Response to Public Comments in Federal Register for Value in Treatment Demonstration - PRA (CMS-10728)

Value in Treatment – PRA: Federal Register Comments & Response

Theme	Comment	Comment/Contact:	CMS Response:	CMS Contact:
Support	● We are writing in support of the Value in Treatment demonstration initiative. We anticipate that a greater number of Medicare beneficiaries will be admitted to OTPs and will be able to remain in treatment as a direct result of this benefit. AATOD will also work with patient advocates in NAMA Recovery and our policy partners as this demonstration program continues.	ATTOD, Mark W. Parrino	● CMS acknowledges the support, and appreciates the ongoing effort in providing assistance to potential applicants and others as the demonstration progresses.	
	● A long-standing barrier to providing comprehensive opioid use disorder (OUD) treatment to Medicare beneficiaries is Medicare's lack of coverage for services provided by Licensed Professional Counselors (LPCs). LPCs can provide the psychosocial interventions that many patients with OUD need to enter and sustain recovery. ASAM applauds CMS for specifically noting that the CMF may be used to cover therapy or counseling services furnished by licensed clinical professional counselors and licensed clinical alcohol and drug counselors who are permitted to furnish such services by state law. This coverage will help fill a crucial	1. Paul Earley, MD, DFASAM: President, American Society of Addiction Medicine 2. Susan Awad, Senior Advisor, Public Policy and Regulatory Affairs at sawad@asam.org or 301-547-4106 (7/28/20)	● As specified in Statute, "services that are furnished for the treatment of opioid use disorders…includes…psychiatric, psychological, or counseling services (or any combination of such services), as appropriate; social support services, as appropriate…" CMS has provided examples of how the CMF and PBIP may be used, but this list is not exhaustive. This list includes "(e)xpand care delivery settings or modalities," with the goal of filling the payment gap identified.	

	Medicare payment gap. ● The proposed Request for Applications notes that participants can use the CMF and performance-based incentives payments made through the demonstration to expand care delivery settings or modalities, including in the beneficiary's home. We agree that this should be a priority in the program as technology to detect OIRD can be safely used in the home.			
	● The AMA commends CMMI for providing examples of what participating OUD Care Teams could do to improve care for individuals with OUD, but not requiring any specific approach. Different approaches will be needed for different types of patients and in different communities, and the focus of the demonstration should be on testing whether providing additional resources and flexibility allows different approaches that improve outcomes for patients, rather than testing any specific approach to care delivery.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Thank you for this comment. CMS agrees.	
Expand Care Delivery/Services	● Expand the demonstration patient population beyond the 5,847 unique annual beneficiaries or add additional model years. Increase the number of beneficiaries that can participate in the model each year, to expand the reach of the demonstration to a larger patient population.	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer tdryer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963	● The statute states that "[n]ot more than 20,000 applicable beneficiaries may participate in the Program at any time" and it also indicates "$10,000,000 shall be available…each of fiscal years 2021 through 2024" for CMF and PBIP.CMS is limited to the statutorily prescribed budget and as a result determined that the CMF rate would have to be reduced for the demonstration to be able to expand demonstration services to more beneficiaries than the 5,847 beneficiaries currently estimated. We've also heard from stakeholders that the CMF rate should not be reduced, as it limits providers' ability to fill in the OUD treatment service gaps ViT envisions to fill. CMS has	

			opted to keep the CMF rate, as proposed, to ensure participating providers are sufficiently paid for ViT services. Without a determination from Congress, CMS will not be able to add additional demonstration years beyond the 2024.	
	● There should not be a cap on the number of beneficiaries that a physician participant is permitted to treat. CMMI should work collaboratively with the participants in the demonstration to adjust the parameters of the program in order to stay within the amount of funds appropriated. ● We recommend that CMS work collaboratively with the participants in the demonstration each year, beginning in the summer/fall of 2021, to review participation rates and determine the most effective ways to adjust the parameters of the program in order to stay within the amount of funds appropriated, such as modifying beneficiary eligibility requirements or payment amounts for different types of patients or different phases of care. Moreover, if the initial results of the demonstration are positive, Congress should be so informed so that it has the opportunity to increase funding for the demonstration.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Thank you for your suggestion. CMS intends to work with Participants to ensure an appropriate number of maximum beneficiaries permitted to furnish OUD Treatment Services under Value in Treatment. For example, the Participant may submit a request to increase the number of Participating Beneficiaries served by the Participant. It is the intention of CMS to serve the maximum number of beneficiaries allowed under the annual $10,000,000. ● Additionally, thank you for suggesting we inform Congress. If additional funding becomes available at some point during the demonstration, CMS anticipates revisiting many of the issues brought forth during this Public Comment Period.	
	● Provide beneficiary education on the importance of opting into data sharing. CMS should provide education to beneficiaries on the importance of opting into data sharing to prevent the burden from falling solely on	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer	● Thank you for this suggestion. CMS will continue to investigate ways in which we can provide education to both ViT beneficiaries and participants.	

