicare initiatives and other federally-funded programs. • Clearly outlines monitoring plan to identify duplicative payments. • Does not exceed maximum page limits, where instructed.

CMS reserves the right to apply additional considerations to limit the number of qualified applicants who may be selected to participate in Value in OUD Treatment. Without limitations, CMS may reject applicants wherein the interested applicant does not provide sufficient information to be reasonably considered or the interested applicant's proposed OUD treatment services/interventions are inconsistent with the objectives of the demonstration.

APPENDIX A: REQUEST FOR APPLICATION (RFA)

All applications will be assessed to determine the applicant's eligibility to participate in Value in Treatment. Applicants that are deemed to be eligible will then be scored based on application scoring criteria outlined above and responses to the following application questions. Applicants must answer all application questions. CMS reserves the right to seek additional information from applicants after the application period closes.

Eligibility Criteria

If the response to any one of the following questions 1-7 is "the applicant is ineligible", then the applicant does not qualify to participate in Value in Treatment and should not proceed with completing the rest of the application unless requesting an exception. This section will not be scored.

1. Is the applicant enrolled in Medicare and eligible to bill for services under the Medicare program?
   - ☐ **YES**
   - ☐ **NO (if no, the applicant is ineligible)**
2. The applicant is one of the following (select only ONE entity that will serve as the participant):
   - ☐ Physician
   - ☐ Group practice comprised of at least one physician
   - ☐ Hospital outpatient department
   - ☐ Federally qualified health center
   - ☐ Rural health clinic
   - ☐ Community mental health center
   - ☐ Clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014
   - ☐ Opioid treatment program
   - ☐ Critical Access Hospital
   - ☐ **None of the above (if none, the applicant is ineligible)**
3. Is the applicant identified by a single tax payer identification (TIN) for billing purposes?
   - ☐ YES (Please provide)
   - ☐ **NO (if no, the applicant is ineligible)**
4. Is the applicant a separate and unique legal entity that is recognized and authorized to conduct business under applicable federal, state, or tribal law?
   - ☐ YES
   - ☐ **NO (if no, the applicant is ineligible)**
5. Is the applicant capable of repaying demonstration payments to CMS, if applicable, and of establishing reporting mechanisms, including but not limited to mechanisms for reporting on quality measures, and ensuring compliance with demonstration requirements?
   - ☐ YES
   - ☐ **NO (if no, the applicant is ineligible)**
6. Does the applicant's OUD care team include the following Medicare-enrolled physicians and/or practitioners (employed or contracted)? Check all that apply.
   - ☐ At least one physician furnishing primary care services or addiction treatment services
     Please indicate how many:
     Primary Care Provider(s):_____
     Addiction Provider(s):_____

- ☐ At least one physician or other health care practitioner authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment
  Please indicate how many:
  Provider(s) authorized to prescribe/dispense narcotics:_____
- ☐ None of the above (if none, the applicant is ineligible)

7. The applicant's OUD care team is able and available to provide OUD treatment services on a face-to-face basis.
   - ☐ YES
   - ☐ NO (if no, the applicant is ineligible)

8. Will the applicant be participating in the following programs as of April 1, 2021? Check all that apply.
   - ☐ Maryland Primary Care Program (MDPCP) (if selected, the applicant is ineligible)
   - ☐ CMMI's Primary Care First (PCF) Model (if selected, the applicant is ineligible)
   - ☐ CMMI's Comprehensive Primary Care Plus (CPC+) Model (if selected, the applicant is ineligible)
   - ☐ None of the above

9. Is the applicant requesting an eligibility exception for one or more of the eligibility criteria noted in Questions 1-8 where the selected response was noted as "the applicant is ineligible"?
   - ☐ YES (if yes, the applicant must complete the requested information in the table below).
   - ☐ NO (if no, the applicant is ineligible)
   - ☐ Not Applicable (applicant meets all eligibility criteria from questions 1-8)

Exception Requested (list each applicable question #)	Explanation (why is the exception need?)	Mitigation Plan (how and when does the applicant expect to satisfy the eligibility requirement?)

Applicant Information and Governance Structure

This section requests information regarding the applicant's governance structure. Governance structure questions are intended to illustrate how applicant's organizational layout or governance can readily accommodate implementation and responsibilities within Value in Treatment. This section is worth a maximum of 10 points.

