AMA
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July 28, 2020

Ms. Rebecca VanAmburg
State Innovations Group
Division of State Innovations Models
Center for Medicare & Medicaid Innovation
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–10728; Value in Opioid Use Disorder Treatment Demonstration

Dear Ms. VanAmburg:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to respond to the proposed information collection regarding the Value in Opioid Use Disorder (OUD) Treatment Demonstration, specifically the Request for Applications (RFA). The AMA strongly supported the enactment of section 6042 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). There is an enormous gap between the number of patients who need treatment for OUD and the number who are receiving it. Well-designed alternative payment models could be extremely effective in reducing this gap. The AMA appreciates the efforts of the Center for Medicare & Medicaid Innovation (CMMI) to seek input from and communicate with the AMA and our colleagues at the American Society of Addiction Medicine (ASAM) as it has worked to design the demonstration program and develop these draft materials.

The AMA believes that a number of changes are needed in order to make the demonstration as successful as possible. The most important changes are outlined below and the details of these and other recommendations are described in the remainder of this letter.

- 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 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.

- 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.

Timeline (p. 6)

As the demonstration program is required by law to begin in less than six months, the AMA is concerned that CMMI has not provided a specific timeline for finalizing the RFA or selecting participants. As the RFA indicates, there are many gaps in current treatment services for individuals with OUD that are caused by barriers in the current payment system. The demonstration program is intended to provide the resources and flexibility for physicians to fill these gaps, but doing so requires delivering new services and existing services in new ways, and physician practices will need adequate time to form OUD Care Teams, plan for new and improved services, and engage the staff and other resources necessary for successful implementation.

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.

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 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.

Participant and OUD Care Team Eligibility (pp. 7-8)

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 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.

The intent of the requirement that a participant be a "separate and unique legal entity" is not clear. We do not believe it is appropriate to exclude small physician practices from participating simply because they are part of a larger corporate entity. **We recommend that this requirement be revised or dropped.**

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. One barrier to delivering OUD treatment services with medication in rural areas is that it is impossible to have health professionals with all necessary skills physically present in the community, and the only way to provide comprehensive care is for some team members to provide services virtually.

Care Delivery Intervention (pp. 9-10)

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.

Care Management Fee (pp. 11-12)

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.

As the law itself specifically recognizes, the time and costs involved in planning and initiation of treatment are greater than for maintenance of treatment, so the absence of higher CMF payments for new patients would discourage OUD Care Teams from taking on new patients and doing the intensive work needed to successfully initiate treatment. In addition, some patients need far more time and assistance than others both initially and after treatment begins. In fact, the RFA explicitly acknowledges that "an individual beneficiary's…level of care required may change as they move through initial engagement and progress toward longer-term recovery." As a result, paying the same CMF amount for all patients could discourage OUD Care Teams from taking on more complex patients and providing the more intensive services they need.

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-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.**

The RFA does not provide a specific justification for the proposed $125 CMF amount. Obviously, the fewer the patients who are enrolled in a practice, the smaller the amount of aggregate revenue that will be generated for a practice by the CMF. Because the Centers for Medicare & Medicaid Services (CMS) is proposing to withhold 10 percent of this amount for as much as 18 months, the payment will really be only $112.50. We do not believe it is possible to know whether this amount is adequate or how it should be changed until after the demonstration begins and participants attempt to support revised services using it. It would be imprudent to continue the program for a full four years with the same payment amount if that amount is insufficient to allow delivery of the services needed to achieve good outcomes for patients. **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.** This will help encourage practices to participate and increase their chances of success.

The draft RFA states that the CMF will be paid "in addition to payments made for medication, counseling, and behavioral therapies, treatment planning, and care coordination services for which Medicare payment is currently made." As bundled payments for office-based OUD 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. Moreover, Rural Health Clinics and Federally Qualified Health Centers should continue to be able to bill for general care management and the psychiatric collaborative care codes in addition to the CMF. The law clearly states that the CMF is to be paid "in addition to any other amount otherwise payable under this title."

Performance-Based Incentive (pp. 12-13)

Although the topics being proposed for assessment of quality are certainly relevant to successful OUD treatment, the RFA states that CMMI is planning to use claims-based measures of these topics. Even though use of claims-based measures may be intended to avoid creating administrative burdens for the participating practices, we are concerned that these aspects of quality cannot be measured accurately or fairly using claims alone. This not only creates the potential for inappropriately penalizing practices, it reintroduces administrative burden by forcing practices to investigate and document the reasons why a claims-based quality measure does not accurately reflect their actual performance. **The AMA recommends significant changes in CMMI's approach to performance measurement, as described below.**

- 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.

- 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.

- **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.** Although the statute requires creation of a performance-based incentive payment, it does not require that it be paid each year or that it be designed as a withhold from a practice's payment. (The statute says only that "a performance-based incentive payment" shall be paid "using a methodology established and at a time determined appropriate by the Secretary.") Alternatively, the performance-based incentive could be designed initially as a bonus payment that rewards practices for submitting clinical and other data needed to refine the quality measures; other CMMI demonstrations have used "pay-for-reporting" incentives initially before transitioning to "pay-for-performance" payments.

- The RFA proposes that participant performance will only be assessed on an annual basis, and that performance-based payments will not be paid until the third quarter following the performance year.

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 on a quarterly basis, as it plans to do in Primary Care First.

- 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.

- 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."

Beneficiary Cost-Sharing (p. 13)

The RFA indicates that CMS plans to 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.**

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.

Multi-Payer Alignment (p. 13)

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 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.**

Beneficiary Eligibility and Attribution (p. 13)

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.

Advanced APM and MIPS Status (pp. 13-14)

We agree that the demonstration qualifies participants for MIPS APM status.

Program Overlaps and Synergies (pp. 14-15)

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 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.

Fraud and Abuse Waivers (p. 15)

Since the goal of the demonstration is to 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.

Monitoring and Reporting (pp. 15-16)

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.

Per Participant Beneficiary Cap (pp. 16-17)

We strongly oppose the quarterly cap on the number of beneficiaries that a participant is permitted to treat. The goal of the demonstration is to increase treatment of OUD, not to restrict it, and it would be highly inappropriate to preclude a participating practice from being paid for treating a patient with OUD and thereby to discourage treatment of that patient simply because the practice had exceeded an arbitrary cap. There will likely be significant variations in the number of patients seeking or willing to accept treatment from a practice during any particular month or quarter, so no matter how caps are defined, it is highly likely that some practices will exceed them while others will fall short during any particular quarter. Moreover, attempting to adjust caps mid-year could exacerbate rather than relieve the problem.

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.

Data Sharing (pp. 16-17)

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.**

Termination (pp. 17-18)

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 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.

Application Submission (p. 19)

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.

Participant Screening (p. 20)

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.

Selection Notification (p. 21)

We urge that participants be selected and notified no later than October 31.

Application Questions (pp. 22-29)

Applicant Information

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.

OUD Care Team

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 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."

Proposed Demonstration Region

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 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.**

Applicant Medicare Patient Volume

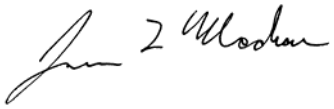
Awarding points to applicants based solely on the number of beneficiaries they have treated or planned to treat will bias participation in the demonstration toward larger practices. **We recommend using the information on patient volume to select a mix of large and small participants.** The information 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.

Program Duplication Assessment

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 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.**

The AMA appreciates the opportunity to share our views regarding the Value in OUD Treatment Demonstration Program and thanks the agency for its consideration of our recommendations. If you have any questions please contact Margaret Garikes, Vice President of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,



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