	providers.	tdryer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963		
	● Medicare reimbursement for the Masimo Bridge product is not available. We believe that more providers would consider use of Masimo Bridge if the performance-based incentive was tied to successful transition into an MAT program and this incentive offset the overall cost of using Masimo Bridge by the participant.	Masimo Paul M. Ordal, Vice president, Government Relations and Public Policy Questions -Kaye.Meier 202-906-9719 Kaye.Meier@Masimo.com	● It is the intention of this demonstration to make MAT more widely available to those with an OUD diagnosis. With the flexibilities offered through Statute, CMS expects Participants will implement technology and services that will improve the health of beneficiaries with an OUD diagnosis. Patient outcomes is something we intend to evaluate, and look forward to understanding more about the services and technology offered through Value in Treatment.	
	● With current and future limitations on research resulting from the COVID-19 pandemic, remote physiologic monitoring technology can enable CMMI to continue its valuable research, while keeping patients and providers safe. ● Both the underlying statute and the Value in Treatment documents stress the need for the program to include enhanced medication-assisted treatment (MAT). However, the inherent danger of OIRD in patients using opioid-based MAT drugs must be recognized. If the goal of the Value in Treatment Program is to enhance MAT programs, medical technology must be included to ensure the safety of these patients. One way to ensure safety of individuals would be to require OIRD-detection technology with an alarm protocol as a part of contingency management. ● Remote patient physiologic monitoring can	Masimo Paul M. Ordal, Vice president, Government Relations and Public Policy Questions -Kaye.Meier 202-906-9719 Kaye.Meier@Masimo.com	● Value in Treatment intends to fill Medicare gaps, including expanding delivery settings or modalities that Medicare does not otherwise cover. CMS expects that Value in Treatment Participants will implement services that are patient centered, and CMS will not be promoting specific technology or services, but will encourage effective OUD treatment services that improves patient health.	

	save lives, but it will also save public health systems significant costs associated with longer-term, more intensive medical treatment. The Value in Treatment Program evaluation criteria4 note that the evaluation of the demonstration will assess the extent to which the demonstration program reduced hospitalizations and emergency department visits, did not increase total Medicare spending, reduced deaths from overdose, and reduced the utilization of inpatient residential treatment. We support that assessment protocol and urge you to include it in the final demonstration protocol. We are confident that remote physiologic monitoring devices with alarm systems will achieve all of those goals.			
	● We also urge that the requirement that OUD Care Team members "must be available to provide services on a face-to-face basis" be modified to clearly allow services provided through telecommunications technology.		● It is the intention of CMS to ensure telehealth flexibilities as they relate to OUD treatment and services under Value in Treatment. CMS encourages one face to face visit. Furthermore, the allowable telehealth services will be outlined in the Participant Agreement	

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Eligible Participants/Care Team Roster	● First, we request that CMMI update the list of eligible participants to include NPs and their practices. The SUPPORT Act granted the Secretary the authority to specify "any other individual or entity" as an eligible participant, in addition to the enumerated list of participants.4 As mentioned above, over 14,000 NPs have obtained their DATA-waivers and including them in the list of eligible participants will greatly increase access in this demonstration.	AANP, David Herbert, Chief Executive Officer	● Thank you for this suggestion. CMS is actively investigating this prospect.	
	● Second, we request that CMMI revise the first requirement that the OUD care team consists of "[a]t least one physician furnishing primary care services or addiction treatment services" to "[a]t lease one physician **or nurse practitioner** providing primary care services or addiction treatment services." The SUPPORT Act granted the Secretary the authority to "waive any provision of this title as may be necessary to carry out the Program under this section."7 NPs are qualified to lead these OUD teams; they were the first waivered providers in hundreds of communities, and are providing a substantial portion of primary care services	AANP, David Herbert, Chief Executive Officer	● Thank you for this suggestion. CMS is actively investigating this prospect.	