10. Contact Information (individual filling out the application)
    a. First and Middle Name:
    b. Last Name:
    c. Title/Position:
    d. Relationship to the Applicant Organization:
    e. Mailing Address (Street Address, City, State, Nine-Digit ZIP Code):
    f. Telephone Number:
    g. E-mail Address:

11. Applicant Information (entity applying as demonstration participant)
    a. Legal Business Name of applicant, as reported to the Internal Revenue Service:
    b. Additional Name(s) (i.e., "Doing Business As"/DBA Name) (enter N/A if not applicable):
    c. Legal and/or financial affiliations to other entities (enter N/A if not applicable):
    d. Mailing Address (Street Address, City, State, and Nine-Digit ZIP Code):

e. Please provide a single TIN and single National Provider Identification (NPI) number to be used for Value in Treatment billing purposes:
   TIN:
   NPI:
f. Applicant's Provider Transaction Access Number (PTAN) for applicants enrolled in Part B (enter N/A if not applicable):
g. Applicant's CMS Certification Number (CCN), for applicants enrolled in Part A (enter N/A if not applicable):
h. Does the applicant confirm that all information in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) is accurate and up-to-date as of the submission of its responses to this RFA?
   ☐ YES (if yes, applicant may proceed with application)
   ☐ NO (if no, applicant must update PECOS information before proceeding with application or request an application exception in Question 9 if applicant is not yet enrolled in Medicare (note that the applicable question to enter in the requested table information is 1).
i. Does the Applicant or any of its affiliates have any outstanding overpayments or other debts to CMS?
   ☐ YES (if yes, please identify amount owed and date of the determination of the amount owed)
      Amount:
      Date of Determination:
   ☐ NO

12. Applicant Governance Structure and Compliance:
   a. In a short paragraph (maximum of 300 word count), please specify applicant's governing body and decision-making process, including the organizational structure for Value in Treatment functions and the designated individual/s making Value in Treatment implementation decisions.

   b. To the best of your knowledge, has the applicant or anyone employed by the applicant had a final adverse legal action (as defined on page 12 of the Medicare Enrollment Application for Physicians and Non-Physician Practitioners, CMS-855i)? Failure to disclose could be grounds for application denial or immediate termination from the demonstration program.
      ☐ YES (if yes, please list each adverse legal action and specify when each occurred and the entity that imposed the action)
      ☐ NO

   c. To the best of your knowledge, has the applicant or anyone employed by the applicant been the subject of an investigation by, prosecution by, or settlement with the HHS Office of Inspector General, U.S. Department of Justice, or any other Federal or State enforcement

agency in the last five years relating to allegations of failure to comply with applicable Medicare or Medicaid billing rules, the Anti-Kickback Statute, the physician self-referral prohibition, or any other applicable fraud and abuse laws? Failure to disclose could be grounds for application denial or immediate termination from the demonstration program.

- ☐ YES (if yes, please list and describe each investigation, prosecution, or settlement)

- ☐ NO

OUD Care Team

The applicant is required to have or establish an OUD care team that employs or contracts with, at minimum, at least one physician furnishing primary care services or addiction treatment services and at least one physician or other health care practitioner authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (these can be the same individual). Applicants may also include in their OUD care team one or more practitioners licensed under state law to furnish psychological, counseling, or social services to applicable beneficiaries. The following questions request information regarding the applicant's OUD care team.

This section is worth a maximum of 20 points.

13. Has the applicant established an OUD care team that includes members who are permitted to furnish psychological, counseling, or social services by state law within their applicable scope of practice? **Check all that apply and indicate number.**

    - ☐ Licensed professional counselor ____
    - ☐ Licensed clinical alcohol and drug counselor ____
    - ☐ Licensed marriage and family therapist ____
    - ☐ Certified peer specialist ____
    - ☐ Community health worker ____
    - ☐ Care Manager ____
      Please list:
    - ☐ Other practitioners licensed under State law____
      Please list:
    - ☐ None of the above

14. Does the applicant have an established formal relationship with each of the OUD care team members identified in questions 6 and 13?
    - ☐ **YES**
    - ☐ **NO (if no, describe the timeline for establishing such relationships with required providers and other OUD care team members):**

Required Providers (Question 6): *Other OUD care team members (Question 13):*

15. Please refer to *Attachment 1* and complete the requested information in accordance to the guidance embedded in the attachment. The number of OUD care team members listed in this spreadsheet should match the number indicated in questions 6 and 13. This attachment is part of the application package and failure to submit will result in the application determined to be incomplete and/or nonresponsive.