	across the country.			
	● We want to advocate for the expansion of participant eligibility requirements to include non-provider organizations operating in the substance use disorder space. ● We recognize and welcome the opportunity to partner with provider organizations in this innovation process. We believe we bring unique depth of knowledge of the environment and resources available for dependent members.	axialHealthcare	● CMS welcomes community-based organizations or other non-provider organizations to partner with applicable participants, including those with expertise in the substance abuse and behavioral health space, as they may be part of the participant's OUD Care Team. We recognize that addressing the complex and unique needs of Medicare OUD beneficiaries may require community partnerships that ensures OUD Treatment is patient-centered.	
	● Masimo clinicians and engineers have extensive experience in the interface between medical technology and providers and patients using it. This experience and knowledge would assist CMMI in the Value in Treatment Demonstration project and we thank you for allowing medical device technology companies to partner with eligible entities on the OUD Care Team so that the highest levels of technological expertise and patient safety can be realized.	Masimo Paul M. Ordal, Vice president, Government Relations and Public Policy Questions -Kaye.Meier 202-906-9719 Kaye.Meier@Masimo.com	● Again, CMS welcomes community-based organizations or other non-provider organizations to partner with applicable participants.	
	● We commend CMMI for providing the maximum flexibility possible under the law regarding the members of the OUD Care Team. Some solo physician practices might be in a better position to participate in the demonstration if they could do so jointly, and it is not clear whether the requirement for a single taxpayer identification number (TIN) will discourage this, so we	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Participants are defined as a single TIN. For claims purposes, Participants must inform CMMI the unique TIN and NPI combination allowed to bill for the demonstration code. Only that unique TIN-NPI combo will be allowed for demonstration claims processing. ● Please note that solo practitioners can independently apply to participate in the demonstration and bill the demonstration with its unique NPI-TIN combination. Alternatively, solo practitioners can partner together to	

	recommend providing the opportunity for multiple TINs to submit joint applications if they wish, along with an explanation of why it is difficult for them either to apply separately or under a single TIN ● As discussed earlier, applications from multiple physicians who have multiple TINs should be considered, without requiring a "separate and unique legal entity." It is not clear why Question 9 appears to also require a single National Provider Identification (NPI) number. As discussed earlier, not all members of an OUD care team should be required to provide services on a face-to-face basis. It is inappropriate to base any portion of an applicant's score on how many pages are in their application.		participate in the demonstration, and partner with other non-healthcare providers to offer ViT services jointly as an OUD Care Team. However, only one unique NPI-TIN combo will be allowed to bill the demonstration code. Under this arrangement, the Participant would have to establish legal and financial arrangements to pay all members of its OUD Care Team for services furnished to a beneficiary. ● CMMI requires one face-to-face visit be offered in a given calendar quarter by any provider that is part of the OUD Care Team, but otherwise gives Participants wide flexibility in the delivery setting and modality used to furnish demonstration OUD Treatment Services. ● An applicant's score is not based on the number of pages in the RFA or who is listed on the OUD Care Team. The RFA requests that applicants not exceed page limits in their responses and that the OUD Care Team roster be complete and submitted for application considerations. CMMI will score applications in accordance to the criteria noted in Table 2 on page 23 of the RFA.	
	● It is inappropriate to require applicants to submit a detailed "care team roster" or to score an applicant based on such a roster. The law requires only that the care team include at least one physician and one practitioner who has a waiver for prescribing OUD medications. It will likely be difficult or impossible for many applicants to determine all of the individuals or organizations that will work together to deliver services before submitting an application, and it is also likely that changes in the composition of teams will occur before or after the	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 margaret.garikes@ama-assn.org	● See response above. The OUD Care Team roster is being collected to verify that the care team includes the providers required by law, and to collect information on the types of OUD Care Team members applicants have partnered with to furnish demonstration services. The application will not be scored based on who is listed in the OUD Care Team roster, but an applicant may not quality for the demonstration if at the providers required by law are not included in its roster. CMS understands that the roster may change over time, and thus anticipates updates made during the performance period.	

	applicant begins delivering services under the demonstration. It is also not clear how this information will be used to determine the points assigned to the application, particularly since the RFA states on page 8 that "CMS does not anticipate creating additional requirements or expectations about who is on the OUD care team beyond what is outlined in statute," and that "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."			
CMF	● The Care Management Fee (CMF) should be higher for new patients and patients who receive more intensive services based on clinical guidelines. In addition, the CMF amounts should be reassessed after the program begins to ensure they are adequate to support the services that physician practices need to deliver to successfully treat OUD. There should be no patient cost-sharing for the CMF. ● The participants in the Listening Session convened by CMMI in May 2019 supported use of a risk-adjusted payment. The RFA states that the payment rate will not be adjusted based on acuity "due to budget limitations," even though a risk-adjusted payment could ensure that the limited funding is more effectively targeted to the patients who need it most. The Patient-Centered Opioid Addiction Treatment (P-	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS considered risk-adjusting the CMF rate, per the recommendation, and agrees that patients requiring more intensive services may cost more. Ultimately, CMS did not risk adjust the CMF payments due to the limited operational budget Congress allocated for the demonstration, as it was resource intensive and cost more than the demonstration could afford. The operational budget is separate from the $10,000,000 Congress allocated for services. CMS opted to set a flat CMF rate considered appropriate and reasonable that standardly applied to all eligible beneficiaries. ● The demonstration is waiving the patient cost-sharing for the CMF; CMS cover 100% of the CMF. ● CMS had reviewed and considered the Patient-Centered Opioid Addiction Treatment (P-COAT) model developed by AMA and ASAM, especially for the payment for Initiation of Medication Assisted Treatment (IMAT) and Maintenance of Medication Assisted Treatment (MMAT). CMS eventually adapted parts of the "Option-C" of the P-COAT payment strategy where a single participant would	

	COAT) model developed by the AMA and ASAM includes payment categories that could easily be adapted for use in this demonstration, and we urge that you do so. ● We do not believe that the single monthly care management fee (CMF) for all participants as described in the draft RFA is consistent with Congressional intent. Section 6042 of the SUPPORT Act requires the Secretary to establish a "schedule" of per beneficiary per month care management "fees" in the demonstration program, and specifically authorized (1) higher payment amounts for beneficiaries who receive more intensive treatment services based on clinical guidelines and; (2) higher payments in the month in which a beneficiary begins treatment than in subsequent months. ●		employ or contracts with the necessary personnel as part of the OUD Care Team to provide OUD treatment services such as medication and counseling services, as well as non-medical needs services such as care management and enhanced social support services to applicable beneficiaries with OUD.	
	● We urge CMMI to make an explicit commitment in the RFA to work collaboratively with the participants during the summer/fall of 2021 to determine whether the amount needs to be changed based on the participants' experience in delivering care.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Thank you for this suggestion. CMS will continue to investigate how we can ensure continued collaboration and transparency with Participants and others.	
	● As bundled payments for office-based OUD	AMA, James L.		

	treatment and Opioid Treatment Programs were just initiated in 2020, it would be helpful for the final RFA to outline more clearly what the current payments are, as well as what other services will continue to be separately payable, such as office visits, so that there is no confusion about that and practices can better assess the full amount of the support for OUD care that they will receive from Medicare should they participate in the demonstration.	Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 margaret.garikes@ama-assn.org	● CMS encourages Participants to refer to all CMS guidance on bundled payments to support OUD care. We will investigate what further detail we can offer on the ViT website.	
	● This section inappropriately implies that participants are prohibited from using funding under the OUD demonstration for services or patients if they are using other funding sources for the same services or patients. As noted earlier, the SUPPORT Act clearly states that the CMF is to be paid "in addition to any other amount otherwise payable." The problem with current payment systems is not just that they fail to pay at all for some services needed to address OUD, but also that they fail to pay adequately for some of the services that they nominally support. The prohibition on "duplication" of payments in the statute clearly refers only to making CMF payments to two different participants for the same beneficiary. It does not prohibit a participant from using a CMF payment to support a portion of the cost of a service in addition to using other payments for the same service. Consequently, demonstration participants should be expected and even	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS is encouraging Participants to use the CMF to compliment already covered services or offer additional services. We will investigate adding the suggested language to the RFA.	