Proposed Demonstration Region

16. Please identify the **state/s and county/counties** in which the applicant proposes to furnish OUD treatment services to applicable beneficiaries under Value in Treatment. List each state with the same format as is listed in ***Attachment 2_ViT Prevalence Rates***.

    State(s): Format is two-digit state abbreviation; separate with comma <”,”> if more than one listed.

    County/counties: Format is state county SSA code; separate with comma <”,”> if more than one listed.

CMS application reviewers will score applicants based on the state and county provided in this application and the prevalence and utilization rates specific to that state and county, as listed in ***Attachment 2_ViT Prevalence Rates***. If the applicant intends to furnish OUD treatment services to applicable beneficiaries residing in multiple states and/or counties, the state and/or county with the highest rates will be used to score this section. This section is worth a maximum of 20 points. Specifically:

- Applicants serving beneficiaries who reside in states with above average national Medicare **OUD prevalence rates** will receive 5 points
- Applicants serving beneficiaries who reside in counties with above average national **Medicare OUD prevalence rates** will receive 5 points.
- Applicants serving beneficiaries who reside in states with above average national Medicare **OUD-related ED visits and hospitalizations** will receive 5 points
- Applicants serving beneficiaries who reside in counties with above average national Medicare **OUD-related ED visits and hospitalizations** will receive 5 points

Medicare Patient Volume

This section requests the applicant's history of treating Medicare FFS OUD beneficiaries. If applicants are unable to provide requested data points based on collected data, please provide best estimates. This section is worth a maximum of 15 points.

17. In CY 2019, to how many Medicare FFS beneficiaries with an OUD diagnosis did the applicant furnish office-based or non-office based visits to? _____

    Is this based on collected data or best estimates?
    - ☐ Collected
    - ☐ Best Estimate

18. Please indicate the proportion of the Medicare FFS beneficiaries with an OUD diagnosis in the applicant's care (as indicated in Question 17) who were:

    a) Dually-eligible for Medicare and Medicaid: _____
    b) Engaged in MAT treatment: _____
    c) Retained in MAT treatment for at least 180 days: _____

    Is this based on collected data or best estimates?
    - ☐ Collected data
    - ☐ Best estimate

19. Does the applicant anticipate being able to provide OUD treatment services to the same number of beneficiaries with an OUD diagnosis indicated in Question 17?

    - ☐ We are prepared to provide OUD treatment services to the same number of beneficiaries.
    - ☐ We are prepared to provide OUD treatment services to a greater number of beneficiaries, if services are applicable and accepted by the beneficiary.
    - ☐ No, we anticipate we will provide OUD treatment services to a smaller number of beneficiaries.

Proposed OUD Treatment Services

Value in Treatment participants will have the flexibility to use the CMF and performance-based incentive to implement tailored and individualized OUD treatment services that best meet an applicable beneficiary's treatment needs. This section serves as the applicant's proposed implantation plan, and requires the applicant to identify current challenges in treating and engaging applicable beneficiaries, how the applicant intends to implement Value in Treatment, and how the CMF and performance-based incentive will be used. This section is worth a maximum of 35 points.

20. Please describe the applicant's current challenges with engaging and retaining applicable beneficiaries in OUD treatment (650 maximum word count).

21. The applicant's proposed implementation plan includes using the CMF payment for the following types of services *(refer to "Care Delivery Intervention" section of this RFA for examples of each)*. Select all that apply. For each service selected, please describe and discuss how each will address the noted challenges above. Cite all relevant evidence-based research or data that helps support your rationale (250 maximum word count for each selection.