	encouraged to use a portion of the payments in combination with other payments and funding sources to support delivery of services to patients with OUD, and we urge CMMI to explicitly state this in the final RFA. _____			
Timing/ Application questions	● How do an FQHC sign up to participate? Please advise. Thanks	Kenneth Waller: Amistad Community Health Center, Inc.; Corpus Christi, TX 78412 kenneth.waller@amistadchc.org (7/10/20)	● FQHCs can sign up to participate in the Demonstration by responding to the RFA if the FQHC meets the participation requirements as outlined, including for example having at least one physician or addiction treatment specialists.	
	● As noted earlier, applicants should have a minimum of six weeks to respond to an RFA. Consequently, if the deadline for submitting applications will be September 30, then the RFA should be finalized and issued no later than August 19. ● We urge that participants be selected and notified no later than October 31.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS appreciates the concern for timeline. We cannot release the RFA until the conclusion of the Paperwork Reduction Act clearance. We are diligently analyzing all possibilities based on this result.	
	● An application would receive more points if an applicant states that they "intend" to furnish OUD treatment in a state or county with an above-average OUD prevalence rate and/or an above-average rate of OUD-related emergency visits and hospitalizations. However, since there is no requirement for the applicant to show how	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@am	● CMS will both look at the physical address of the applicant as well as the self-reported question capturing the areas that will be served by the applicant when looking at OUD prevalence rates. The intention is to ensure CMS serve as many beneficiaries as possible.	

	they would actually provide services in this location, this could inappropriately result in selecting applicants whose intentions exceed their ability. We believe that higher points should be given to applicants who are actually located in a higher-prevalence county or who can show that they will have a physical presence there.	a-assn.org		
	● Awarding points to applicants based solely on the number of beneficiaries they have treated or planned to treat will bias participation in the demonstration toward larger practices. We recommend using the information on patient volume to select a mix of large and small participants. The information related to patient volume will be difficult for many physician practices to obtain, so we strongly support the option for applicants to provide estimates rather than requiring collection and analysis of data.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● The ViT RFA application allows for estimates of patient volume. CMS will not award points based on these volume estimates, but instead award points for the completeness of the reported information. CMS recognizes the importance of selecting a mix of participants, and such selection will not be based on having a higher patient count. Please refer to the RFA scoring criteria table for further information.	

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	● Given the intense pressures that physician practices and other eligible participants are currently under due to the COVID-19 pandemic, and the relatively short time for CMS to publicize the RFA, ASAM encourages CMS to consider a rolling application process or multiple application opportunities for applicants who may not be able to meet the September 30th deadline. Given early reports of increased drug overdose deaths in 2019 and continued increases this year, it is critical that participation in this model is maximized so that as many Medicare beneficiaries with OUD as possible can receive comprehensive treatment services to support their recovery.	Paul Earley, MD, DFASAM: President, American Society of Addiction Medicine 2. Susan Awad, Senior Advisor, Public Policy and Regulatory Affairs at sawad@asam.org or 301-547-4106 (7/28/20)	● CMS recognizes the impact COVID-19 has had nationally and the added strain and pressure providers may be under. As we want to reach Medicare beneficiaries experiencing OUD as soon as possible, we do not intend to delay the initial application, but will consider additional application windows. Please note, however, that CMS may not offer additional application opportunities if the demonstration's beneficiary cap has been maximized given budgetary constraints.	
	● Allow participants in the Comprehensive Primary Care Plus (CPC+) Model to apply for the Value in Opioid Use Disorder Treatment Demonstration. Allow CPC+ participants to apply for the Value in Opioid Use Disorder Treatment Demonstration, with the understanding	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer	● Thank you for your suggestion. CMS will keep this under consideration as the demonstration moves forward.	

	that CPC+ providers could not participate until their participation in CPC+ has concluded (either January 1, 2022 or January 1, 2023).	Theresa Dryer tdreyer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963		
	● The AMA recommends that practices be given at least six weeks and ideally 60 days to prepare an application. Moreover, because practices cannot begin implementing revised services unless they know they will be part of the demonstration, it is important that participants be notified of their selection no later than October 31, 2020.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS appreciates the timing concerns for the ViT application process. We cannot release the RFA until the conclusion of the PRA clearance process, and will evaluate at that time the most appropriate	
	● We also recommend that CMMI invite eligible physicians and other entities to submit brief "letters of interest" as soon as possible. This will not only enable CMMI to ensure that interested physicians are made immediately aware when the RFA becomes available, it will also provide a mechanism to solicit input from them on some of the issues that are not adequately specified in the draft RFA. It is important that the demonstration be designed in a way that encourages participation of small	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-	● CMS is actively pursuing this as a possibility.	

	physician practices and supports their success. The best way to identify potentially problematic provisions is to get direct input from those who are interested in participating.	assn.org		
Performance Measures/PBIP	● ASAM notes that ED utilization may be influenced by factors out of the participant's control and encourages CMS to risk-adjust ED utilization measurement and consider applying it only to participants who indicate they will use the CMF to establish a 24-hour nursing line and/or after-hours care. Moreover, it is unclear how measures developed to evaluate health plan performance can be applied to individual provider or practice performance, especially with proposed caps on per-participant beneficiary participation and concerns about low patient volume per participant.	1. Paul Earley, MD, DFASAM: President, American Society of Addiction Medicine 2. Susan Awad, Senior Advisor, Public Policy and Regulatory Affairs at sawad@asam.org or 301-547-4106 (7/28/20)	● Thank you for this comment. The ED measurement has been under consideration due to Statutory language. However, CMS will continue to consider the most appropriate measures to tie to the performance payments. Please note that the Participant Agreement Payment Methodology will provide more detail in regards to how CMS intends to tie payment to quality, and how we've accounted for patient volume concerns.	
	● Provide participants with aggregate level mental health and substance abuse data. At a minimum, CMS should provide participants with aggregate data reports for their beneficiaries, given that individual-level mental health and substance abuse claims are suppressed	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer	● Thank you for this suggestion. CMS is actively researching how to share data with each Participant within our budgetary constraints.	

	in CMS data.	Theresa Dryer tdreyer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963		

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	● ASAM strongly recommends CMS delay implementation of the performance-based incentive payments for two years to encourage participation in the model without penalty. During the first two years, CMS should provide reports to participants to help them understand their baseline performance and where they may need to redirect resources to meet performance measures. A two-year on-ramp will also enable CMS to specify more clearly its performance measurement plan.	1. Paul Earley, MD, DFASAM: President, American Society of Addiction Medicine 2. Susan Awad, Senior Advisor, Public Policy and Regulatory Affairs at sawad@asam.org or 301-547-4106 (7/28/20)	● Thank you for this suggestion. CMS is actively considering this change to our methodology.		
	● The Performance-Based Incentives should be delayed until the second or third year of the demonstration so that appropriate performance measures can be developed and tested in collaboration with the practices participating in the demonstration.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice	● Thank you for this suggestion. CMS is actively considering this change to our methodology.		

	● CMMI should delay implementation of the performance-based incentive payments until the second or third year of the demonstration so that the measures can be tested and refined before they are used to impose penalties on practices.	President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org			
	● Ensure quality measures and reporting requirements are not burdensome for providers. Introduce quality measures that constitute a low reporting burden for participants, by limiting reporting requirements to data elements that are regularly captured in most Electronic Health Records (EHRs).	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer tdreyer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963	● In order to minimize reporting burden, CMS is considering claim-based measures at this time.		
	● Incorporate sociodemographic status (SDS) data in the risk adjustment. Risk adjust the performance-based incentive for SDS factors that contribute to OUD and prevent OUD treatment.	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer tdreyer@aamc.org 202-683-4673	● CMS will not be risk-adjusting CMF payments under the demonstration due to budget limitations (refer to previous comment).		

		Erin Hahn ehahn@aamc.org 202-828-0963			
	● CMMI should consult with stakeholders prior to finalizing both the aspects of quality to be measured and the methodology for measuring them, and utilize the standards developed by ASAM to the maximum extent possible in defining the measures. The statute explicitly requires the Secretary to consult with stakeholders prior to adopting performance measures and to consider existing clinical guidelines for the treatment of OUD.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS will be publishing the Participant Agreement (PA) draft in the Federal Register for public comments. The PA includes an appendix that outlines the CMF and PBIP payment methodology in more detail. CMS welcomes additional stakeholder input.		
	● CMMI should commit to work collaboratively with the participants in the demonstration during the summer/fall of 2021 to determine whether initial quality measures should be changed based on the participants' experience with them during the initial year, and make any needed revisions.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS will commit to sharing the Participant Agreement during the second public comment period. We may consider stakeholder input on the payment methodology section which contains the measures under question.		
	● It is inappropriate to delay making performance-based payments by as much as 18 months after services are delivered. We urge CMMI to evaluate performance and make performance-based payments	AMA, James L. Madara, MD Questions –	● CMS has investigated the possibility of providing performance-based payments on a quarterly basis. Unfortunately, this will not be feasible with the constraints of the current Value in Treatment operational budget.		