☐ Staff time for Value in Treatment capacity building and infrastructure readiness

☐ Hire or contract staff needed to furnished proposed services

☐ Expand care delivery settings or modalities

☐ Provide enhanced social support services (which must be furnished in compliance with applicable fraud and abuse laws)

☐ Coverage of recovery enabling services

☐ Other

22. The applicant's proposed implementation plan includes offering face-to-face visits for some OUD treatment services.

☐ YES (if yes, please specify. 250 maximum word count)

☐ NO

23. The applicant's proposed implementation plan includes offering after-hours access to OUD treatment services.
    - ☐ YES
    - ☐ NO
24. The applicant's proposed implementation plan includes a protocol to following-up with applicable beneficiaries seen in the ED or hospital. Please select the statement that applies:
    - ☐ Follow-up generally will not occur
    - ☐ Follow-up will occur only if we are alerted by the ED or hospital
    - ☐ Follow-up will occur because we will take proactive efforts to identify our OUD patients who've been admitted to the ED or hospital
    - ☐ Follow-up will be done routinely because we have arrangements in place with the ED and hospital tracking OUD patients to ensure timely follow-up is done.
25. Increasing access of applicable beneficiaries to OUD treatment services may occur by establishing voluntary relationships in the community that can increase awareness of the services offered by the participant. Does the applicant's proposed implementation plan include the following types of voluntary relationships? Select all that apply:

    - ☐ We will engage with EDs and/or inpatient facilities (e.g., by informing them of the services that we will provide to potentially eligible patients and coordinating with them upon referral of an OUD patient).
    - ☐ We will engage with other physical, behavioral, substance use, or community-based partners.
      Please describe (250 maximum word count):

    - ☐ We will not be engaging with external sources
      Please explain (250 maximum word count):

26. Please indicate the OUD treatment services and MAT medications currently furnished by the applicant and OUD care team, and how such services will be enhanced or expanded under Value in Treatment (650 maximum word count).

27. Is the applicant currently participating in a Health Information Exchange (HIE), or will be participating in a HIE during the Value in Treatment performance period?
    - ☐ YES
    - ☐ NO (if no, please describe how patient data will be shared and communicated among the OUD Care Team and other formal partners. 250 maximum word count.)

28. Please confirm the following statements if true. Select all that apply.

- ☐ A strategy for ensuring patient safety and quality is or will be established under Value in Treatment. This includes clinical and procedural protocols for the proposed services, safety monitoring to ensure all protocols are being followed, corrective action for violation of protocols, monitoring of quality measures, and communication strategy to effectively communicate with providers and payers about a beneficiary's OUD treatment plan.
- ☐ A strategy for ensuring the applicable beneficiary agrees to receive OUD treatment services is or will be established under Value in Treatment. This includes a plan for notifying and educating eligible beneficiaries about Value in Treatment via written notice, which includes information on beneficiary rights to opt-out of participation and data-sharing at any time, along with other beneficiary rights, and obtaining beneficiary consent to participate.
- ☐ A strategy for ensuring family and caregivers of an applicable Medicare OUD beneficiary are engaged under Value in Treatment. This includes engaging them in Value in Treatment education and consent, as well as the patient's treatment plan, as needed.

Program Duplication Assessment

The purpose of the Program Duplication Assessment is for applicants to identify other models, programs, or demonstrations that target similar populations and/or services relevant to the applicant's participation in Value in Treatment. Applicants will also identify how they will monitor potential program and funding duplication. Failure to complete the Program Duplication Assessment may disqualify the applicant. CMS, in its sole discretion, will determine whether the information provided by the applicant and/or participant constitutes duplication. Participation in other models, programs, or demonstrations will not preclude applicant from participation in Value in Treatment. This section will not be scored.

29. Will the applicant be participating in any of the Medicare initiatives below as of April 1, 2021? Please check all that apply.

- ☐ Shared savings initiatives
  Please specify:
- ☐ Total cost of care initiatives
  Please specify:
- ☐ Medical home initiatives
  Please specify:

☐ CMS initiatives that pay a care management fee

Please specify:

☐ Other

Please specify:

30. Will the applicant be participating in other federally-funded programs targeting individuals with OUD, including State/Tribal Opioid Response (SOR/TOR), State Targeted Response (STR), Medicaid Demonstration Project to Increase Substance Use Provider Capacity as of April 1, 2021?

☐ YES

Please specify:

☐ NO

APPENDIX B: REQUEST FOR APPLICATION (RFA) CHECKLIST

Below is a checklist detailing the documents that your organization is required to submit for consideration in Value in Treatment. It is the responsibility of the applicant to ensure that all documents required are included with the application. Failure to comply may result in applications determined to be ineligible, incomplete, and/or nonresponsive based on initial screening and may be eliminated from further review.

All documents must be signed, scanned, and attached to the application email. Please retain the original, signed documents. If you have any questions about what your organization is required to submit, please contact CMS at ValueinTreatment@cms.hhs.gov.