	on a quarterly basis, as it plans to do in Primary Care First.	Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org			
	● The RFA does not specify which measures will be used to evaluate performance, but merely provides a list of measures that CMS is "considering" and states that measures will be specified in the participation agreement. It is inappropriate to ask physician practices to develop a plan for delivering care and to submit a detailed application without knowing what outcomes they will be held accountable for and whether payments will be adequate for achieving those outcomes.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● A more refined list of measures will be available in the Participant Agreement, which will be available as a supplementary document in the next round of the PRA review. This will be available to applicants prior to submitting their application.		
	● In addition, the RFA states that if participants do not have a minimum number of patients for quality measures, "CMS will pool participants" for purposes of measurement. Instead, we urge CMS to give participants the option of creating "virtual groups."	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS welcomes additional feedback on what these "virtual groups" look like.		
Cost Sharing	● The RFA indicates that CMS plans to	AMA, James L.	● Thank you for your comment. Cost sharing will be waived for the ViT		

	waive cost-sharing for services delivered by Opioid Treatment Programs and for services furnished through the office-based OUD bundled payments, but the RFA does not state that cost-sharing will be waived for the demonstration's CMF. The AMA is concerned that requiring cost-sharing for the CMF would discourage rather than encourage participation by patients with OUD, so we urge that cost-sharing be waived in order for the demonstration to be successful.	Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	CMF		
	● It appears that CMS is planning to use a portion of the $10 million in annual funds appropriated for the demonstration to pay for cost-sharing waivers for current OUD treatment payments; however, the statute explicitly authorizes the $10 million to be used for "care management fees and incentives." Alternatively, CMS could presumably use a portion of the $5 million appropriated for administrative funding or the general CMMI appropriation to pay for waivers of cost-sharing on other payments.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS is unable to use the one-time appropriation of $5 million for administration activities for other payments because the statute requires CMS to conduct two evaluations of the program and report to Congress, including an intermediate evaluation not later than 3 years and final evaluation not later than 6 years after the implementation of the Program. CMS will revisit policy decisions in the case that increased funding becomes available.		
Overlap	● Provide further details on model overlap. Provide details outlining how model overlap will impact total cost of care calculations in other models, such as ACOs and bundled payments.	AAMC, Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer tdreyer@aamc.org	● The ViT team will work to provide more detail on overlaps with the Shared Savings Program. We anticipate the CMF will count towards the TCOC for those beneficiaries in both the demonstration as well as the model.		

		202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963			
	● The RFA states that primary care practices participating in Comprehensive Primary Care Plus (CPC+), Primary Care First (PCF), or the Maryland Primary Care Program cannot participate in the OUD demonstration "due to potential redundancies in payments for services." The SUPPORT Act specifically states, however, that the demonstration CMFs are to be paid in addition to any other payments that a physician practice is eligible to receive, and the RFA specifically authorizes practices to receive the CMF payments in addition to Medicare physician payment schedule care coordination payments. CPC+ and PCF participants receive monthly payments in place of other existing payments, and they do not receive any additional payments that are explicitly targeted to patients with OUD, so there is no rationale for precluding these practices from participating in the OUD demonstration and receiving CMF payments for their OUD patients. Moreover, it is inappropriate to prevent patients of the CPC+ and PCF practices who have OUD from receiving the enhanced services under the demonstration. The AMA urges CMMI	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Though CMS agrees with AMA's sentiments, these other models/programs do not allow for billing of the Chronic Care Management Fee, where there are no restrictions in ViT. The decision to disallow these overlaps was based on a multitude of factors, with operationalizing being one. At this time, Value in Treatment will not accept providers currently participating in CPC+, PCF, and MDPCP.		

	to allow primary care practices participating in CPC+, PCF, or the Maryland Primary Care Program to participate in the OUD demonstration. The AMA also recommends that CMMI remove the statement that "CMS reserves the right to potentially include additional requirements, revise initiative parameters, or ultimately prohibit simultaneous participation in multiple initiatives." Physician practices need to know what to expect throughout the life of the program before they decide to participate.				
Coordination	● Coordinate with the Department of Health and Human Services (HHS) to support expanded access to evidence-based OUD treatment. The AAMC recommends that HHS increase access to buprenorphine for prescribers, support investments in physician workforce expansions, and adopt current telehealth flexibilities permanently under the demonstration to increase OUD treatment accessibility.	Janis M. Orlowski, M.D., M.A.C.P., Chief Health Care Officer Theresa Dryer tdreyer@aamc.org 202-683-4673 Erin Hahn ehahn@aamc.org 202-828-0963	● Thank you for this suggestion. CMS will continue to work with all of our stakeholders (internal as well as external) as this demonstration unfolds, and welcome continued comment on OUD treatment.		
Multi-Payer Alignment	● The statute requires the Secretary to "encourage" other payers to provide similar payments and to use similar eligibility criteria. Simply publishing the demonstration's payment methodology does not seem sufficient to meet this	AMA, James L. Madara, MD Questions – Margaret	● CMS may investigate multi-payer alignment in the future of this demonstration. We feel strongly that at this time we will not be able to mandate this type of alignment, though we do want to note Medicaid's flexibilities as they relate to covering the non-medical needs of OUD beneficiaries.		