Checklist:

- ☐ Completed Application (Appendix A and B)
- ☐ Completed *Attachment 1* (OUD Care Team Roster)

I understand that CMS provides no opinion on the legality of any contractual or financial arrangement that has been proposed or documented in this application. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS (including its Office of Inspector

General), any law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

I have read the contents of this application and I certify that I am legally authorized to submit the application. Upon submission of this application I certify to the best of my knowledge that all of the submitted information is true, accurate, and complete. If I become aware that any submitted information is not true, accurate, and complete, I will correct such information promptly. I understand that the knowing omission, misrepresentation, or falsification of any submitted information may be punished by criminal, civil, or administrative penalties, including fines, civil damages, and/or imprisonment.

Signature of authorized individual: _____

Date: _____

APPENDIX C: SUMMARY OF LITERATURE DEMONSTRATING IMPACT OF SOCIAL SUPPORT SERVICES ON TREATMENT OUTCOMES, COSTS, AND UTILIZATION

Program Title	Description	Outcomes
Peer Recovery Support[40,41]	• Systematic review of the effectiveness of peer-delivered recovery support services for people with addictions • Peer-based recovery support services are defined as nonprofessional, nonclinical assistance to achieve long-term recovery from substance use disorders.	• Most studies reported statistically significant improvements in outcomes, including substance use; housing stability; probation/parole; health care utilization; and severity of co-occurring mental health conditions
Transition from ED to ongoing OUD treatment [42,43]	• Randomized trial to evaluate the long-term outcomes of OUD treatment at 2, 6 and 12 months following ED interventions. • Treatment arms included referral to treatment, brief intervention, and buprenorphine with linkage to ongoing treatment in primary care.	• The buprenorphine group was retained in treatment at 2 months at a significantly higher rate than the referral or brief intervention groups. • This difference did not persist at 6 months or 12 months.
Mobile treatment[44,45]	• Program evaluation of Project Connections at Re-Entry (PCARE), a mobile buprenorphine treatment program. • A second study compared the retention in methadone maintenance treatment for OUD patients in a Baltimore mobile methadone program with retention in fixed-site treatment programs.	• 67.9% returned for a second visit or more, and 31.6% percent were still involved in treatment after 30 days. • Significantly longer retention time (median = 15.53 months) for mobile program patients compared to fixed site treatment programs (median = 5.02 months).
Waiver of copayment[46]	• Review of claims data to examined the rate and duration of outpatient SUD treatment following inpatient detoxification among commercially insured individuals	• 79% of patients received follow up treatment within 30 days of discharge • Likelihood of follow-up decreased significantly with increasing outpatient copayment • Estimated 43% decrease in follow-up for treatment with $30 copayments and 19% decrease with $20 copayment. • Estimated 24% and 5% increase in follow-up treatment with no copayment and $10 copayment respectively.
Housing Assistance[47,48]	• Longitudinal qualitative study comparing substance abuse and substance abuse treatment utilization between individuals receiving Housing First intervention and individuals receiving Treatment First interventions. • Housing First allows clients to be placed directly into permanent housing without needing to prove their fitness through a series of prerequisites.	• Housing First participants who received housing assistance in conjunction with OUD treatment were significantly more likely to have low/no substance use during the study year than the Treatment First participants, who did not receive housing assistance.

[40] https://www.thenationalcouncil.org/wp-content/uploads/2018/12/Peer-Support-Workers-in-EDs-Issue-Brief.pdf
[41] https://www.sciencedirect.com/science/article/pii/S0740547216000167?via%3Dihub
[42] https://jamanetwork.com/journals/jama/fullarticle/2279713
[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442013/
[44] https://www.sciencedirect.com/science/article/pii/0376871696012732?via%3Dihub

[45] https://www.scopus.com/record/display.uri?eid=2-s2.0-85065549834&origin=resultslist&sort=plf-f&cite=2-s2.0-0030270678&src=s&imp=t&sid=843f959ed492bb7ca14e2f4cf0f72b95&sot=cite&sdt=a&sl=0&relpos=1&citeCnt=0&searchTerm=

[46] https://ps.psychiatryonline.org/doi/full/10.1176/appi.ps.51.2.195?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

[47] https://aspe.hhs.gov/basic-report/housing-options-recovery-individuals-opioid-use-disorder-literature-review

[48] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2916946/