	requirement. Instead, the AMA recommends that as soon as participants are selected for the demonstration, CMMI should (1) send a written request to each of the other payers those practices receive payment from asking that they make similar payments for the patients they insure; and (2) issue a report to the public on the responses from those payers.	Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org			
Beneficiary Eligibility	● To be eligible to receive services in the demonstration, a beneficiary must have a "current diagnosis for an opioid use disorder." The RFA states that this will be determined using the CMS Chronic Condition Warehouse (CCW) Condition Algorithms. However, the current CCW Algorithm for OUD requires that a patient have *two* outpatient claims with an OUD diagnosis or a claim for medication-assisted treatment. This requirement could preclude a patient from being deemed eligible when a physician participating in the demonstration first diagnoses the beneficiary with OUD, particularly if the patient is not ready to start treatment. **The AMA recommends that patients who have not previously been diagnosed with OUD be deemed eligible if a participating physician submits a visit or other claim with an OUD diagnosis.**	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● We appreciate AMA highlighting the current CCW Algorithm for OUD determination. For ViT, the MAC will allow for CMF payment to be made in the case that one OUD diagnosis code be associated to the claim. This methodology will be clearly outlined in the Payment Methodology Appendix of the Participant Agreement.		
Fraud and	● Since the goal of the demonstration is to	AMA, James	● CMS is consulting with Counsel to determine what is allowable.		

Abuse	encourage new approaches to delivering more comprehensive services to patients, including services that are not currently paid for, and the demonstration explicitly requires formation of OUD Care Teams with multiple providers, **we urge that CMMI explicitly indicate what kinds of activities could potentially implicate fraud and abuse requirements.** The vague statement in the RFA that "any arrangement under this demonstration 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" is particularly problematic given that the RFA states on pages 9-10 that participants may use the CMF and performance-based incentive payments for "recovery support services" and that such support services "may include provision of social services that enable recovery (e.g., …beneficiary incentives…)." Failure to clarify this could have a chilling effect on the willingness of physicians to participate in the demonstration, and it could inappropriately discourage participants from utilizing innovative and effective approaches because of their unwillingness to incur large legal fees to protect or defend themselves from fraud and abuse claims.	L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org			

	● The RFA contains a lengthy list of activities to identify fraud and abuse, but it does not describe any actions that CMMI will take to help practices successfully treat patients with OUD. The focus should be more balanced and the RFA should describe how CMS will help practices be successful	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● Thank you for this comment. CMS will take this opportunity for a learning initiative under consideration.		
Data Sharing	● It is essential that physicians participating in a value-based payment program like the OUD demonstration receive timely and detailed data on their patients and their performance. It is not sufficient to state that performance information "may" be shared with participants or that Medicare data "may" be made available. CMMI should explicitly commit to the types of data it will provide to participants and the dates when those data will be provided.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS will work within the budgetary constraints to ensure timely and detailed are provided to Participants in the ViT demonstration.		
Termination	● CMMI should not unilaterally terminate a participation agreement with a participant without providing adequate opportunity for the participant to appeal. It is also inappropriate for CMMI to "require a participant to terminate its agreement with an OUD care team	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of	● Thank you for this comment. Participant termination would result after unsuccessful remedial action. Terms for both actions will be outlined in the Participant Agreement. ● It is not the intent of CMS to micro-manage the staffing of the Participant's care team. Termination of a care team member arrangement would result from noncompliance with the terms of ViT or due to any program integrity issues.		

	member" unless there is clear evidence that the team member in question is harming patients or engaging in fraudulent behavior. If the participant is going to be accountable for outcomes, CMMI cannot micro-manage the staffing or activities of the participant's team.	Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org			
Screening	● CMS should commit to complete all program integrity screenings before selections are made and before applicants are notified. Participants who are selected need certainty about their ability to receive payments under the demonstration in order to assemble the staff and resources needed to implement services.	AMA, James L. Madara, MD Questions – Margaret Garikes, Vice President of Federal Affairs 202-789-7409 Margaret.garikes@ama-assn.org	● CMS appreciates this suggestion. This is the intent of CMS and we will strive to meet that goal.		